

ROWAN INSTITUTIONAL REVIEW BOARDS FAQ

1. What is an IRB?

Institutional Review Boards (IRBs) also known as independent ethics committee, is a committee that is charged by the institution to review, approve or disapprove or require changes to secure approval and monitor biomedical, social and behavioral research involving human research subjects. IRB review serves an important role in the protection of the rights and welfare of human research subjects. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

Research reviewed by the IRB may also be subject to other review and approval or disapproval by administrative officials at Rowan University. However, those officials may not approve research that has not been disapproved by the IRB for Human Participants.

2. How do I know if I am conducting research with human participants? What are some of the definitions used in human subject research?

According to Rowan University Policy and federal regulations, **research** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

According to regulations, **Human subject** means Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. **Obtaining** means, receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

Intervention means both physical procedures by which information or biospecimens are gathered (e.g., venipuncture, taking blood from arms) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject (for example, surveys and interviews).

Private information includes 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 which the individual can reasonably expect will not be made public (for example, a medical record). Private information also includes individually identifiable (i.e., the identity of a participant is associated with the information or the identity may readily be ascertained by the investigator).

Identifiable private information means 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 means a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Institution means any public or private entity, or department or agency (including federal, state, and other agencies).

IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Legally authorized representative means an individual or judicial other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Protocol or study means the formal design or plan of an experiment or research activity or, specifically, the plan submitted to an IRB for review and to an agency for support of the research. The protocol/study includes a description of the research design and methods to be employed, the eligibility requirements for subjects and controls, the treatment regimen(s), evaluation of expected or unexpected problems, risks, and discomforts to study subjects, and the methods of analysis to be performed on the collected data.

Public health authority means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

3. What does "individually identifiable" mean as it pertains to private information or biospecimens, as stated in the definition of a human subject?

According to the "Guidance on Research Involving Coded Private Information or Biological Specimens" (<http://www.hhs.gov/ohrp/policy/cdebiol.pdf>), Office for Human Research Protection (OHRP) generally considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Under Human Subjects Regulations, if an investigator obtains private information about living individuals for research purposes and that private information retains a link to individually identifying information, such private information ordinarily would be considered by OHRP to be individually identifiable to the investigator. However, OHRP does not ordinarily consider such information to be individually identifiable to the investigator if (1) the investigator and the holder of the individually identifying information sign an agreement prohibiting the release of individually identifying information to the investigator under any circumstances, or (2) there are other legal requirements prohibiting the release of the link to the investigator.

4. When am I required to submit a proposal involving research with human participants to the IRB?

All research projects that will involve human participants must be submitted through Cayuse IRB for review and approval before beginning the study. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

5. How do I select the appropriate review category (exempt, expedited, or full board)?

You can use the decision tree in the following website: [DHHS Human Subjects Regulations Decision Charts](#) for guidance related to exempt and expedited review categories.

Please note that the Rowan IRB is the institutional body with the final authority to determine the appropriate review level, but investigators must select the review category that best fits the research design. Rowan IRB may have to select appropriate review category levels due to local issues. If you need additional information, please contact the IRB Office.

6. What if I consider that my research project is non-human subject research?

As the researcher you are responsible for the initial assessment as to whether an activity constitutes human subjects research. The investigator should make this assessment based on the definitions of “human subject” and “research.” Researchers are required to submit a [Cayuse IRB \(CIRB\) application](#) selecting “Non-Human Subject Research” as the level of research. All such requests must include sufficient documentation of the activity to support the determination.

To determine whether the activity is research involving human subjects, please refer to the decision tree in the following website: [DHHS Human Subjects Regulations Decision Charts](#). If you are unsure if your project involves research with human subjects, please reach out to the Rowan IRB office.

7. Who makes the determination whether the proposed activity is human subject research?

As per OHRP guidelines, IRB director or the Chair(s) will review such application(s) and make a determination as to whether the proposed activity constitutes human subject research or not.

