HS-IRBs News

Health Sciences and Minimal Risk IRBs

ADDRESS
University Bay Office Building (UBOB)
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OFFICE HOURS
Monday through Friday
7:45 a.m. to 4:30 p.m.

QUESTIONS?
Please call the IRB Main Office at 608-263-2362 The HS-IRBs Office has an expert staff person available every weekday to answer questions about the IRB review process.

ARROW HELPLINE
For help with ARROW, please call 262-0041.

GENERAL EMAIL
Email general queries to: asktheirb@medicine.wisc.edu

ARROW EMAIL
Email ARROW questions and training requests to: askarrowirb@medicine.wisc.edu

TWITTER
@UW_HS_IRB

REMINDER: All study teams will begin using ARROW (the new electronic submission and review system for the HS and MR IRBs) on November 17, 2010.

Upcoming HS-IRBs Office Closures
The HS-IRBs office will be closed on the following days this November and December:

November 25th (University Holiday)
November 26th (Mandatory Furlough Day)
December 24th (University Holiday)
December 30th (Mandatory Furlough Day)
December 31st (University Holiday)

Modified ARROW Helpline Hours for December 23rd
In addition to the dates noted above, the ARROW helpline will not be staffed the afternoon of 12/23.

REMINDER: Early Deadline for Continuing Reviews
Due to the holidays, the deadline for submitting continuing review applications for the 12/13 HS-IRB meeting is Wednesday, November 24th.

ARROW Mini Quick-Start Training and Open Lab Sessions
The HS-IRBs will be offering brief introductions to ARROW for those who did not attend training earlier this fall. These sessions will be held in the HSLC computer lab, with open lab time to follow for those who want assistance with using ARROW or just want to try out the system.

Mini quick-start sessions will be offered in HSLC 2121 on:

- December 13th from 10-11:30AM
- January 12th from 2-3:30PM
- January 17th from 10-11:30AM

Space is limited, so registration for these sessions is required. To register, please email your request to askarrowirb@medicine.wisc.edu. Be sure to include the date for the session you wish to attend.

UPDATE: UW-Madison HRPP Five Year Renewal Policy
Important guidance about how the campus Five Year Renewal policy will be implemented in conjunction with final rollout of ARROW has been posted to the HS-IRBs website. The guidance explains what studies will be affected by the five year renewal policy as well as how study teams will be informed about the need to submit a replacement study. For details, please review the Five Year Renewal Policy and Replacement Studies in ARROW guidance posted on the Policies and Guidance page of the HS-IRBs website.

ARROW Small-Group Demonstrations Will Resume in 2011
Research groups wanting a more detailed introduction to ARROW may request a small-group demonstration. **NOTE: No small-group demonstrations will be offered for the remainder of 2010. Slots for small-group demos will again be available in January 2011.** Requests for demonstrations should be emailed to askarrowirb@medicine.wisc.edu.

ARROW Tips

- ***Submit Legacy Applications 2 months prior to expiration of IRB approval***
  Study teams should allow additional time to prepare legacy applications and for the IRB to review these applications. The HS-IRBs Office will work to ensure that legacy applications are approved before IRB approval for a study expires. Legacy application submitted less than 1 month prior to expiration of IRB approval, however, will NOT be prioritized over legacy applications already received.
- ***Changes of protocol must be submitted in paper until a study is approved in ARROW***
  Until the first continuing review is approved for a legacy study in ARROW, continue to use the paper process for submitting changes of protocol and reportable events for that study. After continuing review is approved for a legacy study, all further actions for that study will be submitted through ARROW.
- ***New ARROW FAQ: How to Complete Changes of Protocol***
  The process for completing changes of protocol in ARROW is different from the process for completing change of protocol in paper. When preparing a new change in ARROW, please review the FAQ on How to Complete Changes of Protocol for step by step instructions.

Guidance on When to Select the Non-Exempt Medical Records Application Type
The second section of the new IRB application form in ARROW allows study teams to select the most appropriate application type for their study. The Initial Review: Non-Exempt Medical Records application type must be used **only** for studies involving the collection of medical information from medical records (including radiological imaging records) and databases or follow-up medical information from the research subject. Do NOT select Initial Review: Non-Exempt Medical Records for studies involving any other activities, such as medical procedures, tissue analysis, the creation of a research database, or if the researcher is serving as a reading center, statistical analysis center, or core lab. If study activities are not limited to the collection of medical information from medical records/databases of follow-up information from research subjects, the Initial Review Application: Full Review option must be selected.

VA Update
The Veterans Health Administration recently released a new 1200.05, the handbook that describes the VA's requirements for the protection of human subjects research. The new handbook contains a number of changes affecting VA research that will be implemented over the next six months.

One of the changes in the new handbook is the removal of the general requirement for a witness to sign a VA consent form. The Madison VA is immediately removing the requirement for a witness signature line on informed consent forms, except in cases when the IRB determines a witness signature is required. For example, a witness signature is required when a participant lacks the capacity to provide informed consent and a legally authorized representative must the consent document instead.

The Madison VA has conveyed to the Health Sciences IRBs that new protocols will no longer be required to have a witness to the subject signature. As of now, any new protocols coming through the R&D committee will not need a witness signature line unless specifically required by the IRB. Protocols already approved by the IRB that have consent forms requiring witness signatures will still need to have the forms signed by a witness. Previously approved research that was approved with a witness signatures requirement must submit a formal change of protocol prior to removal of the witness signature line. While a research team is using approved consent forms that have signature lines, they must continue to have a witness sign the consent form.

Have questions? The HS-IRBs staff are here to help!
Whether you have a question about a specific protocol, a general question about the submission process, or need clarification about research policy, we have several ways you can reach us.

1. **For general questions**, email asktheirb@medicine.wisc.edu. Please note that this service is for general questions ONLY and no attachments should be included. Turnaround time is typically 2 business days.
2. **For questions about ARROW**, email askarrowirb@medicine.wisc.edu or call the ARROW helpline at 262-0041.
3. **To discuss your question with an IRB staff reviewer**, please call the main HS-IRBs office at 263-2362 and ask to speak with the staff reviewer on call for the day. Please note that IRB staff do not have pagers. If leaving a message, please clearly leave your name, number, and department so we can get back to you in a timely manner.
4. **To receive the newsletter and other IRB updates**, please sign up for the general HS-IRBs listserv. To receive listserv announcements, you MUST subscribe to the listserv by emailing join-hs_irbs_announcements@lists.wisc.edu.
5. **To receive updates about WIRB**, please sign up for the WIRB listsserv by emailing submitwirb@medicine.wisc.edu with a request to be put on the list.
6. **To arrange a free consultation with an IRB staff reviewer**, ICTR members should contact Mike Bates (bates3@wisc.edu or 262-7657). Other researchers should contact Molly Lumley (mah@medicine.wisc.edu or 265-2304). Although not part of the official review and pre-review process, consultations are a convenient way to obtain expert assistance and advice regarding IRB submission and review. Researchers new to the IRB submission process may particularly benefit from the consultation service.
7. **For more frequent IRB updates**, follow the HS-IRBs on Twitter @UW_HS_IRB.

NOTE: You are receiving this email because you are subscribed to the UW-Madison HS-IRBs listserv. To unsubscribe from this listserv, please email leave-hs_irbs_announcements@lists.wisc.edu.