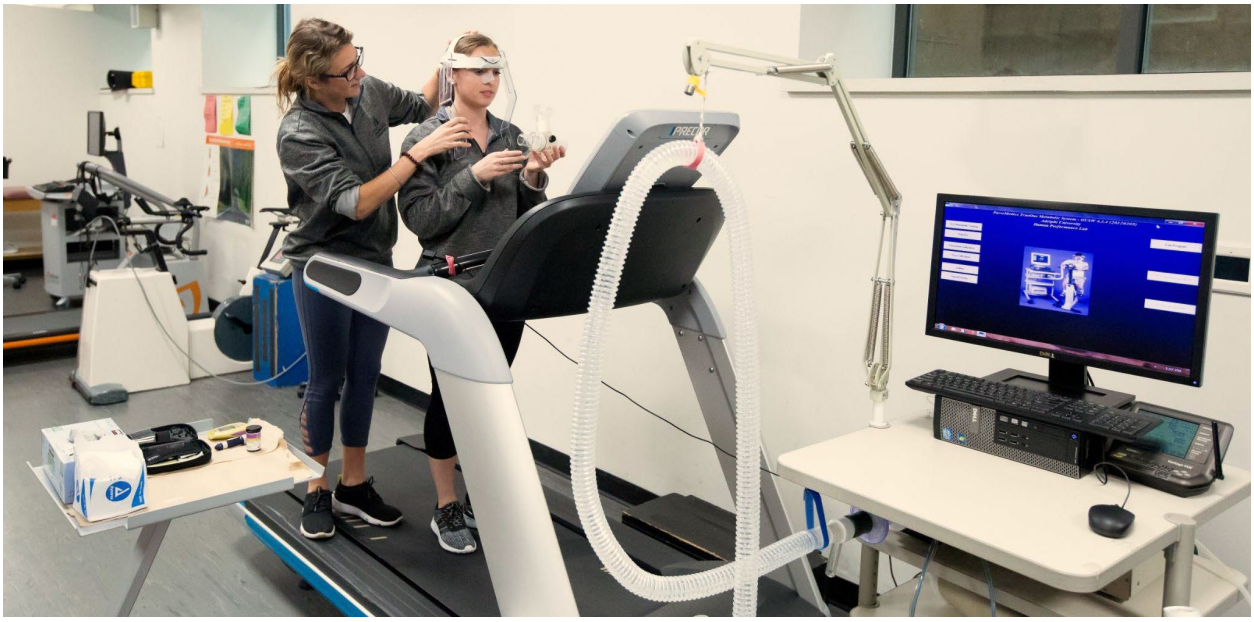
ADELPHI UNIVERSITY

Institutional Review Board (IRB) Manual



Research on human subjects has to be approved by the Institutional Review Board— an independent body made up of professionals and laypeople of diverse races, classes, and backgrounds — to ensure that the research meets the federal government's ethics requirements, including detailed informed consent.

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Acknowledgments

This version of the IRB manual is the result of the dedicated efforts of Dr. Geoffrey Ream who received the Viret Fellowship to review the previous IRB manual and rewrite/update the content to align with federal regulations and best practices of managing an IRB. Adelphi University Office of the Provost thanks Dr. Ream for his efforts. In addition, the ORSP Director, along with the members of the Adelphi IRB worked with Dr. Ream to complete this update process. Portions of this Institutional Review Board Policies and Procedures manual were paraphrased from the United States Department of Health and Human Services, Office of Human Research Protections (OHRP), and those sources cited in this manual. This version was approved by a unanimous vote of the IRB at the April 22, 2024 meeting of the Adelphi IRB. Effective date: September 1, 2024.

IRB Basics

The IRB Manual

This manual contains the procedures of the Adelphi University Institutional Review Board (IRB), along with Adelphi policies that affect research. It is linked on the Office of Research and Sponsored Programs (ORSP)'s web page. The process for preparing and maintaining these procedures is managed by the ORSP, under the purview of the offices of the Associate Provost for Research and Special Projects and the Provost. IRB members advise on this process and may suggest revision and review. Issues of noncompliance with these procedures may be brought to the attention of the Chair of the IRB and the Director of Research and Sponsored Programs.

Authority of the IRB

The IRB ensures compliance with the Federal Policy for the Protection of Human Subjects, which is Title 45, Part 46 of the Code of Federal Regulations[1], called the "Common Rule" because it is held in common among 20 different federal agencies who have co-signed it. The Common Rule directly governs research with human participants carried out by many government entities. Most scientific journals require that authors of human subjects research papers stipulate to an IRB having reviewed their study and having either approved it, determined it to be exempt, or determined it not to be human subjects research as per the Common Rule. The IRB has no authority over faculty activity other than what the Common Rule requires an IRB to have. In matters not limited by the Common Rule, institutional policies, and applicable federal, state, and local laws, Adelphi faculty have academic freedom as per Article VII, part (a) of the Collective Bargaining Agreement (CBA) by and between the Board of Trustees of Adelphi University and the Adelphi University Chapter, American Association of University Professors/American Federation of Teachers (the Union).

The IRB operates independently of the Faculty Senate, the Union's Executive Committee, the Faculty Committee on Retention, Tenure and Promotion, and other faculty and administrative committees. The IRB is not a faculty governance body. The Associate Provost for Research and Special Projects or the Provost may disapprove or restrict the scope of a study that the IRB has approved. However, no official may approve a study that the IRB has not approved, or authorize changes to IRB protocols. Administrators and faculty governance bodies are not to incentivize IRB members toward any particular determination about a protocol.

Relationships to Other Adelphi University Offices

IRB activities are coordinated by the ORSP Director, who reports to the Associate Provost for Research and Special Projects, who reports to the Provost. The ORSP Director is a voting member of the IRB. The ORSP Director chooses and vets the nonscientific, nonaffiliated member, taking committee members' recommendations and feedback into account as appropriate. Schools and departments within Adelphi have their own methods of recommending people to the IRB, but IRB members are officially appointees of the Provost. IRB service counts toward the service

[1] Protection of Human Subjects, 45 C.F.R. § 46 (2024). https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

requirements of faculty under Article XIV, Section 9 of the CBA. The ORSP is responsible for managing the IRB's relationship with regulatory agencies.

An IRB-approved protocol may be reviewed further and either referred back to the IRB or disapproved by the ORSP Director, the Associate Provost for Research and Special Projects, or the Provost. The grounds for disapproval and the expected actions to be taken by the investigator must be described in writing to the investigator.

Ethical Principles Governing the IRB

The primary guiding principle of the IRB is protection of the welfare of human research participants, according to the principles described in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979)[2]. These principles include:

- **Respect for persons.** People are generally thought of as freethinking individuals who can choose for themselves whether to participate in a research study, provided they have enough information to know what will be expected of them and are not being coerced in some way. Respect must also be given to the more limited autonomy of people whose personal characteristics or life circumstances limit their autonomy, such as children, prisoners, and the cognitively impaired. A key application of respect for persons is informed consent.
- **Beneficence.** Research procedures should either not put participants at any risk beyond what they would encounter in their day-to-day lives, or any risk should be minimized and balanced against potential benefits to them or people like them. "Risk" from a research ethics perspective is understood as risk inherent to the study procedures, which has no necessary relationship to whether social science fields call the population they come from an "at-risk population." For instance, asking mentally ill persons about their mental illness symptoms might be determined to be no more than minimal risk if it does not amplify the risk that they already experience. A key application of beneficence is assessment of risks and benefits.
- **Justice.** Where research presents any burden to participants at all besides a few moments out of their day, the burden should be proportionate to the benefit that they and people like them receive from it. The classic story of lack of justice in subject selection is the famous Tuskegee syphilis study, which involved unjust inclusion in research. Unjust exclusion from research is also possible.[3] For example, if a survey circulated in a predominantly Latino area were only offered in English, this would shut the voices of non-English speakers out of the study and result in findings that misrepresent the population. A key application of justice is the requirement that inclusion of any vulnerable populations be justified; declining to include them may also have to be justified. "Vulnerable" from a research ethics perspective is understood as vulnerability to coercion to participate in study

[2] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979, April 18). Ethical principles and guidelines for the protection of human subjects of research ("The Belmont report"). Retrieved November 25 from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

[3] Office for Human Research Protections. (2021). Consideration of the Principle of Justice Under 45 CFR Part 46. Retrieved April 4, 2024 from https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-consideration-of-the-principle-of-justice-45-cfr-46.html

under review. It has no necessarily relationship to whether social science fields would call the participants a "vulnerable population."

Other guiding principles of the Adelphi IRB include:

- **Compliance with the Common Rule.** The Common Rule represents an agreed-upon set of rules and norms for all institutions that conduct research, and adherence to it protects human research participants, Adelphi investigators, and Adelphi University. It creates a common context wherein a study proposed by an Adelphi researcher has the same chance of being approved as it would at other institutions. In reviewing protocols, the Adelphi IRB takes into account whether other, similar protocols have been approved or determined to be exempt at other institutions and their products published in journals.
- **Academic freedom.** The Adelphi IRB and the ORSP uphold faculty members' right to academic freedom under Article VII Part (a) of the CBA. They recognize that business procedures, administrative errors, and compliance burdens beyond the scope of the Common Rule have the potential to delay, stop, or limit the scope of a project, e.g., if an accounting office tries to require that participants sign for incentives even though the approved protocol calls for no collection of identifying information. They further recognize that time spent managing these issues is time not spent doing the project. The IRB is entrusted with approving the procedures and time frames for human subjects research, and faculty who believe they are being required to conduct their research at variance with their approved protocol may contact the ORSP Director.
- **Antiracist, anti-oppressive perspectives.** The Adelphi IRB commits to scrutinizing and undoing racism and oppression in matters under its purview. The inclusion of nonscientific and nonaffiliated members is an anti-oppressive measure that has long been required under the Common Rule. The Adelphi IRB recognizes that the need to protect populations with stigmatizing conditions, marginalized identities, and oppressed positionalities must be balanced against the benefits to those populations of having their experiences represented in scholarly discourse. It also recognizes that a stated aim of many scholars and entire scholarly fields is to undo oppression, as they understand it, and scholars have academic freedom to pursue those aims. The IRB will not create "silencing" or "erasure" by delaying and limiting protocols beyond what is required under the Common Rule.

Required Training and Education

The Training Requirement

The IRB requires all IRB members, people involved in conducting research, and ORSP staff to complete training in human subjects' protection. Adelphi is a member organization of the Collaborative Institutional Training Program (CITI). CITI courses are created by content area experts and regularly updated. All renewals of human subjects protections and all new certifications in human subjects protections must be done through the CITI program. Certifications are valid for three years and then must be renewed.

Registering For Courses

Adelphi subscribes to six different modules: animal care and use, conflicts of interest, good clinical practice, human subjects research, information privacy and security, and responsible conduct of research. To begin a training course (Note: Directions are current at the time of this writing. If something has changed and it is not intuitive what to do, contact the ORSP Director):

- Go to http://www.citiprogram.org
- Click on Register
- Click on "Select Your Organization Affiliation"
- Then start typing Adelphi University - it will take a minute to synchronize. Select Adelphi University
- Check the box to agree to the terms
- Check the box to Affirm that you are an Affiliate of Adelphi University
- Click on "Create Citi Program Account"
- Complete the information for your Personal Information
- Then click on "Continue to Step 3"
- Pick a username and password
- Set a security question
- Set a security answer
- Then click on "Continue to Step 4"
- Complete the information for the Country of Residence
- Complete the information about whether Citi can contact them
- Then click "Finalize Registration"
- Then select whether CE credits are necessary. If this is for course work or faculty research or student research then the answer typically is no.
- Then click "Submit"
- Then they need to select their language of choice
- Make sure to use an Adelphi email. If you don't have an Adelphi email, but you are affiliated with Adelphi, then use the email affiliated with this research.

Then:

- Input the Highest Degree or it can be left blank
- Leave the "Employee Number" blank
- Type in the department that you are affiliated with – if relevant
- Pick your role.
- Leave the rest blank on this page
- Then click "Next"
- On the next section select the courses that needed to add to the profile
    - If this is just Human Subjects Research then scroll to the **Human Subjects Section** which is Question 1 on this page and select the category that best fits your classification:
    - **Biomedical Research Investigators:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Biomedical research with human subjects.
    - **Social & Behavioral Research Investigators:** Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social and Behavioral research with human subjects.
    - **Research with data or laboratory specimens- ONLY:** No direct contact with human subjects.
    - **IRB Members:** This Basic Course is appropriate for IRB or Ethics Committee members.
    - Not at this time.

- For question 2 – leave it blank
- For question 3 – select not at this time
- For question 4 – I am not required to complete the IPS course at this time.
- For question 5 – leave it blank
- For question 6 – select not at this time
- For question 7 – select No
- For question 8 – select No
- For question 9 – select No

Then once that screen is done scroll down a little further and click "Submit." This will bring you to the next screen. Whichever courses you selected should appear in your dashboard, depending on what you picked will be loaded into your profile. You can then take the course.

What To Do with The Certificate of Completion

Upon completion, users receive a certificate of completion which they should e-mail to the ORSP Director and also append to their IRB proposals. While the ORSP Director can look up the CITI completion status for any Adelphi-based CITI user, this process takes time and delays may result, especially in proposals submitted at the last minute. Certificates of completion are valid for a specified amount of time and investigators must make sure their certificates are in date. Investigators are responsible for maintaining their CITI certification throughout the lifetime of the project. The ORSP does not send reminders about CITI certificate expiration.

Requirements for Study Staff & Site

The principal investigator of any study must be 1) a full-time faculty member at Adelphi; or 2) a part-time faculty member, staff member, or student at Adelphi, with a full-time faculty member serving as advisor. A co-investigator must be qualified to serve as an investigator at Adelphi, or at their own institution. A faculty advisor must be a full-time faculty member. Research staff must be qualified to perform the work assigned to them. Everyone who will handle participant data on a project must have current human subjects certification. Everyone named in a protocol must be sufficiently competent to perform the activities described in the protocol to avoid any risks to participants' welfare.[4]

Study sites must be safe for the activities that are to be performed and equipped for safety issues that can be reasonably foreseen as a result of the conduct of the study. Rules for safety should also be made where practical and applicable, e.g., a field research study that mainly involves conducting observations and interviews in public places may have a rule against field interviewers going into private buildings. Institutional requirements for sponsor-investigator studies should be followed.

[4] University of Wisconsin - Madison. (2024). Researcher requirements. Retrieved April 14, 2024 from https://irb.wisc.edu/manual/investigator-manual/researcher-requirements/

Defining Research

Research, as defined by the Department of Health and Human Services, is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Contributing to generalizable knowledge usually means publication or presentation of a research product, with that publication or presentation focused on conclusions that are supposed to be generalizable to other people and situations. The following activities are not considered Research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities conducted by a public health authority, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance, including:
    - Collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority
    - Trends, signals, risk factors, patterns in diseases
    - Increases in injuries from using consumer products
    - Those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health, including natural or man-made disasters
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes
- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions
- Secondary research involving non-identifiable newborn screening blood spots

An IRB has no purview over activities that do not fit the Department of Health and Human Services' definition of research. Scholarship activities that are mostly focused on telling the story of a person, family, organization, or specific community do not require IRB oversight. When oral history was excluded from the definition of research in the 2018 version of the Common Rule, it was observed that oral history and other ways of knowing about the human experience have their own standards for rigor and ethics, and their associated fields uphold those standards.[5]

Defining Human Subjects

A human subject is a living individual about whom an investigator conducting research (1) obtains information or biospecimens through **intervention** or **interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates **identifiable private information** or **identifiable biospecimens**. Definitions of terms within this definition are as follows:

[5] Oral History Association. (2020). Information about IRBs and oral history. Retrieved April 5, 2024 from https://oralhistory.org/information-about-irbs/

- **Intervention:** Physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. This has no necessary relationship with the concept of intervention as it is understood in social work and other helping professions.
- **Interaction:** Communication or interpersonal contact between investigator and subject.
- **Private Information:** Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
- **Identifiable Private Information:** Private Information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- **Identifiable Biospecimen:** A biospecimen for which the identity or the subject is or may be readily ascertained by the investigator or associated with the biospecimen.

An IRB has no purview over research that does not involve human subjects. Investigators who are unsure whether what they are planning to do is human subjects research may contact the ORSP Director. If an investigator submits a protocol for an activity that is not human subjects research, it may be reviewed and an official determination given that the proposed project is not human subjects research and the IRB has no purview over it. The Adelphi IRB recognizes that this is sometimes necessary, e.g., if a proposed study involves death records but all journals that would publish a paper based on the study require documentation of IRB review. A determination that a study is not human subjects research is not the same thing as a determination that it is exempt (defined below).

