

**TRAINING OPPORTUNITY: IRB Updates**

Please join us at one of the following training sessions as we discuss updates to IRB forms and processes.

**Methodist Campus:**  
 Krannert Conference Room E83 (Noyes Pavilion 3rd Floor)  
**May 4, 9-10 am**

**IUPUI Campus:**  
 ROC Auditorium  
**May 5, 8-9am**  
**May 6, 1-2pm**  
**May 6, 4-5pm**

Please note that food and drink is not allowed in the ROC auditorium.

### MOVING FORWARD: NEW FORMS, NEW PROCEDURES

Laws and regulations governing the protection of human subjects are constantly changing, as are best practices for our industry. Research Compliance Administration (RCA) is committed to helping our investigators stay up-to-date with these changes and continue to comply with the ever-changing rules surrounding human subjects research.

Over the past year, RCA staff has collected feedback from both internal and external customers and, as a result of this feedback and recent regulatory changes, has revised its IRB submission forms and procedures. While many of these updates are administrative in nature, there are several major updates to our forms and procedures.

**IRB Submission Process**  
 A new RCA structure described at the bottom of Page 1 requires that the IRB submission process be changed slightly.

Beginning May 11, 2009, all submissions should be made to the particular IRB which has reviewed or will review the research. For full board studies, the principal investigator will make the initial determination regarding the appropriate board based on IRB expertise, and all further items will be submitted to that IRB. Expedited and exempt items will be submitted to a general email box and RCA staff will assign such items to an IRB. Please see page 2 for more information about *Contacting Your IRB*.

To facilitate this new process, all forms have been updated with a check-box for

“Reviewing IRB.” Please choose the appropriate IRB or contact RCA for guidance.

**New Forms**  
 In order to facilitate faster processing, a Co-Investigator Update Form has been added to the list of IRB submission forms. Please use this form when adding or removing co-investigators from the SSS.

RCA has also created a Protocol Template to assist investigators in drafting initial study documents.

**Conflict of Interest Procedures**  
 Conflicts of interest in research continue to be a misunderstood and often overlooked area of compliance in the research world. Institutions around the country are struggling to identify efficient ways to manage disclosed conflicts.

*Continued on Page 2*

### INSIDE THIS ISSUE

Expanding the Scope: Involving Non-Affiliated Investigators in Your Research	2
To Stamp or Not: Understanding Approved Study Documents	3
Contacting Your IRB	3
Upcoming IRB Meetings and Deadlines	4

### MEET YOUR TEAM

The RCA Office has recently restructured the responsibilities of its staff to feature a new “team” structure. In this new structure, each IRB will be supported by a core team of staff consisting of a compliance assistant, a meeting coordinator, and a screener. Investigators can now contact each individual team directly and connect to a core group of people who will be specifically knowledgeable about the studies being reviewed by the respective IRB.

Please see the *Contacting Your IRB* on Page 2 for team contact information.

### MAJOR POINTS

#### AND REMINDERS

- Copy the PI on all communications to the IRB office. Please note that all PI signature lines have been removed from IRB submission forms.
- Download forms each time you make a submission
- Read all forms CAREFULLY
- Use Track Changes
- Contact your IRB team directly
- Update to the newest version of the SSS (v05/01/09)
- Ensure that all conflicts of interest have been disclosed

*Continued from Page 1*

## **MOVING FORWARD: NEW FORMS, NEW PROCEDURES**

This area is of special concern to the IRB. Charged with the protection of human subjects, IRB members must ensure that research participants are fully informed of all financial interests between their study team and the research in order to avoid any perception of impropriety.

In order to facilitate IRB review of conflicts of interest, a special section regarding COI has been added to the SSS. This section asks two major questions: (1) whether any investigators have a potential financial in-

### **EXAMPLES OF FINANCIAL INTERESTS:**

- Stock ownership in the sponsor or manufacturer of the item being studied
- Compensation from sponsor or manufacturer (other than a grant for the conduct of the research)
- Patent or proprietary interests
- Employment

terest which relates to the research, and (2) whether all those interests have been disclosed to and managed by the IUPUI Conflicts of Interest Office.

