U Iowa Human Research Protection Program (HRPP) and WIRB Requirements: Side-by-Side Comparison

Topic	UI HRPP Requirements	WIRB Requirements
Reporting Requirements	Reporting of an event should be done simultaneously between WIRB and UI. All reportable events that occur at the UI must be reported in HawkIRB by initiating a Reportable Event Form (REF). Reporting events, regardless of IRB of record, remain the same as what is documented in the UI Investigator's Guide. The UI HRPP will communicate with WIRB in the event of an unanticipated problem or serious and\or continuing noncompliance to assure all regulatory and institutional reporting requirements are met for the study.	Use the PRI Form to report information to WIRB within 5 days of discovery of an event. The list of relevant events that can be reported is directly on the form. Information not listed on the form (or on our Guide for Researchers) does not require prompt reporting to WIRB. In general, if it doesn't affect subject safety, it may not require reporting. Furthermore if you submit a PRI and do not get a response, that means the information was filed without further action. If further action must be taken, you will receive a letter outlining what the next steps are.
Study Staff Listing	UI HRPP requires a listing of all active research team members to assure all members engaged in research are certified and eligible to do so. Modifications to the research team can be submitted in HawkIRB at any time, but the research team must await UI HRPP approval of the change prior to having the new member engage in research.	WIRB's initial review submission form gathers general information about the number of sub-investigators. WIRB does not require all study staff members to be listed on the initial review form unless the individuals need to be added to all official IRB correspondence. If a staffing change does not represent a change in research or promptly reportable information, WIRB does not need to be notified. In general the only major changes WIRB needs to be notified of are PI changes, and any individuals who must be listed on all official IRB correspondence and/or receive Continuing Review Report Forms. The contact information update form can be found here.
Consent Form Submissions	UI HRPP has specific requirements for certain language in the Informed Consent Document. When a sponsor or a sponsor-investigator makes a consent form available to the research team, the team must add any relevant UI required language before submitting the initial application review. UI required language cannot be changed or altered, except where required, unless a significant justification to do so is provided by the sponsor. Required language is required for the following:	WIRB has required language on file for U Iowa, and no changes can be made to affect the required language without explicit sign-off from the appropriate U Iowa IRB office staff. Redlined changes in research affecting ICF language must be submitted by the site, and cannot be submitted by the sponsor. There are also words that are not permitted in any U Iowa consent form (listed below).

	• Pregnancy testing for females under the age of 18 • HIPAA Authorization • Compensation for Research Related Injury • CMS/Medicare use in research • Social Security Number collection • Legally Authorized Representative option to sign the consent • Conflict of Interest in Research Modifications to the consent form after initial approval must be submitted to WIRB and approved before they can be processed in HawkIRB. A change to the consent form can be submitted to WIRB and the UI HRPP simultaneously, but WIRB approval is required prior to the change being processed in HawkIRB. There should be no changes to the UI required language following initial review and approval by WIRB. Any changes to the UI required language in a modification will require review by University of Iowa Human Subjects Office.	
Training Certifications	UI HRPP requires CITI training certification for all researchers to engage in research. The UI CITI program offers 3 primary courses: Biomedical human subjects protections, social behavioral human subjects protections, and Good Clinical Practice training. If the research team member is involved with a study at University of Iowa Hospitals and Clinics (UIHC) they should complete the biomedical training. For social behavioral researchers, the social behavioral training is sufficient. The GCP training is optional for all researchers but is required for any NIH funded clinical trial In addition, a study sponsor may require this training certification.	WIRB does not require certificates of training. Study teams only need to indicate on the IRSF what training has been completed by members of the study team. WIRB also requires up-to-date medical licenses and CVs of PIs (if WIRB does not already have them on file).

Financial Conflicts of Interest	UI investigators are required to complete an annual eCOI disclosure. During the initial application review, HawkIRB will flag an investigator(s) with a potential conflict of interest. This determination is based on information reported in eCOI.. Any potential conflicts of interest are reviewed by the Conflict of Interest Office for evaluation. Any subsequent management plans or findings of this review are sent to WIRB for IRB consideration.	During the application process, it is required to disclose if the PI (or their immediate family) has financial interests in an entity sponsoring the research. If the Board determines that the financial interest is not a Significant Financial Interest, no further action is taken. If the interest is a Significant Financial Interest, the Board considers whether the interest affects the criteria for approval of research, and if so, does not approve the research unless the interest is eliminated or managed. More information can be found in our Guide for Researchers on page 10, and the FCOI form can be found here.

Words/Phrases that will not be accepted in any U Iowa Consent Form:

In concordance with HIPAA regulation 164.508(c)(iii), it is Iowa's expectation the informed consent documents will provide subjects the "name or other specific identification of the person(s) or class of persons" who will have access to their health information and to clarify what info is being provided and why. This is most commonly identified in documentation of the relationship between the Sponsor and those that work with the Sponsor. The following terms cannot be included (are NOT acceptable) in the body of UI consent forms:

Assignees, Representatives, Others, Recipient, Collaborators, Partners, Notified Bodies, Licensees, Competent Authority, Consultants, Colleagues at other institutions, Associates, Relevant authorities.

Acceptable terms for use are:

Sponsor, and its Affiliate, Agent, Contractor, Subcontractor, Third-Party Payor, Subsidiary, Employees, Foreign Government Agencies, FDA, Outside Labs.

Working with U Iowa and WIRB: FAQ Quick Reference Sheet

Resources:

U Iowa:

- UI WIRB info page - https://hso.research.uiowa.edu/western-irb-wirb-central-irb
- Questions, please email uiwirb@uiowa.edu

WIRB:

- WIRB Guide for Researchers - http://wirb.com/Documents/Guide%20for%20Researchers.pdf#page=2
- WIRB Download Forms - http://wirb.com/Pages/DownloadForms.aspx
- For general questions, please email clientservices@wirb.com.
- For any escalated or regulatory inquiries, please email dhorowitz@wirb.com.