Frequently Asked Questions

We hope that these frequently asked questions will orient you to basic policies and procedures for IRB review and approval. Feel free to call on us as you navigate the process. We are happy to respond to your questions.

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Frequently Asked Questions

1. **What is the IRB?**
   The Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects. The primary purpose of the IRB is to protect the rights and welfare of the human subjects. The IRB is responsible for reviewing all research involving human subjects, ensuring that potential research-related risks are minimized, and that there is full disclosure so that volunteers can make an informed decision about whether or not to participate.
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2. **What research has to be reviewed by the IRB?**
   The IRB reviews and monitors human subjects research that fits the definitions of research and human subject as defined by the Code of Federal Regulations.
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3. **What is research?**
   Research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102 (l)).

   The IRB considers data gathering activities not to be within its scope of review if the data is used for non-research purposes, such as institutional evaluation, and/or if it will not result in presentation or publication. Such activities, including but not limited to course evaluations or alumni surveys, are not typically within the scope of the IRB review.
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4. **What is a human subject?**
   A human subject is defined by Federal Regulations as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) 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.." (45 CFR 46.102(e)(1)).
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5. **Are the following types of research subject to IRB Review?**

   a. *Scholarly and Journalistic Activities:*
      For purposes of this part, the following activities are deemed not to be 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 (45 CFR 46.102 (l)(1).

   b. *Political Polls and Public Opinion Polls:*
      In general, political and public opinion polls do not meet the definition of research as defined by the Code of Federal Regulations. However, if poll results are intended to contribute to generalizable knowledge and/or if results are disseminated or used in news stories, then they would appear to meet the definition of research and should be reviewed by the IRB.

c. *Marketing Research:*
Marketing research that requires IRB review includes research designed with a clear intent to disseminate or publish the results/data.

d. *Program Evaluation*

Program Evaluation is the inquiry into past, present, and potential programs to understand or clarify their need, working process or impact.

There are three major categories of program evaluation: **Needs assessments** (formative evaluations) establish whether or not a program is feasible or necessary; **process evaluations** determine whether or not a program's implementation is congruous with its conception; **impact evaluations** (summative or outcome evaluations) ascertain whether or not a program meets its goals.

Some program evaluations constitute human subjects research and others do not.

Generally, program evaluations not requiring human subjects review involve data internally collected and analyzed for the normal course of business. These evaluations' goals range from simple descriptive statistics to qualitative information, and examples include program enrollment data, constituent demographics, and outcome analyses. Therefore, irrespective of human subject involvement, these program evaluations remain internal and thus do not contribute to generalizable knowledge.

However, if a program evaluation is research and uses human subjects, then it requires approval. Program evaluations that lead to publishing results in scholarly journals or making presentations outside your institution likely require approval. The assumption being that publishing/disseminating the findings generalizes the data.

Moreover, evaluations connected to groups' or individuals' outcomes and affecting the development or implementation of other programs similar in nature, are generalizable human subjects research and require human subjects review.

Furthermore, an evaluation impacting upon the replication of other programs or services and the population at large or public policy, should be reviewed and monitored.

e. *Datasets*

Public and/or published datasets not subject to Human Subjects Review include those that are accessible without restriction (e.g., password not needed*) and containing no readily identifiable, individual information.

Examples include:

- U.S. Bureau of the Census
- National Center for Health Statistic
- National Center for Education Statistics
- National Election Studies
- Public and/or published datasets, accessible without restriction (e.g., password not needed*), and containing readily identifiable information and where individuals can reasonably expect this information to be available to the public (examples include letters to the editor, blogs)

- Public and/or published datasets, with restrictions to access, that contain data that is presented in aggregate form only; thus, individuals cannot be identified.

* or in those cases where you must register with a site or organization to gain access, the registration for login and password must be without qualification – that is, anyone could register with this site.
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6. **What kinds of IRB review are there?**
There are three levels of IRB Review (full board, expedited, and determining if exempt from IRB oversight), determined by the nature of the protocol, level of potential risk to human subjects, and the subject population. The determination of level of review applicable to a particular study is made by the IRB. Regardless of the kind of review, all applications use the same submission form. [Return to Index]

a. **Convened IRB review (full board)**

- Any study involving greater than minimal risk requires a review by the convened IRB. This includes studies with vulnerable populations and sensitive questions as well as studies with the possibility of physical risk.

