The mission of the Harvard University Area Human Research Protection Program (HRPP) plan is to protect the rights and welfare of subjects involved in Human Research that is overseen by Harvard University. In order to do this, we (meaning all of us here at Harvard) have a shared responsibility for the protection of human subjects. While for some us those responsibilities may be more involved, we all play a part. All individuals within the Institution have the responsibility to:

- Be aware of the definition of Human Research.
• Consult the IRB when there is uncertainty about whether an activity is Human Research.
• Not conduct Human Research or allow Human Research to be conducted without review and approval by the IRB.
• Report allegations of undue influence regarding the oversight of the Human Research Protection Program or concerns about the Human Research Protection Program to the IRB or Institutional Official.
• Report allegations or finding of non-compliance with the requirements of the Human Research Protection Program to the IRB or Institutional Official.

Find out more about how we all play a part in human research protection by reviewing our HRPP plan found in the ESTR Library here (just remember to log in to ESTR first).

Pssstttt…have you heard about the 118 Determination?

The “118 Determination” is based in the Common Rule regulation 45 CFR 46.118 - a special carve-out for a type of grant (institutional or training grants), cooperative agreement, or contract, and when the specific activities of the research have not yet been determined because there is significant activity that is needed prior to involving human subjects. The National Science Foundation has also recently acknowledged this type of determination, “pursuant to 45 CFR 690.118, NSF can accept a preliminary approval from an IRB that establishes a limited approval period, requires the PI to submit an amendment or new IRB application prior to the expiration date, and stipulates that no work with human subjects, including recruitment, may be conducted until full IRB approval is obtained.”

While the 118 Determination has historically been requested by various areas of the university through a secret knock on the IRB door, there has never been an
established process to request and document this determination. Recently, we implemented a new Standard Operating Procedure (HRP-095-HUA 118 Determination) and submission form (HUA 118 Request Template) both of which may be found in the ESTR Library to make this process more transparent.

Some things to keep in mind with the 118 Determination:

- A 118 Determination may be the way to go if you need to access your funding but there is ample work to do before you involve human subjects.
- Not all agencies accept the 118 Determination. It is commonly used by federal agencies although some private funders may accept it.
- The 118 Determination IS NOT an IRB approval. It is merely an acknowledgement that there are activities that need to take place before the project involves human subjects.
- Before human subject activities occur, IRB review and approval is required. You will need to submit a new application; not just a modification to the 118 Determination in ESTR.

If an activity involves risk or a vulnerable population, is IRB review required?

Research projects meeting the regulatory definition of research with human subjects require review and approval by an IRB, or a determination that the research is exempt. Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB.
The questions that must be considered when determining whether IRB review and approval is required are 1) whether a project fits the regulatory definition of research ("regulated research"), and if so, 2) whether it involves human subjects.

Inclusion of vulnerable populations, such as prisoners or children, is not a criterion of what requires IRB review. Nor is whether the research activity may involve risk. Whether IRB review is needed rests on the federal definition of research and whether the activity is "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

Even when IRB review is not needed, there may be institutional policies and procedures and professional ethics guidelines that would prevent such research from being undertaken. For example, Provostial Review is one such institutional policy and procedure that is in place for research activities that may be considered especially risky.

Want more information about what requires IRB review? Check out our website here.

Do you speak IRB? "3rd Party Subjects"

What (or who) are third party subjects in research? According to the federal regulations, a person becomes a research subject if a researcher intervenes or interacts with that person for the purpose of research. Receipt of private, identifiable information about a person also makes that person (to whom the data belong) a human subject. But what if additional private, information is obtained from a study subject about another person? Bingo – you now have a third party subject.
For example, if researchers were planning to gather data from a parent not only about themselves but also about their child, the child would be considered a third party subject. Or, if a researcher is interested in household dynamics and interviews one member of the household who then provides information about the other members, those other members would be considered third party subjects. Of course, the same criteria of what constitutes a human subject is at play, namely that the identity of the third party subject can be "readily ascertained". So, there it is – third party subjects - now you know!