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Please note that this is an overview only. The HSO website (available at <http://researchcompliance.iu.edu/hso/index.html>) is the best source of information about working with our office. In addition, HSO staff is always available to answer questions and guide you through the process. Please don't hesitate to contact one of us directly.

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About the Human Subjects Office (HSO)

The IU Human Subjects Office is the administrative office which supports the Indiana University IRBs. The HSO is a Department within the Office of Research Compliance, which is a Division of the Office of the Vice President for Research. The HSO administers the human research protection program (HRPP) at IU. IU's HRPP, which will include the regional campuses effective July 1, 2015, is accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP uses a voluntary, peer-driven educational model to ensure HRPPs meet rigorous standards for quality and human subjects protection. IU's HRPP has been accredited since 2008.

The HSO includes about 30 staff members who support more than 5,000 active human subjects studies and seven IRBs. HSO staff are experts in human subjects protections, and about half have achieved the Certified IRB Professional certification. Staff is divided into three teams, each of which serves a specific set of IU departments. Each department is assigned to a designated staff member who serves as the main contact for that department. Team assignments are listed on page 7.

Review timing

The HSO is committed to ensuring human subjects are protected while employing an efficient review process. You can expect that items submitted to the HSO are reviewed by an HSO staff member within 5 business days of a complete submission. The HSO publishes its metrics in regards to turnaround times and throughput, and these are available at http://researchcompliance.iu.edu/hso/hs_data.html. Please note that an efficient IRB review process is a joint effort between the HSO and study teams. Please review the remainder of this document for more information about your role in ensuring a smooth review.

KC IRB

HSO utilizes a web-based system called KC IRB for entry and management of IRB submissions. **All IRB submissions, with the exception of Closeout Reports, are submitted to the HSO via KC IRB.** HSO uses KC IRB for all aspects of the submission and review process, including communication of revision requests and approvals.

Beginning July 1, 2015, you will use KC IRB to:

- Make all submissions to the HSO
- Complete the IRB application
- Review comments and requested revisions from HSO staff and IRB members, and submit responses and revisions during the pre-review process
- Receive notification of approval
- Retrieve approval information and view approved study documents

The KC IRB Questionnaire Tab utilizes 'smart-form' functionality which allows you to complete IRB applications almost solely within the KC IRB system. As you work from the top of the Questionnaire Tab to the bottom, additional questions are displayed based on previous responses, ensuring that only the questions the IRB needs to review in the application are answered.

Notifications, including approvals and renewal notices, are sent to investigators via the OneStart Action List and, from there, are delivered to the IU-provided email address affiliated with their IU computing account. More information about KC IRB notifications and retrieving your study documents is available on the HSO website at http://researchcompliance.iu.edu/hso/hs_post_approval.html.

Step-by-step instructions for using KC IRB (accessing, submitting, retrieving documents, etc.) are available online at http://researchcompliance.iu.edu/hso/hs_elearning.html. You are encouraged to download the relevant training guide. HSO staff will also be providing KC IRB training at the regional campuses in the fall and are available to guide you through the system via phone at any time. You may also request one-on-one training or training for your entire department by contacting Sara Benken (see below).

KC IRB is accessible via the [Onestart](#) Services tab < Kuali Coeus (KC) < KC IRB.

Your HSO Contacts

Each IU department is assigned to an HSO team and then to an individual HSO staff member. This staff member serves as the main contact for that department and should be your first line of contact with any questions regarding submissions, process, etc. Since much of the research conducted at the regional campuses is social/behavioral/educational research, it is likely that most regional studies will be assigned to Team 3; however, some research, such as nursing, may be reviewed by Team 2. Please see page 7 for specific information regarding team and staff assignments.

