IRB NEWS

A monthly newsletter brought to you by the Harvard University Area IRB, Committee on the Use of Human Subjects

ESTR Update Coming Soon!

ESTR, our online IRB submission system, will be unavailable from 4:00 PM ET on Friday, April 12 until 7:00 AM ET on Monday, April 15. Highlights for this release include:

- Simplified process for single IRB review and management of participating sites (External IRB submissions will only involve *one* submission, not two!)
- All our HRPP Toolkit documents will be located in the ESTR library (check out as many as you wish – no library card or late fines!)
- Updated workspace views (quite aesthetically pleasing!).

View the detailed release notes to learn about key changes expected with this update.
Department Distribution Revision

IRB staff are assigned as the point of contact for specific Harvard schools and departments. On April 15th, we will be rolling out some revisions to this department distribution to better serve our research community.

Beginning on April 15th, you can check out the updated distribution page to find your IRB contact. IRB staff will also be contacting those schools and departments where there has been a change.

Upcoming Training Dates - Revised Rule and URTP

Revised Rule - The IRB office will be holding more drop-in sessions to review the recently implemented Revised Rule with the Harvard research community. Please see below for dates, times and locations. No reservation is needed!

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Location</th>
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<tbody>
<tr>
<td>Tuesday, April 2, 2019</td>
<td>9:00 AM - 10:00 AM</td>
<td>William James Hall, Room B4</td>
</tr>
<tr>
<td>Friday, April 12, 2019</td>
<td>3:30 PM - 4:30 PM</td>
<td>William James Hall, Room B4</td>
</tr>
<tr>
<td>Monday, April 15, 2019</td>
<td>1:30 PM - 2:30 PM</td>
<td>William James Hall, Room 1550</td>
</tr>
<tr>
<td>Thursday, April 25, 2019</td>
<td>3:00 PM - 4:00 PM</td>
<td>William James Hall, Room 1550</td>
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**Undergraduate Research Training Program** - The Undergraduate Research Training Program (URTP) is a comprehensive platform to create better prepared undergraduate researchers. As part of the program, in-person training sessions are held at various dates throughout the academic year. The in-person training sessions are an alternative to the standard online CITI training. The sessions have been developed with students in mind: they are 90 minutes in length, interactive, and full of enthusiasm and energy. Here are some upcoming dates:

<table>
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<tr>
<th>Date</th>
<th>Time</th>
<th>Location</th>
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<tr>
<td>Monday, April 15, 2019</td>
<td>5:00 - 6:30 PM</td>
<td>Lamont Library, Forum Room</td>
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<tr>
<td>Thursday, May 2, 2019</td>
<td>4:30 - 6:00 PM</td>
<td>William James Hall, Room 105</td>
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**Repository Application**

Repositories collect, store, and distribute data and/or other materials for research purposes. Repository activities involve three components: (i) the collection of data/materials; (ii) the repository storage and data management center; and (iii) the distribution of data/materials to the recipient investigators.

While repositories do not conduct research, they are considered a resource to facilitate research. Because of this, repository activities are **required to be reviewed by an IRB**.

While the main IRB application is great for collecting information on most research activities, it is not well suited to collecting repository information. Insert drum-roll, please...
We are pleased to introduce the newest member of our IRB application family, “HRP-504-Repository Protocol,” which will debut on April 15th.

The Repository Protocol will guide researchers through the various parts of the repository architecture: collection, oversight and governance, and distribution. Have questions about repositories or thinking about creating a repository? Contact us – we’re happy to help!

**AAHRP Update / Do you speak IRB? - HRPP & HRPP Plan**

What is a **HRPP**?

The Human Research Protection Program (HRPP) is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. The HRPP is based on all individuals in this Institution, along with key individuals and committees fulfilling their roles and responsibilities as described in the **HRPP Plan**. The HRPP demonstrates the commitment of the entire organization, not just the IRB.

What is the **HRPP Plan**?

The **HRPP Plan** provides an overview of the Human Research Protection Program at Harvard University. The document defines the scope and mission of the HRPP and includes a complete outline of the regulatory requirements that must be adhered to. It also defines and outlines the roles and responsibilities of the Institutional Official (IO), the IRB, and other officials in the University, research education and training requirements, monitoring and audit functions, as well as how to report and manage concerns. It truly is the "30,000 foot view" document that ties all of the pieces of our program together.
Starting on April 15th, you can find the HRPP Plan in the ESTR Library.

Know someone who would be interested in subscribing to our newsletter?

It’s easy! Just share this link with them:

http://calists.harvard.edu/mailman/listinfo/huairb

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