Writing a Protocol

Contents of a Protocol Submission

All protocol submissions to the IRB for initial review should include the following:

- Completed Human Subjects Review Form, which captures the following information:
  - Project title
  - "Nutshell" description of project that alludes to the exempt category that pertains to it or the level of review it should receive
  - Date submitted to IRB
  - Names, titles, and affiliations of project team members and faculty advisors, if applicable
  - Exempt category that might apply to the protocol. Researchers are encouraged to familiarize themselves with the exempt categories. Choosing the wrong one or choosing more than one may delay processing of protocols, especially protocols submitted at the last minute.
  - Additional review criteria, such as whether the study is minimal risk, whether the study has already been approved at another institution, whether the study includes vulnerable populations, and whether waiver of documentation of informed consent is being requested. Checking any of these items in error may delay processing of protocols.

- Adelphi policy considerations, including whether the study involves a large-scale survey of individuals affiliated with Adelphi and whether the study involves external funding.
- A brief description of the project's aims and purposes. In this section, the IRB is generally only interested in information that alludes to whether the participants are (or were, in the case of secondary data analyses) properly informed about what they are/were getting into. Complete grant or dissertation literature reviews cut and pasted into this section generally include more information than the IRB needs and may delay determinations on protocols.
- Dates for initiation and completion of the project
- Number of participants to be recruited
- Demographic characteristics of participants, including vulnerable populations and reasons for including or excluding them. Exclusion criteria and their rationales should be described here.
- Recruitment method
- Research methodology and study design. In this section, the IRB is generally only interested in information about what the participants will experience, or, in the case of secondary data analysis studies, what they experienced. If researchers cut and paste complete methodology and data analysis sections from their grants or dissertations into this section, that is usually more information than the IRB needs and it may delay determinations on protocols.
- Specific activities required of the subjects, including expected time commitment and potential risks, discomforts, or stresses they may experience.
- Measures to limit risks of COVID-19 or other epidemic disease transmission, as applicable.
- Plan for reporting adverse events to the IRB. Adverse events are described in an Office of Human Research Protections (OHRP) guidance document: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html. The default plan is that researchers will report any unexpected adverse events to the IRB chair and Office of Research and Sponsored Programs by email (irb@adelphi.edu) within 24 hours of their becoming aware of them.
- Data security plan, with procedures for where both paper (as applicable) and electronic files will be kept while data collection is going on, while they are being actively analyzed, and after analyses are complete ("cold storage").
- Signature page, including images of signatures for applications submitted electronically. Researchers should not omit signatures for any reason since this may cause delays in processing applications.
- Checklist for typical attachments

- Current human subjects training certificates, usually appended as images to the end of the application
- Recruitment/solicitation materials like letters, fliers, social media posts, scripts, as applicable
- Informed consent text or formatted informed consent documents, as applicable. All consent materials should include the following statement: "This research has been reviewed and approved by the Adelphi University Institutional Review Board. If you have any questions,

concerns or comments, please contact the ORSP Director," and then provide the name and contact information for the ORSP Director.
    - Documentation of informed consent is often waived for anonymous surveys, sensitive data interviews, or other situations where the only risk to the participant's welfare from the research procedures would be a breach of confidentiality, and the only record connecting the participant to their responses or the study at all would be the consent form.[6]
    - Informed consent generally does not apply to secondary analysis of de-identified data, or to secondary analysis of private identifiable information that were already collected in accordance with the Privacy Rule and/or the Common Rule, unless the researcher plans to re-contact subjects.[7]
    - Complete waiver of informed consent is very rare. It generally only applies to settings where participants cannot provide informed consent, like a coma ward.[8] If a researcher applies for complete waiver of informed consent in error, especially if they do not include informed consent materials, they risk their application being returned as incomplete and not reviewable.
    - Adelphi policy may require explicit permission for any audio or video recordings. This may be written into the consent document; a separate rider is not required.
- Parental consent and child assent, as applicable.
- Survey items, with the actual text that will be used in paper or online surveys. If researchers only include the names of standard batteries of measures, without the measures themselves, this may cause delays in processing.
- Schedules and scripts for focus groups and qualitative interviews. It is understood that much of researchers' interactions with participants in focus groups and qualitative interviews is not according to a script or schedule, but researchers who do not include any schedule or script at all risk their protocol being returned as incomplete and not reviewable.
- Letters of cooperation from other organizations or entities that would have to give permission for the research to proceed, or stipulations that they will be obtained and documented before the research proceeds.
- Any IRB approvals or exempt determinations from cooperating institutions.
- Any other information relevant to the application.

All protocol submissions to the IRB for continuing review should include the following:[9]

- The completed continuing review form, indicating whether the intention is to:
    - Continue the study with no modifications
    - Discontinue some activities while continuing others

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[6] Documentation of informed consent, 45 C.F.R. § 46.117 (2024). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117

[7] Office for Human Research Protections. (2021). Exemptions (2018 requirements). Retrieved April 5, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html

[8] Office for Human Research Protections. (1996, March 21, 2016). Informed consent requirements in emergency research (OPRR letter, 1996). Retrieved April 5, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html

[9] Office for Human Research Protections. (2010, June 4, 2019). Continuing Review Guidance (2010). Retrieved April 5, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html#section-c

    - Modify or add some activities
- A brief progress report, including:
    - Number of subjects recruited, with a breakdown by site, experimental condition, or stratum of a stratified random sample, as appropriate
    - Any new or relevant information uncovered during the course of the research that is relevant to risks or benefits to participants
    - A summary of unanticipated problems and adverse events, or a statement that no unanticipated problems or adverse events occurred
    - A summary of withdrawal of subjects since the last IRB review, and the reasons for withdrawal, if known, as applicable
    - A summary of all complaints from the subjects known to investigators, if any
- Any amendments to the research approved by the IRB since its initial approval
- In the case of modifications or additions at the time of continuing review, the original complete protocol with changes, including changes due to amendments already approved, described in a cover letter and highlighted in the protocol

International Research

Researchers performing work in other countries will be subject to the laws and regulations of that country. IRB permission should be acquired from the appropriate body in the country where the work will be carried out. If there is no equivalent to an IRB, then researchers should work with local non-government organizations, researchers, or community leaders to ensure that the research is consistent with cultural and legal expectations, and to secure support for the research.[10] For region specific guidance, refer to the Office for Human Research Protection (OHRP)'s International Compilation of Human Research Standards[11] and related resources. Contact the ORSP Director for further information. Note that, if the study is being conducted entirely at and for another institution that is providing IRB oversight, the Adelphi IRB may determine that Adelphi is "not engaged" in the research (see the Definitions of Terms section) and permission depends on a different IRB.

Reliance on Another IRB

Reliance agreements[12] require prior communication with the ORSP Director. They are appropriate when:

- The study requires full board review,
- Another institution engaged in the research has a fully accredited IRB, and

[10] Cornell University Office of the Vice President for Research & Innovation (OVPRI). (2023, February 1). IRB considerations for international research. Retrieved July 16, 2024 from https://researchservices.cornell.edu/resources/irb-considerations-international-research

[11] Office for Human Research Protections. (2024, June 27). International compilation of human research standards. Retrieved July 16, 2024 from https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

[12] University of Wisconsin - Madison. (2024). New study. Retrieved April 14, 2024 from https://irb.wisc.edu/submission-guidance/new-study/?tab=ceded-application#block_996ec172292894c7a213be3c72025851-ceded-application; University of Wisconsin - Madison. (2024). Single IRB (sIRB) and External IRB: Reliance arrangements. Retrieved April 14, 2024 from https://irb.wisc.edu/submission-guidance/sirb/

- A funding agency requires reliance on a single IRB

Requests for reliance agreements specific to particular studies generally require submission of a complete protocol. The ORSP Director may request IRB members to review a protocol before Adelphi enters into the reliance agreement. Once the typical reliance agreement is in effect, only the IRB of record has authority to suspend or require modifications to the research.

Requirements for Informed Consent

According to the Belmont Report, "Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied." Participants or their legal representatives have to be given sufficient information about what will be expected of them, the information has to be comprehensible to them, and participation has to be voluntary.[13] Whatever form an informed consent[14] communication takes, it must include the following, as per Common Rule part §46.116(b):

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental
   - In deference to modern expectations about "trigger" or content warnings, this section should explicitly mention topics to be covered in interview and survey questions, even in exempt protocols. For instance, a questionnaire about trauma symptoms should be described as a questionnaire about trauma symptoms, not "mood issues."

(2) A description of any reasonably foreseeable risks or discomforts to the subject;
   - Also in deference to modern expectations about trigger or content warnings, participants may be warned that questions about certain topics may cause momentary psychological discomfort, but that research generally finds these discomforts to be no more severe than those which participants affected by the issues under study find in everyday life.[15]

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

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[13] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979, April 18). Ethical principles and guidelines for the protection of human subjects of research ("The Belmont report"). Retrieved November 25 from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

[14] General requirements for informed consent, 45 C.F.R. § 46.116 (2024). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116

[15] Yeater, E., Miller, G., Rinehart, J., & Nason, E. (2012). Trauma and sex surveys meet minimal risk standards: implications for institutional review boards. Psychological Science, 23(7), 780-787. https://doi.org/10.1177/0956797611435131; Rinehart, J. K., Nason, E. E., Yeater, E. A., & Miller, G. F. (2017). Do some students need special protection from research on sex and trauma? New evidence for young adult resilience in "sensitive topics" research. Journal of Sex Research, 54(3), 273-283. https://doi.org/10.1080/00224499.2016.1156047; National Research Council. (2014). Determining minimal risk in social and behavioral research. In Proposed revisions to the common rule for the protection of human subjects in the behavioral and social sciences. https://doi.org/10.17226/18614

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- Generally, participants are told here that their data will be stripped of any positively identifying information in the process of preparing them for analysis, such as IP addresses not collected in online surveys or pseudonyms used in interview transcripts. Participants are also usually told that their data will be stored on secure media to which only the research team has access. If identifying information have to be stored with the data (e.g., to re-contact participants in a panel study), or if data could be used for deductive disclosure of participants identities even without positively identifying information and the data would put participants' reputations at risk if they fell into the wrong hands, then additional confidentiality measures are required.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- Even in a minimal risk study, if there is some theoretically possible risk of being "triggered," e.g., by survey or interview questions, it is common to include referral information to 988 and a local source of help as applicable, like the Counseling Center. It is also customary to include referral information to a helping organization relevant to the issues under study, like a domestic violence shelter or the Legal Aid Society.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
- If the study involves a researcher who is in another role with respect to the participants, e.g., teacher, clinician, or clinician's supervisor, then it should be clearly stated here that research participation or non-participation will not affect anything about services the participant receives.

(9) If the research involves collection of identifiable private information or identifiable biospecimens, one of the following statements:
- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The following additional elements of informed consent may apply under some circumstances as per §46.116(c). They pertain to ongoing medical studies like drug trials, which are rare at Adelphi.

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;
(3) Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
(6) The approximate number of subjects involved in the study;
(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Elements of Broad Consent

Broad consent[16] generally applies to large repositories of biospecimens or identifiable private data collected for research purposes, such as the human genome project or the University of Michigan's Institute for Social Research. Considerations of broad consent do not apply to data that educational institutions and human service agencies collect and use routinely for non-research purposes; research involving these data sources is usually exempt. Secondary analyses of institutional data received by a researcher or research team with no positively identifying information included, even if the researcher or research team is connected with the institution, is exempt research. Elements of broad consent include:

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may reasonably be expected from the research;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

[16] Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, 45 C.F.R. § 46.116(d). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(d)

- (If applicable) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- (If applicable) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
- A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;
- A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which could also be indefinite);
- Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and
- An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Translation of Informed Consent Materials

Informed consent materials should be offered in languages used by the population(s) under study and translated whenever that is necessary to ensure justice in subject selection. Study populations should not be limited to persons fluent in English for the sake of convenience if that would cause injustice in subject selection. Materials should be translated by someone knowledgeable about the requirements of informed consent and sufficiently fluent in the language in question. It is acceptable for investigators themselves or members of their research teams to do their own translation. If a study presents more than minimal risk, the IRB may request an independent back-translation, or have an IRB member or an Adelphi faculty member who is sufficiently fluent in the language in question vouch for the translation. Investigators planning studies in languages other than English should ask the ORSP Director about requirements. The IRB endeavors not to surprise investigators with translation or back-translation requirements at the time of review.

Waiving Elements of Informed Consent

The Common Rule requires that all informed consent language include enough information to allow participants or their legal representatives to understand why they would or would not want to participate, and that it be concise, focused, and comprehensible to the participants. It also cannot include any waiver of the subject's legal rights or any releases of liability for negligence.[17] An IRB may waive or alter other elements of informed consent if:

- A state or local government agency, or a researcher partnering with them, is conducting research for the purpose of evaluating a public benefit or service program, and the research could not reasonably be carried out without the waiver or alteration
- It finds, and documents, that:
    - The research is minimal risk
    - The research could not be done without the waiver or alteration
    - The waiver will not adversely affect participants' rights or welfare
    - Where applicable, subjects or their legal representatives will be given additional pertinent information after participation
    - If the research uses identifiable private information, the research could not be carried out with de-identified data

"Screening" interactions do not require informed consent if:

- The researcher will conduct the screening by oral or written communication with the prospective participant or their legal representative
- The researcher will identify participants by accessing already-collected records or stored biospecimens

Waiving Documentation of Consent

The requirement of legally effective (i.e., signed, in electronic or paper format) informed consent is central to the Common Rule's implementation of the Belmont Report principle of Respect for Persons.[18] The Common Rule allows an IRB to waive the requirement of a signed consent document if it finds any of the following:

- The only record linking the subject to the research would be the consent form, and the primary risk to the participant from participating in the research would be breach of confidentiality.
- The research is minimal risk, and involves procedures like questionnaires and interviews that would not normally require written consent if they were being done for other-than-research reasons.
- The research is minimal risk, written consent is not a norm for the population under study, and the research uses an alternative procedure that fits within their norms.

[17] General requirements for informed consent, 45 C.F.R. § 46.116 (2024). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116

[18] Office for Human Research Protections. Informed consent FAQs. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

If the IRB waives documentation of informed consent, it usually requires a verbal script or written statement to be presented to participants including all elements of informed consent.[19] Like many other IRB's, including that of the National Institutes of Health,[20] the Adelphi IRB generally waives signed consent for exempt research, but still upholds a norm of including all elements of informed consent in informed consent communications to participants. The Adelphi IRB will not determine a study to be exempt if it is both more than minimal risk and requires waiving written consent. If an IRB has concerns about an exempt study, it may refuse to waive written consent for it until those concerns are addressed.

Some Informed Consent Scenarios

Most online surveys and interviews

Signed consent is waived because these procedures are minimal risk, and surveys and interviews for purposes other than research generally do not require written consent. A statement or script including all elements of informed consent is required.

Surveys and interviews which ask for identifying private information which could harm participants' reputations if it fell into the wrong hands

Signed consent is waived because the main risk to participants would be through breach of confidentiality, and the consent form would be the only record that the participants were in the study at all. An informed consent statement or script including all elements of informed consent is required. Participants should be provided with documentation that they were in the study if they request it.

Surveys, interviews, and benign experiments that are exempt and do not involve face-to-face interaction with investigators

Signed consent will generally be waived because the study is minimal risk, the waiver does not adversely affect participants' rights or welfare, or the burden to participants of requiring signed consent would make the study impracticably difficult (response rates for online studies are already low enough). It is common to waive signed consent for exempt research. An informed consent statement or script including all elements of informed consent is required.

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[19] Documentation of informed consent, 45 C.F.R. § 46.117 (2024). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117

[20] Iowa State University. (2021). Informed consent for exempt studies. https://compliance.iastate.edu/wp-content/uploads/sites/4/pdf/exempt-consent-guidance.pdf; University of California San Francisco. (2023). Exempt consent templates and guidance. https://irb.ucsf.edu/exempt-consent-templates-and-guidance; University of Virginia. When consent is not required. https://research.virginia.edu/irb-sbs/when-consent-not-required; Lehigh University. Informed consent process for exempt research. https://research.cc.lehigh.edu/informed-consent-process-exempt-research; University of Nevada. (2021). Informed consent for exempt and minimal risk research. https://www.unr.edu/research-integrity/human-research/human-research-protection-policy-manual/340-informed-consent-for-exempt-and-minimal-risk-research; University of Michigan. Informed consent guidance & templates. https://research-compliance.umich.edu/informed-consent-guidelines;
National Institutes of Health. (2024). Informed consent. https://policymanual.nih.gov/3014-301; Catholic University of America. Guidelines for obtaining consent from human subjects. https://sponsored-research.catholic.edu/resources/Human-Subjects-Protection/index.html

Secondary analysis of identifiable private information collected under a broad consent

No further informed consent is required as long as use of the data stays within the scope of the broad consent.

Secondary analysis of de-identified data

Because this activity does not involve identifiable private information, it has no human subjects as defined under the Common Rule. Informed consent considerations do not apply to it, regardless of the status of any data owner agreement, broad consent, prior plan to use the data for research, or dual-role issue w/re the investigators or their institution.

Surveys, interviews, and benign experiments that involve face-to-face interaction with investigators

There is little reason not to use signed consent, but an investigator could still make a case for waiving consent based on principles described in the Common Rule.

Studies involving deception

Deception has to be scientifically justified, and the informed consent process has to be completed in a debriefing.

Laboratory research

Research requires signed consent if participants take substances they would not normally take, do physical activities they would not normally do, or undergo medical procedures they would not normally undergo at the request of a researcher.

