NIH Office of Intramural Research
Office of Human Subjects Research Protections

IRB MEMBER UPDATE

JUNE 2022

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EIRB SYSTEM IMPLEMENTATION UPDATES

We have a system name! 'PROTECT'

Our system naming campaign has concluded and we have chosen the name 'PROTECT' for the new eIRB system that will replace iRIS. Some of our favorite nominations we received referenced Greek mythology, strong character, integrity, ethics, and even our longest-standing Director of NIH—Francis Collins! It was a joy to read your suggestions. Thank you to all who put thought and time into this engaging exercise!

NIH PROTECT Timeline and Migration

NIH PROTECT Training

NIH PROTECT Presentations

IMPLEMENTATION PROGRESS UPDATE

Our eIRB implementation team has been very productive in working with our vendor, Huron, these past several months, completing onboarding and design sessions for the major areas of the system that we are building. These meetings took place with key stakeholders for each business area of the system. Our progress is noted below, as well as estimated time frames for upcoming testing and training with the community, and a tentative Go-Live timeframe of Oct 2022* *(subject to change)*.

	Onboarding	Design	Development	Testing	Training	Migration	Deployment
IRB	✓	✓	✓	May–Aug	Aug–Sept	Oct	Oct
SRC	✓	✓	In Progress	May–Aug	Aug–Sept	N/A	Oct
RSC	✓	✓	In Progress	May–Aug	Aug–Sept	N/A	Oct
"Ancillary Lites" PRIA/DEC/IBC	✓	In Progress	In Progress	May–Aug	Aug–Sept	N/A	Oct

Matrix table showing where major system areas are in the implementation process. Cells in the table reflect that: all major modules have had Onboarding and Design complete—IRB, SRC, and RSC; that the IRB module has been developed; and that SRC, RSC, and Ancillary Lites–PRIA/DEC/IBC development and design are In Progress. User Testing is slated for May–Aug. User Training is slated for Aug–Sept. Migration for IRB is slated to be complete in Oct. And Deployment is slated tentatively for Oct 2022.

**subject to change.*

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IRB MEMBER INVOLVEMENT OPPORTUNITIES

Testing: We will be conducting live facilitated testing with our end users of various roles through this summer. One of the roles we need to test very thoroughly in order to collect feedback is IRB members. Please consider being a tester in our end-to-end user testing experience. We really value your feedback, and it will be considered in our final iteration of the product. To volunteer to be a tester, complete this poll below and let us know how to best include you:

eIRB System - End User Testing Interest Poll

Training: We are planning to hold a half-day IRB member retreat in September. During this retreat, our trainers will attend to give the IRB members training on their board member/reviewer role in the system. This will also be recorded and shared with members who cannot attend.

Training Resources: In addition, Huron will be providing us with training materials/guides which we will share with the IRB members prior to going live.

COMMUNITY ENGAGEMENT: *TIME TO "GO OUT ON THE ROAD"*

Our Change Management Lead, Sue Tindall, has been going out into the community several times a week to deliver what our OHSRP Director, Jonathan Green, has affectionately named our "Roadshow"—*an eIRB System Intro & Demo of the IRB Module*. We will be targeting all of NIH in the following ways:

Clinical Directors/ICs

OHSRP leadership has reached out to all Clinical Directors of all ICs to begin scheduling this system overview and demo. We have reached out to all who responded to schedule a visit to their IC. We look forward to showing them our progress and answering their questions.

Research Community

Our trainers will schedule regularly occurring sessions for the research community to go over the system overview and demo. Look for an email blast announcing upcoming dates soon.

Visit our eIRB Project website!

We have a page on our OHSRP website devoted to the eIRB Refresh Project. Progress updates and testing and training opportunities can be found here. Please visit anytime to see what's new!

eIRB Refresh Project Page

Questions & Comments

We have created an eIRB Project Mailbox for the community to send us general questions and comments. This is monitored by our eIRB Project Manager, Meredith Mullan, and our eIRB Change Management Lead, Sue Tindall. Send your questions here and one of us will respond to you.

OHSRPeIRBProject@od.nih.gov

IRB vs RCRC—WHAT IS THE DIFFERENCE WHEN IT COMES TO REVIEW OF REPORTABLE EVENTS?

Both the NIH IRB and the NIH Research Compliance Review Committee (RCRC) are duly convened IRBs that are registered with the Office for Human Research Protections (OHRP) and meet the federal regulations for protection of human subjects as they relate to Board composition. While the NIH IRB has a large number of alternate members and the specific members attending varies from meeting to meeting, the RCRC has a fixed membership of nine individuals and four alternates. Both Boards have the authority to suspend or terminate IRB approval of a protocol, and they also can suspend new study enrollment if they believe it is warranted. Both Boards review specific types of events submitted via Reportable Event Forms (REFs).