- Studies with the possibility of physical risk, such as studies involving exercise, should include a medical history and review in order to determine whether or not a person should participate in the study. In some populations, such as the elderly, it is suggested that consent of a primary family doctor be obtained. In all situations where exercise is performed, researchers should be trained in handling emergency situations.

- Studies assigned to full board review are reviewed by members ahead of time, and then discussed at the meeting. The Committee then votes on whether or not to approve the study.

b. **Expedited IRB review**

- Only research involving no more than minimal risk to subjects may be considered for expedited review.

- An expedited review is conducted by an individual reviewer or a few reviewers, rather than going to the full board.

- Federal guidelines provide **categories for expedited review**. Examples of categories include:

  - review of records collected for non-research purposes

  - survey or interview

  - research chart reviews

c. **Exempt**

- Research with very minimal risk to human subjects and that meets one of the categories of exemption as defined by 45 CFR 46 may be exempted from full board review. Although the project does not require full board approval, the IRB chair or designee must certify the exemption before the research study begins. If the risks to human subjects appear questionable or the project does not fit into the federally defined categories for exemption, then the study must undergo either full or expedited review.

- Some research may qualify for an exemption if a limited IRB review is conducted. Limited review is conducted by an IRB member to ensure that appropriate privacy and confidentiality protections are in place.

- An exemption is granted by the IRB upon initial review of the application. Since this constitutes a review, protocols that are deemed exempt are effectively "exempt from continuing review."
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7. **What are some examples of research that might be exempt?**

a. An observational study of the public behavior of persons, as long as you are not video taping or photographing the people you are observing.

b. An anonymous survey or interview (e.g., no names are collected or can be linked to the participants), as long as the survey does not cover sensitive or psychologically distressing topics.

c. Any study using archival documents that are publicly available, such as library archives or legal cases.

d. A study analyzing secondary data sets that do not contain any identifiers. This data may be in the form of reports, computer printouts or other compilation of statistics that will be analyzed for research purposes by a researcher.
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8. **What are some common items that may disqualify research as "Exempt" research?**

a. Use of minors where interaction with researchers is involved (e.g., school settings that go beyond observations or where the researcher has contact with the children);

b. The subject of research relates to sensitive information where the identities of the subjects may be capable of being recognized;

c. Audio taping or videotaping the subjects because then the subjects are not anonymous;

d. Use, in general, of vulnerable populations including minors, pregnant women, prisoners, and cognitively impaired persons. Other groups may be considered vulnerable populations based on the study design.
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9. **How do you define "Psychological Harms"?**
   Participation in research may result in undesired changes in thought processes and emotions (e.g., episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem). These changes may be either transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but researchers should be aware that some research has the potential for causing serious psychological harm.

   Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one's own behavior or attitudes on sensitive topics. These feelings may be aroused when the subject is being interviewed or filling out a questionnaire.

   So, there is potential for risk while completing a questionnaire even before considering the effect after the fact if information became known to parties outside the research team.
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   [*Except from OHRP IRB Guidebook, Chapter III, Basic IRB Review]*

10. **How do I apply?**
    Submit a *Request For Review Of Research Involving Human Subjects*. Instructions accompany the application. Forms are available on the GSRD Forms website. Investigators should always keep a copy of whatever submissions are made to the IRB.
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11. **What are the submission deadlines?**
    Submission deadlines and the meeting schedule are located on the GSRD IRB website.
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12. **What happens after submission?**
    Your study will be assigned an IRB number that should be used on all correspondence relating to the study until the study is closed. The IRB will determine the level of review.

    The IRB will conduct the review and take one of the following actions:

    a. *Approval of research*: Research may proceed upon receipt of written notification of IRB approval.

    b. *Revisions or clarifications required prior to approval*: It is common for the IRB to request some changes to the consent form or protocol prior to approval. These may be minor or substantive in nature. If there are revisions, you will receive a communication from the IRB with details about needed changes. You will generally be asked to "revise and resubmit." If your response is acceptable, your project will be approved and you will receive an approval notification.

