University of Massachusetts
UMASS Medical School

Reliance on Western IRB (WIRB)
(Updated 03/31/16)

This guidance reviews the process for use of Western IRB (WIRB) for IRB review and oversight of research involving University of Massachusetts-Worcester investigators. UMass-Worcester maintains an Agreement for Services with WIRB which sets forth understandings, authority, and responsibilities of both institutions.

The University of Massachusetts-Worcester, in an effort to create a framework that will facilitate the review of industry sponsored phase III multicenter research, has entered into an agreement with Western IRB (WIRB) whereby the UMass IRB may rely upon WIRB for IRB review and approval.

In order for the UMass IRB to be able to extend this agreement to include a specific research study all of the following conditions must apply:

The sponsor of the research is a for-profit entity/company
The project was designed and written by the sponsor
The sponsor holds all INDs/IDEs for the project
The research is a multicenter project
The research is in phase III or IV as defined by the FDA
The research is currently reviewed by WIRB for other sites

If you wish to rely on WIRB, contact the UMMS IRB WIRB Liaisons. Although UMass may rely upon WIRB for review of certain research projects, the Institution is still responsible for the conduct of that research. Therefore, while not responsible for IRB approval of WIRB-submitted studies, the UMass IRB must be aware of and approve of the submission being sent to WIRB through an administrative pre-review. WIRB will not review any UMass study prior to UMass administrative pre-review. Research studies that do not meet the criteria above will be considered by the UMMS IRB on a case-by-case basis.

UMMS IRB WIRB LIAISONS:

- **Primary:** sarah.saliba@umassmed.edu
- **Secondary:** allison.blodgett@umassmed.edu

BASIC PROCESS:

- Email a copy of the sponsor protocol and sponsor consent form template to the Primary UMMS IRB WIRB Liaison and confirm that the submission meets the criteria above.
- If the UMMS IRB grants permission to use WIRB, prepare the necessary documents.
- Ask the sponsor to invite you to the protocol in Connexus (WIRB's electronic submission system). If the sponsor is not responding, WIRB Client Services can also assist you with an invitation.

- Complete the steps through document upload for Submit New Investigator Site in Connexus, **but do NOT submit to WIRB.**
- Add the UMMS IRB WIRB Liaisons to the workspace in Connexus so that the UMMS IRB can conduct an administrative review.
- The UMMS IRB office contacts you by email with any clarifications.
- Update Connexus to address any questions from the administrative review, **but do NOT submit to WIRB**. Respond to the administrative review by email with a point-by-point response.
- Once questions are resolved, **the UMMS IRB submits to WIRB on your behalf**.
- Once WIRB approval is granted:
    - WIRB will contact you to conduct a site visit (at no cost to you) if the PI is conducting an investigational drug study and has not been previously approved by WIRB for a research study.
    - Send subsequent submissions (e.g., modifications, continuing reviews, reportable events) directly to WIRB for review.
    - Maintain a current *HRP-270 External IRB Review Application* and email updates to the UMMS IRB.
    - Email the UMMS IRB when the study closes here at UMass Worcester.

General Tips

- **Never hit a SUBMIT button in Connexus at any time.**
- Tell your sponsor that the UMMS IRB office must submit to WIRB on your behalf.
- Read through these instructions in full before starting.
- Make sure you are working from the most recent instructions and templates for UMMS and WIRB.
- Prepare the necessary documents before starting anything in Connexus.
- Make sure all study staff have completed the required human subjects, GCP, and COI CITI trainings before adding the UMMS IRB WIRB Liaisons to the submission in Connexus.
- **Use the UMMS research injury language from the consent form template and the UMMS stand-alone HIPAA authorization.** WIRB will hold any submission that deviates from these materials.

Necessary Documents for Connexus

- *HRP-270 External IRB Review Application* (http://www.umassmed.edu/ccts/irb/submission/western-irb-wirb/)

- Approvals and mitigation plans from ancillary reviews (e.g., conflict of interest, radiation safety, institutional biosafety), if any
- Copy of PI's CV and medical license
- A copy of the Controlled Substances Registration if the research involves an investigational drug in the state of Massachusetts (i.e., the research is being conducted under an IND) – You will obtain this research registration from the department chair, who holds this license for all PIs in that department. Look for TYPE: RESEARCHER and SCHEDULES: IND printed on the document.
- Consent form showing site specific information as track changes (e.g., add UMMS required research injury compensation language, add compensation, remove embedded HIPAA authorization) and a document providing the rationale for each requested change
    - **WIRB will hold any submission that deviates from the UMMS research injury language from the consent form template.**
- UMMS stand-alone HIPAA authorization
    - **WIRB will hold any submission that embeds HIPAA language in a consent form or uses a sponsor's template.**
- Any local recruitment materials (sponsor recruitment materials that WIRB has already approved and that will be updated to include local contact information do not need to be uploaded)
- *WIRB Initial Review Submission Form*, which includes a place to request a HIPAA waiver (http://www.wirb.com/Pages/DownloadForms.aspx)

TIPS FOR HRP-270 EXTERNAL IRB REVIEW APPLICATION:

