**Oakland University IRB**

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**What is an IRB?**

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human subjects recruited to participate in a research study.

The role of the IRB is to ensure the protection of human participants in a research study. Any institution that receives federal funding to conduct research with human participants is required to establish an IRB and to review and approve studies prior to enrollment of participants or collection of research data.

The Oakland University IRB operates under a Federalwide Assurance (FWA00003480) through the U.S. Department of Health and Human Services, Office for Human Research Protections (OHRP).

**How do I know if I am conducting research with human participants?**

Although the question may seem straightforward, not all interactions with human beings or data collected from humans are considered research under IRB rules. If your project is not considered research, you do not need to submit an application to the IRB office. If your project is considered research under IRB rules, you must submit an application to the IRB office and receive approval before research can begin.

* + Research under IRB regulations (as specified under the ‘Common Rule’ issued by the Office of Human Research Protections, U.S. Dept. of Health and Human Services) and Oakland University policy is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  + 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.

* + Generalizable knowledge refers to information that expands the knowledge base of a scientific discipline or other scholarly field of study and can be expressed in theories, principles, or statements of relationships that can be generally applied to our experiences. Activities designed to contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. The information is collected to share with others in a discipline and is created to make a broad statement (conclusion) about a group of people, procedures, programs, etc.
  + An intervention can include physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment for research purposes (e.g., having students listen to certain kind of music while completing a task).
  + Interaction includes communication or interpersonal contact between the researcher and subject. Online surveys that ask personal or private questions about the participants are interactions.
  + 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 must be individually identifiable (i.e., the identity of a participant is associated with the information or may readily be ascertained by the investigator) in order for obtaining the information to constitute research involving human subjects.

**When am I required to submit an IRB application to the IRB office?**

If your project is considered human subject research under IRB rules, you must submit an application to the IRB office and receive approval before research can begin. Applications must be submitted to the IRB office for review and approval before enrollment of participants or data collection begins. This includes proposed research involving existing secondary data and previously collected human fluid and tissue samples.

If your project has been approved by the IRB and you would like to introduce modifications to the approved research, amendment application(s) must be submitted to be reviewed and approved by the IRB before the change is implemented.

If you are not conducting human subject research, but you need a “Not Human Subject Research” determination letter from the IRB, a Not Human Subject Research Determination Form must be submitted.

IRB applications are submitted through an online system available through the IRB webpage.

**I am just doing a simple survey; do I need to submit my proposal to the IRB?**

Yes, if the study meets the definition for research with human participants, as explained above. Oakland University's Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services states that all research being conducted under the auspices of this institution is subject to review and approval by the IRB. Written approval from the IRB must be in place before any interventions or interactions with human participants (e.g., recruitment) actually begin.

**I am not collecting any identifying information in my human participant research project. Do I need to submit my proposal to the IRB for review?**

Yes, if your research project involves active data collection, IRB regulations require that ALL research involving intervention or interaction with human participants, regardless of whether or not identifying information is being collected, must be submitted for review prior to beginning the study. If your research involves the use of existing data collected from human participants (e.g., secondary datasets, existing biological samples), but there are no identifiers linking human participants to the data/samples themselves, then the activity may not require IRB review and may be considered "not human subject research". Please see OHRP's [Decision Chart at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html](https://www.irb.cornell.edu/documents/IRB%20Decision%20Tree.pdf) or contact the IRB staff for further guidance.

**I am planning to do an oral history project; do I need to submit my proposal to the IRB?**

Research that involves the collection and use of oral histories or life histories to draw generalizable conclusions that can be applied to other populations at other locations may meet the federal definition of "human subjects research" and require an application to the IRB office. However, not all oral history projects fit this description, and thus would not need IRB review.

**I am developing case studies; do I need to submit my proposal to the IRB?**

In general, a case study with three or less participants that does not draw generalizable conclusions does not need IRB review.