       For minor changes, you will be given an expedited review.

       Substantive changes: Sometimes the IRB, in a full board review, determines that substantive changes must be made before approval may be granted. As with minor changes, you will receive a communication from the IRB with details about needed changes. Again, you will generally be asked to "revise

and resubmit." Full board review is required for responses to protocols needing substantive changes.

c. *Disapproval (full board action only)*: If the IRB determines that the research cannot be conducted at Winthrop by employees or agents of the University or otherwise under the auspices of the University, the project, as proposed, is disapproved and may not go forward.

d. *Exemption:* The IRB may determine that your study is exempt from IRB oversight and is not subject to continuing review.
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13. **How long does it take?**
    a. An expedited or exempt review typically takes about 7 business days.

    b. Studies requiring full board review are scheduled for the first available meeting. Submission deadlines and the meeting schedule are located on the GSRD IRB website.

    c. Correspondence from the IRB is sent to the Principal Investigator within one week of full board review.

    d. The Principal Investigator has a significant influence on length of time between submission and approval. Well prepared applications result in fewer requests for stipulated changes or revisions.

    e. Rapid response by the Principal Investigator to requests for changes speeds the approval process.
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14. What happens after I receive approval or exemption notice?
    a. You may begin your research.

    b. Once you begin your research, you have a responsibility to report problems or adverse events that may occur during the research to the IRB. An "Adverse event" or "adverse experience" is an undesirable and unintended, though not necessarily unanticipated, injury or physical or emotional consequence to a human subject.

    c. "Unanticipated Problems" may or may not include specific events experienced by individual subjects, but are developments within the research activity that suggest a potential for increased risks to subjects or others.

    d. Use the form *Adverse Event Report* to report any negative consequences that occur as a result of participation in a research project.
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15. **What if I want to modify/revise the study?**
    a. Once the project is submitted to the IRB, you may not make changes to the study until the IRB has completed the approval process for your original

submission. Once your study is approved/exempted, you may submit modifications.

- Use the form *Request for Modification of Previously Approved or Exempt Protocol* to explain to the IRB how you want to change the protocol, and to request approval of the changes.

- All protocol changes must be approved by the IRB prior to implementation.

- All changes to documents used with subjects (consent forms, questionnaires, recruitment materials such as flyers or brochures, etc.) must be approved by the IRB prior to use.

- The review of the amendment request may be expedited or may require full board review.

- The submission of a revision does not change the expiration date of a project.

- The expiration date is always one year from the time of the initial review or periodic review.

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16. **Where do I send the Request for Modification of Previously Approved or Exempt Protocol form?**
    Instructions for how to submit a modification request are given on the *Request for Modification of Previously Approved or Exempt Protocol* form.
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17. **What if my project continues beyond the original ending date?**
    a. Federal regulations (45 CFR 46.109(e) require IRB committees to conduct continuing review of all research approved via full board review within one year of original approval.

    b. Near the end of the approval period you will receive a reminder notice. If the research is continuing or data analysis is not yet completed, request renewal of approval using the *Request for Modification of Previously Approved or Exempt Protocol* form.

    c. Projects that are more than minimal risk and/or are approved by the full IRB are subject to continuing review through the data analysis phase. At completion of this phase, inform the IRB that your project is completed so the IRB does not continue to inquire about renewal.

    d. Most projects that are no more than minimal risk and/or are approved by an expedited review do not require annual continuing review (renewal.) Such projects will not be assigned an expiration date unless a justification for continuing renewal exists. This will be determined by the IRB. However, the IRB needs to review and approve any modifications in advance.Need to add language for expedited review similar to exempt language below.

e. Projects that the IRB determined to be exempt from further review receive an exemption notice, and no renewal is required. However, the IRB needs to review and approve any modifications to the study in advance.

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18. What happens if I don't apply for IRB approval for my project before doing research?

Engaging in human subject research without IRB approval has serious ethical implications and violates federal policies. Students, faculty, and staff are required to submit IRB applications before embarking on any data collection. Even pilot studies should be approved by the IRB.