About Vulnerable Populations

The Concept of Vulnerability

According to authoritative interpretations of the Common Rule, to "safeguard" a vulnerable population does not mean to categorically exclude them from research. Even vulnerable people have a right to respect for their self-determination and to have their voices heard in a research study that is supposed to represent their experiences. National Institutes of Health (NIH) policy, for instance, discourages excluding vulnerable populations unless there is a valid scientific reason for doing so.[21] Under that policy, for example, a research study on a transitional living program for 16-24 year olds would be expected to include, rather than exclude, the 16 and 17-year-olds. The protocol would be expected to provide justification based on the Common Rule, the Belmont Report, and previous research for why the benefit of collecting data on 16 and 17-year-olds outweighs the harm.[22]

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[21] National Institutes of Health. (2019). Vulnerable and other populations requiring additional protections. https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm

[22] Weir, K. (2019). Studying adolescents without parents' consent: A new APA resolution supports mature minors' participation in research without parental permission. Monitor on Psychology, 50(2). https://www.apa.org/monitor/2019/02/parents-consent; Cavazos-Rehg, P., Min, C., Fitzsimmons-Craft, E. E., Savoy, B., Kaiser, N., Riordan, R., Krauss, M., Costello, S., & Wilfley, D. (2020). Parental consent: A potential barrier for underage teens' participation in an mHealth mental health intervention. Internet Interventions, 21, 100328. https://doi.org/10.1016/j.invent.2020.100328

The Common Rule includes, with reference to United States Department of Health and Human Services policy, the following general bases for risk/benefit determinations about research on vulnerable populations:[23]

- Whether the research is exempt. If the protocol is exempt, e.g., an anonymous online survey, it is not referred to the full board just because members of vulnerable populations might find their way into the study. Some exempt categories do not apply to children.
- Whether the research is minimal risk. Informed consent and, if applicable, assent rules apply.
- If the research is more than minimal risk, but could benefit the participants themselves. The potential benefit would have to be worth the risk, and also potentially greater than some other treatment or procedure already available. Informed consent and, if applicable, assent rules apply.
- If the research is more than minimal risk and would not directly benefit the participants, but could yield valuable generalizable knowledge about the participants' experiences. The risk would have to be a minor increase over minimal risk, the findings would have to be vitally important to understanding people from the participants' population or helping people with their condition, and any intervention or procedure would have to be similar to what they would otherwise receive from medical or social services providers. Informed consent and, if applicable, assent rules apply.
- Whether the research comports with state law, local law, cultural values, and other norms that would ordinarily apply to the activities in the protocol.

Investigators may solicit expert input relevant to any of the above determinations and include it with their application. Investigators may also conduct a literature review in support of any of the above determinations and submit it with their application. The IRB may also consult with experts, including Adelphi faculty, and review existing research in making their determinations.

When Researchers Also Have Other Roles

Employers/agencies researching employees

Of all paradigms for evaluating organizations, the one that would create the least vulnerability would be for all evaluations to be conducted by disinterested outsiders. However, the exigencies of agency work are often that agencies will only give entree for evaluation purposes to someone who already has some connection to them, likely an employee. The IRB does not categorically forbid investigators from researching their co-workers, including subordinates, but it does require that no-one be coerced into participating, and that personally identifiable information be collected, stored, and reported in such a way that the research will not increase risk of human resources consequences. De-identification of data and data owner issues between the research team and the agency would have to be addressed in the protocol, with the understanding that the Adelphi IRB is not in a position to intervene on anyone's behalf to make anyone turn data over to anyone. A study that involves no personally identifiable information is exempt.

[23] Additional protections for children involved as subjects in research, 45 C.F.R. § 46 Subpart D (2024). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html

Clinicians/practitioners/educators researching patients/clients/students

The scientist/practitioner model and "clinical data mining" have long traditions in multiple fields. Moreover, access to many populations who need more research representation is only practical through agencies serving them, and those agencies would only ever give entree to someone who already has some connection to them, likely a volunteer, intern, or employee. The IRB does not categorically forbid this, but it does require that extant obligations under HIPAA and FERPA be upheld, no-one be coerced into participating, access to services not be impacted, and that personally identifiable information be collected, stored, and reported in such a way that the research will not damage anyone's reputation. De-identification of data and data owner issues between the research team and the agency would have to be addressed in the protocol, with the understanding that the Adelphi IRB is not in a position to intervene on anyone's behalf to make anyone turn data over to anyone. Studies that involve no personally identifiable information, even about one's own patients, clients, or students, are exempt. Studies that evaluate educational methods using commonly accepted teaching practices in educational settings are categorically exempt if they involve adults, and also exempt if they involve children and the researcher does not participate.

Specific Vulnerable Populations

Persons with cognitively impaired decision making

Some research questions necessarily involve participants who have various degrees of cognitive impairment. Researchers may use a standardized assessment, such as the MacArthur Capacity Assessment Tool,[24] which would otherwise ordinarily be used to evaluate participants' ability to consent to the activities described in the protocol. Persons who already participate functionally in contexts that require adult decision-making, such as higher education or work for wages, may be assumed to have adult-like capacity to consent to research participation.

Incapacitated persons

Critical medical interventions for incapacitated persons who cannot consent for themselves and whose legal representatives are not available is referred to as "emergency research." It is rare at Adelphi because Adelphi does not have a medical school. An investigator collaborating on such a project would be expected to utilize a Reliance Agreement to have the research overseen by the institution where it is being conducted. Investigators should not ask for exceptions from informed consent on the basis that informed consent is inconvenient or prohibitively difficult to obtain. The policy about emergency research refers to people who cannot consent for themselves due to a medical condition,[25] so it would not apply, for example, to refugee children separated from their parents. Other policies may be used to justify waiving parental consent, but not this one.

[24] Karlawish, J. (2008). Measuring decision-making capacity in cognitively impaired individuals. Neurosignals, 16(1), 91-98. https://doi.org/10.1159/000109763

[25] Office for Human Research Protections. Informed consent FAQs. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

Pregnant women, human fetuses, and neonates

Pregnant women are not assumed to have limited decision-making capacity just because they are pregnant. Research that would have any impact at all on human fetuses or neonates is rare at Adelphi because Adelphi does not have a medical school. A study that had any impact on human fetuses or neonates would have to be minimal risk or, if it were more than minimal risk, provide some direct benefits. A study on nonviable neonates would be expected to comply with all applicable laws.[26]

Prisoners or other institutionalized persons

For research on prisoners, §46.304(b) requires that one member of (one of) the IRB(s) approving the research be a prisoner or prisoner representative. If the Adelphi IRB does not have a prisoner or prisoner representative at the time of the application, then the investigator may contact the ORSP Director about the possibility of a temporary IRB member or a Reliance Agreement. In all research on institutionalized persons, benefits that would come from participating in the research should not be so great as to coerce them into participating in the study. Also, the research should be about issues that affect institutionalized persons and offer some benefit to them or the population they come from. At no point should institutionalized persons be used for convenience.

Children

Department of Health and Human Services resources define a participant as a "child" for research purposes if they are under the age when they could otherwise ordinarily consent to the activities in the research protocol.[27] This means that many people under 18 could be regarded as mature minors or even adults for the purposes of some protocols, especially if they are minimal risk or exempt. Outside of research contexts, a 17-year-old college student playing Prisoner's Dilemma, a 16-year-old participating in confidential HIV risk screening, a 12-year-old taking an online personality test, and a 6-year-old playing a benign educational video game would require no explicit signed consent or assent from anyone. The Common Rule does not support that any activity becomes riskier, or the decision to do it more complex, just because it is part of a research protocol. The Common Rule also does not call for prohibitive "safeguards" against children finding their way into studies when they fit inclusion criteria in all other respects but age. Protocols for anonymous or confidential surveys are not automatically referred to the full board based on the mere suggestion of the theoretical possibility that someone under 18 might click their way past screening criteria (i.e., lie about their age) and take the survey.

The Common Rule stipulates that the following additional safeguards should be in place for research on children, in addition to the safeguards common to all vulnerable populations described above:

- Some protocols that are exempt for other populations require full board review if the participants are children. Surveys and interviews of children are not exempt. Research on

[26] Additional protections for pregnant women, human fetuses and neonates involved in research, 45 C.F.R. § 46 Subpart B (2024). https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html

[27] Office for Human Research Protections. Research with children FAQs. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html

public behavior or educational tests is not exempt if the researcher participates in the activities being observed.

- Unless parental permission is waived, both parent consent and child assent are required for the child to participate in the research, to the extent that the child can assent to the study. A protocol would have to make a very strong case if it wanted to allow parents or legal representatives to compel children to participate, or not tell children competent to understand the situation that they were in a research study.
- Child assent should be affirmative, and documented in an appropriate format. A child who is simply uncritically following adult directions is not assumed to have consented to participate in research.

Waivers of parental consent are possible, and even common, in particular situations, such as:[28]

- Even telling the parent that the child is in the study may lead to questions about the child's identity, behavior, or associates that could result in the parent and/or their community harming the child
- Requiring parental consent would reduce response rates, either overall or differentially across populations of interest, to the point where study results would be invalid
- Parents are entirely unavailable, and no-one who could act as the child's legal representative is available

The reason for waiving parental consent should not be for the convenience of the researcher, but because it would be in the best interests of the child, or of the population under study which includes children, to do so.

If a researcher is already a mandated reporter of child abuse and neglect due to some licensure or certification that they hold, e.g., MSW, and information may come up in the study that would trigger the researcher's mandated reporter responsibilities, then the researcher should disclose this in the informed consent and assent processes. They should also describe in the protocol how they would carry out their responsibilities. If a researcher was not already a mandated reporter, then conducting a research study does not turn them into one.[29]

Beyond situations like pre-existing mandated reporter responsibilities, there is no expectation that a researcher shall intervene on a participant based on information they receive for research purposes in a research study. Researchers are not expected to change their protocols to allow them to assess and intervene on participants more readily. This would raise the possibility of unwanted intervention, which research has shown to be not necessarily either ethical or helpful,[30] especially outside of a normal practice setting by someone who is not a trained professional. Crisis phone

[28] Bauman, L. J., Mellins, C. A., & Klitzman, R. (2020). Whether to waive parental permission in HIV prevention research among adolescents: Ethical and legal considerations. Journal of Law, Medicine, & Ethics, 48(1), 188-201. https://doi.org/10.1177/1073110520917010

[29] New York State Office of Children and Family Services. Summary guide for mandated reporters in New York State. https://ocfs.ny.gov/publications/Pub1159/OCFS-Pub1159.pdf

[30] Rowe, M., Frey, J., Bailey, M., Fisk, D., & Davidson, L. (2001). Clinical responsibility and client autonomy: Dilemmas in mental health work at the margins. American Journal of Orthopsychiatry, 71(4), 400-407. https://doi.org/10.1037/0002-9432.71.4.400

lines staffed by people trained to assess and intervene are available for several issues that could emerge for participants, and providing information on these to participants is often considered sufficient to safeguard their welfare.

Levels of Review

Determining Level of Review

The general practice at Adelphi is for all research projects to be submitted for the IRB's consideration. Upon receiving a protocol, the ORSP Director forwards it to the IRB Chair and one or more experienced IRB members. In choosing reviewers, the ORSP Director is expected to consider conflicts of interest, fair distribution of workload, and matching reviewers with proposals that would be appropriate to them. The ORSP Director is also expected to try to avoid assigning a proposal to reviewers who have already communicated that they will not be present for the next full board meeting. IRB members may request to receive an increased or decreased number of review assignments as needed to fulfill service requirements under Article XIV, Section 9 of the CBA. The ORSP Director and IRB Chair choose whether they wish to participate as reviewers. The reviewers make one of the following determinations:

- The protocol is exempt, either as is or pending minor changes that designated reviewer(s) can vet
- The protocol is not exempt, but may be approved as expedited, either as is or pending minor changes that designated reviewer(s) can vet
- The proposal is neither exempt nor eligible for expedited review, and should receive full board review
- The protocol is not complete and should be returned to the investigator

If a proposal is incomplete, the ORSP Director or a reviewer will often try to contact the investigator before the proposal is reviewed to request corrections and additional materials. This is less feasible for proposals submitted at the last minute.

Reviewers on a proposal usually operate by consensus. If they disagree even after discussion:

- If at least one reviewer says that proposal is incomplete and should be returned to the investigator, then it is returned to the investigator.
- If no reviewer says the proposal is incomplete but at least one says the proposal should receive full board review, then it is referred to the full board
- If no reviewer says that the proposal is incomplete or should receive full board review, but one reviewer says that it can receive expedited approval, then it may receive expedited approval.

Proposals referred for full board review are placed on the agenda for a convened IRB meeting, usually the next one for which the protocol met the submission deadline.

Applications for continuing review receive expedited or full board review, as appropriate to the research activities that are still planned. Continuing review is not required if the only activities that

remain in a protocol are data analysis, even of private identifiable information, or inclusion of follow-up data from procedures that participants would undergo as part of their clinical care.[31]

Exempt Research

About exempt research

Many proposals submitted to the Adelphi IRB are exempt,[32] and researchers should familiarize themselves with the requirements for exempt research.[33] The IRB review form is not written to contain everything investigators need to know about exempt categories to prepare their proposals. Checking the wrong exempt category or more than one exempt category on the form is one of many errors that may create delays in processing. The IRB takes no responsibility for disruption to thesis, dissertation, or grant workflows over this issue. Some exempt categories apply differently, or do not apply, to research on children.[34]

The Common Rule's discussions of exempt research categories do not mention risk levels with respect to methodologies other than experiments, and it does not mention the population under study at all. Exempt determinations are based on the method. It is theoretically possible for a study to be exempt but more than minimal risk, e.g., interviewing people who regularly engage in some illegal behavior using fully encrypted recording media, but studies like this are rare at Adelphi.

Exempt determinations do not expire. As long as the researcher makes no changes to the protocol that would turn it into a study that is no longer exempt, it does not require continuing review.

Exempt categories include the following:

Evaluation of teaching methods

Applies to studies that will be "conducted in established or commonly accepted educational settings" and involve "normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction." Applies to research on children.[35]

Secondary analysis of publicly available information

Applies to studies that exclusively involve data that have already been collected and are publicly available, like the General Social Survey. Applies to research on children.[36]

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[31] IRB review of research, 45 C.F.R. § 46.109 (2024). https://www.ecfr.gov/on/2018-07-19/title-45/section-46.109

[32] University of Wisconsin - Madison. (2024). WORKSHEET: Exemption and limited IRB review. Retrieved April 14, 2024 from https://uwmadison.app.box.com/s/i1k5zf99rhm541n38opgmuoudl1cdta2

[33] General requirements for informed consent, 45 C.F.R. § 46.104 (2024). https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104

[34] National Institutes of Health. (2021). 3014-402 - Research involving children. https://policymanual.nih.gov/3014-402

[35] Exempt research, 45 C.F.R. § 46.104(d)(1) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(1)

[36] Exempt research, 45 C.F.R. § 46.104(d)(4)(i) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(4)(i)

Secondary analysis of de-identified data

Applies that involve only secondary analysis of "Information, which may include information about biospecimens…recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects."[37] Secondary analysis studies of panel data, even data about sensitive topics, and clinical data mining studies in which participants already gave broad consent (see elsewhere in this manual) for the type of research described in the proposal, usually meet this qualification. Applies to research on children.

Anonymous survey

Applies to a study that "only includes interactions involving educational tests…survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)" in which "the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects." Studies involving MTurk, Prolific, etc., often meet this qualification.[38] Only applies to research on children "if the research involves educational tests or the observation of public behavior when the investigator(s) does not participate in the activities being observed."[39]

Survey or interview that does not collect stigmatizing information

Applies to a study that "only includes interactions involving educational tests...survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)" in which "Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation." Most psychology questionnaire studies meet this qualification, although studies that involve instruments that are commonly accepted to positively diagnose stigmatizing conditions (rare) may be considered to be collecting stigmatizing information.[40] Only applies to research on children "if the research involves educational tests or the observation of public behavior when the investigator(s) does not participate in the activities being observed."[41]

Confidential survey or interview

Applies to a study that only involves "interactions involving educational tests...survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)"

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[37] Exempt research, 45 C.F.R. § 46.104(d)(4)(ii) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(4)(ii)

[38] Exempt research, 45 C.F.R. § 46.104(d)(2)(i) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(2)(i)

[39] National Institutes of Health. (2021). 3014-402 - Research involving children. https://policymanual.nih.gov/3014-402

[40] Exempt research, 45 C.F.R. § 46.104(d)(2)(ii) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(2)(ii)

[41] National Institutes of Health. (2021). 3014-402 - Research involving children. https://policymanual.nih.gov/3014-402

in which "identity of the human subjects can readily be ascertained"[42] and "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."[43] Most qualitative interview studies with appropriate data security plans and without fieldwork components fit this qualification. Surveys and interviews that collect stigmatizing information under an adequate data security plan also meet this qualification. Only applies to research on adults.