IRB REF review

The NIH IRB, in addition to reviewing actions such as initial and continuing reviews and amendments, reviews events referred to the board that are possible unanticipated problems (UPs) or new information that may affect subjects' willingness to enroll or continue in a study. When these events are initially submitted in the electronic IRB system, compliance analysts gather any additional information from investigators that is needed to better understand the reported event. Each week, members of OHSRP leadership (Directors of OHSRP and the IRBO as well as the Deputy Director of IRBO and the IRB Executive Chair), known as the "REFerees," review REFs that have been submitted. Events that are possible UPs or new information as described above, are sent by the Compliance Analysts to IRBO to be scheduled for review at an upcoming IRB meeting. If the PI reporting the event believes that an update to the consent form and/or the protocol is warranted, the amendment with these proposed changes is usually scheduled for review at the same IRB meeting. The IRB does not make determinations related to noncompliance and if, as may infrequently occur, the Board discovers possible noncompliance (for example, at the time the Board is conducting a continuing review), they may require that the PI submit a REF describing the noncompliance for review by the REFerees and possible subsequent referral to the RCRC.

RCRC REF review

At the weekly meeting, if the REFerees review an event that they believe may constitute serious and/or continuing noncompliance (NC), the event is referred for review at an RCRC meeting. Unlike IRB meetings, PIs who submit a REF that will be reviewedby the RCRC are routinely invited to attend part of the RCRC meeting to explain the event to the Committee and answer Committee members' questions. The RCRC meetings are scheduled for once each month and approximately two events are reviewed at a given meeting, though meetings are canceled if there are no events referred for review. As mentioned above, the same primary members are scheduled for these meetings which helps ensure that similar events are handled in the same manner, which promotes consistency of the RCRC's determinations.

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For additional information, please see the IRB member tip sheet, *Responsibilities of the NIH IRB vs. the RCRC Regarding Review of Research Related Events* on the OHSRP website under the IRB Member Tip Sheet section of the IRB Member Review Resources page. Feel free to submit questions or comments on this topic to our Compliance and Training mailbox at OHSRPCompliance@od.nih.gov.

IRB CONSENT WAIVERS

IRB WAIVER OF INFORMED CONSENT AND WAIVER OF *DOCUMENTATION* OF CONSENT

Waiver of obtaining informed consent vs. waiver of need to document informed consent

A **waiver of consent** occurs when an IRB waives the requirement to obtain informed consent for research, and **alteration of consent** means an IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in the regulations. The IRB may only waive or alter elements of informed consent or documentation of informed consent when the IRB determines and documents that the requirements for waiver or alteration are met. An IRB may **waive the requirement for *documentation* of consent** (in which case the investigator is not required to obtain a signed informed consent form for some or all subjects) only if specific regulatory requirements are met.

IRB review of request for waiver or alteration of consent

Federal regulations require that certain criteria be met for the IRB to waive the requirement for study subjects to provide consent to participate in research. IRB members need to review the explanation and justification provided in the protocol as to why waiver of consent is being requested and determine if the justification is adequate. A somewhat common example is a PI's request for waiver of consent related to the requirement to otherwise obtain consent from minor subjects when they reach adulthood in cases where the PI wants to continue to analyze identifiable biospecimens or data previously collected from these subjects when they were minors. In cases when the newly adult subjects have been lost to follow up or have been taken off study, the PI may request a waiver of consent and must make the case as to how the required criteria discussed below are met.

Under the relevant Health and Human Services (HHS) regulations at § 46.116.(f).(3), there are five specific criteria that must all be met for waiver or alteration of consent with which IRB members should be familiar. These are listed below along with additional IRB considerations:

1. Research involves no more than minimal risk to the subjects: Has the PI included justification describing why the probability of harm anticipated in the study poses no more risk than the subject will experience or encounter in daily life or during the performance of routine physical examination or blood draw?
2. Research could not practicably be carried out without the waiver or alteration: Has the PI provided adequate justification about why it would be impossible to carry out the research without a waiver of consent? (Reasons such as inconvenience, cost, or that too many people might refuse are not acceptable.)
3. 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: Has the PI explained why the data/specimens must retained in an identifiable manner?