Ramifications for Students:

- Credit may be withheld: Winthrop may refuse to grant students course credit for research conducted without IRB approval.
- Thesis work may not be accepted.
- Degrees may not be awarded for work based on non-IRB reviewed projects.
- Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication.
- Funding may be withheld: IRB approval is required if you are a participant in a grant program. These programs will not release funds without IRB approval.

Ramifications for Faculty and Staff

- Funding may be withheld: Federal sponsors, and virtually all private sponsors, require IRB approval as a condition of funding. Sponsors may postpone review of proposals for which review is not complete or pending at the time of proposal submission.
- Many sponsors will not release funds to the University for the investigator's use without IRB approval.
- Articles may not be published: Most professional journals require evidence of IRB approval when considering articles for publication.
- Liability issues arising from unapproved research may become the responsibility of the investigator. Persons conducting unapproved research are deemed to be acting outside the scope of authority granted them by the University.
- Suspension of Research: The University may suspend all research activities for a specified time frame as a disciplinary measure.

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19. **Do I have to get consent from study participants?**

- The standard expectation is that all subjects will sign a document containing all the elements of informed consent.

- The informed consent gives potential subjects a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate.

- The consent form should provide readily understandable information in an amount appropriate to the level of risk in participating.

- A signed informed consent document may be waived under certain circumstances, but volunteers must still give their informed consent to participate in the research.

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20. **Does Winthrop have a consent form template?**
Yes, Winthrop uses a common consent form template which can be viewed on the GSRD IRB website.
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21. What information must be included in a consent form?

a. 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;

b. A description of any reasonably foreseeable risks or discomforts to the subject;

c. A description of any benefits to the subject or to others that may be reasonably expected from the research;

d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained;

f. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the Principal Investigator for that project, whereas questions concerning the rights of human subjects

should be referred to the Executive Director of Grants and Sponsored Research Development.

h. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

i. If the research involves the collection of identifiable private information or identifiable biospecimens, one of the following statements must be included:

- 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.

j. Other requirements may apply.
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22. **How do I obtain consent from Non-English speaking participants?**

a. Researchers should take great care when obtaining informed consent from individuals who do not speak English or whose understanding of the language is limited.

b. Researchers should be fluent in the subject’s language or an interpreter should be available during the consent process and throughout the subject’s participation as needed.

c. Consent forms should be prepared in the language understandable to potential subjects.

d. See Guidelines on International Research and Research with Non-English Speaking Participants on the GSRD IRB website for additional information.
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23. **What are the exceptions to informed consent requirements?**

a. While standard procedure is that the informed consent of research participants should be documented through a written and signed consent form, the requirement for a written, signed consent form may be waived by the IRB if the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

c. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained; or

d. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine (a)public benefit or service programs; (b)procedures for obtaining benefits or services under these programs; (c)possible changes in or alternatives to those programs or procedures; or (d)possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration; or

e. The research involves no more than minimal risk to the subjects, the waiver will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

f. Waiving the requirement for a signed, written consent form does not waive the requirement that subjects be informed of the nature of the research, and that their consent (or permission of their legal representatives, when appropriate) be obtained. In cases where a written consent is not used, the researcher should provide the subject with a statement or cover letter of the research that includes all relevant elements of informed consent.
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24. What is assent?

a. Assent is basically the same as consent yet involves minor children (under age 18) who are not authorized to give legally valid informed consent because of their age.

b. Assent is written in child friendly language and describes the research participation, risks, benefits, and other elements of consent.

c. Assent does not waive the requirement for informed consent to be obtained from a parent or legal guardian.
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25. **What is the CITI Human Subjects Protection Training?**
The Collaborative IRB Training Initiative (CITI) is a web-based training package on issues relating to human subjects research. The CITI web site is maintained by the University of Miami, with content developed by a national consortium. CITI contains modules on topics like informed consent, vulnerable populations, ethical principles, and IRB regulations. Each module has a short quiz at the end to assess understanding. Over 400 institutions are using CITI for their mandatory training.
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26. **Who is required to complete the CITI modules, and when?**
Human Subjects Protection Training is mandatory for all faculty, staff, and students who are engaged in the planning, conduct, or analysis of research at Winthrop University that involves human subjects.