Projects that use multiple case studies to draw conclusions that are applicable in a generalizable context, or to address a hypothesis, may meet the federal definition of "human subjects research" and require review by the IRB office. Other projects involving case studies may not require IRB review.

**Does journalism require IRB review?**

The reporting of current events, trends, newsworthy issues or stories about people or events generally does not meet the federal definition of "human subjects research" and therefore requires no application to the IRB office. However, reporting intended to draw generalizable conclusions that can be applied to other populations at other locations may require review by the IRB.

**Do research projects conducted by Oakland University students need IRB approval?**

Yes, studies conducted by Oakland University undergraduate and graduate students need IRB approval, if the project fits the definitions of "research" and "human participants" as described above.

If the project is to be used in a classroom setting only to teach research methods, the project may *not* constitute human participant research. However, this means that at no point during or after the conclusion of the course can the results or the data be used for research purposes. Therefore, students should discuss these limitations with their instructor or faculty advisor so that they can determine whether IRB review is necessary.

**What does "exempt" mean? Does this mean I don't have to submit an application for review?**

Studies that are defined as research with human participants may fall under certain "exempt" (as opposed to "expedited" or "full board") review categories as specified by IRB regulations (the 'Common Rule' issued by the Office of Human Research Protections, U.S. Dept. of Health and Human Services).

In order for a research study to be deemed "exempt", investigators will need to submit an application to the IRB office, along with study related materials (e.g., consent forms, surveys, questionnaires, interview scripts/outlines, recruitment materials etc.). Please note that this determination of exemption must be made by IRB staff. The letter issued by IRB staff is an exemption letter, not an approval letter.

**I will be collaborating with another institution. Do I need to submit to Oakland University's IRB and the other institution?**

If you are an Oakland University faculty, staff member or student, and you are the person responsible for the conduct of the study (principal investigator), you must receive Oakland University IRB approval to conduct your research regardless of where the research takes place.

Investigators should contact the IRB office whenever collaborative research is occurring. Based on the type of collaboration and the location of the research, review by an IRB from one of the collaborating institutions should be sufficient. However, an IRB Reliance Agreement may be arranged between the institutions to establish one IRB of record as the designated IRB to review and approve the research. The use of an IRB reliance agreement is applicable when the collaborating institutions have Federalwide Assurance with the Office of Human Research Protection.

**My research will be done in another country. Do I have to obtain IRB review and approval from Oakland University?**

Yes, if you are an Oakland University faculty, staff member or student, and you are the person responsible for the conduct of the study (principal investigator), you must receive Oakland University IRB approval to conduct your research regardless of where the research takes place. You should also be aware that your project may need local IRB approval (or the equivalent ethical review) in addition to Oakland University's review. Investigators should contact the IRB office to help figure out if the international site has a Federalwide Assurance with the Office of Human Research Protection and the use of an IRB Reliance Agreement is applicable.

**My research will be done in Europe or using participants who reside in Europe or are present in European countries at the time of the research. Are there any additional regulations I should know about?**

Yes, most European countries follow the General Data Protection Regulation (GDPR). This is an important regulation about personal data privacy and has additional requirements regarding obtaining informed consent from participants. If your project involves collecting data from individuals who reside or are present in European countries at the time of research, refer to the OU IRB webpage for more information about the GDPR and contact an IRB staff to help you navigate the requirements.

Considering the seriousness of penalty for noncompliance with this law (fine up to 4% of annual revenue or €20 Million for insufficient consent to process data), the consent form may need to be reviewed by OU legal to ensure compliance with GDPR.

**I want to conduct a study that involves the use of deception or incomplete disclosure of the real purpose of the research. Is this allowed? What do I need to consider?**

The use of deception or incomplete disclosure in research is allowable by the federal regulations and Oakland University as long as the research involves no more than minimal risk to participants. However, because at some level the use of deception in research violates the trust that the participant puts in the researcher, this method should be considered carefully. Deliberate deception of participants may occur only in situations where withholding information about the nature of the study is necessary to ensure valid results, and never to get participants to do something that they would not do if the information was fully disclosed to them.