Contact information for Team 3 is as follows:

Name	Title	Phone
Baker, Senta	Research Compliance Associate	(812) 855-0945
Benken, Sara	Associate Director	(812) 856-3753
Blackburn, Marlise	Research Compliance Consultant	(812) 856-2487
Mills, Adam	Research Compliance Associate	(812) 856-4687
Moran, Sharon	Compliance Assistant	(812) 856-7357
Mumaw, Casey	Research Compliance Consultant	(812) 855-1741

If you cannot reach your staff member, or have additional questions/concerns, please don't hesitate to contact a member of the management team.

Shawn Axe, CIP
Senior Associate Director
saxe@iu.edu
(317) 278-9211

Amy Waltz, CIP
Associate Director, Team 2
acthurst@iu.edu
(317) 278-5431

Beth Johnson, CIP
Associate Director, Team 1
bwinnie@iu.edu
(317) 278-7831

Sara Benken, CIP,
Associate Director, Team 3
slbenken@iu.edu
(812) 856-3753

Previously-Approved Research

The HSO will not require that research previously approved by a regional campus IRB be re-reviewed. All research activities may continue as usual, but the process to make ongoing submissions to the IRB will change as described below.

Exempt Research

- Exempt research does not require annual review and may continue until completed. Since additional review is not required, exempt studies will not be entered into the KC IRB system at this time.
- Minor changes may be made to exempt studies without prior IRB/HSO review and approval, given that they do not change the nature of the research. Please review the [HSO guidance on Exempt Studies](#) for more information or contact your HSO staff member if you have questions about submitting an amendment to an exempt study.
- Upon completion of an exempt study, investigators may send an email notifying the HSO that the study is closed to irb@iu.edu.

Expedited and Full-Board Research

- All previously-approved expedited and full Board studies will be entered into KC IRB and may be accessed in the system by the study teams beginning July 1, 2015 (if not earlier).
- Expedited and full-Board research must receive annual review prior to the expiration date provided by your campus IRB. Investigators will receive a renewal notification from the KC IRB system approximately 60 days prior to expiration and. Information about study renewal is available on the website at http://researchcompliance.iu.edu/hso/hs_renewals.html.
- Upon receipt of the notification, investigators will need to [submit a renewal via KC IRB](#) which will prompt the HSO to begin the annual review process.
- Any [amendments](#) to expedited and full Board research must be submitted to the HSO via KC IRB for IRB approval prior to implementation.
- Upon study completion, investigators should send an email, attaching the Closeout Report, to irb@iu.edu.

Before You Submit

The HSO has several submission requirements which must be met before a submission will be considered complete and ready to be reviewed by HSO staff. **These requirements must be complete before a submission will be processed by HSO.**

- The PI identified in KC IRB must be eligible to serve as principal investigator. Students, residents, and fellows are not eligible to serve as PI and must have a faculty advisor serve as the PI of record; however, students should be listed as co-Principal Investigator (Co-PI, Student, Resident) in the KC IRB system.
- The PI and all key personnel and non-key personnel must be listed in KC IRB on the Personnel tab.
 - Key Personnel are those investigators responsible for the conduct and/or reporting of research. Such individuals may include, among others: investigators making critical decisions regarding eligibility of subjects, investigators obtaining consent for greater than minimal risk research, investigators listed on the FDA 1572 form or investigator agreement, and students who have designed and are conducting research in order to complete an education requirement under the mentorship of a principal investigator.
 - Non-key Personnel include any investigator who conducts research procedures under the direction of the principal investigator or key personnel, but who are not considered responsible for the conduct and/or reporting of research.
- The PI, key personnel, and any non-key investigators who are interacting with subjects must complete the required CITI educational modules. The CITI modules are the same at all campuses and are accepted for five years after completion.
- The PI and all key personnel are required to complete the IU annual conflict of interest disclosure form.

More information regarding these requirements is available at http://researchcompliance.iu.edu/hso/hs_inv_req.html.

Level of Review

Before submitting your IRB application, it's important to know the required level of review (exempt, expedited, or Full Board) so you can choose the appropriate option in KC IRB. Levels of review applied by the HSO may be slightly different than the level of review which would have been applied by your previous IRB, so investigators are encouraged to utilize the protocol decision tree tool located on our

website at http://researchcompliance.iu.edu/hso/hs_level_review.html or contact an HSO staff member prior to submission. Please note that inclusion of a vulnerable population, e.g. children, or research on a sensitive topic does not necessarily result in a higher level of review.