Anonymous minimal risk experiment

Applies to studies that involve "Benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and...The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects." Studies of performance in online games usually meet this qualification. Only applies to research on adults.[44]

Minimal risk experiment that does not collect stigmatizing information

Applies to studies that involve "Benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and...Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation." In-person laboratory studies on benign topics usually meet this qualification. Only applies to research on adults.[45]

Confidential experiment

Applies to studies that involve "Benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection" and "there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." Laboratory studies involving video recording of individuals may meet this qualification. Only applies to research on adults.[46]

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[42] Exempt research, 45 C.F.R. § 46.104(d)(4)(iii) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(4)(iii)

[43] Exempt research, 45 C.F.R. § 46.104(a)(7) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.111#p-46.111(a)(7)

[44] Exempt research, 45 C.F.R. § 46.104(d)(3)(i)(A) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(3)(i)(A)

[45] Exempt research, 45 C.F.R. § 46.104(d)(3)(i)(B) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(3)(i)(B)

[46] Exempt research, 45 C.F.R. § 46.104(d)(3)(i)(C) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(3)(i)(C)

Some reasons why studies are not exempt

- **The study is an experiment and not minimal risk.** Physical or psychological examinations or procedures that are routine, such as psychological tests, blood draws, physical sensors placed on the body, moderate exercise, noninvasive biospecimen collection, using an approved drug or device for its approved indication according to its label, and most imaging techniques that do not involve sedation, anesthesia, x-rays, or microwaves can all be minimal risk.[47] Anything can be more than minimal risk if there is some reason to believe that it might be risky for part of the intended target population, e.g, blood draws from people who weigh less than 110 pounds.[48] Investigational drugs, some imaging techniques, most treatment studies involving people with serious mental illness, and interventions to prevent or treat conditions associated with early death, significant self-harm, or danger to others are not minimal risk.[49] When stigmatizing information must be handled in a manner that cannot entirely avoid the possibility of their falling into the wrong hands and being identified with specific participants at some point in their chain of custody, this is not minimal risk.
- **The protocol involves doing mental health treatment or a social work intervention.** These do not fall into the category of "benign behavioral interventions" mentioned in the Common Rule's discussion of exempt categories. If the mental health treatment or social work intervention has already taken place and Analyses of data on a mental health treatment or social work intervention that has already taken place are usually exempt.
- **The protocol uses identifiable private information about subjects collected under a broad consent and there is a question about the interpretation of that broad consent.** The IRB has discretion to waive broad consent to use identifiable private information unless the application is coming from researchers to whom the participant already refused to give broad consent. Broad consent is only an issue with identifiable private information; analysis of de-identified data is exempt.[50]
- **The study would be exempt, except that it involves children as subjects.** Evaluations of educational methods, secondary data analysis, and observational studies of public behavior with children are usually exempt. Experiments and surveys specifically recruiting children are not.
- **The study recruits from vulnerable populations.** Investigators often build reasonable boundaries into their protocols to screen vulnerable populations when their inclusion would be problematic. Investigators should give due consideration to the possibility that

[47] National Institute of Mental Health. NIMH guidance on risk-based monitoring. Retrieved April 14, 2024 from https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring

[48] University of California San Francisco. Levels of review. Retrieved April 14, 2024 from https://irb.ucsf.edu/levels-review; Indiana University. (2023, February 1). Conduct and review of research involving exercise testing and training. Retrieved April 14, 2024 from https://research.iu.edu/compliance/human-subjects/guidance/areas/exercise.html; Lucero, M. L. (2023, November 7). Review of human subjects research risk. Retrieved April 14, 2024 from https://www.tc.columbia.edu/institutional-review-board/irb-blog/2023/review-of-human-subjects-research-risk/

[49] National Institute of Mental Health. NIMH guidance on risk-based monitoring. Retrieved April 14, 2024 from https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring

[50] Office for Human Research Protections. (2017). Attachment C - Recommendations for broad consent guidance. Retrieved April 14, 2024 from https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html

participants might make mistakes in answering screening questions or lie about their eligibility, but the mere existence of this possibility is not a reason to stop a study.

- **Another institution will serve as "IRB of Record" for the study or has already approved the study, and Adelphi is being asked to cede responsibility for it to them.** Does not apply if the other institution has already determined the study to be exempt.
- **Stigmatizing information.** Refers to information that could harm a participant's reputation if 1) it were positively identified with them, even through deductive disclosure, and 2) their identity connected with the information fell into the wrong hands. If a study recruits only people with a stigmatizing condition or life situation, then the mere record that they took part in the study could be stigmatizing information, and investigators would be expected to plan around this.
- **Some research activities have already taken place.** An IRB can retroactively determine a study to be exempt, but it cannot retroactively determine a study to be approved.
- **The research involves some contract or agreement between Adelphi and another institution.** Some of these processes require full board approval, even of research that could be interpreted to fall into an exempt category.

Expedited Review

When expedited review is appropriate

Some proposals are not exempt, but qualify for expedited review. Examples[51] include:

- Effects of a drug that is not investigational, e.g., caffeine
- Blood collection from healthy adults weighing at least 110 pounds
- Non-invasive biospecimen collection, e.g., "spit tests" for COVID
- Physical sensors placed on the body which are routinely used in clinical testing
- Moderate physical exercise and fitness testing (consult appropriate standards for the definition of "moderate")
- Analyses of sensitive data that were originally collected for non-research purposes
- Collecting voice, video, digital, or image recordings for research purposes
- Long-term follow-up with subjects recruited in an approved protocol

Research that is categorically *ineligible* for expedited review involves:

- More than minimal risk to participants
- Stigmatizing data that can only be collected in a way which presents some risk that it will fall into the wrong hands, e.g., non-encrypted recording media taken into the field

Expedited review caveats

Investigators may be interested in expedited review if their research qualifies for it and especially if there are time-sensitive issues involving outside grants or collaborative relationships with other

[51] Office for Human Research Protections. (1998, March 21, 2016). Expedited review: Categories of research that may be reviewed through an expedited review procedure (1998). Retrieved April 14, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

institutions. Level of review is something the IRB has to decide, however, based on statutes and precedents about which an IRB does not have the authority to make judgment calls.[52]

It is theoretically possible for research that is more than minimal risk to be exempt, but research must be minimal risk to qualify for expedited review. If an IRB member believes that a non-exempt protocol is more than minimal risk and must receive full board review, the Common Rule explicitly requires that the IRB keep a record of their rationale for this.[53]

Reviewers of expedited proposals cannot render a final determination of Not Approved. Not Approved determinations may only be made by the full board.

Communicating Results of Exempt and Expedited Reviews to Investigators

If all reviewers agree that the proposal is approved via expedited process, or if they agree that it is exempt, then that is the determination on the proposal and the ORSP Director communicates this determination to the investigator. If all reviewers agree on a set of minor revisions, then the ORSP Director communicates these to the investigator, who may revise and resubmit within 45 days as per the process for approved pending proposals being considered for full board review. If, after synchronous or asynchronous discussion of the proposal among the reviewers, one or more reviewers say that it is incomplete, then the protocol will be returned to the investigator. If, after synchronous or asynchronous discussion of the proposal among the reviewers, one or more reviewers say that it should receive full board review, then it will be placed on the agenda for a convened IRB meeting, generally the next one for which the protocol met the submission deadline.

Full Board Review

The full board review process

In full board reviews, a designated reviewer presents the proposal to the IRB along with a synopsis of other IRB members' feedback communicated before the meeting. All IRB members are expected to read and provide feedback on all proposals requiring full board review. The full board operates by consensus when a consensus emerges, and by a majority vote if not. The ORSP Director is a voting member. The full board may make one of the following determinations:[54]

Approved as is determinations

Approval may be conditional upon a data provider signing a contract, an agency sending a letter of support for the study, certain study team members finishing their CITI training, or other processes necessary for the study to proceed which the ORSP Director can manage with no further input from the IRB. If this determination is made, the ORSP Director notifies the researcher as soon as possible after the meeting.

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[52] Office for Human Research Protections. (2003, June 19, 2019). Expedited review procedures guidance (2003). Retrieved April 5, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-expedited-review-procedures/index.html

[53] IRB records, 45 C.F.R. § 46.115(a)(9) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.115#p-46.115(a)(9)

[54] University of Wisconsin - Madison. (2024). IRB review decisions. Retrieved April 14, 2024 from https://irb.wisc.edu/manual/investigator-manual/irb-review-process/irb-review-decisions/?tab=types-of-decisions

Approved pending revisions determinations

Approval is contingent upon specific revisions required by the IRB. This determination is made if the needed changes could feasibly be made in one round of revision without the full board having to re-review the proposal. If this determination is made, the ORSP Director sends notification along with required revisions to the investigator as soon as possible after the meeting. The investigator is expected to submit their revised proposal within 45 days. If all reviewers agree that the revisions are satisfactory, then the proposal is approved and the ORSP Director will communicate that determination to the investigator. If a reviewer believes that the revisions are not satisfactory or were incomplete, then the ORSP Director along with another IRB member may either continue to try to work with the investigator or impute a determination of "not approved" to the proposal. In that case, the ORSP Director will draft a list of reasons for non-approval and, after sending them to the IRB full board to confirm, communicate the non-approval determination and reasons for it to the researcher.

Not approved determinations

The proposal is entirely inappropriate, could not feasibly be made appropriate for approval in one set of revisions, and/or would have to go back to the full board for reconsideration. If this determination is made, the ORSP Director will draft a list of reasons for non-approval and, after sending them to the IRB full board to confirm, communicate the non-approval determination and reasons for it to the researcher. Any resubmission of the same proposal will be processed as an entirely new proposal. If the researcher resubmits the proposal in a form that requires full board approval, then that proposal will be scheduled for review at an upcoming IRB meeting. If the researcher changes their study so that it fits into an exempt category, then it may receive an exempt or expedited determination according to the usual process for exempt or expedited research. In either case, the researcher may make a request that it go to either the same or different reviewers, but choice of reviewers is ultimately up to the ORSP Director's discretion.

Criteria for Approval

General Criteria

Reviews of non-exempt research consider compliance with the Common Rule, other applicable laws, and the Belmont Report[55] principles of beneficence, respect, and justice. Specific criteria[56] include:

- The convened IRB has adequate expertise to review the proposal, or has obtained it through consultation
- The principal investigator is not under some injunction against doing the research described in the protocol

[55] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979, April 18). Ethical principles and guidelines for the protection of human subjects of research ("The Belmont report"). Retrieved April 14, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

[56] University of Wisconsin - Madison. (2024). WORKSHEET: Criteria for approval. Retrieved April 14, 2024 from https://uwmadison.app.box.com/s/nz2rgwsfzepaj42rrbal6i6u3fkay2sa

- The application was complete, especially with respect to participant-facing materials
- Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result
- In studies involving diagnostic or treatment procedures, risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes
- In studies that are not minimal risk, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
- There are adequate provisions to protect the privacy of subjects, such as at what stage data will be de-identified and by whom
- There are adequate provisions to maintain the confidentiality of data, including an adequate data security plan
- There is adequate scientific justification for excluding participants or populations who could benefit from the research and its applications
- There is adequate scientific justification for including vulnerable populations such as prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons
- The research design is sound and valid to answer the study's research question
- Waiver of documentation of informed consent is justified (note: this is common in survey and interview studies, especially studies about sensitive topics)
- Waiver of any and all informed consent is justified (this is rare)
- Informed consent text contains all necessary elements
- In general, informed consent processes are structured so that participants or their legal representatives make an informed choice about participation[57]
- Dual roles with respect to participants, such as clinician/researcher, appropriately managed[58]

Additional criteria specific to vulnerable populations are described in other sections. Investigators who believe their studies will be scrutinized over a particular criterion should specifically address it in the proposal, e.g., a social worker who will be using data about their own clients should clarify that the project will not negatively affect the clients' experience of receiving services.

Conflicts of Interest (Investigator)

All Adelphi employees are bound by Adelphi's current Conflict of Interest Policy[59] to avoid situations where it would be difficult for them to act in the best interests of the University or the students. Adelphi investigators working on federally-funded research grants are further bound by

[57] University of Virginia. 7.4 Criteria for IRB approval of research. Retrieved April 14, 2024 from https://research.virginia.edu/sites/vpr/files/2019-08/07-04-Criteria-for-IRB-Approval-of-Research.pdf

[58] University of Wisconsin - Madison. (2024). Research with special populations. Retrieved April 14, 2024 from https://irb.wisc.edu/manual/investigator-manual/conducting-human-participant-research/research-with-special-populations/#m_2267-children

[59] Adelphi University. (2018, July 21). Conflict of interest. Retrieved April 14, 2024 from https://www.adelphi.edu/policies/conflict-of-interest/

Adelphi's current Financial Conflict of Interest policy[60] to disclose any "significant financial interest" as per federal agencies' requirements. All Adelphi investigators are additionally bound to properly disclose and manage conflicts of interest, as described in the Definitions section, which would prevent them from acting in the best interest of study participants and the communities directly impacted by their research. This manual's definition of conflict of interest does not cover obligations toward partnering organizations, funding authorities, employees, colleagues, identity groups, or broader ideological concerns. The IRB does not expect all investigators to always completely avoid conflict of interest because, sometimes, only someone with a potential conflict of interest would have access to do the study. An example of this would be an agency executive, whose job includes securing ongoing funding, who also wants to conduct a randomized controlled trial of an intervention at their agency because it would raise the agency's profile. Doing the study at another agency might not be an option if agencies in general could not reasonably be expected to partner with a researcher to do such a study who did not already work there.

Conflict of interest is not seen as necessarily harmful or risky toward participants as long as researchers create an appropriate plan to manage it and follow their plan. Investigators are expected to disclose conflicts of interest and describe plans for managing them in their proposals. Plans for managing conflict of interest may include:[61]

- Agreements with funding authorities and partnering organizations not to interfere with objectivity of data collection, analysis, or reporting of results
- A mention of the researcher's financial relationship to the sponsor in informed consent materials
- Monitoring of the research by independent reviewers
- Disallowing trial sites, research team members, or partnering organizations who insist on "controlling the message" or other threats to objectivity

Anyone who believes an investigator to have a conflict of interest not disclosed in a proposal may ask them to come forward with it, but anyone who wishes to formally or informally accuse someone of a conflict of interest should recognize that this is a serious matter of professional conduct. This should only be done with documentation that satisfies an appropriate burden of proof.

State and Local Laws

The IRB does not have the authority to permit investigators to break state and local laws. Investigators should be aware of state and local laws as they apply to any of the following (not an exhaustive list):[62]

- Use of controlled substances
- Medical experimentation
- Surrogate decision makers
- Reporting of diagnoses of sexually transmitted infections
- Confidentiality around human immunodeficiency virus (HIV) status information

[60] Adelphi University. (2012, October 18, 2022). Research financial conflict of interest. Retrieved April 14, 2024 from https://www.adelphi.edu/policies/research-financial-conflict-of-interest/

[61] https://ori.hhs.gov/education/products/columbia_wbt/rcr_conflicts/foundation/index.html#2_6

[62] https://officeofresearch.ucsc.edu/compliance/files-irb/ucsc-irb-policy-state-and-local-laws.pdf

- Use of state death records
- Confidentiality around records involving hereditary disorders
- Assisted reproductive technology
- Involvement of prisoners in research
- Mandatory reporting of elder abuse
- Mandatory reporting of child abuse or neglect
- Parent or guardian permission
- When a minor may consent as an adult, e.g., if state law considers them to be emancipated

Applicability of HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) is inclusive of the Privacy Rule and other Rules found at 45 CFR parts 160, 162, and 164.[63] The Privacy Rule requires all covered entities (e.g., health plans, healthcare clearinghouses and healthcare providers) who engage in the electronic transmittal of protected health information to notify patients about their privacy rights and how their information can be used. Protected health information (PHI) is defined as individually identifiable health information, such as name, address, employer, relative's names, dates (of birth, admission, discharge, death), age, telephone number, fax number, email or IP address, Social Security number, medical record number, account numbers, certificate/license numbers, vehicle identifiers, voice/ fingerprints, photos and any other unique identifying numbers, characteristics or codes.

Researchers are generally not "covered entities[64]" under HIPAA unless they or their employer are their participants' health care provider and they intend to utilize PHI obtained in their practice for research. Even when researchers are or work for covered entities, HIPAA allows covered entities to release de-identified data sets without a patient's authorization if a researcher 1) needs them to prepare a research protocol and agrees to only use them for that purpose, as in preliminary studies for a grant application, or 2) uses them for actual research under an IRB-approved protocol involving alteration or waiver of individuals' authorization for the use or disclosure of PHI.[65] Where HIPAA authorization forms are used, it is the responsibility of the covered entity, not the researcher or the IRB, to ensure that the authorization form is valid. An IRB is only in a position to review HIPAA authorization language if it is included in the Informed Consent document, which is recommended if HIPAA authorization has to be obtained along with informed consent.