When using deception or incomplete disclosure, researchers need to describe for the IRB the method, rationale and the process of informing participants of the true or complete purpose of the research. Participants should be informed of the true and complete purpose of the study as early as is feasible - preferably at the conclusion of an individual's participation but no later than at the conclusion of data collection - through a "debriefing" process to permit participants to withdraw their data, if they choose to do so. Additionally, researchers should provide a justification for the deception techniques and document that there are no equally effective non-deceptive techniques available.

**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. An approval letter will be sent to you via the online system when your project has IRB approval.

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

That depends on the nature of your study and the characteristics of the people you intend to recruit.

Research projects may be eligible for an exemption. Exemptions take about 1 week for IRB review. Well written projects may be exempted sooner.

Research projects that involve only minimal risks may be eligible for expedited review. This takes about 4 weeks for IRB review.

Projects that involve greater than minimal risk to participants will need to go to the convened full board committee for review. IRB Meetings are generally scheduled for the last Thursday of every month. Applications should be submitted at least two to three weeks prior to the meeting dates to be reviewed by primary and secondary reviewers before it is shared with the full board. For applications requiring full board review, you should allow at least 4-6 weeks for review and approval of your study.

**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. Data collected without IRB approval cannot be used in publications. If data were 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.

Data related to human subject research that were collected without IRB approval cannot be used in publications.

**The Application Process:**

**I don't know where to start to write an application. What needs to be included?**

Currently, the OU IRB uses IRBNet to manage protocol submissions. [www.irbnet.org](http://www.irbnet.org).

New researchers must create a username and password for access to this site.

Applications and templates are available on this website under the Forms and Templates tab on the left side of the screen. Every new protocol submitted to the IRB must include completed and signed applications and all associated materials. See the first page of the Exempt Application and the first page of the Expedited/Full Board Application for complete submission instructions.

**IRBNet has a numbering system. How does it work? Is there a difference between a Project and a Package in IRBNet?**

Once you register with IRBNet and affiliate with Oakland University, then you can “Create a New Project” by clicking the tab on the left side of the screen. You will be assigned an IRBNet seven digit number with a hyphen for your project such as 1415985-1. The 1415985 is your Project Number. The -1 is your Package number. IRB Staff uses these numbers for organizational purposes.

After your project is approved or exempted, you may want to make changes by filing an amendment. DO NOT “Create a New Project”. Instead, find your approved project number under “My Projects”. Open your project. Then click “Create a New Package” from the left side of the screen. This will show up with the same seven digit IRBNet number, but have a different number after the hyphen, such as 1415985-2. This is the same project, but a new package.

**How do I know if my project is Exempt, Expedited or Full Board?**

An easy way to start is to download the Exempt Application from the Forms and Templates library in irbnet.org. Page 3 of the Exempt Application contains a set of screening questions to assist you in determining which application you should fill out. If you need further assistance, consult with your faculty advisor or contact the IRB staff for additional help.

**Are there "sample" protocol submissions available for research projects in specific disciplines?**

Unfortunately, not at this time. The IRB staff is available to answer questions about the IRB review process and to assist investigators. Researchers can also consult with an IRB member from their unit. A list of IRB members is available on the IRB webpage.

**What does the IRB look for in an application? Are there standard criteria for evaluation?**

The IRB evaluates every research protocol according to the ethical principles described in the [Belmont Report](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html), which are based on the following three principles: 1. Respect for the person; 2. Beneficence; and 3. Justice. Basically, this means the IRB considers whether individuals being asked to participate are adequately informed about the research and its possible risks/benefits, evaluate the risks and benefits of a study to make sure they are acceptable and managed appropriately, and ensure that the burden of the research is not unfairly imposed on the targeted participants population.