8. What are some of the areas of research considered non-human subject research?

- A. **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.
- B. **Public surveillance activities**, including the collection and testing of information or, biospecimens conducted, supported and requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow public health authority to identify, monitor, assess or investigate potential public health signals, onset of disease outbreaks or conditions of public health importance (including trends, signals, and risk factors, patterns of disease outbreaks or conditions, or increasing injuries from using consumer products.). Such activities include 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).
- C. **Collection and analysis of information, biospecimens**, or record by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- D. **Authorized operational activities** (as determined by each agency) in support of intelligence, homeland security, defense or other national security missions.
- E. **Private information or biospecimen not to be individually identifiable** when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems when information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals. When the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or bio specimens when the holder of the code does not release the identifiers.
- F. **Researchers making use of certain data such as Public Use Data** (publicly available) and de-identified data **not** derived from other research projects.
- G. If the proposed studies involve a group of individuals who are **consultants and have been chosen for their expertise to improve the research design** (rather than testing), such consultations are considered non-human subjects research.
- H. If the studies involve a group of individuals who are **brought in to test a new product (e.g. software, equipment, surveys) to identify “bugs” or problems**, the research considered non-human subjects research because the data collected is about the product and not about the individuals.

7. What are some examples of studies considered human subject research requiring IRB review?

- A. Clinical research or study
- B. Clinical trial
- C. Investigator-initiated Clinical investigation
- D. Social, educational and behavioral research through interaction, intervention, experimentation or observation
- E. Studies involving an “investigational device” that is the object of research investigation or evaluation, but not clinical use
- F. Studies involving an “investigational new drug” (IND) either new or “off-label” use of a drug
- G. Studies involving “biological products” in an “investigational study”
- H. Studies involving use of a new diagnostic method or article
- I. Studies involving use of a new treatment modality, surgical procedure, or psychological measure in a “clinical investigation or study”
- J. Epidemiologic studies
- K. Existing or prospective chart reviews or records
- L. Data mining from electronic records

- M. Surveys
- N. Some quality improvement activities.

9. My study involves a simple survey, interview or questionnaire; do I need to submit my proposal to the IRB?

Yes. Almost all surveys, interviews or questionnaires that involve interventions or interactions whether using identifiers or without the use of identifiers (anonymous), they are subject to review and approval by the IRB since they are used in the conduct of human subjects research. Most often such surveys, interviews or questionnaire are reviewed as “Exempt” or “Expedited” review categories depending upon whether the surveys, interviews or questionnaires are collecting identifiable information.

10. I am conducting a simple surveys, interviews or questionnaires, what method should I use to conduct such research?

There are two methods to conduct surveys: One of the methods uses paper survey (manual method) in which the surveys are mailed or sent using papers. The other method is to use **Qualtrics** (electronic method) to distribute collect the responses from a survey. Surveys, interview script/questions, or questionnaires whether paper or electronic must be attached in the Cayuse IRB submission for review by the IRB.

If you are surveying or collecting **existing information** without the use of identifiers, such projects will be reviewed under exempt review Category 4. Please read FAQ# 4 above if coded information or specimens are used in your research.

11. Do I need to use a consent form to conduct surveys, questionnaires or interviews?

If you are not collecting identifiable information, there are alternate consent forms for “Paper Survey” and “Online Survey” posted on the website ([Rowan IRB Consent Forms Webpage](#)). Depending upon the method you are using, use the appropriate consent form. Please note that this alternate consent form should be part of your survey and the consent form should be placed on top of the survey for the subjects to read first before they take the survey.

Surveys that collect private individually identifiable data may require the use of an electronic or physical written, signed consent. Written, signed consent will be required when individually identifiable data includes information about whom that is sensitive or put individuals at risk for civil or criminal liability. Sensitive data includes data that may harm individuals reputation, insurability, employability, or be stigmatizing.

Please make sure to use the most recent version of the consent form. Otherwise, the IRB approval may be delayed until a recent version of the consent form is submitted, reviewed and approved by the IRB.

Example 1: If your research involves clinical or medical research involving adults, you must use “Adult Consent Form - Medical Research RowanSOM IRB.”