An IRB does not interpret or enforce HIPAA, and it is not within an IRB's mandate under the Common Rule to withhold approval from research protocols over a suggestion that investigators, who are usually not covered entities anyway, might obtain PHI and handle it in a way that is

[63] Health Information Privacy. (2022). Combined regulation text of all rules. Retrieved April 4, 2024 from https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/combined-regulation-text/index.html

[64] Centers for Medicare & Medicaid Services. (2024). Are you a covered entity? Retrieved April 4, 2024 from https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa/covered-entities

[65] Health Information Privacy. (2022). Summary of the HIPAA Privacy Rule. Retrieved April 4, 2024 from https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html This document does not mention exempt research, which may be read to imply that waivers of individual authorization for disclosure of PHI ought to receive full board review.

inconsistent with both HIPAA and their own protocols.[66] However, investigators are supposed to follow all applicable laws in the conduct of their research, and the IRB may intervene on a study if there was a positive finding that a covered entity violated HIPAA in the conduct of their research. Faculty and staff handling PHI should be aware of their covered entity status and follow HIPAA as it applies to them.

Mandatory Reporting

New York State mandatory reporting law applies if a child, someone responsible for a child, or (in the case of social service workers) anyone else is "before the mandated reporter" and "the mandated reporter is acting in [their] official or professional capacity."[67] A psychologist, social worker, teacher, nurse, or student in one of these fields who has proceeded far enough in their training to have taken required mandatory reporter training and be placed in an internship is arguably "acting in [their] professional capacity" if they are involved in research on human subjects. However, anonymous survey participants, people whose data are already in databases, and contributors of data to exempt studies in general, are not "before" them.

If an investigator is a mandated reporter, and is conducting the research in such a way that their mandated reporting responsibilities may be triggered (e.g., in-home observation, in-person interview), they should disclose this in their informed consent materials. Investigators are not required to alter their research plans to make their mandatory reporting responsibilities more easily triggered. Investigators are not required to omit questions about abuse experiences from anonymous surveys and interviews on grounds that they would be unable to identify participants and engage in mandated reporting.

Reporting to Emergency Services

Researchers should be generally willing to act to protect participants' safety and welfare, but there is not, at the time of this writing, any broad legal requirement that investigators call 911 or 988 in any particular situation. Researchers are not required to report crimes, medical emergencies, suicidal crises, or harmful ideations to anyone in particular. If such reporting is required or expected in the agency, school, or local context where the research is being conducted, or if the investigator chooses to impose a requirement of mandatory reporting on themselves, then this should be disclosed in informed consent materials.

Situation-Specific Considerations

FDA-Regulated Research

Because Adelphi does not have a medical school or agriculture department, research on food additives, medical devices, drugs, and biologics is rare. Moreover, the Adelphi IRB usually does not have medical doctors serving on it who could provide the appropriate expertise to review

[66] Health Information Privacy. (2022). Institutional Review Boards. Retrieved April 4, 2024 from https://www.hhs.gov/hipaa/for-professionals/special-topics/research/institutional-review-boards/index.html

[67] New York State Office of Children and Family Services. Summary guide for mandated reporters in New York State. https://ocfs.ny.gov/publications/Pub1159/OCFS-Pub1159.pdf

protocols for investigational drugs or biologics, or for humanitarian use devices. Investigators involved in medical studies like drug trials should familiarize themselves with applicable Food and Drug Administration (FDA) regulations. An Adelphi investigator working with a hospital or a university with a medical school would be expected to work toward creating a Reliance Agreement in which Adelphi could defer to their IRB. Reliance Agreements may involve the Adelphi IRB reviewing the protocol at the same level as the partnering institution. The Adelphi IRB will not require that applications written for other IRB's be reformatted and restructured to fit the Adelphi IRB's forms, but the application should contain all information requested on the Adelphi IRB's form. Reliance Agreements require prior communication with the ORSP Director.

Common practices for expanded access, emergency use, compassionate use, and treatment investigational device exemptions are to balance the urgency of the patient's situation against protecting their rights under the Common Rule. Expanded access, emergency use, compassionate use, and treatment investigational device exemptions are only appropriate if the patient has some serious condition and there is no comparable or satisfactory option. A request for expanded use, compassionate use, or treatment investigational device exemption requires documentation that the patient has some serious or immediately life-threatening condition, there is no comparable or satisfactory alternative, the foreseeable potential benefits outweigh the risks, and FDA regulatory requirements have been satisfied. The investigator submits this narrative to the IRB overseeing the project. An investigator may request waiver of full IRB review for expanded use directly from the FDA with the concurrence of the IRB Chair before treatment use begins for a single patient.

Reports of emergency use should be made within five days[68] and contain the same elements as a request for expanded use. The IRB will review these to ensure that patients rights were respected.[69]

Research Methods Courses

Most of the activities involving human subjects in psychology, social work, and other research methods courses are demonstration projects, not research. An activity is only considered to be research if it is supposed to lead to a publication, presentation, scholarly book chapter, white paper, or other contribution to generalizable knowledge. Activities that are not research do not need to be reviewed by the IRB. Activities that do not involve human subjects, as defined above, also do not need to be reviewed by the IRB. If a student research project involves sensitive topics or a vulnerable population, or if the student or faculty member are not sure whether an activity requires review, they should discuss this with the ORSP Director.[70] Submitting for IRB approval can be a valuable learning opportunity, and most student research projects, even those involving sensitive topics or vulnerable populations, would be determined to be exempt if they were submitted for review. Faculty and students involved in research methods courses should follow all of the ethical

[68] Exemptions from IRB requirement, 21 C.F.R. § 56.104 (2024). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-A/section-56.104

[69] National institutes of Health. (2020, April 16, 2021). 3014-502 - Expanded access, including emergency use of investigational drugs, biologics, and medical devices (test articles). Retrieved April 14, 2024 from https://policymanual.nih.gov/3014-502; U.S. Food & Drug Administration. (2019). Expanded access for medical devices. Retrieved April 4, 2024 from https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices

[70] UC Berkeley. What needs CPHS/OPHS review. https://cphs.berkeley.edu/review.html

guidelines described in this manual in their work with human subjects even if they do not intend to publish their results.

Occasionally, students or instructors decide they would like to publish or present something based on work involving human subjects from a research methods course. They should remember that, the moment the intention to publish or present takes shape, all of the work with human subjects that went into that publication or presentation becomes human subjects research, and it is under the purview of the IRB. An IRB can review a project in progress and determine that all of the activities on it have been exempt the whole time. An IRB cannot, however, grant expedited or full board approval to any non-exempt research activity that has already occurred. One possible outcome of the IRB process is that the investigator(s) can keep collecting data under their protocol, but they cannot use any data that they collected before the protocol was approved. Another possible outcome is that the protocol is limited and modified so that utilization of data that they have already collected can be reframed as a separate and discrete research activity which is exempt.

K-12 settings

- Schools may require that researchers have IRB approval from their own institution before even soliciting approval from the school. In situations like this, the Adelphi IRB may approve a project and then require the investigator(s) to forward their approval letters to the IRB.
- Some schools limit video and audio recording on their premises. Some schools also require that research personnel obtain background checks. Investigators are responsible for knowing schools' institutional policies and tailoring their protocols accordingly.
- An IRB does not have the authority to give researcher permission to break institutional policies governing the sites where they do research. If a research protocol requires breaking institutional policy or concealing information from institutional authorities, this should be clearly described and a case made for it in the protocol.
- The New York City Department of Education has its own IRB, and IRB's generally require that any research conducted on their institution's premises have approval from them.
- Some exempt categories, such as evaluations of teaching methods conducted in commonly accepted educational settings, apply to research on children. Others, like surveys and interviews, do not.
- Parental consent and child assent are required for research on children. Assent documents and scripts should be tailored to the child's comprehension.
- If teachers and staff help with the study in the capacity of research assistants, then they must receive human subjects training and be listed on the IRB application.

Secondary Analysis

Secondary analysis[71] studies are definitely exempt if the data are:

- Publicly available

[71] University of Wisconsin - Madison. (2024). Different types of research. Retrieved April 14, 2024 from https://irb.wisc.edu/manual/investigator-manual/conducting-human-participant-research/different-types-of-research/#m_2288-research-registries-and-repositories

- Stripped of any personally identifiable information by the time the research team receives them
- Records that educational institutions and human service agencies would normally collect and use for non-research purposes, even if the organization had talked about eventually doing research
- From an exempt study

Secondary analyses are not exempt, but may qualify for expedited review, if the data:

- Contain information like geocodes and specific demographic details that could be used to deduce a participant's identity
- Are part of a larger investigation like a panel study that involves re-contacting participants
- Are not publicly available
- Will be used to identify particular participants

Secondary analyses require full board review if the data:

- Were originally collected for research purposes, as in a large panel study
- Contain personally identifiable information collected under a broad consent, but the project does not clearly fall within the scope of that broad consent
- Contain personally identifiable and stigmatizing information that must be transmitted or accessed in such a way that they could, theoretically, fall into the wrong hands

Secondary analysis protocols may involve a discrete step in which data are stripped of identifying information and provided to the research team for analysis. This may involve an "honest broker," a person or organization who serves as a firewall between the researchers and any positively identifying information contained in the data. The honest broker is generally not a member of the research team. Secondary analysis protocols may also involve particular data security concerns. A data set that would not otherwise have been considered to contain private identifying information might become a secure data set after it is merged with zip codes or geocodes. Data set providers may require researchers to store data in a particular way or only analyze data on their remote access platform. The Adelphi IRB will usually consider a successfully negotiated restricted data use agreement with a data set provider to be adequate documentation that human subjects' rights will be protected. The Adelphi IRB will generally not approve a study that requires an investigator to break a secure data use agreement.

The Adelphi IRB supports the premise that secondary data analysis has one inherent ethical advantage over primary data collection, which is that it does not involve any additional burden to participants. There are no secondary data analysis scenarios that are categorically not approvable; a case may be made for any study on the basis of conformity to tenets of the Common Rule and Belmont Report considerations of beneficence, respect, and justice. Investigators who are interested in searching for a suitable source of secondary data for their work should contact the ORSP.

Social Media

Social media posts are considered to be publicly available data unless the research team would need to create password-protected accounts and log in to see them. If that is the case, then the researcher would have to either obtain consent from the users whose data they want to use, or make a case to the IRB for including their private interactions in a research data set without their informed consent.

Some work with social media is more within the realm of communications science or journalism and is not human subjects research. For example, an investigator wanted to do a content analysis of images of children in publicly available social media posts, then the units of analysis would be posts, not children, and the activity would not be considered human subjects research.[72]

Social media sites have been known to sell de-identified data sets to researchers, and some studies have been conducted by using software to "scrape" data without the knowledge or consent of the social media site or its users. The Adelphi IRB will consider these protocols on a case-by-case basis.

If a protocol involves violation of a social media site's terms of use, this should be described in the protocol. An IRB has no authority to authorize an investigator to violate a social media site's terms of use, and research team members should not expect social media sites to allow them to violate their terms of use on the grounds that they have an approved protocol. However, the Adelphi IRB will not automatically disallow a study solely on the grounds that it may violate a social media site's terms of use. The Common Rule requires investigators to follow all applicable laws, but terms of use are not laws, and the Common Rule sets no requirements around terms of use. If an investigator proposes a study that violates a social media company's terms of use, the Adelphi IRB will evaluate it according to its impact on human subjects, not on the social media company. An IRB is not expected to enforce investigators' stated or implied obligations toward organizations that are not knowingly and willfully partnering with them in the research.

Data Security Levels

Adelphi investigators should consider data security levels[73] when creating their data security plans. This section makes a distinction between "no risk" and "minimal risk" that is not used elsewhere in this manual. An example of "no risk" data would be surveys of personal opinions about trails available for hikers. An example of "minimal risk" data would be interviews and observations of families experiencing food insecurity. Minimal risk data falling into the wrong hands would not cause reputational harm as American law conceptualizes it, but it would still make participants uncomfortable and violate their trust. The distinction of greater than minimal risk data is used elsewhere in this manual and refers to private identifiable information that could cause reputational harm if it fell into the wrong hands, such as qualitative interviews with users of illegal drugs.

Level 1 requirements are that all research data be shared and stored so that only authorized participants could readily get access. Computers used to store data should have fully patched operating systems and current antivirus software with current virus definitions. Level 1 applies if:

- Data are not identifiable to researchers or others, either through direct identifiers or a list of codes, and a breach of confidentiality would cause no or minimal risk; or
- Data are identifiable to researchers or others, either through direct identifiers or a list of codes, and a breach of confidentiality would cause no risk

[72] University of Wisconsin - Madison. (2024). Different types of research. Retrieved April 14, 2024 from https://irb.wisc.edu/manual/investigator-manual/conducting-human-participant-research/different-types-of-research/#m_2288-technology-new-media-research

[73] Oregon State University. Data security. Retrieved April 14, 2024 from https://research.oregonstate.edu/irb/policies-and-guidance-investigators/guidance/data-security

Level 2 additional requirements are that data may not be disclosed to additional parties without prior IRB approval specifically authorizing this disclosure. Cloud storage is permissible with commercial servers dedicated to this purpose, such as Qualtrics, or appropriate institutional file spaces such as Adelphi's Google Drive or OneDrive. A plan for routine backups should be in place. Level 2 applies if:

- Data are not identifiable to researchers or others, either through direct identifiers or a list of codes, but a breach of confidentiality would cause greater than minimal risk, or
- Data are identifiable to researchers or others, either through direct identifiers or a list of codes, and a breach of confidentiality would cause minimal risk

Level 3 additional requirements are that information be stored in a local system of record, such as a local server or approved cloud. Any mobile computer systems or portable storage media should be encrypted with the 256-bit encryption common in operating systems and encoding devices sold in the United States. If there is a linked list of participant code numbers and identifiers, this should be stored separately from the data. Identifiable information should not be stored on student researchers' computers or in their Google Drive or OneDrive space after the study has ended. Computers should have host-based firewalls enabled in addition to being behind a networked firewall context. A plan for routine backups of all data should be in place, with backups also encrypted and physically secure. Level 3 applies if:

- Data are identifiable to researchers or others, either through direct identifiers or a list of codes, and a breach of confidentiality would cause more than minimal risk

Adelphi researchers may request that Adelphi's information security offices or other appropriate information security officials review their data security plan and stipulate to it. Some data set providers require this kind of review. The ORSP Director or the reviewers on an IRB proposal may also request review by Adelphi's information security offices. If a data security plan is required under an arrangement between the investigator(s) and a data set provider, the Adelphi IRB will usually accept that it is appropriate, especially if Adelphi's information security offices have reviewed the plan.

Artificial intelligence (AI)

Artificial intelligence (AI) is a next frontier in human subjects research. It has the potential to make progress toward a vision that quantitative researchers have had for decades of simulating mathematical models of human conditions with at least a fraction of the complexity of real life and then researching those models with minimal inconvenience to actual human subjects. It also has the potential to invade privacy, reinforce harmful stereotypes inherent to the data used to train the AI, distress participants with its "hallucinations," and create data, models, reports, or citations that are fake, incorrect, or just not germane. The Adelphi IRB is actively monitoring the evolving situation of AI in research. In AI and in other areas, the Adelphi IRB maintains a body of "case law," so that investigators will generally be allowed to use AI similarly to past approved studies unless there is a good reason not to. Best practices as per the Common Rule, which was not written with AI in mind, seem to regard the AI as a combination software tool and research staff member, with the investigator(s) entirely responsible for its ethical behavior.

Current, broadly-available technology allows investigators to use AI to:[74]

- Collect data through interaction, as in an adaptive survey, or intervention, as with an AI therapist
- Obtain informed consent
- Access, compile, and analyze data
- Answering questions for potential, current, or past human research participants
- Transcribe audio (Zoom's transcription service has been reviewed for privacy, confidentiality, and security)
- Identify text in still pictures or video, or do other rudimentary coding
- Translate audio or text
- Write study materials
- Serve as an "honest broker" creating a de-identified data set or model from identifiable private information

It is always the investigator's responsibility to ensure that any identifiable private information they provide to an AI in the course of their research remains confidential. In general, investigators should avoid more handling or transferring of private identifiable information than is necessary to complete their research.

Investigators will generally be required to notify participants about any use of AI that would affect participants' rights or experience of being in the study in their informed consent documents. They should describe what the AI will do with their data, including plans to upload data to an AI from which it cannot be removed. An AI is generally not allowed to collect legally effective consent. An AI should not be provided with informed consent documents. If consent is audio recorded, then the audio recording of the consent process should be removed from any audio file uploaded to an AI. An AI should not be provided with more demographic information than it needs to conduct its analyses. Investigators may be required to create test cases or replications tests to assess whether biases and stereotypes inherent to the data used to train AI's may be affecting their output.

The following data should not be provided to an AI in an identifiable format, including with combinations of indirect identifiers that could reasonably identify a participant:

- Biospecimens, including blood samples
- Genomic data
- FERPA-protected data
- Stigmatizing information
- HIPAA-protected data, unless collected under a consent that would allow AI use

The Adelphi IRB will probably not approve a study in which an AI is given direct access to an electronic health record (EHR) system. Health record data would need to be de-identified before being provided to the AI tool.

Data scraping studies are usually permitted. The investigator(s) would need to describe the limitations and parameters placed on the AI tool in their protocol.