Effective May 1, 2007 completion of the CITI Basic Course is required of all study personnel, including faculty advisors for students engaged in human subject research.
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27. **How do I complete the CITI training?**
To complete the CITI training, log on to the CITI website and register for training as follows:

    a. Log on to the CITI website: **http://www.citiprogram.org**

    b. Click on "New User Register Here"

    c. Click on "The Protection of Human Research Subjects"

    d. On the "Select you Institution or Organization" page, scroll down the Participating Institutions" drop down box and select "Winthrop University".

    e. At this point you will be asked to create your own username and password. Make a note of your selection as you will need this information the next time you log in to the system.

    f. Select your learner group based upon the type of research you will be conducting: *[See FAQ #28: Which CITI modules should I complete?]*
        - Biomedical Research Investigator
        - Social & Behavioral Research Investigator
        - IRB Member

    g. This completes the registration process and you are now ready to start the training. Each training module has reading material followed by a short quiz. The average time required to complete the training is approximately 2 to 3 hours. A successful score is 80% correct answers. You may retake the quiz until you have achieved a successful score.
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28. **Which CITI module should I complete?**
The modules are grouped by categories of research. You only need to complete one group of modules. You should choose the group that best fits the type of research you normally conduct.

    a. **Group 1: Biomedical Research:** Medical, physiological or pharmacological studies that typically involve direct contact with subjects. Includes, but is not limited to, research with drugs, devices or other interventions.

    b. **Group 2: Social and Behavioral Research:** Studies on sociological, psychological, anthropological or educational phenomena that typically involve direct contact with subjects. Does not include drug or device studies.

    c. **Group 3: IRB Member:** This group of modules is required for all members of the Winthrop Institutional Review Board and is a combination of Biomedical Research and Social & Behavioral Research modules.
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29. **Why am I required to take the CITI training?**
Human subject research presents many challenges. As with any complex and evolving

area, continuing education is critical. Inadequate training in these issues is recognized as one reason that some researchers and their institutions have experienced problems. Winthrop is committed to upholding the highest standards of ethical conduct and regulatory compliance in research. The enhanced training available through CITI will increase the level of awareness and understanding about research issues, and help us fulfill these important obligations.
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30. **How much time will it take to complete the CITI training?**
This will depend on your experience with human research issues. Most modules will take about 10-20 minutes to complete. Researchers familiar with these topics may require three hours or less to complete all of the required modules. If you are not already familiar with research topics, it may take approximately 4 to 6 hours to complete. You do not have to complete all the modules at once. CITI is designed for you to work at your own pace, and allows you to exit and return at a later date to complete all the required modules in your chosen learner group.
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31. **What is a passing score on the CITI training quizzes?**
You must receive a total passing score of 80% after completing all the required modules. You can track your progress on-line by selecting the link to GRADE BOOK. If you do not obtain a total passing score of at least 80%, you can return to the modules and retake the quizzes.
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32. **How will the IRB know training is complete?**
The Executive Director for Grants and Sponsored Research Development (GSRD) at Winthrop serves as the University's administrative representative for CITI training program. CITI notifies GSRD each time an individual affiliated with Winthrop University successfully completes the training, and which Learner Group the individual completed. GSRD reviews all Request for Review of Research Involving Human Subjects forms prior to their being giving to the IRB for review, and will certify to the IRB that training has been completed.

    In addition, you are required to indicate on the Request for Review of Research Involving Human Subjects form the CITI training you completed and the date of completion. If you indicate that you have completed the training, but CITI has not notified GSRD of this completion, then an inquiry will be made for clarification. The possibility exists that your training certificate may have been affiliated with a different university.
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33. **Is there a fee for taking CITI training?**
Winthrop University pays an annual fee for all Winthrop users. Individual Winthrop users are not assessed a fee for the CITI training.
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34. **Do I have to renew my training?**
Certification is valid for four years from the date of the successful completion of the training program unless otherwise noted.
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35. **What if I have additional questions?**

    - The GSRD IRB web site is a good source of additional information, providing links to many ethics, research, and regulatory sites.

- The Code of Federal Regulations: Protection of Human Subjects **45CFR46** is the basis for the IRB policies and guidelines.

- We are happy to respond to your questions. Feel free to call or email us. Contact information is located on the GSRD website.
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