University of Massachusetts
UMASS Medical School

Reliance on Western IRB (WIRB)
(Updated 03/04/19)

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 facilitates the review of industry sponsored multicenter research, has an agreement with Western IRB (WIRB) whereby the UMMS IRB may rely upon WIRB for IRB review and approval.

In order for the UMMS 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 II or higher 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 UMMS may rely upon WIRB for review of specific research projects, the Institution is still responsible for the conduct of that research. Therefore, the UMMS IRB must be aware of and approve of the submission being sent to WIRB through an administrative review. WIRB will not review any UMMS study prior to UMMS IRB administrative review.

Research studies that do not meet the criteria above will be considered by the UMMS IRB on a case-by-case basis, unless they are Phase I trials. The UMMS IRB will not currently cede review for Phase I trials.

UMMS IRB WIRB LIAISONS:

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BASIC STEPS:

- Email the UMMS IRB WIRB Liaisons and request permission to use WIRB. Provide a copy of the sponsor protocol, the name of the UMMS PI, and a brief description of how the protocol fits the criteria listed above or merits an exception.
- One of the liaisons will verify the status of the sponsor protocol, if necessary, and then email you to let you know if you may proceed. If you are cleared to proceed:

- Request a Connexus account if you do not have one (https://connexus.wcgclinical.com).
- Ask the sponsor, clientservices@wirb.com, or UMMS-WIRB Account Manager Jon Gellert (jgellert@wirb.com) to invite you to the protocol in Connexus and to send you the WIRB approved Sponsor Template ICF. Set the study invite email aside.
- Download the *Initial Review Submission Form PDF* fresh from WIRB. http://www.wirb.com/Pages/DownloadForms.aspx
- Read this guidance document and prepare your materials offline.
- Login to Connexus and select "My Studies." Select the correct study, and then select "Submit New Investigator." Upload your documents into Connexus.
- **Do NOT submit to WIRB.**
- In the study workspace, click on the PI's name. Add **all** UMMS IRB WIRB Liaisons to the workspace in Connexus as **Site Participants** with **Access Level: Manager** and **Invitee Represents: Institution**. This automatically notifies the liaisons that the submission is ready for administrative review and provides the necessary access to the submission.
- One of the liaisons will email you 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 may 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.
    - Email the liaisons with any proposed changes to research injury compensation or conflict of interest declarations before submitting to WIRB. Otherwise, send all subsequent submissions (e.g., modifications, continuing reviews, reportable events) directly to WIRB for review.
    - Email the liaisons with changes in study staff, financial interests related to the research, etc., via an updated *HRP-270 External IRB Review Application*.
    - Email the liaisons when the study closes here at UMass Worcester and notify them of any unanticipated problems involving risks to subjects or others, reports of serious and/or continuing non-compliance, or IRB suspension or termination.

See the following pages for more information:

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 for Initial Review.
- Read through these instructions in full before starting.
- Make sure you are working from the most recent instructions and templates for UMMS and WIRB (including the Template ICF).
- Prepare the necessary documents before starting anything in Connexus.
- Before adding the UMMS IRB WIRB Liaisons to the submission in Connexus:
    - Make sure all study staff have completed the required human subjects, GCP, and COI CITI trainings
    - Make sure all ancillary reviews are complete
- **Use the UMMS research injury language from the consent form template.** WIRB will hold any submission that deviates from the boilerplate.
- These instructions apply to industry-sponsored multi-site trials for which UMMS is being added as a site. If you are seeking to use WIRB in a different context, contact the UMMS IRB liaisons.

LIST OF DOCUMENTS TO PREPARE FOR CONNEXUS

- A PDF version of the *WIRB Initial Review Submission Form*
    - http://www.wirb.com/Pages/DownloadForms.aspx
    - The form includes a place to request a HIPAA waiver
    - The PDF version of the submission form does not require the PI Signature Page

- *HRP-270 External IRB Review Application*
    - http://www.umassmed.edu/ccts/irb/submission/western-irb-wirb/
    - The following CITI trainings must be completed before the form is uploaded to Connexus:
        - Group 1: Biomedical Research Investigators and Key Personnel
        - Conflict of Interest mini-course
        - GCP (when applicable)

- 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.

