Leaving Harvard?

We understand that there are a lot of things to take care of when leaving Harvard, one of which is your existing IRB submissions. If you have on-going research that is approved under the expedited or full IRB review category, active IRB approval is always needed. Here are some quick tips on what to do:

*If you are moving to a new institution and will continue your research, you should:*

- Contact your new institution’s IRB office for instructions on how to open the study(ies) there.
- Close your study(ies) via ESTR.

*If you no longer plan to conduct the research, you should:*

- Close the study(ies) via ESTR.

*If you plan to transfer your research to another Harvard PI, you should:*

- Determine if the identified individual is “PI eligible”. If not, you will need to also identify a Faculty Sponsor for this individual.
- Submit a modification via ESTR to change the PI on your study. Information on how to submit a modification to change the PI may be found [here](#).
- NOTE: to change the PI, select the “Other parts of the study” in the modification ESTR SmartForm.

**PLEASE PLAN AHEAD and TAKE ACTION PRIOR TO YOUR DEPARTURE.** If you will no longer have a formal affiliation at Harvard:

- Your Harvard IRB approval will no longer be active;
- You will no longer be able to access ESTR to make any changes; and
- The Harvard University Area IRB will no longer be your IRB of record and will not be able to provide IRB review for you.

**IRB Office Hours**

Earlier this year, the IRB office started an “IRB Office Hours” initiative. IRB Office Hours provide the research community from a specific School or Department with an opportunity to discuss questions about the IRB process, the ESTR system, or general assistance with protocol submissions face to face in a collegial environment on your turf. Time slots are limited to 20-minutes per person and we request that
you sign-up ahead of time. We want to make this time as efficient and convenient as possible and to prevent long wait times.

IRB Office Hours are now active at the following locations.

For the Harvard Kennedy School research community, IRB Office Hours are scheduled on the 3rd Wednesday of each month from 2-4 pm in the RAO conference room. To sign up for a timeslot, email Carrie Kachoria, Director of the HKS Research Administration Office, at carrie_kachoria@hks.harvard.edu

For the Harvard Psychology Department research community, IRB Office Hours will be scheduled on the 3rd Thursday of each month from 1-3 pm in the William James Hall 2nd floor conference room, WJH 226. To sign up for a timeslot, use the poll that may be found here: https://calendly.com/cuhs/20min?month=2019-07

Starting September 3rd, the Harvard Graduate School of Education will be hosting IRB Office Hours the first Tuesday of the month from 10am – 12 pm in the Read House conference room on the 1st floor. More details coming soon!

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Do you speak IRB? “Foreseeable Risks”

You may recognize the following question from our IRB Protocol Template:

*Describe the foreseeable risks associated with your study. Please include discussion of any physical risks and non-physical risks, such as economic, psychological, social, and legal harms.*

What is a “foreseeable risk”? Does this mean that all risks that may affect a study subject now and, in the future, should be included? Or, only for the duration of the study? And, why is this important?

Identification of foreseeable risks assists the IRB in assessing the risks posed to
study subjects in conjunction with the proposed benefits. Specifically, “Risks to research subjects posed by participation in research should be justified by the anticipated benefits to the subjects or society.” And, from the Common Rule, “In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.”

Identification of foreseeable risks is also used in a study’s informed consent form to apprise study subjects about what risks can be expected. The identification of foreseeable risks also creates a distinction between those risks that are expected and those that are not and forms the basis of what needs to be reported as a UPIRTSO. In case you forgot about last month’s newsletter, a UPIRTSO is an “Unanticipated Problem Involving Risks To Subjects or Others” and must be reported to the IRB. Need more UPIRTSO? Check out last month’s IRB Newsletter [here](#).

Is a foreseeable risk an exhaustive list of every possible risk? Not exactly. According to the OHRP Guidebook, a classic and now archived piece of IRB history, “In the process of determining what constitutes a risk, only those risks that may result from the research” should be considered. And that, “IRBs should not consider possible long-range effect of applying the knowledge gained through research as among those research risks that fall within the purview of its responsibility.”

When completing your IRB submission, here are some items to think about when determining “foreseeable risks”:

- Identify known risks associated with the research.
• Consider only those risks that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
• Do not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy).
• Foreseeable risks may be physical, psychological, social/economic, legal, or pertain to loss of confidentiality.