Considered another way, investigators could look at their 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.

**The Consenting Process:**

**What does "informed consent" mean? What are its essential components?**

Fully informing participants of the risks, benefits, and procedures involved in a study is a standard requirement in research with human participants. Ethically and legally, consent is not considered to be "informed" unless the investigator discloses all the facts, risks, and discomforts that might be expected to influence an individual's decision to willingly participate in a research protocol. This applies to ALL types of research including surveys, interviews, and observations in which participants are identified, and other experiments, such as diet, drug and exercise studies.

Oakland University has sample templates available that contain all the required consent elements, available on the IRBNet.org website under the Forms and Templates tab on the left side of the screen.

Researchers are reminded that consent is an ongoing process and doesn’t stop when the document is signed. Researchers should be available to answer questions from participants after the research has begun.

**Are there different types of informed consent? What are they?**

The informed consent process can take various forms:

* + **Signed informed consent** is the standard expectation in research with human participants. This is in the form of a document with the elements of informed consent, signed and dated by the participant and kept as a record by the researcher. The participant will also receive a copy of this document.
  + In research with children (individuals under 18 years old), **assent** of the child and **parental permission** are standard requirements.
  + In exempt research, the researcher can issue an **Information Sheet** and not collect a signature. Since the project is exempt from the regulations, a signature is not required. This is NOT a waiver of consent.
  + For minimal risk projects (exempt and expedited projects) that occur online, consent may be obtained from the participant by a click of an “I agree to participate” button in the online survey. In this case, the researcher should ensure that the participant can print the consent if desired. Clicking on the “I agree to participate” is considered an active consent for minimal risk projects and a signature is not collected. This is NOT a waiver of consent.
  + In some circumstances, investigators can seek alternatives to standard informed consent procedures, such as:
    - A waiver of obtaining consent (e.g., conducting the research without obtaining participants’ consent). This process is allowable under certain regulatory criteria which are explained under a later question entitled “What is a waiver of informed consent?”
    - A waiver of collecting a signed consent form (e.g., giving participants an information sheet but not collecting signatures). This process is called a “Waiver of Documentation of Consent” and allowable under certain regulatory criteria (see a later question entitled “What is a waiver of documentation of consent?”)
    - A waiver of written consent (e.g., using oral consent procedures). This process may include the use of a short form and a witness. Contact the IRB staff for additional information
    - A waiver of some or all of the elements of informed consent (e.g., in research that involves deception)

**How do I write a consent document?**

Template Information Sheets, Consent Forms, Child Assent Forms and Parental Permission forms are all available in IRBNet.org under the left side tab labeled Forms and Templates. Directions for completion of these forms are embedded within the documents.

**What do the terms "consent" and "assent" mean? Aren't they the same thing?**

Both consent and assent involve informing potential participants about the research and its risks and benefits, and documenting their understanding and agreement to participate.

The reason the different terms are used has to do with the age of the participants.

In research involving adults, **"consent"** is obtained from individuals to participate in the study.

In research involving minors (under 18 years old), a parent must give “**permission”** to allow the child to participate in the research, and children who are able to understand information about participation are asked to **"assent"** or agree to participate as well.

**Can a researcher waive child assent or waive parental permission?**

In some cases, child assent can be waived if the child is too young or unable to provide assent. In any case, parental permission is required.

Even though federal regulations allow for the waiver of parental permission under certain criteria, Oakland University requires the use of parental permission. Any researcher who would like to waive parental permission must contact OU Office of Legal Affairs for permission and contact the IRB staff for additional guidance.

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

In general, researchers should obtain informed consent from their research participants. The Oakland University 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.. Waiver of consent is allowable for no more than minimal risk research under specific regulatory conditions. A request for waiver of informed consent must be specifically justified by the researcher in the proposal to the IRB.

