SWEDISH INSTITUTIONAL REVIEW OFFICE – FREQUENTLY ASKED QUESTIONS

What is an IRB?

IRB is the acronym for Institutional Review Board, a committee that has the responsibility to review, approve, disapprove or require changes in research or related activities involving human participants. The IRB’s primary role is to ensure the protection of human participants as subjects of research. Any institution that receives federal funding to conduct research with human participants, such as Swedish, is required to establish an IRB (or establish a relationship with an external IRB) to review all research that directly or indirectly involves human participants, and to set forth institutional policy governing such research. Research reviewed by the IRB may also be subject to other reviews by committees or officials at Swedish, but those officials may not approve research that has not been approved by the IRB.

How do I know if I am conducting research?

Research is defined in the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

In order to determine whether a project meets the definition of research (as opposed to quality improvement or similar projects), the IRB has been designated by Swedish as the entity to determine whether research is being conducted. Please submit a written protocol or abstract to ReviewBoard@swedish.org and IRB staff will work with you to determine whether IRB review is required. This includes projects involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

All submissions determined to be research involving human participants must be submitted for approval before beginning the study.

My research won’t be performed at Swedish, I just want to recruit Swedish study subjects. What do I need to do?

Advertisements used to recruit study subjects, i.e. public service announcements, radio, television, internet or newspaper advertisements, and posters/fliers/brochures are seen as an extension of the informed consent and subject selection process. The IRB must review the methods used to recruit subjects for a study to ensure that the information is not misleading or coercive. Recruitment materials may not be used until the investigator receives written approval from the IRB.

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

Yes, if the study meets the definition of research with human subjects (data and/or specimens) as explained above. Swedish has a Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services which 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 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, all research involving human participants, regardless of whether or not identifying information is being collected, must be submitted for assessment prior to beginning the research study. At that time the IRB office can determine the level of review required or whether the study may qualify as exempt from IRB review. If your research project involves use of existing information collected from human participants (e.g., secondary datasets, existing biological samples), but there are no identifiers linking individuals to the data/samples, then the activity may not require IRB review.
What is meant by an "exempt" protocol?
Under certain circumstances, human participant research activities may be granted exempt status. Technically, exemption means that all the research activities fall under one or more of the exemption categories specified by the federal regulations at 45 CFR 46.101(b)(1-6). In order to have a research project recognized as exempt, investigators will need to submit the research for an initial assessment by the IRB.

The significance of exempt status is that the activity, while research, is not monitored by the IRB. Assuming the project does not change, it also is not subject to continuing IRB oversight. Exempt status does not, however, lessen the ethical obligations to subjects and investigators conducting exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints. Swedish policy does not allow investigators to self-exempt their human participant research projects. Instead, determining if a project is exempt from IRB review is an administrative review process delegated to IRB staff.

I will be collaborating with another institution. What do I need to do for IRB oversight?
Investigators should contact the Research Center and IRB office whenever collaborative research may occur. Separate applications for each institution may be necessary, or an IRB Authorization Agreement may be arranged with the other institution to establish one IRB as the designated IRB.

I am developing a case study; do I need to submit my proposal to the IRB?
Yes, you should obtain an assessment from the IRB office to confirm whether your project is a case study or research. Some case studies may draw conclusions applicable in a generalizable context, or to address a hypothesis, and these can meet the federal definition of human subject research and require review by the IRB office. Other case studies may not require IRB review.

When may I begin my study?
You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis.

Will I have to attend the IRB meeting for my new study submission?
Yes, the principal investigator of a new study that requires full IRB review will be asked to present his/her study to the IRB at a convened meeting (or by phone) and answer any questions. The Institutional Review Office will send an invitation to the principal investigator via Click (the IRB electronic submission application) to inform the investigator of the meeting date, time and location. If the principal investigator is not available, a sub-investigator may present the study. Study staff, such as research coordinators or research managers, may attend but are limited to two staff members. If the principal investigator or sub-investigator is not able to attend, review of the study will be rescheduled.

Will I be charged for IRB review?
Generally speaking, internal research is charged an IRB review fee if the study is funded by a federal grant with no indirect fee paid to Swedish, or if the study is funded by an industry-supported grant or contract. External Research is charged an IRB review fee if the researcher or Swedish is not primarily awarded a grant and/or staff support through the Swedish Research Center.
I already completed conflict of interest reporting to the institution. Do I need to report this to the IRB?
All investigators and study staff need to complete and submit a Conflict of Interest Disclosure Statement annually for existing studies and upon submission of each new study. The IRB evaluates Conflict of Interest disclosures in relation to individual research studies, separate from institutional reporting.

