



Harvard University Area IRB Monthly Newsletter

April 2022



Important Things to Know

New NIAAA Data Sharing Policy – Effective Immediately

Effective immediately, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) expects genomic data and data related to bio-samples to be deposited in the newly developed NIAAA Data Archive ([NIAAA](#)).

The new policy applies to new, competing renewals, revisions, and resubmissions of grant proposals going forward. Know that this policy does not

supersede the general [NIH \(National Institutes of Health\) Genome Data Sharing Policy](#) which is also undergoing revision.

You can find more about the new NIAAA policy here -

<https://grants.nih.gov/grants/guide/notice-files/NOT-AA-22-011.html>

Revision to Department/School Distribution Coming Soon

Starting in late April, we will be implementing some minor revisions to our IRB review distribution. We will be reaching out to Departments and Schools where there is a change in IRB Reviewer, and we will revise our distribution page found here - <https://cuhs.harvard.edu/find-your-departments-irb-contact-person> to reflect these changes.

Questions? Feel free to contact us - (617) 496-2847 or cuhs@harvard.edu

Removing Study Team Members?

When removing a study team member from your study in ESTR, the online IRB submission system, it is important to check the ESTR SmartForm, your protocol, and all ancillary study documents to see if the name of the study team member that you wish to remove is listed in any of these

documents. The reason for this is that the type of modification that you choose can limit what documents you are able to edit.

If the study team member that you wish to remove is only found in the ESTR SmartForm, choose the modification type “Study team member information”.

If the study team member that you wish to remove is found in the ESTR SmartForm *and* other study documents, choose both modification types: “Study team member information” *and* “Other Parts of the Study”.

By doing so, you will be able to edit the ESTR SmartForm and all other study documents included in your submission. This will save you additional submission and some time!

Modification / Continuing Review / Study Closure

*** What is the purpose of this submission?**
To request Continuing Review OR Study Closure, select the Continuing Review option.

Continuing Review

Modification/Update

[Clear](#)

Modification scope:

Study team member information

Other parts of the study

Collaborating with Another Institution? Check out our updated website page.

The Single IRB page on our website has been updated to provide clear and simple instructions on how to request a reliance agreement through our online submission system, ESTR. You can check out the revised page here - <https://cuhs.harvard.edu/ins-and-outs-forging-reliance-agreement> and clicking on the tab “How to Submit a Request”

Submit button

Have you ever found yourself wondering why the IRB is taking so long to review your study? Have you not received any correspondence from your IRB Reviewer? It might not be the IRB. The reason behind the silence might be that you did not click the submit button on your submission.

The submit button is available if the submission is in the “pre-submission” status (see top left corner of the study space) and is found directly under the buttons on the left side. Remember that only the Principal Investigator will see the submit button when the study is being reviewed for the first time. After the initial approval or determination by the IRB, the Principal Investigator may assign a PI Proxy who can then submit on their behalf.

If a video tutorial would be helpful, check out the instructional video here - https://estrsupport.fss.harvard.edu/files/estr/files/how_to_submit-with_audio.mp4?m=1525629919

Do You Speak IRB?



Deception and Incomplete Disclosure

Deception studies intentionally provide misleading or false information.

Examples include:

- Participants complete a quiz and are falsely told that they did poorly, regardless of their performance.
- Participants who do not know they are in a research study are observed to see how they behave when they find valuables (e.g., wallet, laptop) unattended in a public location.
- An anxiety study, in which participants are told to expect mild pain during the study, but no painful procedures are administered.

Incomplete disclosure studies withhold information about the true purpose or nature of the research. Examples include:

- Participants are given general information about the study purpose, but the information is not detailed enough to reveal the researcher's main or specific objective.
- Participants are given truthful information about a study procedure but are not fully informed about the expected findings.
- Participants are asked to take a quiz for research but they are not told that the research question involves how background noise affects their ability to concentrate.

Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are experimental. Deception increases ethical concerns and should be used with discretion because it interferes with the ability of the subject to give informed consent. The IRB recognizes that deception or incomplete disclosure may be necessary for certain types of behavioral research. Because people act differently depending on circumstances, full knowledge of the subject might bias the results in some cases.

Specific requirements for deception or incomplete disclosure projects:

Waiver of Informed Consent

Because participants are not provided with all the details of the proposed research at the time consent is obtained, deception projects must meet the criteria for waiver of informed consent including that the project poses no more than minimal risk to the subjects.

Debriefing

In most circumstances, subjects have the right to full disclosure as soon as possible after participation in deception or incomplete disclosure research; a post-participation debriefing is usually required. The debriefing should disclose the full or true purpose of the research and allow the subject to indicate that their data is not used in the study. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects should not be exposed to undue stress or embarrassment and should have the right to full disclosure of the purpose of the study as soon as possible after the data has been collected. There may be circumstances when debriefing is not appropriate. This may be when disclosure of the information may cause more distress to subjects than if not disclosed or when disclosure may bias the scientific integrity of the study.

Exempt Category 3 Requirements

While the use of deception and incomplete disclosure is acceptable in expedited level of studies that require convened IRB review, it has not historically been permitted in exempt level research, until now.

Exempt Category 3 is a new type of exempt research that was included in the 2018 revisions to the human subject protection regulations. Exempt Category 3 requires that the intervention only includes adults, be brief, harmless, and painless, among other criteria.

This exemption also permits research involving deception or incomplete disclosure. However, this is only permitted when the subject agrees to participate in research following disclosure of the fact that he or she will be unaware of or misled regarding the nature or purpose of the research. Without this statement, deception and incomplete disclosure are not permitted. If your exempt study will involve deception or incomplete disclosure, please keep the

following statement (as found in the HUA Consent Script for Exempt Research (HRP-502c) in the ESTR library) in your exempt consent script:

“As part of this research design, you may not be told or may be misled about the purpose or procedures of this research. However, the purpose or procedures of the research will be disclosed to you following your participation.”

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