Example 2: If your research involves Social and Behavioral Research involving adults, you must use “Adult Consent Form - Social and Behavioral Research Glassboro/CMSRU IRB”.

Example 3: If your research involves children, for clinical and medical research, you must use “Parental/Guardian Consent Form - Medical Research RowanSOM IRB”

Example 4: If your research involves children, for Social and Behavioral Research, you must use “Parental/Guardian Consent Form - Social and Behavioral Research Glassboro/CMSRU IRB”.

Example 5: If you are from College of education, you must use “College of Education ONLY - Passive Letter of Consent for Action Research Projects.”

Example 6: If your research involves interviews, you must use “Interview Consent Form” - This form is only applicable for expedited review categories. Full board interviews require adult consent forms.

Note: When children are subjects in a study, an “Assent Form” may be required.

Example 7: If you are planning for verbal consent go to the following to download the consent template. New Verbal Consent Script Template can be found in the Consent Templates section. [Rowan IRB Consent Forms Webpage](#).

12. I am a graduate/undergraduate or medical student at Rowan. Do research projects conducted by me (a student) need IRB approval?

Student research when it meets research and human subject definition as described under FAQ #5 above needs IRB approval. All research conducted by any student will be conducted under the advisorship/mentorship of their professor. Those professors will be the principal investigators of the project; students can be identified as a co-investigator.

13. What is a pedagogical and methodological activity?

Pedagogical and methodological activities are classroom/course instruction on conducting research and often employ the use of human subjects research practices and procedures, including but not limited to recruitment, consent and enrollment, planning, and interaction with living individuals. Classroom-based activities/studies often are not designed to develop generalizable knowledge because they are not shared or presented outside the classroom/course and data is not used for research purposes.

Please review the Rowan IRB webpage and consult with your faculty PI regarding classroom setting only activities ([Submitting Pedagogy & Methodology Activities](#)).

14. I am a researcher and I am a participant in my own study. Does this require an IRB review since this involves self-experimentation?

All experiments including self-experimentation require IRB review to evaluate risks, harm and assure safety of all participants. The Common Rule and Food and Drug Administration (FDA) do not regard research on oneself as different from research involving other human subjects.

15. I am conducting a quality control/quality improvement study. Do I need to go through IRB approval to conduct this study?

Quality Assurance (QA) activities are done to assure known quality. These activities are mechanisms to assure that organizations function optimally. Quality Improvement (QI) activities are done to improve quality of programs, improve services, or improve the provision of medical care, customer service, etc. QA/QI projects are usually done for internal purposes only. However, some QA/QI projects may fall under the federal definition of research, and therefore, may require IRB review.

If the QA/QI projects are systematic and leads to generalizable knowledge and the findings are shared outside of institution, department or division, then the project is considered human subject research requiring IRB review. If the data is used solely to administrative purposes and not disseminated outside the institution, they are considered normal conduct of work and they do not require IRB review.

16. What is an “exempt” from IRB review protocol?

The federal regulations identify categories of research methods that can be exempted from IRB review. ([OHRP Exempt Requirements/Categories](#)) These categories imply that the protocol is minimally risky and certain aspects of the study do not require the Board’s continuous review. However, the institution as required by regulations requires investigators to submit a request for Exemption from an IRB review to make sure that the proposed study meets one of the categories of exempt review, which is generally determined by a person who has the expertise and experience to make this determination. Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report ([The Belmont Report](#)) and in disciplinary codes of professional conduct. Thus, depending on the circumstances, investigators performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints.

Some parts of Exempt review categories may NOT eligible for exempt review if the research involves pregnant women, prisoners and children. Please read additional guidelines on the following website: [Rowan University Guidance on Human Subjects Research](#).