How long will it take for me to obtain approval to do my study?
That depends on the nature of your study and the amount of preparation required to prepare it for IRB review. Research projects that involve only minimal risk are eligible for expedited review, while research that involves greater than minimal risk will need to go to the full Board for review and will be scheduled according to availability. The Swedish IRB currently meets once a month. For applications requiring full board review, you should allow 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. If data was collected for purposes that the IRB determines to be non-research (e.g. quality improvement), the IRB can provide documentation of this determination.

What does "informed consent" mean?
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.

Are there different types of informed consent? What are they?
The informed consent process can take on various forms:

- Written and 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 described in the federal regulations, signed and dated by the participant and kept as a record by the researcher.
- In research with children (individuals under 18 years old), assent of the child and parental permission are standard requirements.

In some circumstances, investigators can seek alternatives to standard informed consent procedures, including:

- A consent procedure which does not include or which alters some of all of the elements of informed consent.
- A waiver of consent (e.g. consent is not required).
- A waiver of documented consent (e.g., giving participants an information sheet but not collecting signatures, or verbal consent).
- ‘Short form’ consent (e.g. oral interpretation of the IRB-approved English consent document, in conjunction with a written “short form” consent document stating that the elements of consent have been presented verbally to the participant, as well as a written summary of what is presented verbally). This is limited to 2 occurrences and then full translation is required.

It is not uncommon for a research project to involve one or more of the above scenarios. For more information, please refer to HRP-090-SOP-Informed Consent Process for Research, located in the Click Library in the ‘Standard Operating Procedures’ tab.
Do I always have to obtain the informed consent of research participants?
In general, yes, but there are some limited exceptions. 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.

What is a waiver of informed consent?
A waiver of informed consent waives the requirement to obtain informed consent, provided all of the following are true:
- The research involves no more than minimal risk;
- The waiver will not adversely affect the rights and welfare of the subjects;
- It is not practicable to conduct the research without the waiver or alteration; and
- Whenever appropriate, participants will be provided with additional pertinent information after their participation.

Examples of types of studies in which some or all elements of consent have been waived include retrospective chart reviews or studies of existing pathology specimens. Note that there are restrictions for when the IRB may waive the requirements for child assent and parental permission.

What is a waiver of documentation of informed consent?
A waiver of documented informed consent is a request whereby a signed consent document is not required. Examples include verbal consent and/or use of an information sheet in lieu of a signed consent form. Consent will still be obtained from participants; however, they will not be required to sign a consent form. There are two circumstances in which the IRB may waive the requirement to obtain a signed consent form:
- The only record linking the research participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or
- The research presents no more than minimal risk of harm to participants and involves no procedure for which written consent is normally required outside of the research context.

The IRB will take into consideration the risks and potential harms involved in the research and consent process before granting a waiver of documented informed consent.

What is the difference between "consent" and "assent"?
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, children who are able to understand information about participation are asked to "assent" or agree to participate (a parent must also give permission to allow the child to participate).

I'd like to offer participation in my study to non-English speakers. What is required?
Information given to a potential research participant must be presented in a language understandable to the participant.
- If non-English patients will be candidates for participation in a research study, whenever possible, he/she must be given a certified written translation of the IRB-approved English version of the consent document. The translated consent document and the translation certification form must be submitted for IRB approval prior to use.
Alternatively, an oral interpretation of the IRB-approved English version of the consent, in conjunction with a written “short form” consent (which states that the elements of consent have been presented orally to the participant), and a written summary of what is presented orally, may be used. A witness to the oral interpretation is required. This is limited to 2 occurrences and then full translation is required.

Are there any protocol or consent form templates available for review?
Yes, these can be found in the Click Library in the ‘Templates’ tab and are also available from the Institutional Review Office at ReviewBoard@swedish.org.

What are the IRB requirements for training?
All investigators and research staff are required to successfully complete two CITI Program courses for the protection of human subjects: the Biomedical Research Investigators and Key Personnel basic course and the required Conflict of Interest modules. Researchers conducting socio-behavioral research may substitute the Social & Behavioral Research module for the Biomedical module, although the Conflict of Interest modules are still required.

When these modules are completed, if you have listed Swedish Medical Center as your affiliated institution, your completion information will be automatically forwarded to Click. If you’ve already completed HSP training through a source other than CITI, a copy of that course documentation is required.

When should a modification or amendment to an approved research study be submitted?
Any and all changes to an approved research study must be submitted as a modification for review and approval prior to implementing the change(s) into the research study. This includes changes to the protocol, study design, informed consent, or study team. Depending on the potential risks of the modification, it will be assigned to either expedited or full committee review.

