



HS-IRBs News

Health Sciences and Minimal Risk IRBs

ADDRESS

University Bay Office
Building (UBOB)
Suite 105
800 University Bay Dr.
Madison, WI 53705
Ph.: 608-263-2362
Fax: 608-265-5811

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 must use ARROW for all new IRB submissions and most continuing reviews. Please see [the ARROW page](#) on the HS-IRBs website for more information.

Upcoming HS-IRBs Office Closure

The HS-IRBs office will be closed on Monday, January 17th for a university holiday. The ARROW helpline also will not be staffed on January 17th.

ARROW Mini Quick-Start Training and Open Lab Sessions

The HS-IRBs are offering brief introductions to ARROW. 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:

- January 18th from 2-3:30PM
- February 7th from 10-11:30AM
- February 16th 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. Please include the date for the session you wish to attend.

ARROW Small Group Demonstrations for 2011

Research groups wanting a more detailed introduction to ARROW may request a small-group demonstration. Requests for demonstrations should be emailed to askarrowirb@medicine.wisc.edu. Please note that slots for demonstrations are limited, so please submit your requests as soon as possible.

REMINDER: 2011 Meeting Dates

Meeting dates for both the HS and MR IRBs have been posted on [the Meeting Dates page](#) of the HS-IRBs website.

UPDATE: Guidance on When to Select the Non-Exempt Medical Records Application Type: Radiological Imaging

As mentioned in the November HS IRBs newsletter, 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 and use of medical information from medical records and databases, including studies analyzing radiological images collected for medical purposes. However, do NOT select Initial Review: Non-Exempt Medical Records for studies involving use of clinical images to test newly developed imaging software or tools. If study activities include using the images to test new software or imaging tools and are not limited to re-reading of radiological images, the Initial Review Application: Full Review option must be selected.

How to Update the Point of Contact for Legacy Studies in ARROW

To update the point of contact for existing studies that have been migrated in to ARROW (also called legacy studies) AND for which the continuing review has not yet been approved in ARROW, study teams should use one of the following options:

Option 1: If the new point of contact is already listed as key personnel in the IRB file (e.g., on the list of key personnel in the continuing review application or initial review application, whichever is most recent), email the requested update to askarrowirb@medicine.wisc.edu. Be sure to include the IRB protocol number in the subject line.

Option 2: If the new point of contact is NOT already listed as key personnel in the IRB file, submit [a personnel change form](#) in paper to the HS-IRBs office.

After the request or personnel change form has been reviewed and approved, the HS-IRBs office will then update the POC in ARROW.

NEW: Community-Based Research Working Group

The Health Sciences IRBs Office continues to see an increase in community-based and type 2 translational research requiring IRB review and oversight. This type of research can pose unique regulatory challenges. As a result, the HS IRBs Office has formed a working group that will focus on improving the HS IRBs review processes for community-based research that involves health care interventions or occurs in health care settings. The working group consists of individuals from the research community with varying expertise in community-based research as well as representatives from the HS IRBs office. In the coming year, the working group has plans to solicit feedback from the research community regarding the IRB review process for community-based research. Updates on the progress of the working group and opportunities for providing feedback will be included in future newsletters.

Updates to the Protocol Exceptions and Deviations Reporting Guidance

The HS-IRBs will issue updated guidelines for research teams regarding the reporting of protocol “exceptions” and “deviations” to the IRB, which will replace the guidelines first issued March 31, 2003. The new guidelines will be posted on the HS IRBs website on the “Policies and Guidance” page by January 24, 2011 and a link will be included in the February newsletter. The Health Sciences IRBs recognize that research teams cannot always adhere to protocol requirements and developed these guidelines to clarify the threshold for reporting deviations to the IRB.

If you have any questions about the new guidelines, whether a deviation falls under these guidelines, or whether the divergence from the protocol instead constitutes a change of protocol, noncompliance, or an unanticipated problem, please contact the Health Sciences IRBs Office at 608-263-2362.

Multisite Webpage Updates

Several new FAQs have been posted to [the HS-IRBs multisite webpage](#), including guidelines for IRB of record and IRB deferral requests as well as how to submit IRB of record and deferral requests in

ARROW. Additional revisions to the multisite webpage will be made in the coming weeks and will be announced in future newsletters. If you have suggestions for information you would like to see posted to the multisite webpage, please email them to Carol Pech at cap@medicine.wisc.edu.

Legacy Application Tips

- To enter a legacy application in ARROW, first search for the IRB protocol number to locate the record for that study in ARROW. Do NOT create a new IRB application to enter a legacy study.
- Legacy studies must be submitted **2 months** prior to the expiration of IRB approval.
- If you need to submit a change of protocol while a legacy application is under review, please contact the HS-IRBs office first for guidance.
- For additional guidance on preparing legacy applications, several FAQs and guidance are posted on [the ARROW page of the HS-IRBs website](#).

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.