17. What is an “Expedited” review?

The federal regulations identify categories of research methods that meet Expedited review. ([OHRP Expedited Requirements/Categories](#)). The requirements are: 1) present no more than minimal privacy, psychological and/or physical risk to human subjects, and 2) involve only procedures listed in one or more of the expedited categories, may be reviewed by the IRB through the expedited review procedure authorized by federal regulations (OHRP and FDA). The activities listed should not be deemed to be of minimal risk simply because they are included on the expedited checklist. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in the expedited checklist apply regardless of the age of the subjects, except as noted. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human subjects. The standard requirements for informed consent and authorization (or their waiver, alteration, or exception) apply regardless of the type of review.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Examples are:

- Drawing blood from a patient
- Studies that will involve the collection of output data obtained as a result of moderate exercise undertaken by healthy volunteers
- Research involving materials (data, documents, records—including medical records—or biological specimens) that have been collected or will be collected solely for research purposes
- Research with no direct interaction with participants (e.g. secondary use of data)
- Collection of data from voice, video, digital or image records made for research purposes

- Research on individual or group characteristics or behavior (e.g., focus groups, surveys, interviews)
- Mobile applications that only track information and do not directly inform care of the research subject

For prisoner population, minimal risk means, research in which "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons."

18. What is a "Full Board" review? What are the requirements?

Any research study that involves human subjects, but does not qualify under exempt and expedited review categories, any research project that is subject to FDA or Common Rule definition of human subjects research, and any human subject research that is above minimal risk, and does not qualify under exempt or expedited review categories, requires full board review. Full board review means that the research is reviewed at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. This type of review applies to studies that are greater than minimal risk, or minimal risk but do not qualify for expedited review.

19. What is a continuing review? When does this apply?

Continuing Review (also known as "Periodic Review") is a reevaluation of an approved study conducted at least once a year, as mandated by federal regulations.

Continuing review is required so long as the study is ongoing, that is, until research-related interactions and interventions with human subjects or the obtaining and analysis of identifiable private information described in the IRB-approved research plan have been completed. Continuing review applies to all studies that use protected health information or collect sensitive information.

20. What is Progress report?

This review allows the IRB to monitor the progress of the study and ensure that it continues to meet the requirements for approval. The continuing review process starts after the Principal Investigator submits the continuing review form to the IRB Office.

A **progress report** is a form of continuing review requiring minimal review by the IRB. A determination whether a continuing review or a progress report is required is made by the IRB at the time of initial review or when the study was reviewed and approved the first time. Progress report should be submitted annually unless the study is complete. If the study is complete, a final report to close the study must be submitted and approved by the IRB. If an approved study requiring annual progress report, any modifications (change the in the personnel, changes to the protocol or study, study location, changes to the consent form) an amendment to modify the study must be submitted for review by the IRB and such changes must only be implemented after receiving IRB approval.

21. What happens when continuing review or progress is not submitted?

If continuing reviews or progress reports are **not** submitted in time, the protocol will expire. No research activities may be conducted until the continuing review or progress report is approved by the IRB. There is a limited time for submitting continuing review if the protocol has lapsed. The IRB reserves the right to close the study if continuing review or progress report is not submitted within 45 days of the expiration.

If continuing review has lapsed and if the investigator intends to continue the study, a new IRB application must be submitted and approved by the IRB before the study can recommence.

22. I want to make a change to the approved protocol. How can I do that?

Do not implement any changes to the protocol without IRB approval. To make a change, you can submit a modification via Rowan Cayuse IRB describing what changes are going to be made and how the change overall affects the risk to subjects and whether the changes necessitates revision of the consent documents.

23. How can I close the study? What happens if I don't close the study?

When the study is completed it is the responsibility of the principal investigators to close the study by submitting a "Final Report" and receive approval from the IRB confirming that the study has been closed. If a study has not been closed, a continuing review or progress report has not been submitted, Principal Investigators are responsible for not closing or continuing a study. Faculty PI college and school administrators may be notified of continued non-compliance by faculty PI who do not close studies in a timely manner.

24. Data collection for my study is complete. All I am doing now is data analysis. What should I do in that case?

You no longer required to submit a continuing review or progress report to conduct de-identified data analysis only. In that case, you are required to submit a final report to close the study. Please note that if you close the study, you are no longer allowed to collect additional data.