Does approval of an amendment to an approved research study extend the original expiration date?
No. The expiration date of the original approval is not changed by the review and approval of an amendment.

How do I obtain continued approval (renewal) for my research study?
It is the responsibility of the principal investigator (PI) to ensure continued approval of his or her human participant research study by submitting an application for continuing review prior to expiration of approval. As a courtesy, the IRB office will send automatic reminders to the principal investigator and primary study contact via Click, alerting them to the impending approval expiration.

How do I report a protocol deviation or an unanticipated problem/adverse event?
Adverse events, protocol deviations or research non-compliance must be reported to the IRB via a Reportable New Information submission in Click. Prompt reporting is important, as unanticipated problems often require some modification of study procedures, protocols, and/or informed consent processes that will require IRB review and approval. These events must be reported to the IRB within 10 working days of knowledge of the event.

How do I know if an adverse event is reportable?
Federal regulations make the distinction between ‘adverse event’, a broad term used for any untoward or unfavorable medical occurrence in a human subject that is temporally associated with the subject’s participation in the research, and ‘unanticipated problems’, which are more specific. Unanticipated problems are a type of adverse event that must meet all of the additional following criteria in order to be reportable:
1. Unexpected (in terms of nature, severity or frequency);
2. Related or possibly related to participation in research;
3. Suggests a greater risk of harm than was previously known or recognized.

Depending on the severity of the event, it may be reviewed by the IRB Chair or the fully convened IRB.

**What is a serious unanticipated problem?**

A serious event involves at least one of the following:

1. Results in death;
2. Is life-threatening (places subject at immediate risk of death from the event);
3. Results in inpatient hospitalization or prolongation of existing hospitalization;
4. Results in a persistent or significant disability/incapacity;
5. Results in a congenital anomaly/birth defect; or
6. May jeopardize the subject’s health and may require medical or surgical intervention to prevent one or more of the above.

**Can the IRB request revisions to the protocol or 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/or the informed consent form may be requested.

**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. Depending on the investigation results, the IRB may request changes to a research study or permanently discontinue the research study.

**Are there non-research scenarios that still require IRB review?**

Yes, there are some non-research activities that do require IRB review, such as:

- **Humanitarian Use Devices** (HUDs). This refers to an investigational medical device intended to treat or diagnose a disease or condition but that is exempt from the effectiveness requirements of the device regulations. HUDs can be used in both a clinical and research context. HUDs used in a clinical setting without the collection of research data are not considered research, but IRB review is required before a HUD can be used at a facility.
- **Single patient or group expanded access** (commonly referred to as compassionate use). This refers to use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient’s disease or condition (as opposed to research). This is initiated when there are no comparable treatment alternatives or existing alternatives have failed.
- **Emergency use**: Immediate use of an investigational drug or device required to preserve the life of a patient. Written documentation of the emergency use must be submitted to the IRB as a new submission within five (5) working days of use of the drug or device.

**My research is complete. Do I need to close the study with the IRB?**

Yes, upon completion of the study, the investigator should submit a request for closure to the IRB via Click. This should include any updated study information, including the number of total participants enrolled at this site, findings and/or statistics. If the research is in data analysis and the study data is completely de-identified at that point, IRB oversight may no longer be required and the investigator can submit a closure request.
Who can I talk to if I have a question about my research project involving human participants?
The IRB staff is available to provide assistance to investigators who are engaged in research with human participants. You can reach the Institutional Review Office at **206-215-2536** or **ReviewBoard@swedish.org**.

Standard Operating Procedures (SOPs) and institutional templates can be obtained from the Institutional Review Office or the Library of the on-line IRB submission system Click at **https://eirb.providence.org**.

To request an account for the Swedish eIRB system:
- Click IRB URL:  **https://eirb.providence.org**
- Under **External users**, click on the button for ‘Request an Account’. In the request window, be sure to describe why you’re requesting a Click account and provide your contact information for any questions.

Once you receive a Click account:
- If you’re already logged in to the Swedish/Providence system when you access Click, you won’t need a password. Select the login button under the ‘**Caregivers**’ heading.
- Go to ‘My Inbox’ and select ‘Create New Study’, fill in the Smart Form and attach your protocol and other study documents.
- Click eIRB training documents, manuals and templates are available within Click (choose the **Library** link).
- Click users will receive important announcements and reminders from **no-reply@eirb.providence.org** and should add this email address to their spam whitelists so that they do not miss important notifications.
- Technical Questions: Contact the Application Analysts at **ORPOPeResearchSupport@providence.org**