IRB SUBMISSION ACTIVITY & ACTIONS AVAILABLE

Browsers Currently Supported: Windows and Macintosh - Mozilla Firefox; Google Chrome

*Please **do not** use Microsoft Internet Explorer or Microsoft Edge*

Actions / Activities to Take within a Record
* Activity tabs in Record: These are tabs on the left side of the record that you click to perform certain actions within the record itself (e.g., send correspondence, submit study, etc).

Principal Investigator (PI), Study Team, IRB, & HRPP	
Activity Tabs in Record*	**Action**
Add Comment	Comments added can be a form of communication between the Principal Investigator (PI), Key Personnel and HRPP, if needed, as all comments will be visible to anyone with access to the submission. All comments will appear in the project's History tab.
Add Participating Sites	*(multi-site/collaborative study)* Add participating sites for this multi-site study.
Add Private Comment	Only for committee reviews do private comments get removed from the submission. Private comments can only be viewed by those chosen to see them (e.g., IRB Coordinator) such as assigned reviewers and administrators. Private comments do not display in the project's History tab.
Add Related Grant	***(Function will be available when Grants module is active)*** Add grants that relate to the IRB submission.
Add Related Submission	Link additional submissions to a Reportable New Information (RNI) submission.
Assign PI Proxy	The PI proxy can only be someone listed as a Study Team Member. The Proxy performs PI responsibilities on their behalf, such as submitting the study to the IRB, modifying the study, and submitting continuing reviews.
Assign Primary Contact	Primary contact is typically the PI, however, if a different person is chosen for this role, they will receive all

	communications from the HRPP.
Close Site	Shown in record of a multi-site study, where the HRPP staff can close the site and its related external site if it is a pSite. Modifications get closed if any are open, however, RNIs will not be closed automatically.
Copy Submission	Submission may be copied, but it will be in a Pre-Submission state and the PI will remain as the PI on this submission.
Correspond with sIRB	*(Function will be available when Grants module is active)* At any point during the review process you can correspond with sIRB researchers and coordinators.
Correspond with Site	*(Function will be available when Grants module is active)* Contact a participating site for a multi-site study. This is available before a site is submitted for review and while it is going through the review process.
Discard	Discard will permanently remove the submission, however, there will still be a history of it existing in the system.
Manage Ancillary Reviews	Manage Ancillary Reviews allows for the PI/proxy or HRPP staff to add organizations or people to provide additional review of the submission.
Manage Guest List	Manage Guest List allows for additional people to view the submission other than the PI, Primary Contact, Study Team Members, and Ancillary Reviewers.
Manage Participating Sites	*(when study is only a multi-site/collaborative study and NOT external IRB review)* Users can manage invitations to participating sites.
Report Continuing Review Data	Report continuing review data for enrollment totals at the investigator's site.
Submit	Once the IRB application is complete, the PI/proxy can click Submit to send it to HRPP for pre-review.
Submit Pre-Review	Once pre-review is complete, click "Submit Pre-Review" and complete the fields to move the submission along within the workflow to the IRB Manager for review and approval.
Submit Response	Submit Response is where the PI/proxy can submit their response to the HRPP/IRB clarification requests. Once

	you input your clarifications or upload your document that needed revising, and click OK, it automatically sends.
Submit Site Materials	(*appears after site is created and invitation decision is submitted*) Execute when all site materials have been received from the participating site.
Update Documents	Allows site managers and staff to add, edit, and delete supporting documents.
Withdraw	The PI can withdraw their submission and it will bring them back to the Pre-Submission state to fix anything they unintentionally added, etc and then they can make the changes and resubmit. Withdraw discontinues the IRB's review of the submission.

IRB / HRPP Only	
Activity Tabs in Record*	**Action**
Add Review Comments	*(IRB / HRPP only)* Committee members can comment on the submission.
Approve Meeting Minutes	*(IRB Chair / HRPP only)* Approve meeting minutes.
Assign to Committee Review	*(HRPP only)* Assign to Committee Review is clicked after the submission is assigned to a meeting. This will then push the submission to committee review. The HRPP staff member can assign a study to the one committee member to review or to a committee meeting for all committee members to review.
Assign Coordinator	*(HRPP only)* The individual chosen will receive all communications during the submission process. The Coordinator will have the submission appear in "My Inbox" within Huron.
Assign Designated Reviewer	*(HRPP only)* Assign Designated Reviewer is chosen if the submission should follow the non-committee review path (e.g., expedited, exempt reviews). The reviewer will receive an email about the review and the study will appear in the reviewer's IRB inbox.
Assign IRB	*(HRPP only)* If a committee review is needed, Assign IRB, will allow the user to select the date/schedule of the IRB meeting that this submission is needed to be