If data analysis includes identifiable information or may involve an interaction with subjects then the study should remain open and a continuing renewal submission in Cayuse IRB is required.

25. I am going on sabbatical or my study sponsor wants to "inactivate" a protocol. Can this be done? If so, how can I reactivate the study that has been inactivated?

You can submit a request to inactivate the study at any time. If the study has already enrolled subjects, your inactivation request must include a summary of activities up to the point of request to inactivate including number of subjects enrolled and any history of adverse events with those subjects. When you make a request to reactivate the study, indicate why you are reactivating and are there any changes made to reactivate the study. IRB may request for a new application, if there are overt changes to the protocol.

26. Can the IRB approve a project "retroactively?"

No. There is no provision in the federal regulations that allow for IRB approval of research that has already been conducted. If data was collected for purposes that the IRB determines to be non-research (e.g., program evaluations for library or educational programs not initially intended to be used for research), IRB approval can be sought for the data analysis going forward.

27. How long will it take for me to obtain approval to do my study?

That depends on the nature of your study, the characteristics of the people you intend to recruit and how thoroughly the IRB application has been submitted. Research projects that involve only minimal risks are eligible for expedited review, for which you should allow at least 3 weeks for IRB review.

Research projects that involve greater than minimal risk to participants will need to go to the full board for review, which may take at least 4-6 weeks for review and approval of your study.

28. What does an IRB protocol review look like?

IRB reviews protocols using “reasonable person” standards. The IRB evaluates every research protocol according to the ethical principles described in the Belmont Report. Basically, this means the IRB considers whether the risks and benefits of a study are acceptable and managed appropriately, and whether individuals being asked to participate are adequately informed about the research and its possible risks. Additional items IRB reviews include whether the study includes vulnerable subjects such as children, pregnant women, prisoners, conflict of interest, recruitment methods, etc.

Considered another way, the review may include plans from the point of view of a subject, or an observer concerned about responsible research. Who are the subjects and how are they recruited? Could they be lured or coerced to participate? Is it through an institution that may have responsibilities toward them (e.g., a school or hospital) and should be consulted? Do they understand, in advance, what they are agreeing to participate in and give their consent willingly? What will they actually do, and what is done to them, during the study? Is it possible that the experience might be injurious, painful, uncomfortable, needlessly boring, embarrassing, offensive, or otherwise stressful? Might there be long-term consequences? Could the subject be endangered, compromised or embarrassed if information collected leaked out? There are many possible considerations, but they should not be difficult to understand if one assumes the subject's perspective. The IRB's role is to look at the study from this perspective and to ensure that proper precautions are taken to protect individuals when they agree to participate in research.

29. When may I begin data collection for my study?

You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis. A memo will be sent to you via e-mail when your project has IRB approval.

30. If I am collaborating with another institution, do I need to submit my application to Rowan IRB?

If you are a member of Rowan University faculty or staff, or a student, and you are the person responsible for the conduct of the study (PI) and if your study is conducted at Rowan, you must get Rowan IRB approval to conduct your research regardless of where the research takes place.

Investigators should contact the IRB office whenever collaborative research is occurring. Separate applications for each institution may be necessary; however, to avoid duplicate review, an IRB Authorization Agreement may be arranged with the other institution to establish one IRB as the designated IRB to review and approve the research.

If you are a member of Rowan University faculty or staff, or a student, and you are NOT the person responsible for the conduct of the study (PI), but you are only a collaborator and recruiting subjects at Rowan, you must submit the IRB application naming yourself as the PI. However, to avoid duplicate review, an IRB Authorization Agreement may be arranged with the other institution to establish that the outside IRB as the designated IRB to review and approve the research.

31. I or another co-investigator at another institution are receiving NIH funds to conduct human subject research. In such a case, which IRB should I use to receive approval to conduct the study?