- Make sure all study staff have completed the required human subjects, GCP, and COI CITI trainings. Team members can print copies of their completion certificates for you if they log into CITI at https://www.citiprogram.org/.
- Information regarding COI training, including a list of UMMS personnel who have completed the CITI COI training module, is available through the Office of Research: http://www.umassmed.edu/research/compliance/financial-conflict-of-interest/overview/
- Information regarding human subjects training is available on the IRB website: http://www.umassmed.edu/ccts/irb/CITI-GCP/
- Item 3.10 is asking if UMass-Worcester personnel will conduct the research outside the state.
- Item 3.14: *SOP: Informed Consent Process for Research (HRP-090)* is now *HRP-802 INVESTIGATOR GUIDANCE: Informed Consent* (http://www.umassmed.edu/ccts/irb/investigator-guidance/)
- Item 3.15: *SOP: Written Documentation of Consent (HRP-091)* is now *HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent* (http://www.umassmed.edu/ccts/irb/investigator-guidance/)

- Item 3.16: *Third Sky* refers to the School/Hospital's online conflict of interest disclosure system (http://coi.umassmemorial.org/coi/)
- Item 3.17: **Do NOT guess.** Each member of the study team, including the PI, must answer this question for you.
- It's okay to leave Funding Source ID and Grant Office ID blank at initial submission.
- Any changes to the *HRP-270 External IRB Review Application* over the life of the study must be sent to the Primary UMMS IRB WIRB Liaison shown on page 1 of this document as changes are made.

TIPS FOR WIRB INITIAL REVIEW SUBMISSION FORM:

Where the WIRB form asks for:	**Choose:**
Submission Source (Type of submission)	Site being added to existing protocol
Protocol Information • To whom are you submitting this application	Western IRB (WIRB) even if the sponsor is working with Copernicus
Company or Company Name	Use one term consistently throughout your application (e.g., UMass-Worcester, UMMS, UMass Med, University of Massachusetts Medical School, UMass Memorial, UMass Memorial Medical Center, UMMMC, UMass Memorial Healthcare, UMMHC)
Training and Experience	Collaborative IRB Training Initiative (CITI), plus any others that may apply
Subject Recruitment • Will the PI or research team receive recruitment bonuses	See *HRP-800 INVESTIGATOR GUIDANCE: Investigator Obligations* 2.15 and 2.16 before answering this question (http://www.umassmed.edu/ccts/irb/investigator-guidance/)
(when applicable) Consent Process – Legally Authorized Representatives • How will you verify who constitutes an LAR in your state?	Other – Explain that you will follow *HRP-021 Legally Authorized Representatives, Children and Guardians* and upload a copy to Connexus along with your description of how you will determine the capacity of cognitively impaired subjects (http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/)
Contact Information	Provide 24 hour contact information unless the

	study is observational
Sites • Are any sites part of an institution that is covered by an OHRP Federalwide Assurance (FWA) for the protection of human subjects? • Have any of those institutions indicated on Section 4.b of their FWA that they voluntarily elect to apply the HHS regulations to all nonexempt human subjects research regardless of the source of support?	• Yes • No
Specific Site Information • Does a local IRB have jurisdiction over this research site?	• No

TIPS FOR CONNEXUS

- **Never hit SUBMIT.**
- To obtain a user name and password, visit https://connexus.wcgclinical.com/Default.aspx
- If you experience any technical issues with Connexus or need assistance while working in the system, use the Live Support Online chat or contact client services by email (clientservices@wirb.com) or phone (306-252-2500 or 800-562-4789). WIRB client services are available from 10am to 8pm ET M-F.
- Prepare the necessary documents described earlier in this document before starting a submission in Connexus.
- Ask the sponsor to invite you to the protocol in Connexus. If the sponsor is not responding, WIRB Client Services can also assist you with an invitation.
- Log in to Connexus. Follow *Quick Access Links/Training* to find downloadable instructions for *Submit New Investigator*, **but ignore all instructions to submit to WIRB.**
- As you follow steps to Submit New Investigator, provide the following answers:
  - *Is this site an Institution or Medical Center? YES*
  - *Submission Types: Select Initial Review*
  - *Would you like to use the online form? NO*
- When you upload documents, be sure to provide the document type. Documents missing document type will be dropped from the submission.

- **DO NOT SUBMIT TO WIRB;** use the save and submit later button to save your submission. Once the documents are uploaded, follow *Quick Access Links/Training* to find downloadable instructions for *Manage Access*.
- Add the UMass WIRB liaisons listed on page 1 of this document as **Site Participants** with **Access Level: Manager** and **Invitee Represents: Institution**. Connexus will automatically send an email notification alerting them that the study is now ready for UMMS IRB review. If you have added someone and cannot see them, make sure you have clicked on the specific investigator site on the Manage Access tab.

UMMS IRB WIRB LIAISON ADMINISTRATIVE REVIEW PROCESS:

- Review the online documents in WCG Connexus application for completeness and accuracy.
- Verify the research injury compensation language.
- Verify that the HIPAA authorization is a stand-alone document.
- Verify the study team has completed all required CITI trainings.
- Email the PI and study contact with any requested changes or clarifications.
- Once all questions are resolved and the submission is ready to be released to WIRB, complete the New Review Cover Letter/Checklist. Upload it to Connexus and submit.
- Email the PI and study contact to let them know that the submission has been released to WIRB.