THE UNIVERSITY OF ARIZONA Research Innovation & Impact

HSPP Process Changes for eIRB

Background

As of 9/14/2021, all submissions to the Human Subjects Protection Program (HSPP) will occur in eIRB. This document summarizes changes for submitting projects in eIRB.

Key eIRB Definitions
• PI Proxy: a research personnel assigned on a project who is designated by the PI to submit the project on the PI's behalf. o Only the PI and the PI Proxy can submit projects in eIRB. o There can be multiple PI Proxies assigned to a project. o The PI Proxy receives notifications from eIRB.
• Primary Contact: once assigned to a project, the Primary Contact has access to edit a submission and receives notifications from eIRB. o There can only be one primary contact assigned to a project.
• Local Study Team Member: Any person who shares the responsibility of Conducting Research. o This includes, but is not limited to, the Co-Investigator (Co-I), Project Director (PD), Co-PD, Senior/Key Personnel, and any other person, regardless of title or position, who is responsible for Conducting Research performed by or under the auspices of the University. o Conducting Research includes the design, development, testing, evaluation, conduct, reporting, review, and oversight of a program of scientific inquiry. o All Local Study Team Members have the ability to edit documents and data on a project.
• Guest: once assigned to a project, a Guest has read-only access to view all documents and data on a project.
• Follow-on Submissions: any submissions that occur on a project after initial IRB approval. o Modification: amendment submissions in eIRB. o Continuing Review (CR): submissions to renew approval on continuing projects. o Modification/CR: combined amendment and renewal submission. o Study Update: a specific amendment submission type for projects relying on an External IRB. o Reportable New Information (RNI): reportable event submissions and/or notification submissions to the IRB.
• Submission ID: the ID# generated in eIRB for a specific submission. o Every submission in eIRB will generate a unique submission ID.

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Previous Process for New Submissions	*Current Process for New Submissions*
• Submit applications via email to VPR-IRB@arizona.edu inbox.	• Submit applications via eIRB.
• Anyone can submit to the IRB.	• Anyone can create a submission in eIRB and prepare all required documents. • Only the project's PI or the PI Proxy can submit to the IRB.
• No visibility for researchers on IRB submission status or required training statuses.	• Researchers can clearly see where their project is in the IRB workflow. • Researchers and IRB have access to view institutional requirements, such as COI approval and training status, in eIRB.
• Projects maintain one IRB protocol # throughout the life of the project.	• Unique submission ID #s are generated for every submission created in eIRB. • A follow-on submission will have a different submission ID from the initial approved project.
• Include all research personnel on the List of Research Personnel HSPP form.	• Include all research personnel on the Local Study Team Members Smart Form in eIRB.
• For additional required approvals, an email acknowledgement in place of an actual signatured is preferred.	• Additional required approvals can be submitted in multiple ways: ○ Email attached as a document in eIRB ○ Signed attestation forms attached as a document in eIRB ○ Approver signs via the "Comment" feature in eIRB
• Attach fillable PDF HSPP forms and required approvals to the submission email.	• Attach Word HSPP forms and required approvals to the submission in eIRB.
• For funded research, submit to the IRB at any time.	• For funded research, submit to the IRB only after the Institutional Proposal or Award # is created, and within 60 days of expected funding.

HSPP Process Changes for eIRB

Previous Process for New Submissions	*Current Process for New Submissions*
• For projects where the PI is a student or resident, advisor approval is required.	• For projects where the PI is a student or resident, an eligible Co-I is required. If eligible, the Co-I may be the same person as the advisor.
• For multi-site projects, submission of the main application and any multi-site documents occur in the same submission email.	• For multi-site projects, submission of the main application is a Study submission in eIRB. • Additional relying sites are added as separate Site submissions in eIRB.
• For projects relying on an external IRB, UA can grant approval before receiving approval from the external IRB.	• For projects relying on an external IRB, UA provides a letter agreeing to cede oversight to the external IRB. • UA requires approval from the external IRB before the submission is approved.
• Identification of COI Investigators on HSPP List of Research Personnel Form	• For unfunded research, eIRB creates COI triggering events and displays the completion status. • For funded research, HSPP will validate COI only for research personnel who are listed both in eIRB and on the Institutional Proposal or Award that's linked for the protocol in eIRB. It is the responsibility of the Principal Investigator (PI) to ensure that the correct personnel are listed as an Investigator on the SPS Institutional Proposal or Award. All other personnel, for both funded and unfunded research, are independently responsible for ensuring that they have submitted all appropriate disclosures and are in compliance with the Conflicts of Interest and Commitment Policy.