If the SSS indicates that an investigator has a potential interest relating to the research, two further steps must be taken. First, a financial interest statement must be added to the informed consent document, regardless of the amount or type of the financial interest. IRB-approved language for the financial interest statement has been added to the informed consent template. Second, the investigator must ensure that the IUPUI COI Office has disclosed and managed the conflict.

### **Continuing Review Impacts**

Several of these updates will have a significant impact at time of continuing review.

Most importantly, due to updates to the SSS, all studies which are open to enrollment or are reconsenting

### **Financial Interest Statement:**

*One or more individuals involved in this research might benefit financially from this study. The Institutional Review Board (an ethics committee which helps protect people involved in research) has reviewed the possibility of financial benefit. The Board believes that the possible financial benefit is not likely to affect your safety and/or the scientific integrity of the study. If you would like more information, please ask the researchers or study staff.*

subjects must update to the SSS dated v05/01/09 (the most current version) at time of continuing review. We apologize for any inconvenience; however it is extremely important that this additional information be collected on every study.

New submission forms as well as information regarding the new submission process will be available on the RCA website beginning May 11, 2009. Please familiarize yourself with these forms and feel free to contact RCA staff with any questions or concerns regarding these updates. Please also join us for one of the training sessions listed on Page 1.

## **EXPANDING THE SCOPE:**

### ***Involving Non-Affiliated Researchers in Your Research***

Investigators often need to include external colleagues, experts, or consultants who are not affiliated with IU or Clarian in their research. These non-affiliated investigators may provide data analysis, conduct specific study procedures or even consent and interact with subjects. Follow this step-by-step guide to involving non-affiliated investigators in your research.

1. **Will the nonaffiliated individual be (i) playing a role in the design, conduct, or reporting of the research, (ii) obtaining consent and handling identifiable information, or (iii) making independent decisions about the inclusion or exclusion of participants in the study?**

If so, the individual is considered a non-affiliated investigator and should be listed in Section XXI(C) of the updated SSS. Please complete all fields.

2. **Will the nonaffiliated investigator be directly interacting or intervening with subjects?**

If so, the investigator must either pass the IU human subjects protections test or provide documentation of passing an otherwise-approved test.

3. **Does the nonaffiliated investigator have local IRB approval for the protocol from another IRB?**

Some investigators, such as Purdue faculty members, may have a local IRB which has already approved the protocol. If the nonaffiliated investigator's participation has not been approved by another IRB, the IUPUI/Clarian IRB is responsible for oversight. In such cases, the nonaffiliated investigator must enter into a nonaffiliated investigator agreement. Please see Guidelines for Participation by Non-Affiliated Investigators on the [RCA website](#) for the agreement and additional instructions.

## TO STAMP OR NOT:

### *Understanding Approved Study Documents*

Tracking document versions and remembering which study documents are most current can be one of the most time-consuming and mistake-ridden activities involved in research compliance. In order to alleviate the tracking issues often involved, RCA will now return all approved versions of submitted documents. Here's a reminder of what's what.

#### **Stamped, Secured Documents:**

Documents which are provided to subjects must be stamped by the IRB and are secured to ensure that approved documents are not modified subsequent to IRB approval. These documents are returned in PDF format with an IRB approval stamp at the end of the document, and include informed consent, assent, and authorization documents. (Please note that advertisements are no longer being stamped by RCA.) Only current stamped documents should be presented to potential subjects.

#### **Unstamped, Unsecured Documents:**

All other documents which are submitted to the IRB are returned unsecured without stamps in the format in

which they were submitted. These may include the SSS, protocol, recruitment checklist, and unstamped Word versions of the informed consent, assent, and/or authorization forms. These unstamped documents are considered by the IRB to be the current, approved study documents and should be used only for future IRB submissions. These documents may not be used to consent or recruit subjects, as they are not stamped by the IRB. Doing so will result in a situation of noncompliance.

#### **Tracking Your Changes:**

Unstamped and unsecured documents should be used as the starting point for any updates or changes to study documents. Please remember to use the Track Changes function in Microsoft Word (Tools > Track Changes) to communicate your changes to the IRB. The Track Changes function greatly decreases the time and effort needed to review changes and updates, and helps to decrease IRB turnaround times.

