

Policy Changes and Clarifications Affecting Researchers and/or Zipline

HSD concurrence for use of electronic consent *(Implemented March 25, 2021)*

UW research that is being reviewed by an external IRB must obtain HSD concurrence before implementing the use of e-signatures for consent and/or HIPAA authorization. Studies previously authorized to use an external IRB who later decide to add the use of e-signatures must submit an update to their application and obtain HSD concurrence before submitting a modification to the reviewing external IRB.

Administratively discarding non-responsive submissions *(Implemented April 29, 2021)*

In certain cases, HSD may administratively discard submissions in Zipline due to non-response.

- (1) The submission is clearly not needed or not able to be processed (e.g. a CR for an exempt study) and has been sitting for 60 days without researcher response to a request that the submission be discarded
- (2) For all other submissions, the item has been sitting for 6 months without researcher response

These criteria apply to RNI in pre-submission, withdrawn studies in pre-submission, modifications, continuing reviews, and external updates. Studies in the Pending sIRB Review state can only be discarded if it has been confirmed that they are no longer needed. The PI, PI proxy, and primary contact will be contacted by email two weeks before the item is administratively discarded.

System Release Highlights

Notification Updates

- The External IRB Annual Reminder has been revised to add “You are planning to implement e-consent” to the list of reasons that the study team must update the Zipline record
- The Response Time Exceeded Clarification Reminder has been revised to add a statement that the submission may eventually be discarded by HSD

System Release Highlights

SmartForm: Modification / Continuing Review / Closure

- An information bubble has been added as a reminder that a 'Study team member information' modification will only change who can edit the study in Zipline

SmartForm: Local Site Documents

- “Curriculum vitae (CV) or biosketch for the local principal investigator” has been added to the list of suggested attachments for the Other Attachments question of the Local Site Documents SmartForm

SmartForm: Study Scope

- The following new required question has been added to the Study Scope SmartForm:
“This question is only about UW School of Medicine employed faculty. As part of this research, will the faculty member be practicing their licensed healthcare profession at a non-UW Medicine approved site of practice?”
- **Note that researchers will be required to complete this field before submitting an existing application, responding to a clarification request, or submitting a new modification**

Workspace: Submissions

- Relying sites and site modifications that are in the review process will now show on the In-Review tab on the Submissions workspace in addition to the Relying Sites tab

Help Text Updates

SmartForm: Basic Information, Rely on UW IRB

- Removed instruction that ‘Yes’ should be selected if UW is the primary recipient of a federal award for research that includes an international site
- Added a reminder to complete the SUPPLEMENT Multi-Site or Collaborative Research if ‘Yes’ has been selected

SmartForm: Study Scope, Sites of Practice

- NEW: Added link to list of UW Medicine sites of practice

Updated Documents Highlights

APPLICATION IRB Protocol

- Uploaded version 3.3, revised 04/29/2021, to Zipline. Changes from previous version uploaded in Zipline:
 - Clarified instructions for question 2.4 Prisoners to remove old reference to WORKSHEET Prisoners and refer to new GUIDANCE Prisoners, and clarify that the definition of a prisoner is not necessarily tied to the type of facility in which a person is residing
 - Revised wording of question 2.4.i Prisoners to ask about locations instead of prisons/jails

Updated Documents Highlights

- Revised wording of question 2.4.iv Prisoners to reference specific federal departments and agencies, and to add pardon decisions to the assurance
- Clarified in question 4.2 Recruitment materials that recruitment letters and emails sent to the subject should be uploaded to Zipline
- Differentiated between written documentation of consent and electronic documentation of consent for recruiting and screening activities in question 4.7 Consent for recruiting and screening
- Added subpart to question 5.7 Protected Health Information (PHI) asking whether HIPAA authorization will be obtained electronically
- Added reference to TEMPLATE Other E-Signature Attestation Letter to question 8.4.b Electronic consent signature
- Removed question 13.3 UW ITHS COVID review

APPLICATION IRB Protocol, No Contact with Subjects

- Uploaded version 2.8, revised 04/29/2021, to Zipline. Changes from previous version uploaded in Zipline:
 - Clarified instructions for question 2.3 Prisoners to remove old reference to WORKSHEET Prisoners and refer to new GUIDANCE Prisoners
 - Revised wording of question 2.3 Prisoners to ask about locations instead of prisons/jails
 - Removed question 10.3 UW ITHS COVID review

APPLICATION Status Report

- Uploaded version 1.5, revised 02/25/2021, to Zipline. Changes from previous version uploaded in Zipline:
 - Clarified instructions for question 2 Subject number details to note difference between number of subjects who have completed the study and number of subjects who have enrolled

REQUEST External IRB Review

- Uploaded version 3.3, revised 03/25/2021, to Zipline. Changes from previous version uploaded in Zipline:
 - Clarified question 4.9 to indicate that documentation of HIPAA authorization can be obtained electronically, add note that use of e-signatures requires advance concurrence from HSD, and add reference to new TEMPLATE Other eSignature Attestation Letter
 - Removed question 4.11 Confirmation of UW ITHS COVID review
 - Added SUPPLEMENT Other REDCap Installation or Other E-Signature Attestation Letter to the list of required attachments in Section 5

LETTER TEMPLATES

- The Approval and Modification Approval templates have been revised to remove the statement about approval of DocuSign from the body of the letter. Approval of DocuSign is documented in the determinations, waivers, and regulations table