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**Data Safety System, Revised HRDSP, and other changes – Coming Soon!**

Have you noticed all the new tabs that are part of the overall Research Compliance System? We know that you are already familiar with the ESTR tab for all of your IRB needs and the Agreement tab for all of your DUA needs but did you know that there is a new tab? May we introduce the newest tab, Safety. Safety is short for “Data Safety”, a new application intended to support tracking, monitoring, and compliance associated with the data security requirements for research data sets. Data Safety is still in a soft launch period however during this period, researchers have the option to use the system to complete required reviews and provide feedback.

The official start date of the Data Safety system will coincide with the implementation of the revised Harvard Research Data Security Policy on April 15, 2020. Beginning on that date, all Research Data Security reviews must be submitted through the Data Safety system.
You may be wondering what other changes are taking place, well…

As mentioned, Harvard Research Data Security Policy (HRDSP) has been revised. The revised data security policy provides greater clarity on roles and responsibilities as well as providing a comprehensive overview of security requirements and the overall review process. The HRDSP is in effect on April 15, 2020. You can get ready for the new policy by visiting the Research Administration and Compliance Systems page for more information or register for an upcoming information session.

The HRDSP also changes how the IRB applies data security levels. Gone are the days of receiving a numeric level from the IRB! Instead, the IRB will assign a binary determination to research data – non-sensitive or sensitive. Those studies that are assigned a sensitive determination will be required to receive additional security review.

And, with the Safety system up and running, the IRB will no longer need to collect all that additional information about how and where you will be storing your data. Instead, this information will be collected in the Safety tab. Yep, that means a slightly shorter IRB application!

NEW! Local Context Forms

When one IRB provides review for another IRB, there are some specific items that need to be known by the Reviewing IRB. These items are specific to the institution and as such, must be handled by the institution even though the IRB review is not. For example:

- Are any financial conflicts for those from the other institution?
- If activities will be taking place at the other institution that include radiation, is there a need for that institution’s radiation safety oversight committee to provide a review?
- Are there any other applicable state or local laws and regulations?

As there are many considerations to take into account, a Local Context Review Form has been created to ease the capture of this
information.

*When would you use a Local Context Review Form?*

You would use this form if your study involves a reliance agreement either because the HUA IRB is providing review for another institution or if another institution is providing review for you through a Harvard External IRB submission.

*When will this form be available?*

The form will officially be available with the next ESTR upgrade which will take place in mid-Spring 2020. However, during the interim, our trusty IRB Reliance Administrator will be distributing this form to select researchers that are using a reliance agreement in their studies.

Need more information about Reliance Agreements and what types of studies might qualify for one? Check out our website [here](#).

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**Do You Speak IRB? Principal Investigator Assurance**

For each application submitted to the IRB, the Principal Investigator must acknowledge a “Principal Investigator Assurance Statement” in ESTR. The Principal Investigator Assurance includes statements that *ensure* that the research will be conducted ethically, safely, and according to federal, local, state, institutional, and other requirements.

These statements include:

- I will not start Human Research activities until I have obtained all other required institutional approvals, including local ethics committee review for international sites; and approvals of departments or divisions that require approval prior to commencing research that involves their resources.
• I will ensure that there are adequate resources to carry out the research safely, e.g. sufficient investigator time, equipment, and spacing.
• I will ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study. 4. I will update the IRB office with any changes to the list of study personnel.

The Principal Investigator must adhere to each requirement throughout the duration of the study - from initial submission to study closure. This is done by clicking “OK” before the final submission of any action to the IRB - initial application, modification, study closure, etc.

You can find the full text of the Principal Investigator Assurance in the ESTR Library under the tab “Ancillary Review and Other Reference”