	reviewed at.
Assign to Meeting	*(HRPP only)* Assign to Meeting is the HRPP staff choosing a meeting date and time.
Assign to Non-Committee Review	*(HRPP only)* If the submission went to committee review accidentally, it can be changed back to non-committee review.
Assign Reviewers	*(HRPP only)* After a submission is assigned to a committee review, HRPP can assign specific committee reviewers.
Close Meeting	*(HRPP only)* Close IRB meeting.
Close Study (Admin)	*(HRPP only)* Close a study administratively.
Confirm Attendance	*(IRB / HRPP only)* Confirms committee member attendance at the meeting within the schedule.
Confirm Reliance	*(HRPP only - external study, multi-site study)* Confirm reliance on the sIRB for the study.
Convene Meeting	*(HRPP only)* Convene IRB meeting.
Deactivate Site	*(HRPP only)* Allows HRPP staff to move the site to the inactive state.
Decline Attendance	*(IRB / HRPP only)* Declines committee members' attendance for the present meeting.
Edit Committee Info	*(HRPP only)* Change committee name, description, etc.
Edit Meeting Attendance	*(HRPP only)* Edit meeting attendance.
Edit Meeting Details	*(HRPP only)* Allows administrators to reschedule the meeting.
Edit Members	*(HRPP only)* Add and remove committee members.
Edit Pre-Review	*(HRPP only)* Edit Pre-Review allows the HRPP staff member to change the options selected under Pre-Review (e.g., regulatory oversight, special determinations and waivers, type of research, add'l study features).
Edit sIRB Decision	*(HRPP only)* (*external IRB review and HRPP recorded sIRB decision, this activity appears*) If the record of the sIRB decision needs to be edited or no letter needs to be sent from Post-Review.
Finalize Documents	*(HRPP only)* Select the submission's supporting

	documents that should be finalized and have a permanent record created for them. Finalizing creates a PDF copy of each document and stamps it with the watermark for its specific category.
Finalize Updates	*(HRPP only)* Appears for external review studies, after creating an update Site.
Manage Tags	*(HRPP only)* IRBC/IRBD can add tags to a submission for ease of finding and for reporting purposes.
Notify Reviewers	*(HRPP only)* Notify reviewers of a submission to review.
Prepare Agenda	*(HRPP only)* Allows the administrator to generate or upload the agenda for the meeting.
Prepare Letter	*(HRPP only)* Draft letters or templates with the system can be edited here and generated.
Prepare Minutes	*(HRPP only)* Create the meeting minutes for review or discussion.
Record sIRB Decision	*(HRPP only)* Record the decision made by the sIRB after you have confirmed reliance.
Remove from Agenda	*(HRPP only)* Remove from Agenda allows the submission to be removed from the current IRB Agenda. The study would then need to be assigned to a meeting again, when ready, etc.
Request Clarification by Committee Member	*(IRB only)* Board members can request clarifications directly from the PI.
Request Pre-Review Clarification	*(HRPP only)* If clarifications are needed during pre-review, they can be sent to the study team through this action tab. There is also a spot to include supporting documents, if necessary.
Return to Post-Review	*(HRPP only)* Returns the submission to post-review.
Send Agenda	*(HRPP only)* Send Agenda to selected committee members.
Send Letter	*(HRPP only)* Sends the HRPP/IRB decision regarding the human subjects submission to the PI, proxy, and primary contact.
Submit Committee Review	*(HRPP only)* Submit Committee Review keeps track of the vote from the Board meeting and can be used as a place to put meeting minutes (the committee's determination for that submission). Submit Committee

	Review submits the board's determination to the PI / proxy. If HRPP accidentally chose an incorrect determination made by the IRB, they could click back into "submit committee review" to change the initial decision.
Submit Designated Review	*(HRPP only)* Submit Designated Review appears after choosing Assign IRB.
Submit Invitation Decision	*(HRPP only)* Submit participating site invitations.
Submit Pre-Review	*(HRPP only)* After pre-review has been completed, submit pre-review to record determinations made by the IRBC to move workflow to the next step.
Suspend	*(HRPP only)* Suspend the approval of a submission.
Terminate	*(HRPP only)* Terminate the submission.
Update Eligible Designated Reviewers	*(HRPP only)* Update the list of committee members that are able to serve as a designated reviewer.
Update Other Agenda Items	*(HRPP only)* Allows committee members to add agenda items to the meeting.