



HS-IRBs News

Health Sciences and Minimal Risk IRBs

ADDRESS

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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

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:

- February 16th from 10-11:30AM
- March 23rd from 2-3:30PM

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.

Upcoming Human Research Protection Seminars

As part of the Graduate School's human research protections seminar series, HS-IRBs and Legal Services staff will be giving presentations on reportable events, community-based research, and FDA regulations later this month. Registration is required and is available through [the OHRD catalog](#).

- **Understanding Reportable Events: What Needs to Be Reported to the IRB and When** with Jessica Johnson on February 8, 2011 from 1:00-2:30 in HSLC 1345
- **Community-Based Research and the IRB Review Process** with Staci Taylor Lowe, PhD and Carol Pech, PhD on February 16, 2011 from 1:00-2:30 in 1309 HSLC
- **FDA Regulations in Human Subjects Research** with Lisa Wilson, JD, on February 25, 2011 from 1:30-3:00 in 1309 HSLC

ICSC IRB Drop Box Feedback

The December newsletter included an announcement that the HS-IRBs would eliminate its drop box in ICSC as of March 2011. If your study team would like the ICSC drop box to be retained past March 2011, please email asktheirb@medicine.wisc.edu with your feedback. If enough demand for the drop box exists, arrangements will be made to keep it in place for an additional period of time.

UW Health Sciences Institutional Review Boards ♦ Visit us online at: <http://www.medicine.wisc.edu/irb>

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Continuing Review Application Tip: Data Analysis and Long-Term Follow-Up

When completing the continuing review application in ARROW, be sure to select the correct status for your study on the Study Design: Continued page. Please keep the following guidance in mind when selecting either the data analysis or long-term follow-up option:

- Activities for studies in data analysis must be limited to analysis of data already collected for the study. **Do NOT select the data analysis option if sample analysis (e.g., analyses of tissue) or any other study activity is ongoing.** Tissue or specimen collections studies should select data analysis ONLY after all tissue/specimen analysis is complete and analysis of data alone is ongoing.
- Activities for studies in long-term follow-up should be limited to long-term follow-up of subjects who have completed all other study interventions. Long-term follow-up typically applies only to clinical trials. Observational studies that follow subjects for long periods of time should NOT select the long-term follow up option.
- Select the data analysis option for studies migrated in to ARROW (i.e., legacy studies) ONLY if a) the study's activities are limited to analysis of data already collected for the study and b) no future changes (apart from personnel changes) to the study are expected. NOTE: Study teams will NOT be able to submit any changes other than personnel changes for legacy studies that are in data analysis. Study teams will need to submit a new initial review application if changes other than personnel are required, so please use care when selecting the data analysis option.

NEW: Uploading the CTRC Application in ARROW

When preparing a new IRB application for a study that will use the CTRC, please upload a copy of the CTRC application in the Submit activity form. The Submit activity form is visible when clicking the Submit link on the left-hand side of the submission workspace. The Submit activity form includes instructions on where to upload the CTRC application. **Do NOT upload the CTRC application within the IRB application itself.** A FAQ about this process will be posted soon and a link will be included in a future newsletter.

How to Find Personnel in the Pop-Up Lists in ARROW

If you are having trouble locating someone in the pop-up lists in ARROW, it may be because that person does not have a netID or has not yet logged in to ARROW. For help with getting personnel entered in to ARROW, please see [the FAQ on How to Find Personnel in ARROW](#).

NEW: Protocol Exceptions and Deviations Guidance

As mentioned in the last month's newsletter, the HS-IRBs have issued revised guidelines for research teams regarding the reporting of protocol "exceptions" and "deviations" to the IRB. The new guidelines are now posted [on the HS IRBs website](#). 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 Jessica Johnson at 608-263-0835.

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.