If the Rowan University and the principal investigator at Rowan is coordinating a multisite study and the study is going to be conducted at Rowan University, the Principal Investigator at Rowan University must document how the important human subject protection information will be communicated to the other participating facilities engaged in the research study. The investigator is responsible for serving as the

single liaison with outside regulatory agencies, with other participating facilities, and for all aspects of internal review and oversight procedures. The investigator is responsible for ensuring that all participating facilities obtain review and approval from their IRB of record and adopt all protocol modifications in a timely fashion. The investigator is responsible for ensuring that the research study is reviewed and approved by any other appropriate committees at the coordinating facility and at the participating facilities (e.g. VA Research and Development Committee approval) prior to enrollment of participants.

On the contrary, if Rowan University is a collaborating institution in a grant, the principal Institution's IRB will be the IRB of record. In such case, Rowan University IRB will rely upon the IRB approving the study while making sure that the concerns of Rowan University and its principal investigators are communicated to the IRB of record and such concerns are considered during the IRB review at the reviewing institution.

In a multisite study, only one IRB will have the jurisdiction on the study.

32. I am conducting research in another country. Do I have to obtain IRB review and approval from Rowan?

Yes. If you are a member of the Rowan University faculty or staff, or a student, and if you are the person responsible for the conduct of the study (PI), you must get Rowan IRB approval to conduct your research regardless of where the research takes place. Please be aware that your study may also have to be approved by a local IRB or ethics committee in the country where you will be conducting the research.

33. I want to make an application using Cayuse IRB. Is there an investigator manual to take me through the process of application?

The Rowan IRB website has information about submitting to the Cayuse IRB. The website address is: [Accessing Cayuse IRB](#).

Cayuse IRB submission system has a Help function that can be used by researchers when completing a Cayuse IRB submission in the system, and the Rowan IRB submission in cayuse provides some instructional text in the submission itself for researchers to review and follow.

34. Who can I talk to if I have a question about my research project involving human participants?

The IRB staff at Glassboro and Stratford are available to provide assistance to investigators who are engaged in research with human participants. Contact information is posted on the website [IRB Office Contacts](#).

35. Are there sample protocols and consent forms available for IRB submissions?

Yes, please go to the Rowan IRB website to download and use a protocol or consent form template.

36. What is an informed consent?

Informed consent is an important part of the research process. It is a dynamic interactive process between the researcher and the participant in which potential subjects are provided with a document to make a true informed decision about whether or not to participate in a research study. Informed consent should be clear and explain the nature of the research project; why they are the best candidates for that specific research, what risks, benefits, and alternatives are associated with research and explain what rights they have either to agree or not agree to participate in research. Consent form must be written and presented in a language that is understandable to the subject so that the participant will

agree to participate in the study without coercion. The IRB site provides several templates to assist the investigator in the design of the informed consent.

When children are subjects of a study, parental permission is required in lieu of adult consent form. In general, parental permission does not differ from adult consent form. When children are adolescents, IRB may consider an adult consent form to be an acceptable form of consenting,

37. What is an assent?

“Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. In other words, the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. The IRB has the discretion to judge children’s capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.

Researchers should take into account (IRB too) the nature of the proposed activity and the ages, maturity, and psychological state of the children involved when constructing the assent form. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

38. What is a “waiver” of consent and documentation of consent?

In some special circumstance, the IRB may allow a waiver, or an alteration for the requirement for informed consent. In order to secure a waiver, the researcher should make a request to the IRB requesting for a waiver or alteration for the requirement for informed consent. In order to secure the waiver/alteration, the research must involve no more than minimal risk, research could not be practically conducted without the waiver/alteration and whenever appropriate, the subjects will be provided with additional pertinent information for the participation. That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. Please note that the IRBs carefully review the waiver request and IRBs will document that a waiver is being applied and how the criteria for a waiver are being present.

A request for waiver will not approved by the IRB when the study involves the potentially identifiable student’s education record per FERPA regulations. Generally, educational agencies and institutions must have written permission from the student (or parent if the student is a minor) in order to release any personally identifiable information from a student's education record unless it meets one of a list of specified conditions for which release is allowed. (For example studies to improve instruction conducted by organizations for or on behalf of the educational agency or institution). Other than under such a condition, if an investigator from a local university's college of education requests a waiver of consent to review the educational records (grades and GPA) of students at the university for the past 20 years and maintain identifiers for a research project, the rights granted to students under the federal legislation of FERPA would be violated and the criteria for waiver of informed consent at 45 CFR 46.116(d)(2) could not be met.

