



Harvard University Area IRB Monthly Newsletter May 2023



Reminder about Closure Requests on Exempt Studies

We understand how completely satisfying it can be to close an IRB submission. No more modification requests or continuing reviews, and more importantly no more “to-do” notices from ESTR. However, before you submit that closure request, be certain that your study has not received an exempt determination. As mentioned in last month’s [newsletter](#), exempt determinations are different. As an exempt determination is a **determination**, not an approval, a continuing review, closure, and most modifications are not required. An exempt determination lasts as long as the exempt-determined research activity is taking place.

Remember - closure requests are not needed for your exempt study.



A (very) Brief Overview of Faculty Sponsor and PI Eligibility

For individuals who are not eligible to be a [Principal Investigator](#), a Faculty Sponsor is required.

A Faculty Sponsor must be eligible to be a Principal Investigator at their respective school and must be willing to accept the same responsibilities of a Principal Investigator. So, what does this mean?

In addition to completing the [Faculty Sponsor Assurance process](#) in ESTR, the Faculty Sponsor must confirm that they will oversee the research and ensure that the listed Principal Investigator complies with all IRB requirements:

- Ensuring that there are adequate resources to carry out the research safely.
- Ensuring that Research Staff are qualified.
- Submitting to the IRB any reportable new information within five business days.
- And other responsibilities.

You can find the full list of Faculty Sponsor responsibilities in the [ESTR](#) Library under the tab “Ancillary Review and Other Reference”.

Do You Speak IRB?



Primary Contact or PI Proxy - what's the difference?

ESTR requires that roles be assigned to all study staff on a study. In addition, there are some other roles that provide specific permissions to the ESTR system.

From the very helpful [ESTR IRB Study Submission Guide](#) (see page 44):

What is a PI Proxy?

Once an individual has been listed as a study member on the team and the study has received an initial approval or determination, the Principal Investigator may assign proxy permissions so that ESTR system activities only available to PIs can be completed by another member of the study team.

The purpose of assigning a system-based proxy is to assist with the management of follow-on submissions (for example, Modification/Updates and Continuing Review or Closures).

PI Proxy permissions do not imply that the named proxy has PI responsibilities,

only the Principal Investigator and Faculty Sponsor (if there is one) hold Principal Investigator responsibilities.

Once a PI Proxy has been assigned, the Proxy:

- Can submit follow-on submissions and study materials on behalf of the PI.
- Will receive all system notifications pertaining to the study.
- Cannot assign additional proxies; the PI is the only person who is able to designate a PI Proxy.

Note that if you are a Faculty Sponsor that is listed on any student project, you **will not** receive system notifications by default. Faculty Sponsors may be added as a PI Proxy so that they will receive system notifications about the study.

What is a Primary Contact?

In addition to the PI and PI Proxy, the Primary Contact is a recipient of all system emails (including notification of IRB determination, or when the IRB requests clarifications). Changing the Primary Contact does not require a modification that gets reviewed by the IRB. Making this change takes effect immediately and can be changed at any time. For example, it may help to provide a contact person in addition to the PI if the PI does not check e-mail frequently. The primary contact can also edit the study just as a study team member can.

Notes:

- To change the primary contact, you must be a member of the study team, or the IRB coordinator assigned to the study.
- By default, the person who created the study in the system is the primary contact.
- The PI and any PI proxy continue to receive notifications regardless of the primary contact assignment.
- Modification/updates or continuing reviews have the same primary contact as the initial study. To change the primary contact on these submissions, do so in the main study workspace.

It is important to note that indicating a person as Primary Contact is for administrative purposes and does not give permission for this individual to work with human subjects. If the Primary Contact also has human subjects responsibilities, their involvement with human subjects must be reviewed by the IRB before they may begin that portion of their work.

For more information, see the [ESTR IRB Study Submission Guide](#).

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