## JOIN YOUR IRB

Ensuring diversity in background and education is extremely important to conducting a well-rounded and successful IRB. RCA is currently reviewing IRB membership for the 2009-2011 term. If you are interested in serving on an IRB, please contact Amy Waltz at [acthurst@iupui.edu](mailto:acthurst@iupui.edu).

## CONTACTING YOUR IRB

If you have a...	Make submissions to...
<b>Submission to IRB-01</b> Research in the behavioral and social sciences	<a href="mailto:irb01@iupui.edu">irb01@iupui.edu</a>
<b>Submission to IRB-02</b> Biomedical research in hematology/oncology, nephrology, infectious diseases, pediatrics, neurology, endocrinology, genetics, and general medicine	<a href="mailto:irb02@iupui.edu">irb02@iupui.edu</a>
<b>Submission to IRB-03 (Methodist)</b> Biomedical research conducted solely or primarily at the Methodist Hospital campus or at a Methodist affiliate site (i.e. the majority of the subjects will be enrolled at Methodist Hospital or a Methodist affiliate site)	<a href="mailto:mhirb@clarian.org">mhirb@clarian.org</a>
<b>Submission to IRB-04</b> Biomedical research in pediatrics, hematology/oncology, dentistry, cardiology, psychiatry, surgery, OB/GYN, and general medicine	<a href="mailto:irb04@iupui.edu">irb04@iupui.edu</a>
<b>Submission to IRB-05</b> Biomedical research in infectious diseases, pediatrics, ophthalmology, radiology, hematology/oncology, gastroenterology, psychiatry, surgery, endocrinology, and general medicine	<a href="mailto:irb05@iupui.edu">irb05@iupui.edu</a>

If you have a...	Make submissions to...
<b>Submission to IBC or BHC</b>	<a href="mailto:ibcbhc@iupui.edu">ibcbhc@iupui.edu</a>
<ul style="list-style-type: none"> <li>• <b>New expedited protocol</b></li> <li>• <b>Submission for exempt review</b></li> <li>• <b>Submission for NCI CIRB facilitated review</b></li> <li>• <b>Application for Research Not Subject to FDA or Common Rule</b></li> <li>• <b>Application for Non-Research Student Projects</b></li> </ul>	<a href="mailto:irbexp@iupui.edu">irbexp@iupui.edu</a>
<b>General Question</b>	<a href="mailto:resrisk@iupui.edu">resrisk@iupui.edu</a>
<b>Submission for review via the WIRB facilitated review process</b>	<a href="mailto:iuwirb@iupui.edu">iuwirb@iupui.edu</a>

# UPCOMING IRB MEETINGS & DEADLINES

## MAY 2009

Sun	Mon	Tue	Wed	Thu	Fri	Sat
					1 IRB-01 Meeting IRB-04 Deadline	2
3	4	5 IRB-03 New Study Deadline	6	7	8 IRB-05 Deadline	9
10	11	12 IRB-02 Meeting	13	14 IRB-03 Meeting	15	16
17	18	19 IRB-04 Meeting	20	21	22 IRB-01 Deadline IRB-02 Deadline	23
24	25	26 IRB-03 Deadline	27 IRB-05 Meeting	28	29 IRB-04 Deadline	30
31						

## JUNE 2009

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	1	2 IRB-03 New Study Deadline	3	4	5 IRB-01 Meeting IRB-05 Deadline	6
7	8	9 IRB-02 Meeting	10	11 IRB-03 Meeting	12	13
14	15	16 IRB-04 Meeting	17	18	19	20
21	22	23 IRB-03 Deadline	24 IRB-05 Meeting	25	26 IRB-01 Deadline IRB-02 Deadline	27
28	29	30				

## JULY 2009

Sun	Mon	Tue	Wed	Thu	Fri	Sat
			1	2 IRB-02 Deadline	3	4
5	6	7 IRB-03 New Study Deadline	8	9 IRB-03 Meeting	10 IRB-01 Meeting IRB-05 Deadline	11
12	13	14 IRB-02 Meeting	15	16	17	18
19	20	21 IRB-04 Meeting	22	23	24 IRB-01 Deadline IRB-02 Deadline	25
26	27	28 IRB-03 Deadline	29 IRB-05 Meeting	30	31 IRB-04 Deadline	