**What is signed informed consent?**

Used most commonly, signed informed consent allows prospective participants to document their agreement to take part in research activities by signing and dating the consent document.

**What is a "waiver" or “alteration” of informed consent?**

A waiver of informed consent is a request whereby the research is conducted without obtaining participants’ consent. For example, conducting research with hundreds of thousands of existing personal records may be undoable without a waiver of consent.

Alteration of consent is a request whereby the researchers alter some or all of the required elements of the informed consent form. For example, in research with deception, the real purpose of the research is not fully disclosed to participants. Disclosing the true purpose of the research may alter the scientific validity of the results.

Researchers requesting waiver or alteration of consent need to complete the applicable appendix and submit it along with the IRB application in the online system.

The IRB may approve waiving consent or altering some or all of the required elements of informed consent provided all of the following are true:

* + The research presents no more than minimal risk to the subjects;
  + The research could not practicably be carried out with the requests waiver or alteration;
  + If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
  + The waiver or alteration will no adversely affect the rights and welfare of the subjects; AND
  + Whenever appropriate, the subject or legally authorized representatives will be provided with additional pertinent information after participation.

Note: The IRB will take into consideration the risks and potential harms involved in the research and consent process before granting a waiver of documentation of informed consent. In the case of international research, there may be unique cultural or social circumstances that factor into the review process.

**What is a "waiver of documentation" of informed consent? And how does it differ from a “waiver or alteration” of informed consent?**

"Waiver of documentation of consent" means a participant may consent by oral or implied consent without having to sign a consent form, versus a "waiver of informed consent", which could: (1) alter some or all of the required elements of informed consent, or (2) completely waive the requirement to obtain informed consent (with or without a signature). Examples of types of studies in which some or all elements of consent have been waived include retrospective chart reviews, studies of existing pathology specimens, and studies that require deception or passive (opt-out) consent.

Note: The IRB will take into consideration the risks and potential harms involved in the research before granting a waiver of informed consent. Additionally, there are restrictions for when the IRB may waive the requirements for child assent and parental permission. Please contact the OU IRB staff if you are considering waiving parental permission.

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

Yes. If the researcher has access to identifiable private information, Oakland University IRB requires informing participants about the research either through an informed consent form or an information sheet (when applicable). If the proposed study is truly "anonymous" - no collection or use of any identifiers (e.g., names, addresses, phone numbers, signatures, social security numbers, driver’s license numbers, etc.) - a modified informed consent form (often called an information sheet) may be used. 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.

**How is the consent process handled for internet-based research?**

For minimal risk projects that occur online, consent may be obtained from the participant by a click of an “I agree to participate” button in the online survey. In this case, the researcher should ensure that the participant can print the consent if desired. Clicking on the “I agree to participate” is considered an active consent for minimal risk projects and a signature is not collected. This is NOT a waiver of consent.

If 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. Participants 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).

**What are the consent requirements for phone-based research?**

For research projects involving oral consent, the following information is required to be communicated to the participants:

* + 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 possible to email your participant the consent form prior to the phone interview. In this way, the participant has time to read the document and ask questions.

**Are there any sample consent forms or consent form templates available for review and use?**

Consent templates are available on the irbnet.org website under the Forms and Templates tab on the left side of the screen.

**Training Related Topics:**

**What are the IRB requirements for training?**

At Oakland University, all investigators and research staff much 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.

Additionally, investigators and research staff must be qualified by training and experience for the research they will be conducting. It is important to understand that the responsibility for the welfare of participants lies with the principal investigator, even when participants have given consent. Investigators and research staff must have the necessary training and expertise to:

* + Ensure the rights, welfare and safety of participants are protected
  + Comply with regulations concerning IRB review and approval, including
    - Informed consent requirements
    - Reporting requirements
    - Maintenance and retention of records (keep signed consent forms for 3 years after research ends)
  + Supervise research conduct
  + Apply relevant professional standards that are applicable to the research

**Who is required to complete the IRB human participants training?**

All faculty (serving as researchers or as faculty sponsor/advisor), students, staff and key personnel proposing to use human participants in research under the auspices of Oakland University are required to complete the IRB 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 IRB staff.