HSPP Process Changes for eIRB

Previous Process for Follow-on Submissions	*Current Process for Follow-on Submissions*
• The IRB can only process one submission per project at a time.	• The IRB can process the following submission types simultaneously: ○ Modification: Changes to study team members (except for PI changes) ○ Modification: PI changes and all other study-related changes ○ Reportable New Information ○ Study Updates (for External IRB projects) ○ Continuing Review
• Amendment submissions, reportable items, and notifications to the IRB are captured in one HSPP form.	• Modification submissions: Submit a Modification/CR or a Study Update • Reportable items or Notifications: Submit a Reportable New Information (RNI)
• Continuing reviews cannot be combined with an amendment submission.	• Researchers can submit a combined Modification and Continuing Review.
• Low risk projects are given a 3-year or 5-year expiration date. • Provide an update on the project's status by submitting the Project Update HSPP form.	• Unless otherwise required by the IRB, low risk projects will not be given an expiration date. • Provide an update on the project's status via the Comment feature in eIRB.
• Continuing reviews must be submitted within 45-30 days of the expiration date in order to maintain the same expiration date for the following year. • Department head approval is required to renew projects that are still open to enrollment.	• Continuing reviews must be submitted and approved before the project's expiration date. • Renewed projects will always receive a new expiration date. • Department head approval is no longer required to renew projects.
• Expired projects require the resolution of an administrative closure and the submission of a new IRB application.	• Expired projects enter a "Lapsed" state and can be re-opened with a Continuing Review submission in eIRB; however, no human research activities can take place, unless approved by the IRB

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Previous Process for Follow-on Submissions	*Current Process for Follow-on Submissions*
• For projects relying on an external IRB, email the UA with the external IRB's continuing review approval.	• For projects relying on an external IRB, use the Report Continuing Review Data feature to document continuing review approval.

Previous HSPP Forms (PDF)	*Current HSPP Forms (Word)*
• Determination of Human Research	• IRB Protocol for Determination of Human Research
• Application for Human Research	• Individual forms depend on the type of submission: ○ IRB Protocol for Human Subjects Research ○ IRB Protocol for Human Subjects Retrospective Data Review ○ IRB Protocol for Projects Using External IRBs
• List of Research Personnel	• No longer used in eIRB. Research personnel are captured in the eIRB Local Study Team Members Smart Form.
• Appendix for Vulnerable Populations	• Individual forms, depending on population: ○ Appendix for Children and Wards ○ Appendix for Cognitively Impaired Individuals ○ Appendix for Native Americans and Indigenous Populations ○ Appendix for Pregnant Women, Neonates, and Fetuses ○ Appendix for Prisoners
• Appendix for Devices	• Appendix for Devices
• Appendix for Drugs	• Appendix for Drugs
• Appendix for Alterations/Waivers of Consent or PHI	• Appendix for Waiver or Alteration of Consent or PHI

HSPP Process Changes for eIRB

Previous HSPP Forms (PDF)	*Current HSPP Forms (Word)*
• Appendix for Exception from Informed Consent (EFIC)	• Appendix for Exception From Informed Consent (EFIC)
• Project Update Form	• No longer used in eIRB. Instead, for projects that don't require a Continuing Review, researchers will simply log a comment explaining the project's status.
• Renewal/Closure for Human Subjects	• Continuing Review Supplemental Document
• Appendix for Multi-Site Research	• Appendix for Multi-Site Research
• Multi-Site List of Research Personnel	• No longer used in eIRB. It has been incorporated into the Appendix for Multi-Site Research form.
• Multi-Site Renewal/Closure of Human Research	• No longer used in eIRB. Instead, researchers will Report Continuing Review Data for each site.

What's Staying the Same
• Reference HSPP guidance for current requirements and expectations for human research conducted at or on behalf of the University of Arizona.
• Always use the current HSPP forms and ICF templates from the HSPP website.
• Ensure all additional approvals are received before submitting to the IRB. Refer to the Guidance Other Approvals Required.

• Reminder: Department head approval is required for the following:
  ○ New submissions
  ○ Changes in PI
  ○ Reportable items