Waiver also requires documentation of consent unless documentation of consent is waived by the IRB. This process is often used in **minimal risk** research involving the administration of online or mailed surveys, telephone interviews, or when anonymous sensitive information is collected and there is a desire to not have written documentation that links the participant to the research study. The IRB may waive the documentation if the written script of the information to be provided orally and all written information to be provided include all required and appropriate elements of consent disclosure and the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether or not he or she wants documentation linking him or her to the research. The participant's wishes will govern.

Waiver of documentation of consent for clinical trials that fall under FDA regulations is not permitted.

For studies that fall under HIPAA regulations, when requested by the researcher, the privacy board or IRB may provide a waiver or alteration of HIPAA authorization if there is:

- An adequate plan to protect health information identifiers from improper use or disclosure
- An adequate plan to destroy identifiers at the earliest opportunity absent a health or research justification or legal requirement to retain them, and
- Adequate written assurances that the PHI will not be used or disclosed to a third party except as required by law, for authorized oversight of the research study, or for other research uses and disclosures permitted by the Privacy Rule; When research could not practicably be conducted without the waiver or alteration; and
- Research could not practicably be conducted without access to and use of PHI

39. Do I always have to obtain the informed consent of research participants?

In general, yes, but there are some limited exceptions. The IRB is responsible for ensuring that basic ethical principles are abided by in all research. The expectation that the informed consent of research participants be obtained is based upon the Belmont principle of respect for persons, and regarded as extremely important in conducting ethical research. The IRB has the authority to waive some or all of the federal requirements for informed consent in certain extenuating circumstances. A request for waiver of informed consent must be specifically justified by the researcher in the proposal to the IRB.²⁹

40. I am not collecting any identifying information. Do I still need an informed consent form?

Yes. If the proposed study is truly "anonymous" - no coding for identifiers (e.g., names, social security numbers, driver's license numbers, etc.), a modified informed consent form (often called an information sheet or alternate consent for paper or online) may be used ([Rowan IRB Consent Form Templates.](#))

That is, all of the elements of consent must be documented for the participant, but the signature line is replaced with a statement informing the participant that completion and return of the survey is considered implied consent. If, however, the procedures involve risk or biological sample collections that contain subject identifies, a written consent may be required.

41. What is "implied" consent?

Implied consent is the tacit indication that a person has knowingly agreed to participate in research by performing a research activity or task. By completing the research task (e.g., completion of a questionnaire, interview, survey, etc.), the participant has provided consent to participate in the research.

Implied consent is actually a type of a waiver of documentation of informed consent. Before granting such a waiver, the IRB may require the researcher to provide the participants with a written summary or an information sheet about the research, including: (1) purpose of research; (2) time involved; (3) assessment of minimal risk; (4) statement regarding benefit to participants; (5) contact for questions about the research; and (6) contact for questions about rights as a research participant.

There are a number of instances where this type of consent is helpful. For example, you wish to mail out a survey. The survey does not ask for any identifiable information. The cover letter accompanying the survey could be written in such a manner as to serve as the "implied" informed consent form. The letter would need to contain a statement indicating that completion and return of the survey implies consent to participate in the research.

42. How is the consent process handled for Internet-Based research?

For Internet-based surveys, it is sometimes appropriate to use implied informed consent. Participants would still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey.

If, for study design purposes, the researcher needs to keep track of who participated or if the IRB determines that some sort of documented consent is required, instead of "signed" informed consent, the researcher may email the consent form to participants who may then type their name and the date into the spaces provided on the consent form, and return it to the researcher via email. This process may be appropriate for data collected via email, chat rooms, online interviews, etc. Alternatively, some Internet-based survey vendors and/or software packages provide a means to record whether a respondent has consented to participate before beginning a survey (e.g., a date/time stamp feature).

