

**Guidance on the Meriter Hospital and University of Wisconsin-Madison
Institutional Review Board (IRB) Partnership**

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What is the Meriter Hospital/University of Wisconsin-Madison (UW) IRB Partnership?

Several UW investigators conduct research that involves patients, samples, or records from Meriter Hospital. In the past, IRB review and approval from both the Meriter Hospital and a UW IRB was required for these studies. In order to assist our researchers and streamline IRB review, the UW and Meriter Hospital have entered into a joint agreement to allow for a single IRB of record (i.e., one institution can defer IRB review to another) between these institutions. This agreement means that for most research conducted by UW employees or students involving Meriter Hospital patients (or their records or samples) will now be reviewed by a single IRB (i.e., Meriter or a UW Health Sciences IRB). There will still be some cases when both the Meriter IRB and a UW IRB will need to retain oversight of a research study and researchers will then need to submit their proposals to both IRBs or cases where researchers will need to obtain approval from other IRBs in addition to a UW or Meriter IRB.

Which UW IRBs are covered by this agreement?

Currently, only studies submitted to the UW Health Sciences IRB and Health Sciences Minimal Risk IRB are covered by the agreement with Meriter Hospital. The UW Social & Behavioral Sciences IRB and Education IRB are not part of this initiative at present.

Which studies fall under this agreement?

Any non-exempt human subjects research conducted by employees and students under UW purview that has not yet undergone IRB review and involves Meriter Hospital patients (or their records or samples) may qualify for review by a single IRB. The following projects do not qualify for consideration of IRB deferral between UW and Meriter because they are likely to qualify for exemption and are best handled internally by each institution:

- projects that do not constitute research (e.g., quality assurance initiatives)
- projects that do not involve human subjects

Which IRB is likely to serve as the IRB of record?

The table below provides an overview of which IRB would be expected to review and maintain oversight of a research project and identifies situations when dual IRB review may still be necessary. Decisions will be made on a case-by-case basis and both institutions reserve the right to retain IRB review of a project even if listed in the chart below as one likely to be deferred to another institution.

Characteristic of Study	Meriter Review	UW HS-IRB/MR-IRB review	Both institutions review	Notes
all subjects recruited, medical records used, or study activities occur at Meriter	X			
retrospective chart review, including Meriter records & UW/UWHC/UW MF records*	X			*Access to UWHC records and HealthLink records may be reviewed by the Meriter IRB only when the PI is a UW

Characteristic of Study	Meriter Review	UW HS-IRB/MR-IRB review	Both institutions review	Notes
				health sciences faculty member and the same access is being granted to Meriter records as to UWHC and HealthLink records.
studies limited to the use of discarded specimens collected for clinical purposes from Meriter and UW/UWHC/UWMF patients, except tissues collected for creation of Induced Pluripotent Stem (IPS) cell lines and gametes	X			Use of discarded specimens from UWHC patients must also be approved by the UWHC Pathology department, unless exempt under UWHC Policy #7.01(IV)
studies limited to collection of biological specimens through venipuncture or noninvasive means for research purposes from Meriter and UW/UWHC/UWMF patients unless for the creation of embryonic stem cell lines or IPS cell lines	X			
studies involving collection of data through noninvasive procedures routinely employed in clinical practice (except x-rays, microwaves, or devices not cleared/approved for marketing) that involve Meriter and UW/UWHC/UWMF patients	X			
research involving subjects drawn from Meriter Child & Adolescent Psychiatry Unit, or Meriter Addiction Medicine and no drug or device is involved	X			If study involves investigational drugs or devices, deferral to Meriter by UW unlikely
studies involving the testing of investigational drugs or devices			X	Decision as to whether deferral would be granted depends on where drugs are administered or devices implanted; IRB of record likely to be the committee that has purview over the site at which the administration or implantation occurs
studies, other than those noted above, that involve UW/UWHC/UWMF patients, records, or facilities		X		
donations of embryos for research purposes involving Meriter and UW/UWHC/UWMF patients or research involving embryonic stem cells		X		
collection of tissues for the creation of IPS cell lines		X		

Characteristic of Study	Meriter Review	UW HS-IRB/MR-IRB review	Both institutions review	Notes
creation and maintenance of tissue banks or databases for research purposes that involves samples and/or data from both Meriter and UW/UWHC/UWMF patients		X		
epidemiological research that includes subjects from Meriter and UW/UWHC/UWMF		X		
multi-site research that involves institutions or clinical practices beyond those that fall under UW or Meriter purview		X		Unless UW's involvement in the research is limited
research involving prisoners		X		
research involving the Madison VA		X		

How do I initiate a request for consideration under the Meriter Hospital/University of Wisconsin-Madison (UW) IRB Partnership?

After reviewing the table above to determine the IRB most likely to serve as the reviewing IRB for a study, the principal investigator submits a formal request to that IRB Office. Please see the *Instructions for Requesting Deferral of IRB Oversight* posted at: **XXX**. These instructions will walk you through the process.

Before the IRB Office from the deferring institution finalizes approval of the deferral, it will ensure that relevant institutional requirements are met, such as conflict of interest and other institutional approvals.

If the UW defers IRB review to Meriter Hospital, is the project excused from scientific review?

If the project would otherwise be required by the UW Health Sciences IRBs to undergo scientific review by the Institute for Clinical & Translational Research (ICTR) Scientific Review Committees (SRCs) or UW Comprehensive Cancer Center Protocol Review & Monitoring Committee this requirement will not be waived if the UW agrees to defer IRB review to Meriter Hospital. The ICTR SRCs have agreed to review appropriate studies on Meriter Hospital's behalf.

Which consent form template should I use?

Consent documents should be created based on the template provided by the expected IRB of record. In future, a joint consent document may be developed. The UW requires certain wording to be included in consent forms, particularly specific compensation for injury language. Please review the UW consent form requirements at the following link to help ensure your documents meet institutional standards: <http://info.gradsch.wisc.edu/research/hrpp/hsirbs/hs.InformedConsentAndRecruitment.html#additrequiredlang>.

Which HIPAA authorization form template should I use?

If the research falls under the HIPAA Privacy Rule requirements and an authorization form separate from a consent form is used, the HIPAA documents should be created

based on the template provided by the expected IRB of record. The UW has a program that assists research teams in creating HIPAA authorization forms available at <https://rcr.gradsch.wisc.edu/cfwauth/start.asp?wisc>.

Which human subjects training is required?

Both UW and Meriter require personnel engaged in human subjects research complete training modules within the CITI system. The institutions differ, however, in their specific training requirements. Currently, UW employees and students are required to complete the CITI training modules designated under campus policy (see guidance at <http://www.grad.wisc.edu/hrpp/10010.htm>).

Who do I contact if I have questions about this process?

For submissions to Meriter Hospital, contact Liz Michaels, Institutional Review Board Coordinator, Meriter Hospital, at (608) 417-6411 or LMICHAELS@meriter.com.

For submissions to the UW Health Sciences IRBs, contact the IRB Submission Specialist at 265-2304.