[74] The University of Tennessee - Knoxville. Artificial intelligence (AI) tools: Guidance on the use of AI in human subjects research. https://research.utk.edu/research-integrity/artificial-intelligence-ai-tools/

Intervention studies, e.g., for therapy chatbots, can also be permitted. Investigators would need to describe the following:

- A full description of the planned interaction between the participant and the AI tool
- A description of the data that the AI tool will be designed to collect
- Documentation of the parameters or limits placed on the AI tool for the intervention, data collection, and (if applicable) data analysis
- Scripts or texts of instructions that will be read or provided to participants as part of the interaction with the AI tool
- A plan to monitor the safety of participants and their data during and after the intervention.
- The IRB recommends, and may require, investigators to directly monitor any direct interaction between AI tools and participants.

For studies involving AI to be exempt, they must meet all of the other criteria for exemption in their category in addition to the stated requirements for AI.

- Evaluations of teaching methods (Category 1) must meet all of the following criteria:
    - The AI will not access identifiable data about children
    - The AI will not access stigmatizing data about participants of any age
- Research in which the only interactions with participants involve educational tests, survey/interview procedures, or observations of public behavior (Category 2), and taste and food quality and consumer acceptance studies (Category 6), must meet one of the following criteria:
    - The AI can only access deidentified data
    - The AI's access to identifiable data is limited to non-stigmatizing information
    - The AI tool is not accessible to the public, the investigator(s) document how they will protect the privacy and confidentiality of participants, and the participants consent to the use of the AI tool
- Minimal risk experiments on adults (Category 3) must meet all of the following criteria:
    - When the study involves a direct interaction between the AI tool and the participant, intervention guidance provided above is followed
    - Criteria for Category 2 are satisfied
- Secondary analysis of publicly available information (Category 4, i) must meet the following criterion:
    - The AI only accesses publicly available data
- Secondary analysis of de-identified data (Category 4, ii) must meet all of the following criteria:
    - The AI tool will not have access to identifiers, including previously existing code keys
    - Documentation exists and is provided that confirms the AI tool is not permitted to attempt to re-identify participants within the dataset.

Activities that are not exempt, but which may still be approvable, if they use AI:

- Secondary analysis of identifiable health information only for purposes of health care operations or research (Category 4, iii)
- Secondary research for which consent is not required when the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities (Category 4, iv)

There are several scenarios of AI use that have been considered,[75] including using it to:

- Deductively discover the identity of a study participant even more efficiently than existing software tools
- Simulate a real individual based on questionnaire information, and then have that simulated individual participate in research
- Simulate data on entire groups of individuals based on variables chosen with stereotypes in mind, which can be analyzed to confirm those stereotypes
- Impute data on individuals based on biases and stereotypes present in the materials used to train the AI
- Scrape data that people would never knowingly provide to a research study, and then package them for research as de-identified data
- Conduct entire analyses on private identifiable data that participants would never have consented to contribute to a research investigation
- Upload private identifiable data to a cloud for translation, transcription, or other processing, where they could be scraped and from which they cannot be removed
- "Hallucinate" in the process of asking questions of a human subject, resulting in interactions that are off-script and disturbing to subjects

Some scenarios for AI-related harms to participants are realistic, and others are more futuristic. In its determinations, the Adelphi IRB will consider harms that have actually happened to participants with more weight than harms that cannot be documented to have ever actually happened. The Adelphi IRB will also allow that investigators are generally good-faith actors within the limits of their expertise, and will not assume that just because an AI tool could be used a certain way means that it probably will. An IRB is required to consider an investigator's competence to use any tool or do any procedure that might involve risk to participants. Investigators are welcome to stipulate to their expertise and experience with AI tools in their applications. They are also welcome to cite research supporting the safety of their methods, previous studies that have used the methods they plan to use, scholarly and governmental organizations' position papers about their methods, and other sources to create a case for why their study is safe.

Processes After Initial Review

Dates of Approval and Continuing Review

A protocol requiring full board approval is considered approved as soon as the full board determines it to be approved and enters the determination into its minutes. A protocol with expedited approval is considered approved as soon as the ORSP Director receives feedback from all reviewers along with their own determination in favor of approval. The date for subsequent continuing review is usually one year after the official communication of initial approval is transmitted to the investigator(s). Investigators should remember that the Adelphi IRB does not send warnings that their protocols are about to expire. Dates of exempt determinations are recorded, but exempt protocols are considered to have always been exempt and exempt

[75] Office for Human Research Protections. (2022, July 21). Considerations for IRB review of research involving artificial intelligence. Retrieved April 14, 2024 from https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-e-july-25-2022-letter/index.html

determinations do not expire. An IRB can determine a research activity to be (technically, to always have been) exempt at any stage of the project.

Communicating IRB Determinations

The ORSP is notified of all determinations on all proposals. Determinations about protocols requiring full board approval are transmitted to investigators within two business days of the meeting when they were discussed. Determinations about exempt and expedited approvals are transmitted to investigators within two business days of the ORSP Director receiving feedback from all reviewers.

Investigators' Response to Required Modifications and Clarifications

If a protocol is approved pending modifications or clarifications, the investigator may submit a complete revised protocol with changes highlighted and listed in cover text to the ORSP Director, the IRB Chair, and the original reviewers, often by replying to the email that they were sent. The cover text should especially address the investigator's reasons for not making changes that the IRB required. They should do this within 45 days. If the revised protocol may be approved or determined to be exempt as is, then this can happen according to an expedited process among the ORSP Director, the IRB Chair, and the original reviewers. If the revised protocol may not be approved or determined to be exempt as is, or if 45 days have passed, then any resubmission is treated as a new protocol and sent to either the same or different reviewers at the ORSP Director's discretion.

Communicating Not Approved Determinations and Investigators' Process for Responding

If a protocol is disapproved,[76] then the investigator may revise it to address the concerns and submit it as a new protocol, optionally with changes highlighted and cover text. The ORSP Director may send it to the same or different reviewers at their discretion. If an investigator wishes to dispute the IRB's decision on a protocol without making revisions, they may only do so on the basis of new information that was not available at the time of the application, or of a clear and convincing case that the IRB did not follow the Common Rule, the Belmont Report, and/or its own manual. The disputation may be e-mailed to the ORSP Director and the IRB Chair. If either of them agree with the disputation, then the ORSP Director will reprocess the protocol as a new protocol and assign it to the same or different reviewers at their discretion.

An investigator may not misuse this process to pressure the ORSP Director or the IRB into changing a fairly rendered determination. Third and subsequent submissions of the same protocol without making required revisions and/or with unsupported arguments for its approval may be considered noncompliance and place the investigator at risk for sanctions.

Continuing Review

[76] University of Wisconsin - Madison. (2024). IRB review decisions. Retrieved April 14, 2024 from https://irb.wisc.edu/manual/investigator-manual/irb-review-process/irb-review-decisions/#m_2291-disagreeing-with-irb-decisions

Time frame for continuing review

Almost all expedited and full board approvals by the Adelphi IRB are for one year. The Common Rule has no provisions for approval periods of longer than one year. Grounds on which the IRB may require a shorter approval period include:

- The study is known to be risky, or risks are uncertain
- The subject population is vulnerable
- The investigator is inexperienced in the activities they will be performing as part of the protocol
- There have been compliance problems with the researcher, the protocol, or the sponsor
- Participants have complained about the study

Approval letters for periods of less than one year will include a description of the concerns that led to a shorter approval period and specifically how a shorter approval period is supposed to help address those concerns. The Adelphi IRB does not shorten approval periods over vague concerns about safety or risk, or because they think the investigator does not need an entire year to complete the research. Determinations about the approval period and continuing review interval are e-mailed by either the ORSP Director or the IRB Chair to investigators and their research teams.

Verifying adherence to the protocol

The Adelphi IRB does not often handle proposals where verification would be needed from sources other than the investigator that no material changes have occurred in the project since the last IRB review. This determination might be made based on the complexity of the project, prior compliance issues with the investigator, or whether the continuing review form suggests that changes have happened which should have been reported earlier. Investigators who foresee issues in this area should consult with the ORSP Director prior to submitting their applications.

Studies that need more than one year of IRB approval

Because most research projects at Adelphi involve less than a year of activities that would require IRB oversight, the ORSP does not notify investigators when their proposals are about to expire. It is up to investigators to take initiative to submit continuing review forms before the IRB deadline that would precede the meeting before the date their approval expires. This generally means submitting continuing review forms 30-60 days before the end of the approval period.[77]

- All activities that would need expedited or full board approval are complete, such as recruiting participants into research that required expedited or full board approval, completing ongoing courses of interventions and treatments, and handling private identifiable information
- The only activities that remain in a study are those that would only need expedited approval if proposed to the IRB at that stage, such as analyzing de-identified private identifiable information, accessing information collected from participants as part of routine clinical care under an established secure data plan, or preparing manuscripts for publication

If IRB approval lapses, researchers must temporarily cease activities that would need expedited or full board approval, except in cases where doing so would harm or remove some benefit from participants, e.g., by discontinuing some ongoing intervention or treatment. Up to three months

[77] University of Michigan. Continuing review process. https://research-compliance.umich.edu/continuing-review-process

after the date that a proposal has lapsed, it is within the ORSP Director's discretion to allow them to submit for continuing review. After three months, a proposal to restart a lapsed study must be submitted as a new proposal and also satisfy conditions of continuing review.

Changes to IRB Protocols

Communication of Policy to Investigators

Investigators are informed in approval letters that they may not make changes to their protocols without prior IRB review and approval. When a protocol is more than minimal risk, which is rare at Adelphi, they are further informed that they may make changes in emergencies to protect subjects' welfare. If this happens, investigators should inform the ORSP Director via email within 24 hours.

"Minor" vs. Other Changes in Research

The Common Rule does not define "minor change" in a research protocol or distinguish how minor changes in exempt vs. approved protocols should be handled. A change can be argued to be "minor" if it does not alter:[78]

- The risks or benefits involved in the study (beneficence)
- Parameters of informed consent (respect)
- The populations being recruited and the premise under which they are recruited (justice)
- Whether the study is exempt, or the exempt category it fits into

Some examples of minor changes include:

- Recruiting more subjects under the same protocol
- Personnel changes that do not involve the PI or faculty advisor, or anyone with a potential conflict of interest
- Corrections or updates to study documents, including consent documents, that do not change their substantive meaning, such as updating contact information and fixing typos
- Changing surveys and interviews in ways that would not meaningfully affect participants' experience, such as substituting one measure of depression for another
- Modifications to study procedures that would not affect participants' willingness to be involved in this study, expand on the research objectives, or result in collection of sensitive information
- Changing the physical location of the study to a comparable location elsewhere in a way that would not affect participants' safety or privacy
- Translating documents, if that was already discussed in the protocol
- Committing internal funds to a study
- Using a recruitment method that is similar to what was already approved, such as emailing information was already included in a social media post
- Changing eligibility criteria in a way that does not result in adding a new subject population
- Adding new publicly available data
- Adding new records to a database of private identifiable information under the same Data Security arrangement, such as an additional year of a panel study

[78] University of Wisconsin - Madison. (2018, January 5). Exemption change table. Retrieved April 14, 2024 from http://irb.wisc.edu/wp-content/uploads/sites/2/sites/2/2022/08/exemptionchangeFAQtable_1-5-2018.pdf

- Adding new records to a database of private identifiable information in a way that does not change the population being accessed, the HIPAA status of the study, or risk to participants' confidentiality
- Change in data storage that will maintain a similar or increased level of protection to participants' confidentiality

Some examples of changes that are not minor include:

- The person(s) or institution(s) ultimately accountable for the study, such as a change in PI or site
- Adding personnel to the study who have a conflict of interest that must be disclosed
- Adding survey instruments or interview questions that cover sensitive topics not discussed in the original protocol
- Adding study procedures that may affect participants' willingness to participate in the study
- Change in data ownership or access to data that may affect participants' privacy
- Research instruments translated into a language that was not described in the protocol
- Adding a funding source that may result in new regulatory requirements
- Adding a new recruitment method that may use different technology or target a new population
- Adding an entire new participant population, or changing eligibility requirements to reach a new participant population
- Increasing compensation to a point where it may become coercive toward a vulnerable population
- Removing compensation from participants who may have been led to expect it
- Change in a data security agreement with another institution
- Adding a new source of private identifiable data that are not publicly available
- Collecting or accessing sensitive data that were not discussed in the protocol
- Changes to consent documents that affect their substantive meaning

Submitting Changes for IRB Review

Investigators submitting minor changes for review may send an email to the ORSP Director including the name and identification number of the protocol, its original approval date, a description of the modification(s), and a case for why they should be considered to be a minor change.

Investigators submitting non-minor changes for review should submit the entire protocol with changes highlighted and described in a cover letter. Investigators who are not sure whether their proposed changes are minor should submit the entire protocol with changes highlighted and described in a cover letter which should include their case for why the changes should be considered minor.

IRB Review of Changes in Research

Minor changes to exempt protocols

These do not need to be reviewed; the e-mail to the ORSP Director is a notification rather than a submission for review. If the ORSP Director, IRB Chair, or other reviewers consulted believe the

change to be non-minor, the ORSP Director will e-mail the investigator and advise them to wait for a review process.

Non-minor changes to exempt protocols

These receive expedited review according to the usual exempt review process. One possible outcome of the expedited review is that the reviewers decide that the study no longer fits into any exempt category and should receive expedited or full board review. If the reviewers make this determination, and the investigator has submitted only a letter describing changes, the ORSP Director will contact the investigator and advise them to submit the whole protocol with changes highlighted.

Minor changes to full-board-approved protocols

These receive expedited review according to the usual exempt review process. One possible outcome of the expedited review is that the reviewers decide that the change is actually non-minor. If the reviewers make this determination, and the investigator has submitted only a letter describing changes, the ORSP Director will contact the investigator and advise them to submit the whole protocol with changes highlighted.

Non-minor changes to full-board-approved protocols

These receive full board review. Only the full board may reject a change to a protocol; all other review processes defer to the full board in case of an adverse finding.

Does the Consent Form Need Revision?

The Common Rule does not provide guidance on assessment of whether the IRB-approved informed consent form requires revision. National Institutes of Health (NIH) policy requires that investigators "Submit revised informed consent documents to the IRB for approval when there is new information that may affect the willingness of subjects to enroll or remain in research."[79] The Adelphi IRB does not have to review changes like updating contact information, changing letterhead, fixing typos, or alterations to formatting and layout. A substantive change to the language that would affect the terms of consent is at least a minor change and should be reviewed by the IRB. In cases of ongoing studies, changes to the terms of consent may involve re-consenting existing subjects.

Processes after Changes are Reviewed

Communicating determinations about changes

The ORSP is notified of all determinations on all proposals. Determinations about modifications requiring full board approval are transmitted to investigators within 48 hours of the meeting when they were discussed. Determinations about expedited approvals are transmitted to investigators within 48 hours of the ORSP Director receiving feedback from all reviewers. Receipt of notification about minor changes to exempt protocols is communicated to the investigator by the ORSP Director or IRB Chair within 48 hours.

Investigator's response to required modifications or clarifications about changes

If a change is approved pending modifications or clarifications, the investigator may submit a complete revised protocol with changes highlighted and listed in cover text to the ORSP Director, the IRB Chair, and the original reviewers, often by replying to the email that they were sent. The cover text should especially address the investigator's reasons for not making changes that the IRB required. They should do this within 45 days. If the revised protocol may be approved or determined to be exempt as is, then this can happen according to an expedited process among the ORSP Director, the IRB Chair, and the original reviewers. If the revised protocol may not be approved or determined to be exempt as is, or if 45 days have passed, then any resubmission of the change is treated as a new request for modification and sent to either the same or different reviewers at the ORSP Director's discretion.

Determinations not to approve changes, and investigator's process for responding

If a modification is disapproved, then the investigator may revise their application to address the concerns and submit according to the process for non-minor changes, with differences highlighted and a cover letter. The ORSP Director may send it to the same or different reviewers at their discretion. If an investigator wishes to dispute the IRB's decision on a modification without making revisions, they may only do so on the basis of new information that was not available at the time of the application, or of a clear case that the IRB did not follow the Common Rule, the Belmont Report, and/or its own manual. The disputation may be e-mailed to the ORSP Director and the IRB Chair. If either of them agree with the disputation, then the ORSP Director will

[79] National Institutes of Health. (2021, February 13, 2024). 3014-301 - Informed consent. Retrieved April 14, 2024 from https://policymanual.nih.gov/3014-301

reprocess the protocol as a new protocol and assign it to the same or different reviewers at their discretion.

An investigator may not use this process to pressure the ORSP Director or the IRB into changing a fairly rendered determination. Third and subsequent submissions of the same modification without making required revisions and/or with unsupported arguments for its approval may be considered noncompliance and place the investigator at risk for sanctions.

Informing IRB of Study Completion and Closeout

Investigators may notify the IRB of study closeout using the Continuing Review form. The Common Rule requires keeping research records for three years,[80] and Adelphi policy is to keep records for seven years. Students using Adelphi's cloud storage should keep their records in a shared folder on a faculty or staff member's file space or in an administrative account set up for them by Information Technology (requires sending a request to the HelpDesk). This is so that they can be accessed for audit purposes without the auditors encountering FERPA-protected information in their student accounts.