If you are submitting exempt research, please take a few moments to review our guidance available at http://researchcompliance.iu.edu/hso/hs_exempt.html.

The Submission Process

All IRB submissions, with the exception of Closeout Reports, are submitted to the HSO via KC IRB. For each submission (e.g. new study, amendment, renewal), you should complete the following:

- Create an entry in KC IRB.
- Complete the associated questionnaire. Please be sure to read all questions carefully and provide thoughtful and complete responses to all questions. As part of the conversion from our previous forms to the questionnaire, a new tool called the Crosswalk was created for navigating the questionnaires and completing the IRB application. The Crosswalk is available on the HSO website [Policies & Guidance](#) page. You are encouraged to download the Crosswalk document before submitting a new study.
- Use the Notes & Attachments tab to provide additional study information to the HSO. For example, you should upload any recruitment materials, informed consent statements/study information sheets, data collection tools, surveys, and protocols/study plans. Ensure the information in uploaded documents is consistent with the information you provide in the questionnaire.
- Take the Submit for Review action in KC IRB. This action notifies the HSO that your submission is ready for review.

The Pre-Review Process

After a submission is received via KC IRB, HSO staff ensures that all submission requirements are complete (see section “Before You Submit above”); if so, the submission is assigned to an HSO staff member, or screener, for review. The screener performs pre-review on the study by reviewing all the information you’ve submitted and making sure the submission is complete, complies with all relevant laws and regulations, and is in an approvable state. The screener will also make sure that you’ve submitted all the documents that you need to for your study.

If the screener notices any problems with your submission, you will receive a notification from OneStart directing you to log in to KC IRB to review and address the screener’s comments. In order to ensure an efficient review process, you are requested to respond to the screener’s requests within 14 days or your submission may be withdrawn. If your submission is withdrawn for lack of response, you may resubmit at any time.

Final Review

Once pre-review is complete, the submission is ready for final review. Exempt studies may be reviewed and approved by qualified HSO staff members. Expedited studies are reviewed by an IRB member, and full Board submissions are assigned to the next available IRB meeting for review. Any requests from the Board are communicated back to the study team immediately after the meeting.

Upon approval, you will receive a notification from KC IRB via OneStart. The notification will instruct you to log in to KC IRB to retrieve your approved documents. More information about KC IRB notifications and retrieving your study documents is available on the HSO website at http://researchcompliance.iu.edu/hso/hs_post_approval.html.

Additional Resources

- Human Subjects Office Website: <http://researchcompliance.iu.edu/hso/index.html>
- KC IRB Training Guides: http://researchcompliance.iu.edu/hso/hs_elearning.html
- REDCap: <https://www.indianactsi.org/redcap>
 - Easy-to-use research data collection and sharing tool
 - Free to all IU investigators



INDIANA UNIVERSITY

Human Subjects Office

Service & Support Teams

Team 1

Bethany Johnson

Associate Director, + CIP

Kara Brocious + CIP

Kanti Crain + CIP

Michele Garvin

Danielle Giltner + CIP

John Henry

Theresa Joyce

Heather Mullins-Owens + CIP

Avril Pitt

Sherri Ream

- Adolescent Medicine—**Danielle/Kanti**
- Critical Care/Allergy—**Danielle/Kanti**
- Developmental Peds—**Danielle/Kanti**
- Endocrinology—**Kanti/Danielle**
- Gastroenterology—**Kara/John**
- Hematology/Oncology—**John/Heather**
- Infectious Diseases—**Kara/John**
- Nephrology—**Heather/Kara**
- OB/GYN—**Kanti/Danielle**
- Neonatology—**Danielle/Kanti**
- Peds Hem/Onc—**John/Heather**
- Peds Intensive Care—**Danielle/Kanti**
- Peds Stem Cell Trsplnt—**Heather/John**
- Pulmonary—**Danielle/Kanti**
- Radiation Oncology—**John/Heather**
- Urology—**Heather/Kara**
- VA—**Rick/Heather**