43. What are the consent requirements for phone based research?

IRB approval for phone-based consent may vary depending upon the nature of the research activity. For protocols involving oral consent the following information is required to be communicated to the participant:

- study purpose and procedures involved
- what will participant be asked to do - as well as the amount of time participant will spend
- the voluntary nature of participation in the study
- the participant is free to withdraw at any time
- the information collected will remain confidential
- offer the participant contact information for the researcher and/or the IRB

It may be pertinent to request the PI to offer additional information depending on the nature of the study. It is up to the IRB to suggest additional information to be included in order to further protect the participant.

44. What is HIPAA? What is HIPAA authorization for research? What is HIPAA waiver of authorization for research?

The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research.

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information (PHI). Under the Privacy Rule, covered entities (hospital and clinics) are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. To use or disclose protected health information without authorization by the research participant, a covered entity must obtain HIPAA waiver of authorization. HIPAA rule applies to all members of RowanSOM.

HIPAA privacy rule contains other components such as “preparatory to research”, “limited data set agreements” and “Decedents Health Information.” Please contact the Privacy Officer or the IRB office to obtain more information on the application of HIPAA regulations on HIPAA and medical research.

45. I am a faculty or student at Glassboro campus. Do I need HIPAA authorization or HIPAA waiver of authorization for my research?

In general HIPAA rules do not apply to research conducted at the Glassboro campus except for those research projects which collect protected Health Information (PHI) for research purposes. If there is going to be use of PHI, such projects will be sent to RowanSOM IRB for review and approval. Such use and collection of PHI with or without the use of identifiers; may require HIPAA authorization or HIPAA waiver of authorization. Please contact the IRB office ([Research Compliance Administration Contacts.](#)) for further information on the application of HIPAA rules at the Glassboro campus.

46. What are the IRB requirements for training?

At Rowan University, all investigators and research staff must successfully complete the CITI Program for training in the ethical conduct of research with human participants and update it at least once every three years. There are three levels of training depending upon the type activity: 1. IRB Chairs and members training; 2. Social and behavioral training and 3. Biomedical and basic science training. A refresher course must be taken every three years. A reminder for refresher will be sent by CITI official.

47. Who is required to complete the human participants training?

All faculty, students, and staff proposing to use human participants in research under the auspices of Rowan University are required to complete the human participants training. Approvals for including human participants in proposed research projects will not be granted until this training has been completed and verified by the IRB office. For additional information on CITI training, go to: [Rowan IRB CITI Webpage.](#)

In addition, the Office of Research Compliance offers periodic workshops on human subjects protection and IRB process. Individuals are encouraged to attend these workshops.

48. In the case of a potential unanticipated problem involving risks to participants or others, when is the principal investigator expected to report this occurrence to the IRB?

Serious adverse events must be reported to the IRB immediately through the Rowan Cayuse IRB, with a written report by the PI following within 24 hours of the PI's becoming aware of the event. Serious adverse events are (1) death of a research participant; or (2) serious injury to a research participant.

All other non-serious unanticipated problems should be reported to the IRB within 2 weeks of the first awareness of the problem by the Protocol PI or another researcher, ORIA, or a member of the IRB. Prompt reporting is important, as unanticipated problems often require some modification of study procedures, protocols, and/or informed consent processes. Such modifications require the review and approval of the IRB.

49. Can the IRB temporarily or permanently discontinue a research project as result of an unanticipated problem involving risks to participants or others?

Yes. If an unanticipated problem poses a risk(s) to the participants or others, the IRB may temporarily discontinue a research project until a thorough investigation has been conducted. Dependent on the investigation, the IRB may request changes to a research study or permanently discontinue the research study. Please see SOP #6, Suspensions and Terminations of IRB Approval of Research Protocols.

50. Can the IRB request revisions to the approved research study and the informed consent form as a result of an unanticipated problem?

Yes. As a result of the IRB's investigation of the unanticipated problem, revisions to the approved research study and the informed consent form may be requested.

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