Audit and Intermittent Review

Sufficient grounds for implementing an IRB audit may include, but are not limited to:

- Questions of noncompliance with the approved protocols in the conduct of the study, such as informed consent not being obtained
- Subject complaint
- Serious adverse events reported to the IRB by the principal investigator or study sponsor

The IRB may carry out random audits of active protocols to provide internal quality assurance, and to protect the rights and welfare of the human subjects. Principal investigators shall be prepared to undergo an internal audit, which may be initiated at any time, without prior notice. Audits may be conducted by the IRB Chair and/or ORSP Director and at least two standing members of the IRB.

All ongoing research at Adelphi may be subjected to intermittent review(s) for a periodic update of the progress and issues encountered. The IRB will inform the researcher or primary investigator of the review.

When There is a Problem

Participant Complaints and Questions

Informed consent materials direct participants with complaints to contact the IRB Chair and/or ORSP Director as appropriate. Complaints are handled from a dispute resolution standpoint. [81] If the IRB Chair and/or ORSP Director believe non-compliance has occurred, then they will notify

[80] IRB records, 45 C.F.R. § 46.115(b) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.115#p-46.115(b)

[81] Underhill, K. (2014). Legal and ethical values in the resolution of research-related disputes: how can IRBs respond to participant complaints? Journal of Empirical Research on Human Research Ethics, 9(1), 71-82. https://doi.org/10.1525/jer.2014.9.1.71

the Associate Provost for Research and Special Projects or the Provost, as appropriate, and initiate investigation procedures.

Unanticipated Risks or Harms

Investigators are responsible for reporting unanticipated problems involving risks to human subjects or others to the ORSP Director and IRB Chair. Investigators do not need to report, and are not accountable for, risks or harms to participants that do not result from their research. Reporting is only expected if the problem was:[82]

- Caused by or associated with study participation
- Unanticipated, meaning that the informed consent form did not mention it
- Involves risks to human subjects or others, meaning that it is not simply a complaint or disagreement
- Related to the rights, safety, and welfare of subjects, as they pertain to study participation
- Suggestive that the research presents different or greater risks than the approved protocol describes

Incidents in which participants were physically injured or at risk of death, such as severe drug interactions, or that required intervention from emergency services, should be reported within one business day. Other problems, such as another organization contesting data ownership in a way that could put participants' confidentiality at risk, should be reported within five business days. Reports should include a written summary of the unanticipated problem, the outcome, and any steps taken to prevent recurrence.

Noncompliance by Investigators

Incidents of serious or continuing noncompliance, as described in the definitions section, may be reported by any Adelphi investigator about any other Adelphi investigator, and should be reported by people the protocol describes as investigators, co-investigators, or faculty advisors. Reports should be made to the ORSP Director and IRB Chair within five business days of the reporter becoming aware of the incident. The ORSP Director will report noncompliance to partnering organizations and funding authorities as required under Adelphi's contracts and agreements with them. Unsupported, false, or spurious reports of noncompliance are not within the scope of Adelphi's academic freedom protections and may be investigated as academic or professional misconduct. The outcome of this process may be appealed to the Associate Provost for Research and Special Projects and the Provost. Noncompliance by a faculty or staff member may be addressed by the person with management authority over them, generally their Dean. Noncompliance by a student may be addressed by their faculty advisor or the instructor of the course for which the research is a requirement.

[82] University of Wisconsin - Madison. (2017). Health sciences IRBs unanticipated problems reporting decision tree. Retrieved April 14, 2024 from https://irb.wisc.edu/wp-content/uploads/sites/2/sites/2/2022/07/AEdecisionguidewithFDAVAupdate_10_31_17.pdf

Suspending or Terminating Research

What happens if a study is suspended

The ORSP Director or Associate Provost for Research and Special Projects may suspend IRB approval on an emergency basis pending further review by IRB members. Under suspension, the investigator may be required to:

- Stop all research activities under the protocol completely
- Stop all intervention or treatment related to the research
- Stop recruiting and enrolling participants
- Stop collection and/or analysis of private identifiable information

Suspended projects are still active and subject to continuing IRB review. The institutional official who suspended the project will notify other institutional officials as applicable, the IRB Chair, and the investigator(s) about the suspension and the reasons for it via email, and the suspension will take effect the next business day after the email is sent.

If investigators wish to continue their studies

If investigators of suspended projects wish to continue their research, they must submit a complete amended protocol, including details of what led to the suspension and any changes they are making, to the IRB. The IRB will review it according to their usual review and approval process.

IRB review of amended protocol

The ORSP Director will refer the complete amended protocol to a panel of three reviewers, who may come to any of the following determinations:

- The suspension may be lifted and the study may continue, with any amendments that the investigator stipulated (must be unanimous)
- The protocol is incomplete and should be referred back to the investigator for more information (requires 2/3 vote)
- This is a study that would normally require full board approval under policy, so it will be referred to the full board (requires 2/3 vote; the ORSP Director may also impute this determination)
- The suspension should continue, but the investigator may reapply (must be unanimous)
- IRB approval should be terminated, so the protocol will be referred to the full board for a final determination

If the panel of reviewers is unable to come to any of the above determinations, the protocol will be referred to the full board.

Reviewing a suspended protocol, the full board may come to any of the following determinations, by majority vote upon a motion by any member present:

- The suspension may be lifted and the study may continue, with any amendments that the investigator stipulated
- The protocol is incomplete and should be referred back to the investigator for more information
- The suspension should continue, but the investigator may reapply
- IRB approval is finally and entirely terminated

Informing investigator(s) of determinations

The ORSP Director will inform the investigator(s), the IRB Chair, and other institutional officials as appropriate about the lifting of a suspension and the stipulations around it, or a termination and the reasons for it, as applicable via email within two business days, and the lifting of the suspension or the termination will take effect on the business day after the email is sent. The ORSP Director may choose to allow the principal reviewer on the proposal to send either of these notifications. Terminated protocols are inactive and not subject to continuing review. The ORSP Director will inform funding authorities and partnering organizations about terminations of IRB approval if required under agreements and contracts with them. Investigators are responsible for informing funding authorities, partnering organizations, conference organizers, and journal editors about the IRB approval status of their work as required under their circumstances and according to commonly accepted best practices in their fields.

Investigators' responsibilities if their studies are suspended or terminated

In the case of ongoing studies, particularly studies that involve some intervention or treatment that is not complete at the time of suspension or termination, investigators will inform participants about:

- The suspension or termination
- Any risks or benefits to them from the intervention or treatment that have been discovered
- Their options to quit the intervention or treatment
- Anticipated risks and benefits of both quitting and continuing the intervention or treatment

Investigators must create a plan for any or all of the following, as applicable, and submit it to the IRB within five business days of a suspension or termination:

- Completing any intervention or treatment participants wish to complete
- Transfer of participants to other clinical care
- Another research team taking over the research activities
- Secure transfer or deletion of private identifiable information

Caveats about suspension and termination

An IRB's authority over an investigator is limited to stopping research activities under a particular protocol. An IRB does not have the authority to:

- Stop activities by investigators that are not under an IRB's purview
- Compel Adelphi investigators to do anything for any other organization that is not already required under a contract or other agreement
- Interpret or enforce contract language about matters that are not under its purview
- Interfere with a Chair, Dean, or Provost's management authority over an investigator

IRB Processes

IRB Membership

The IRB shall consist of at least eight members. Members are chosen to represent the demographics of the Adelphi community in terms of race, ethnicity, immigrant status, sexual/romantic identity, gender, and other relevant demographics characteristics. The IRB should include one, preferably two, representatives from each school/college engaged in human research

– College of Arts and Science, Gordon F. Derner School of Psychology, Robert B. Willumstad School of Business, Ruth S. Ammon College of Education and Health Sciences, College of Nursing and Public Health, School of Social Work. The IRB shall consist of no less than two scientists and no less than two nonscientists. The IRB will also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. All IRB members shall have faculty profiles updated as of the time of their appointment or later and current human subjects training.

Members are nominated by the Dean or a vote of the faculty at their respective school, according to their chosen process. In addition, at least one nonscientific, nonaffiliated member shall be included on the IRB. Individual schools/colleges may have their own procedures for suggesting nominations (or removals) to their Deans, but these are not binding upon the Deans or the Provost. The IRB chooses its own Chair, who should be an experienced reviewer, by majority vote or by acclamation. The term of the Chair is two years. Chairs may serve for multiple consecutive terms, if necessary.

Alternate members are selected by the ORSP Director, with suggestions from faculty, department Chairs, Deans, or Provost-level administrators as applicable, and appointed and serve only when a primary member will be unable to attend meetings for an extended period of time, e.g., when a primary member is on sabbatical leave or extended medical leave. The reason for the substitution should be documented in the minutes. Alternate members should have similar experience, expertise, background, professional competence, and knowledge to those of the primary members they are selected to replace. If an alternate member and their corresponding primary member are at a meeting together, the primary member votes. The alternate member may be called upon to speak at the meeting, but does not vote.[83]

If the Chair cannot attend all or part of a meeting, another experienced reviewer in attendance is selected as temporary Chair, by majority vote or by acclamation of IRB members present at the time.

IRB Service

The chairperson of the IRB will be confirmed by a majority vote of the IRB, confirmed by the Provost, and will serve for two years. Chairs can serve consecutive terms. Alternate members shall have the same voting rights as primary members and should be counted when
determining the existence of a quorum at a meeting. Members shall be appointed for a term of two years. Members may be reappointed. Members are expected to complete reviews assigned to them by the ORSP Director, who is expected to prioritize even distribution of work over appropriateness of proposals to particular reviewers. Members are expected to document, in the IRB's electronic workspace:

- Specific changes they would require to a proposal before voting for its approval or supporting its exemption, with rationale as applicable
- Rationale for advocating that a proposal submitted as exempt or expedited receive full board review. If the reviewer's rationale is that the proposal is more than minimal risk, then

[83] Office for Human Research Protections. IRB registration process FAQs. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/irb-registration-process/index.html

they must document their reasons for believing the proposal is more than minimal risk, since the Common Rule requires IRBs to keep records specifically about these determinations.[84]

- In the case of principal reviewers, rationale for voting not to approve a proposal under full board review

Members are expected to attend two thirds of the IRB meetings per year.

Members may be removed by the Provost. Members may be removed for such reasons as non-attendance at meetings, non-completion of assignments, non-disclosure of conflicts of interest involving self or others, advocating for determinations on proposals that are inconsistent with the Common Rule, or allowing their human subjects training to fall too far out of date. Cases for removal of IRB members may be brought to the Provost by the ORSP Director, the Associate Provost for Research and Special Projects, the IRB Chair, or via a Union grievance against the Provost's office under Article VII(a), "Academic Freedom," of the CBA. An IRB member's votes and determinations about proposals are also protected under Article VII(a) of the CBA, and consequences for votes and determinations at variance with the Common Rule should be limited to removal from the IRB.

Conflicts of Interest (IRB Members)

All Adelphi employees are required to follow Adelphi's Conflict of Interest Policy,[85] which mostly concerns business relationships with Adelphi. Conflict of interest in service on the IRB refers to the circumstances described in the Definitions section, and also to any situation at all in which an IRB member feels they cannot be independent. IRB members are expected to disclose conflicts of interest as soon as they know about a proposal submission that involves a conflict of interest for them. According to 45 CFR 46.107(d), IRB members recuse themselves from discussion of any proposal in which they have a conflict of interest. Their presence does not count toward quorum for purposes of discussing that proposal, they do not vote on the proposal, and they may be required to leave the meeting while the proposal is being discussed, at the discretion of the Chair and the ORSP Director.

Anyone who believes an IRB member to have a conflict of interest may ask them privately to disclose it. Formally or informally accusing someone of a conflict of interest before others, however, is a serious matter of professional conduct. This should only do so with documentation that provides clear and convincing evidence.

Scheduling and Format of Meetings

The IRB will have at least nine scheduled meetings per year, or as needed, to adequately review initial submissions and ongoing studies. IRB members will be advised in advance regarding the date, time and place of each meeting. Meetings will be held during the fourth Monday of each

[84] IRB Records, 45 C.F.R. § 46.115(a)(9) (2024). https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.115#p-46.115(a)(9)

[85] Adelphi University. (2018). Conflict of interest. Retrieved April 4, 2024 from https://www.adelphi.edu/policies/conflict-of-interest/

month at a time mutually acceptable to a majority of the members, unless otherwise noted. A meeting schedule will be conveyed by email to members of the IRB.

For regular meetings, members shall receive an agenda and the research proposal applications at least five days prior to the meeting. If there is no IRB business for the month, the chairperson may cancel the meeting and notify all members of such action.

The IRB Chair or ORSP Director may convene additional meetings. Emergency meetings may be convened, as appropriate, and require at least a 48-hour notice. Alternate members may be utilized when IRB members are unable to attend.

The presence of a majority (51 percent) of the appointed members, including at least one non-scientific member,[86] will constitute a quorum for the conduct of business at regular meetings of the IRB. Decisions will be reached by a simple majority of the appointed members present.

A report of proposals approved via expedited procedures and determined to be exempt since the last meeting is given at each meeting.

Handling of Protocols

Protocols are added to the IRB's secure file storage space (OneDrive or Google Drive) as the ORSP receives them. Also added to this space is the agenda for the next month's convened IRB meeting, which includes all reviewers assigned to all proposals. All IRB members can see all proposals and make comments that all other IRB members can see. This system allows for expedited reviews and exempt determinations to be carried out asynchronously.

Use of Consultants

The ORSP Director and/or the principal reviewers of a protocol may determine, at the time of review of the protocol, that consulting someone outside the IRB would be helpful. Consultants may be experts in (not an exhaustive list):

- IRB procedural, legal, or ethical matters
- Research methods, data security, or statistics
- Mental or physical health conditions
- Interventions or treatments
- Members of a minoritized identity group discussed in the proposal

A consultant may also be a native speaker of the language in which the research is to be conducted.

The ORSP Director and/or the principal reviewers of a protocol may reach out to a consultant without notifying anyone else. If the consultant's opinion has a significant effect on the disposition of the protocol, then the consultant's name, who contacted them, the reason they were consulted, and a summary of their opinion should be noted in the minutes of the IRB meeting where the protocol is discussed (if it requires full board approval) or reported upon (if it is exempt or

[86] Harvard University. Become an IRB member. Retrieved April 14, 2024 from https://cuhs.harvard.edu/become-irb-member

expedited). If a proposal is under discussion by the full board, then the full board may decide by majority vote that the proposal cannot be approved until a consultant's opinion can be heard, imputing a disposition of approval pending revisions or disapproval as appropriate. Insistence on a consultant's opinion may not be used by a minority of the IRB members present to stall a proposal that a majority of IRB members vote to approve.

IRB Records

The ORSP Director maintains required IRB records, including:[87]

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects
- Minutes of IRB meetings
- Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review
- Copies of all correspondence between the IRB and the investigators.
- A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant
- Written procedures for the IRB
- Statements of significant new findings provided to subjects
- The rationale for an expedited reviewer's determination that research which otherwise fit into one of the categories referenced in §46.110(a) was more than minimal risk and thereby required full board review
- Documentation of arrangements in which IRB's other than the Adelphi IRB oversee Adelphi investigators' nonexempt research, including Adelphi's and the other institution's responsibilities for ensuring compliance as per §46.103(e).
- The ORSP also maintains a tracking system for the length of study approvals.

IRB records are stored in secure institutional cloud storage (either Google Drive or OneDrive) to which all IRB members, ORSP staff, the Associate Provost for Research and Special Projects, the Provost, and their staff have access. Present IRB processes do not involve creating any new hard copy records. Any hard copy records will be kept in the ORSP office or in other secure office or storage space designated by the ORSP. The ORSP Director determines whether and when to digitize hard copy records.

The Common Rule requires these records to be kept for at least three years, and also requires records relating to research that is conducted for at least 3 years after completion of the research. Adelphi policy is to keep them for seven years. All records shall be accessible for inspection and

[87] IRB Records, 45 C.F.R. § 46.115 (2024). https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.115

copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.[88]

IRB Meeting Minutes

The ORSP Director will keep minutes or designate someone else to do so. Minutes shall include:[89]

- Names of people in attendance at the meetings, including late arrivals and early departures that affected quorum and/or whether principal reviewers were present to discuss a proposal
- Actions taken by the IRB
- The vote on these actions, including the names of members voting for, against, and abstaining; or if the vote was by acclamation
- Approval periods for protocols
- Continuing review intervals for protocols if they are shorter than one year
- The bases for requiring changes in or disapproving research
- A written summary of the discussion of controverted issues and their resolution
- Votes taken by email after a proposal was discussed at a meeting

Administrative Matters

Administrative support staff duties are as assigned by the ORSP Director or Associate Provost for Research and Special Projects. The ORSP Director and the Office of the Associate Provost for Research and Special Projects are responsible for registering the IRB and updating the Federalwide Assurance.[90] If the Adelphi IRB were to close somehow or otherwise be unable to continue oversight of studies, then the ORSP Director, the Associate Provost for Research and Special Projects, and the Provost would coordinate transferring oversight of studies under review to other institutions or IRBs.