Any OU researcher or key personnel must take the Oakland University CITI training course in Human Subject Research. There are two courses: One for Faculty and the other for Students and Faculty Advisors. The OU IRB may accept alternate training that is equivalent to the CITI training, especially if the researcher is from another institution. This alternative training document must contain information related to the training course/s, the institution offering the training, the date of completion and the score received. Such documentation should accompany the proposal submission.

**How can I take the required CITI training?**

You can access the CITI website at www.citiprogram.org. New users must register on the website and affiliate with Oakland University. Researchers need to complete the basic course along with any additional modules that are applicable to the research project. Additional instructions regarding CITI training are available on pages 1 and 2 of the Exempt and Expedited/Full Board Applications.

Please note that the CITI website is used by many other departments at Oakland University. Read the instructions on the front of the IRB applications and on the CITI website carefully to avoid taking extra or duplicate courses.

**Does the IRB Office provide any other training for investigators about the IRB?**

Yes. The OU IRB staff members strive to provide information and assistance to investigators and research staff in several ways. The IRB may hold formal seminars to help educate the research community about different IRB and human research topics. Arrangements can also be made to have IRB staff present informational sessions for small groups, which can be tailored for the needs of a specific group (e.g., classrooms, departmental meetings, etc.).

**Lifecycle of the Protocol:**

**When should an amendment to approved research be submitted?**

Any and all changes to approved research must be submitted for review and approval prior to implementing the change(s) into the research. IRBNet.org contains three Amendment Forms to complete and file for review, as applicable. These forms are located in the Forms and Templates tab on the left side of the screen in IRBnet.org. Additional instructions are provided on the first pages of the Amendment Forms

After completion of this form(s), click on Create a New Package to file this form in irbnet.org under your currently approved project. Add any additional documents only if you have changes in them.

**Do I need to obtain continued approval (renewal) for my research study?**

It is the responsibility of the principal investigator to ensure timely continued approval of his or her human participant research study, when required\*. As a courtesy, several weeks in advance of the approval expiration date, the IRB office will send an email to the principal investigator and the faculty advisor (when applicable), alerting them to the impending approval expiration. If no continuation form is submitted in advance of the expiration date, a notice indicating the approval for the study has expired will be sent to those same individuals. **If IRB approval expires, all research on the study must cease until continuing approval is granted. NOTE: Data collected for research purposes without IRB approval cannot be used in publication.**

\*For all more-than-minimal risk studies (i.e., full board), progress of approved research must be reported in the manner prescribed by the IRB no less than once per year. The expiration date is printed on IRB approval letters.

Expedited studies do not necessarily require continuing review and approval, unless the IRB determines otherwise on a case-by-case basis. (Note: The requirement for continuing review of Expedited studies was removed in the [Revised Common Rule](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html), with this specific burden-reducing provision effective on January 19, 2019).

Exempt Studies do not have an expiration date and continuing review is not required.

**Unanticipated Problems/Adverse Events:**

**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, with a written report by the principal investigator (PI) 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 5 days of the first awareness of the problem by the PI or another researcher, or a member of the IRB. Prompt reporting is important, as unanticipated problems may require some modification of study procedures, protocols, and/or informed consent processes. Such modifications require the review and approval of the IRB.

The Event Reporting Form is located in the Forms and Template tab on the left side of the screen in irbnet.org.

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

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.

The regulations require the IRB to investigate and report substantiated unanticipated problems and noncompliance determinations to the Institutional Official. If the human subjects research project is federally funded, the Institutional Official must report unanticipated problems, serious and/or continuing noncompliance, and suspensions and terminations to federal sponsors and/or agencies.

**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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