+ can sign exempt studies

*Updated 5/7/15

Team 2

Amy Waltz

Associate Director, + CIP

Marcie Bjork +

Ashlye Brink +

David Brown

Lainna Cohen +

Chantel Colavecchia + CIP

Rick Erny + CIP

Eric Felde + CIP

Maggie French

Kimberly Smith

- Anesthesia—**Eric/Ashlye**
- Biostats—**Chantel/Marcie**
- Cardiology—**Eric/Ashlye**
- Clinical Pharmacology—**Chantel/Marcie**
- Dentistry/Oral Health—**Marcie/Chantel**
- Dermatology—**Chantel/Marcie**
- Emergency Medicine—**Chantel/Marcie**
- Family Medicine—**Chantel/Marcie**
- General Surgery—**Marcie/Chantel**
- Health/Rehab Sciences—**Lainna**
- Internal Medicine—**Ashlye/Eric**
- IUSM—regionals—**Chantel/Marcie**
- Medical/Molecular Genetics—**Marcie/Chantel**
- Microbiology/Immun—**Chantel/Marcie**
- Neurology—**Lainna**
- Neurosurgery—**Lainna**
- Nursing—**Lainna**
- Ophthalmology—**Lainna**
- Optometry—**Lainna**
- Orthopedics—**Marcie/Chantel**
- Otolaryngology—**Eric/Ashlye**
- Pathology—**Chantel/Marcie**
- Peds Health Services—**Ashlye/Eric**
- Peds Hosp Medicine—**Ashlye/Eric**
- Pharmacy—**Chantel/Marcie**
- Physical Med/Rehab—**Lainna**
- Plastic Surgery—**Marcie/Chantel**
- Psychiatry—**Lainna**
- Radiology—**Eric/Ashlye**
- Rheumatology—**Chantel/Marcie**
- Surgery—**Marcie/Chantel**
- Transplant Surgery—**Marcie/Chantel**
- Vascular Surgery—**Marcie/Chantel**
- VA—**Rick/Kara**

Team 3

Sara Benken,

Associate Director, + CIP

Senta Baker +

Marlise Blackburn + CIP

Adam Mills +

Sharon Moran

Casey Mumaw + CIP

- Administrative Offices - **Adam**
- Bioethics - **Adam**
- Center for Evaluation & Education Policy - **Casey**
- Center for Urban Policy - **Casey**
- Centers for Philanthropy - **Adam**
- College of Arts & Sciences - **Adam**
- Criminal Justice—**Senta**
- Economics—**Senta**
- Gender Studies — **Casey**
- Geography—**Senta**
- Global & International Programs—**Adam**
- Herron School of Art & Design - **Adam**
- Jacobs School of Music - **Adam**
- Kelley School of Business - **Senta**
- Kinesiology—**Casey**
- Kinsey Institute - **Casey**
- Maurer School of Law - **Senta**
- Medical Sciences Program - **Casey**
- Psychological & Brain Sciences—**Senta**
- Psychology— **Senta**
- Purdue School of Science—**Casey**
- Robert H. McKinney School of Law - **Senta**
- School of Continuing Studies - **Adam**
- School of Engineering & Technology - **Casey**
- School of Education - **Adam/Casey**
- School of Informatics - **Casey**
- School of Informatics & Computing - **Casey**
- School of Journalism - **Casey**
- School of Liberal Arts - **Adam**
- School of Library & Information Science - **Casey**
- School of Physical Education & Tourism Management - **Casey**
- School of Public & Environmental Affairs - **Casey**
- School of Public Health - **Casey**
- School of Social Work - **Adam**
- Social & Historical Sciences—**Adam**
- Speech & Hearing Services - **Casey**
- Telecommunications—**Senta**
- VA—**Rick/Kara**