[88] IRB records, 45 C.F.R. § 46.115(b) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.115#p-46.115(b)

[89] IRB Records, 45 C.F.R. § 46.115(a)(2) (2024). https://www.ecfr.gov/current/title-45/part-46/section-46.115#p-46.115(a)(2)

[90] Office for Human Research Protections. (2021, December 14). IRB registration. Retrieved April 14, 2024 from https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/index.html

Definitions of Terms

Some of these definitions[91] are used in this manual, and others are here for reference.

Alternate IRB member: Alternate IRB members are selected to assure comparable qualifications to the primary member. Comparable expertise is decided based on discipline, expertise, and/or education and professional experience.

Assurance of Compliance (Human Subjects) or Federalwide Assurance: An assurance is a written commitment to protect human research participants and comply with the requirements of the Common Rule.

Certificate of Confidentiality: A Certificate of Confidentiality is a document issued by a component of HHS pursuant to The Public Health Service Act Section 301(d), 42 U.S.C. 241(d) amended by Section 2012 of the 21st Century Cures Act, Public Law 114-255, to protect the privacy of individuals who are subjects of certain specified research activities by authorizing researchers to withhold from all persons not connected with the conduct of such research the names or other identifying characteristics of such participants. Persons so authorized to protect the privacy of such individuals may not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

Certification: The official notification by the institution to the supporting Federal department or agency component that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Child. Department of Health and Human Resources guidance defines someone as a "child" for research purposes if they are under the age when they could otherwise ordinarily consent to the activities in the research protocol.[92]

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Collaborative Study: A study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

Compassionate Use: Use of an investigational device to treat or diagnose an individual patient or a small group of patients with a serious disease or condition when there are no available alternative options. Requires approval from and follow-up reports to the FDA.[93]

Conflict of Interest: All Adelphi employees are required to follow Adelphi's Conflict of Interest Policy,[94] which mostly concerns business relationships with Adelphi, and Financial Conflict of Interest Policy, which concerns federally funded research grants.[95] Conflict of interest in this manual refers to situations in which an individual or the individual's spouse, domestic

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[91] University of Wisconsin - Madison. (2024). SOP: Definitions. Retrieved April 4, 2024 from https://uwmadison.app.box.com/s/ynthois06rwfral5oa66tbohxmcne3k3

[92] Office for Human Research Protections. (2024). Research with Children FAQs. Retrieved April 4, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html

[93] U.S. Food & Drug Administration. (2019). Expanded access for medical devices. Retrieved April 4, 2024 from https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices

[94] Adelphi University. (2018). Conflict of Interest. Retrieved April 4, 2024 from https://www.adelphi.edu/policies/conflict-of-interest/

[95] Adelphi University. (2012, October 18, 2022). Research financial conflict of interest. Retrieved April 14, 2024 from https://www.adelphi.edu/policies/research-financial-conflict-of-interest/

partner, children, and dependents have any of the following interests in the sponsor of the research, the product or service being tested, or a competitor of the sponsor of the research, which is/are held by the individual or the individual's immediate family:

- Involvement in the design, conduct, or reporting of the research
- Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds
- Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research
- Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement
- Board or executive relationship, regardless of compensation
- Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center
- Any personal or romantic relationship that may cause bias or create the appearance of bias by the member in the review of the research

"Interest," from the perspective of the Common Rule, is generally defined as financial/material. Many Adelphi faculty and staff are advocates for service sectors and identity groups of which they themselves are a part. Affinity with and/or advocacy for an identity group, service sector, or political position does not, in and of itself, constitute conflict of interest.

Deductive disclosure: Some providers of data sets containing sensitive information recognize the possibility that someone using their data for purposes other than research could deduce a participant's identity by triangulating among race, age, gender, zip code, and other demographic variables and connect them to stigmatizing information about them. Based on this, the provider may require that the data be handled as identifiable private information.

Emergency use: The use of an investigational drug or biologic on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.[96]

Engaged in Research: This refers to the boundary beyond which an investigator, investigative team, or organization is actually doing research, rather than conducting preliminary studies, preparing to do research, or conducting what would be business as usual for them. A person or organization is generally considered to be engaged in research if they present an informed consent document to participants, or if they interact with participants or manipulate their environment in a way that is primarily intended to generate research data. A person or organization is generally not considered to be engaged in research if they provide services or collect information or biospecimens in a way that they normally would if no research project were going on, and the data generated are not, at the time, supposed to be used for research. People and organizations are not considered to be engaged in research if they merely inform potential participants about a study. An organization is not considered to be engaged in research if its only involvement in a project is to facilitate researcher access to participants or secondary data. Preliminary studies such as testing

[96] Definitions, 21 C.F.R. § 56.102 (2024). https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-A/section-56.102

survey instruments does not constitute engagement in research as long as data from them are not, at the time, supposed to be used for a publication or presentation.[97][98]

Expanded Access: Providing an investigational drug or biologic to a patient who was not designated to receive it under the approved IRB protocol. Providing expanded access is not research. Data gained from providing expanded access may not be used for research purposes.

Experienced IRB Member: An IRB member is considered experienced if the IRB Chair or ORSP Director considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.

Expiration Date: The end date of the approval period.

External Collaborator: An individual with no institutional affiliation involved in Adelphi research.

External Institution: Any institution other than Adelphi University.

External IRB: An IRB other than Adelphi University's.

Finding of Non-Compliance: Non-Compliance in fact.

Honest Broker: An individual, or system, acting on behalf of the database, registry, or repository, that will collect and provide de-identified information/samples to a research team per the standard operating procedures of the database, registry, or repository.

Human Subject: See previous section.

Humanitarian Use Device: A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.

Identifiable Biospecimen: See previous section.

Identifiable Private Information: See previous section.

Immediate Family: Spouse, domestic partner; and dependent children.

Interaction: See previous section.

Intervention: See previous section.

Institutional Official/ Organizational Official (IO/OO): The individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. The IO is responsible for ensuring that the IRB functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA). Depending on how Adelphi's administration is constituted at the time, the IO may be the ORSP Director, the Associate Provost for Research and Special Projects, or the Provost.

Investigation: A searching inquiry for facts; detailed or careful examination.

IRB Member: A regular member for whom a formally appointed and comparably qualified alternate member may substitute.

IRB of Record: An IRB that assumes IRB responsibilities for the review of Human Subjects Research. This is Adelphi University's IRB unless there is an explicit agreement to share responsibilities with another IRB or rely entirely on another IRB. Similar terms include Single IRB (sIRB) and Central IRB (cIRB).

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[97] University of Wisconsin - Madison. (2022, July 29). WORKSHEET: Engagement. Retrieved April 14, 2024 from https://uwmadison.app.box.com/s/vvlnq2glr39vxx9yhgn0aymdthrlrlgs

[98] Office for Human Research Protections. (2008, March 7, 2016). Engagement of institutions in human subjects research. Retrieved June 16, 2024 from https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

IRB Reliance: A term to describe agreements between or among institutions Engaged in Human Research to identify the reviewing IRB and the roles and responsibilities of each institution. These agreements are documented in Reliance Agreements. Similar terms include ceded review and deferred review.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures(s) involved in the research. Unless there is some other law or institutional policy addressing this issue, then this is whoever would have the authority in a non-research context to consent on behalf of the participant to the procedures involved in the research. For research on legal minors, this is usually a parent or guardian.

Local Context/Local Research Context: Knowledge of the institution and community environment in which Human Research will be conducted. In order for an IRB to agree to serve as the IRB of Record for another institution or entity, it must have adequate knowledge of that institution's or entity's local context. This may include local research policies and other institutional requirements.

Mature Minor: Everyone under 18 is considered to be "vulnerable" for research purposes due to their legal status and that vulnerability should be addressed in protocols. The concept of a "mature minor" also applies in research, and it refers here to situations in which health care, education, and other systems have made reasoned ethical decisions to allow persons under 18 with similar characteristics to the intended subject pool to consent as an adult to activities described in the protocol. A mature minor may be in a life situation where adult-like health care decisions apply to them, such as pregnancy, HIV+ status, homelessness, or substance use.[99] The New York University School of Medicine has a mature minor norm based on its own institutional policy dating back to 1985, and determines it based on legal status and/or life situation. A mature minor may have moved on from their parents' care by getting married, joining the armed forces, becoming emancipated (sometimes de facto if they are "throwaway" youth), or being incarcerated. New York State allows certain runaways or homeless youth who are receiving crisis or support services to consent to medical, dental, health and hospital services.[100] Several states have mature minor doctrines permitting some adolescents of a certain age to receive certain healthcare without their parents' consent, subject to the provider's judgment.[101]

The American Psychological Association has supported extending mature minor laws to research. A panel of experts discussing research on HIV in 2020 found a variety of practices and interpretations of "mature minor" and other distinctions across IRB's, but they seemed to agree that an IRB should not go forward as though there is no such thing as a mature minor. Article 5 of the 1989 United Nations Convention on the Rights of the Child supported taking into account "the evolving capacities of the child," and studies in adolescent medicine have found that children as

[99] NYU Langone Health. Regulations for research involving children. https://med.nyu.edu/research/research-resources/clinical-research/sites/default/files/research-study-development-templates/guidance-vulnerable-children.docx

[100] SchoolHouse Connection. (2023). State laws on minor consent for routine medical care. Retrieved April 4, 2024 from https://schoolhouseconnection.org/state-laws-on-minor-consent-for-routine-medical-care/

[101] Bauman, L. J., Mellins, C. A., & Klitzman, R. (2020). Whether to waive parental permission in HIV prevention research among adolescents: Ethical and legal considerations. *Journal of Law, Medicine, & Ethics, 48*(1), 188-201. https://doi.org/10.1177/1073110520917010

young as 12 are as competent as adults in providing research consent.[102] Competence to provide consent is not the same thing as whether someone could be compelled to participate in research because of their legal status (c.f. "vulnerable").

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the participant's daily lives or during the performance of routine physical or psychological examinations or tests. Under the Common Rule, "risk" means risk of harm inherent to the research procedures, not an attribute of the population or subject matter under study. Studies on research about trauma [103], suicide[104], sex[105], substance use among adolescents[106], mental illness among people who are not actively psychotic[107], and sexual health among youth with minoritized sexual and gender identities[108] affirm that asking survey and interview questions about this subject matter does not involve more than minimal risk. Also, some people's daily lives involve risk. Some, like emergency responders and combat soldiers, have risky jobs, and others, like foster care youth and refugees, have already experienced harm and are at risk for even more. Accordingly, the Common Rule's discussion of exempt research, e.g., surveys and interviews, does not mention exceptions to exempt categories based on the subject matter or population under study. A physical or psychological examination or procedure that is routine, such as a blood draw, a Rorschach test, an MRI, or wearing a heart rate monitor on a treadmill,[109] can be argued to be minimal risk. Some imaging techniques, treatments for serious mental illness, and interventions to prevent or treat conditions associated with early death, significant self-harm, or danger to others are not minimal risk.

Multi-Site Study: A study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol.

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[102] American Psychological Association. (2018). APA resolution on support for the expansion of mature minors' ability to participate in research. Retrieved April 4, 2024 from https://www.apa.org/about/policy/resolution-minors-research.pdf

[103] Jaffe, A. E., DiLillo, D., Hoffman, L., Haikalis, M., & Dykstra, R. E. (2015). Does it hurt to ask? A meta-analysis of participant reactions to trauma research. *Clinical Psychology Review, 40*, 40-56. https://doi.org/https://doi.org/10.1016/j.cpr.2015.05.004

[104]Mathias, C. W., Michael Furr, R., Sheftall, A. H., Hill-Kapturczak, N., Crum, P., & Dougherty, D. M. (2012). What's the harm in asking about suicidal ideation? *Suicide and Life-Threatening Behavior, 42*(3), 341-351. https://doi.org/10.1111/j.1943-278X.2012.0095.x

[105] Yeater, E., Miller, G., Rinehart, J., & Nason, E. (2012). Trauma and sex surveys meet minimal risk standards: implications for institutional review boards. Psychological Science, 23(7), 780-787. https://doi.org/10.1177/0956797611435131

[106] Briney, J. S., Brown, E. C., Kuklinski, M. R., Oesterle, S., & Hawkins, J. D. (2017). Testing the question-behavior effect of self-administered surveys measuring youth drug use. *Journal of Adolescent Health, 61*(6), 743-746. https://doi.org/10.1016/j.jadohealth.2017.06.026

[107] Yanos, P. T., Stanley, B. S., & Greene, C. S. (2009). Research risk for persons with psychiatric disorders: a decisional framework to meet the ethical challenge. *Psychiatric Services, 60*(3), 374-383. https://doi.org/10.1176/ps.2009.60.3.374

[108] Macapagal, K., Coventry, R., Arbeit, M. R., Fisher, C. B., & Mustanski, B. (2017). "I won't out myself just to do a survey": Sexual and gender minority adolescents' perspectives on the risks and benefits of sex research. *Archives of Sexual Behavior, 46*(5), 1393-1409. https://doi.org/10.1007/s10508-016-0784-5

[109] National Institute of Mental Health. NIMH guidance on risk-based monitoring. Retrieved April 4, 2024 from https://www.nimh.nih.gov/funding/clinical-research/nimh-guidance-on-risk-based-monitoring

Non-Compliance: Failure to follow the Common Rule, New York State law, Adelphi policy, or the requirements or determinations of the IRB.

Non-scientist: IRB Members will be considered "non-scientists" when the totality of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from a standpoint outside of any biomedical or behavioral science discipline. Examples of Non-Scientist members include, but are not limited to, lawyers, clergy, and ethicists.

Participating Site: An institution that participates in a Single IRB (sIRB) Study.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Private information: See previous section.

Related to the Research: A financial interest is Related to the Research when the interest is in:

- A sponsor of the research;
- A competitor of the sponsor of the research;
- A product or service being tested; or
- A competitor of the product or service being tested.

Reliance Agreement: The formal written agreement between two or more entities that documents respective authorities, roles, responsibilities, and communication between an institution/organization serving as the IRB of Record and the institution relying on that IRB. An agreement may be developed to cover a single Human Research study, categories of Human Research, or Human Research within a research program.

Relying Institution: Also called "Relying Organization." The institution or organization that has ceded IRB review to another IRB to provide IRB review and oversight for a specific study or set of studies. Relying on another IRB to provide IRB oversight is also referred to as ceding or deferring IRB review.

Research: See previous section.

Restricted: Applies to researchers who are delinquent in meeting IRB requirements.

Reviewing IRB: The External IRB or entity taking on the role of providing IRB review and oversight. Also called the "Central IRB (cIRB)," "Single IRB (sIRB)," or IRB of Record.

Scientist: IRB Members will be considered "scientists" when the totality of their training, professional experience (type, duration) and personal experience would incline them to view scientific activities from the viewpoint of a scientist. Examples of a Scientist includes but is not limited to nurses, pharmacists, other behavioral or biomedical health professionals, geologists, statisticians, etc.

Serious Non-Compliance: Non-Compliance such that the failure to follow federal regulations, state laws or institutional policies relevant to human participants research or any determinations of the reviewing IRB and involves one or more of the following: substantive harm or genuine risk of substantive harm to the safety, rights and welfare of research participants or others, or decreases potential benefits to participants.

Single IRB (sIRB) Study: A study in which two or more institutions coordinate to complete the research activities, but all institutions rely on a single institution's/organization's IRB for ethical review. The reviewing IRB may or may not be affiliated with any of the institutions.

Suspension of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.

Systematic: Having or involving a system, method, or plan.

Termination of IRB Approval: An action of the IRB, IRB designee, Institutional Official/Organizational Official, or designee of the Institutional Official/Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.

Treatment Investigational Device Exemption: Use of an investigational device to treat or diagnose a group of patients with a serious or immediately life-threatening disease or condition when the device is also being studied for the same use under an approved Investigational Device Exemption.[110]

Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated, (2) related to the research, and (3) indicates that subjects or others are at increased risk of harm.

Vulnerable. "Vulnerable" as per the Common Rule means "vulnerable to coercion or undue influence [to participate in the research]." It has no necessary relationship to whether social or health science related fields, or any political or ideological worldviews, consider the population to be "vulnerable." The Common Rule establishes additional protections for children, prisoners, pregnant women, human fetuses, and neonates, under the premise that they are vulnerable. Beyond this, it does not stipulate what would make a population vulnerable, or what "additional safeguards" would be appropriate for them.[111] IRB's commonly also consider people to be vulnerable if they have neurological differences or educational background that would limit their understanding of the protocol. Other contexts for vulnerability include dual-role situations, such as supervisors or agencies researching their own employees or human services practitioners researching their own clients.

[110] U.S. Food & Drug Administration. (2019, June 21). Expanded access for medical devices. Retrieved April 14, 2024 from https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices

[111] Gordon, B. G. (2020). Vulnerability in research: Basic ethical concepts and general approach to review. Ochsner Journal, 20(1), 34-38. https://doi.org/10.31486/toj.19.0079