    - As of January 2019, in accordance with Massachusetts regulations, WIRB may require the PI to hold the CSR in cases where an investigational new drug is or will be administered.

- WIRB approved Sponsor Template Consent form with visible track changes to show UMMS specific information (e.g., add UMMS required research injury compensation language, add compensation)
    - **WIRB will hold any submission that deviates from the UMMS research injury language from the consent form template.**

- HIPAA authorization if not using a compound consent/authorization

- 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)

PREPARING THE HRP-270 EXTERNAL IRB REVIEW APPLICATION FORM:

- 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. Do not check *yes* just because the study is multi-site.
- 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 UMMS IRB WIRB Liaisons shown on page 1 of this document as changes are made.

PREPARING THE WIRB INITIAL REVIEW SUBMISSION FORM:

Where the WIRB form asks for:	**Choose/Indicate:**
Destination Institutional Review Board (IRB)	Western IRB (WIRB) even if the sponsor is working with a different IRB in the list
Submission Type	Site being added to existing protocol or change of principal investigator
Federal Funding	There is nothing to attach. UMMS has an MSA on file with WIRB.
Clinical Pharmacology Unit Services, (CPUS)	No, this is not a submission to WIRB CPU Service
IRB Determinations	NO – WIRB may not issue an exemption YES – WIRB may consider the research to be minimal risk
Principal Investigator (PI) Information/ Company/Institution/Organization	University of Massachusetts Medical School (UMMS) – All research at our site happens under the auspices of the Medical School
Institutional Services	Yes, UMMS has a Master Services Agreement; name of organization is UMMS; WIRB Institution #81969
Principal Investigator (PI) Licensure Are all medical licenses on file with the IRB	NO – this is not a UMMS IRB function
The following questions apply to all research locations	NO – Our communities have a positive attitude NO – UMMS is covered by an MSA NO – There are no state or local laws to mention
Research Team Information	The number and type of personnel must match the HRP-270 form
Research Team Training	Although WIRB may permit options other than CITI, UMMS requirements still apply
Legally Authorized Representatives How will you verify who constitutes an LAR in the legal jurisdiction where the research is conducted?	Institutional Policy – You must follow *HRP-021 Legally Authorized Representatives, Children and Guardians*

	(http://www.umassmed.edu/ccts/irb/policiessops--checklistsworksheets/sop/)
Consent Form Processing Does your organization have pre-approved consent language on file with the IRB	YES – There is required research injury compensation language Start from the IRB-approved template so that you can choose this method and option: The IRB should review the attached forms that have the pre-approved consent language tracked (red-lined) onto the IRB-approved template. Ensure the consent itself or the form provides 24-hour contact information unless the study is observational
HIPAA Waiver of Authorization	A partial or full waiver of authorization will come with the usual requirement for the Principal Investigator to complete the required Accounting of Disclosures (https://www.umassmed.edu/ccts/human-research/privacy-and-security/)
Methods to Maintain Confidentiality	You must adhere to UMMS policy regarding data storage and encryption https://www.umassmed.edu/it/policies-and-guidelines/policies/
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/)
Special Instructions	If you require permission to use short forms to enroll speakers of languages other than English, add this information here

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 8am to 8pm ET M-F.
- Prepare the necessary documents described earlier in this document before starting a submission in Connexus.
- Ask the sponsor, clientservices@wirb.com, or UMMS-WIRB Account Manager Jon Gellert (jgellert@wirb.com) to invite you to the protocol in Connexus and to send you the WIRB approved Sponsor Template ICF.
- 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, click on the PI's name to add the UMMS WIRB Liaisons. 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 the study team has completed all required CITI trainings.
- Verify that all ancillary reviews are complete and documented.
- 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.

WIRB CONTACT INFORMATION:

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