4. Waiver will not adversely affect the rights and welfare of the subjects: Does the IRB agree with the PI's rationale in this regard?
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation: If the research may reveal information that is important for individual subjects to know, does the protocol provide a plan to inform them? If the research requires a waiver of certain elements of consent in order to disguise the true purpose of the project, does the protocol include a plan to debrief the subjects after their study participation is completed?

IRB members need to realize that in cases where a waiver of consent is being requested for **FDA regulated research**, the FDA regulations are not identical to the HHS regulations and, in some cases, FDA does not permit waivers or alterations that are now included in the HHS 2018 Common Rule requirements. For FDA regulated For FDA regulated research, the IRB may allow an exception from the requirements for informed consent for emergency research as specified in 21 CFR parts 50.23 or 50.24.

However, waiver of informed consent is not permitted for certain research with vulnerable populations. Per, "Waiver of Informed Consent Requirements in Certain Emergency Research," because of special regulatory limitations relating to research involving prisoners and research involving fetuses, pregnant women, and human in vitro fertilization, the waiver for emergency research is not applicable to these categories of research. For additional information about FDA regulated research and IRB waiver or alteration of informed consent, refer to the July 2017 FDA guidance: *IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects*.

IRB review of request for waiver of *documentation* of consent

There may be some circumstances when obtaining **documentation** of consent with a signature on the consent form does not contribute in a meaningful way to the protection of the proposed study subjects. In some cases, documentation of the consent process may put subjects at increased risk (e.g., confidentiality is at risk because the subject signed a consent form.) The following are the three provisions in the 2018 Common Rule (§ 46.117.(c)) under which an IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects as well as examples:

1. 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.[1]
    - » Example: A study of individuals who have experienced intimate partner violence resulting in physical harm. The research includes questionnaire and interviews about the subjects' experience. The IRB determined that if the partner who caused the harm found the signed consent form that described the type of information to be collected, the subject might be placed at additional risk.
2. 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.[2]

[1] *Cannot be applied to research that is FDA-regulated*
[2] Ibid.

» Example: A study entailing collection of health information from Indians from a part of Mexico where there is no written language. The investigator will collect information related to diet and concomitant health risk factors as they may relate to high incidence of diabetes in this group. The IRB reviewed/approved a verbal script that would be conveyed in the local language of the participants and approved a verbal consent process.

3. 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.[3]
   » Examples:
   - A study to evaluate the relationship between perceived self-reported symptoms of stress and dietary intake over a 6-month period in obese subjects with BMI between 30 and 35. A standard questionnaire will be used to evaluate daily stress, and participants will complete a daily diary listing all food and beverages they consume.
   - Research involving assessments, surveys or psychological tasks conducted over the phone or online.

The investigator should clearly describe the proposed consent process in the protocol so that the IRB can determine if providing a waiver of documentation of consent can be approved. In cases in which the consent documentation requirement is waived, the IRB may require that the investigator provide subjects or legally authorized representatives with a written statement regarding the research. In some cases, such as the first example above, the subject may be permitted decline receipt of a copy of the information sheet. The investigator should document the consent process in the research record.

Waivers of consent for research involving children as participants

Under certain circumstances, an IRB may waive the requirements for obtaining **parental or guardian permission** if it makes and documents specific findings. In addition to the provisions for waiver of consent noted above, if the IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive parental permission requirements provided that an appropriate mechanism is in place to protect the children, and provided that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in research depends on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child's age, maturity, status, and condition.

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[3]For FDA regulated research, documentation of consent may only be waived if the research meets this criterion.

IRBO COUNTS ON *YOU*!

When you sign up to attend an IRB meeting via the scheduler, you receive an email with a calendar meeting invite as an attachment. Please download this meeting invite and add it to your calendar as soon as you receive this initial email.

As a reminder, to ensure that we have quorum, please let us know as soon as possible if you find that you have a conflict and will no longer be able to attend the IRB meeting you signed up for. If the meeting you are scheduled to attend is greater than a week away, please go into the scheduler, and remove yourself from that meeting. If it is less than a week prior to the meeting, then please contact the IRB Analyst who is assigned to that meeting to let them know ASAP.

While we certainly understand that last minute emergencies may arise, canceling your availability for a meeting after the final agenda has been sent out the week prior to the meeting can be problematic. The IRB Office spends a considerable amount of time trying to match IRB members to the IRB submissions to ensure the proper expertise; then the IRBO must scramble to find an additional member, with specific expertise, at the last minute. Without your attendance, there is a potential risk that quorum will not be met and the meeting may be canceled; this, in turn, this delays the review of research.

Thank you in advance for your cooperation!