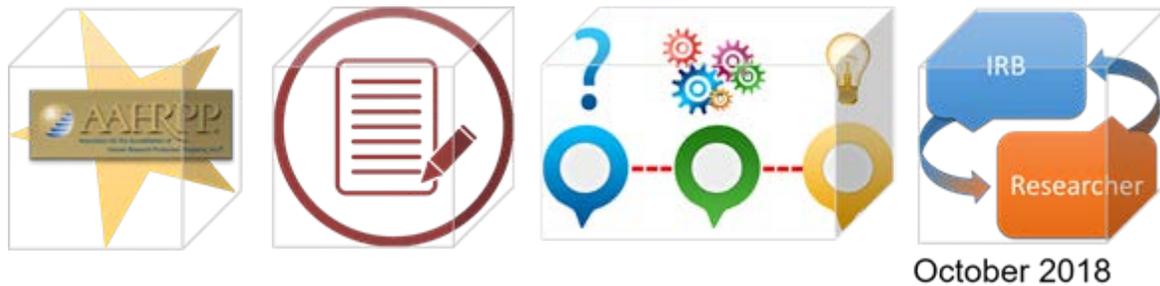
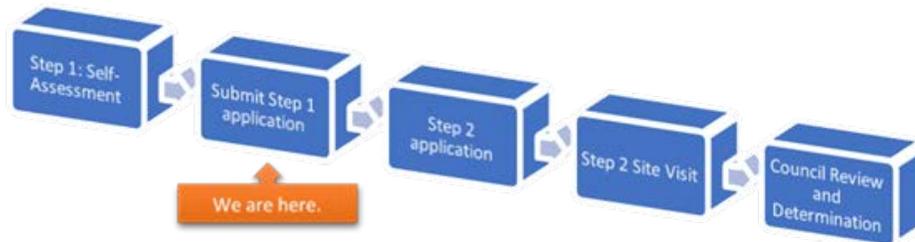

IRB NEWS

A monthly newsletter brought to you by the Harvard University Area IRB,
Committee on the Use of Human Subjects



Accreditation Spotlight



Once the self-assessment is complete, and areas of improvement are identified and rectified throughout the HRPP (Human Research Protection Program – see [September 2018 Newsletter](#)) plan, it is time to prepare the **Step 1** Application.

The **Step 1** Application is comprised of:

- Section A - Application Form: The application form requests basic information about your HRPP including the type of research that is reviewed, the number of studies that

are reviewed on an annual basis, as well as the regulations that the HRPP adheres to (e.g., HHS, FDA, HIPAA, etc.).

- Section B - Overview of HRPP
- Section C - Element by Element Index to Supporting Documents: This Element by Element index lists the supporting document for each AHRPP (Association for the Accreditation of Human Research Protection Programs) Element. It is the crosswalk document that links the HRPP documents to the AAHRPP Elements.
- Section D - Supporting Documents: The supporting documents are comprised of the HRPP standard operating procedures (SOPs), Investigator Manual, checklists, worksheets, forms, templates, websites, guidance documents, etc.

Once the **Step 1** Application is complete and submitted, AAHRPP will review the application materials and, if needed, request revision or additional documentation.

Following approval of the **Step 1** Application, we move on to the Step 2 Application (*hint* - to be covered in next month's newsletter).



IRB Submission Forms on the IRB Website

You may have noticed that we have removed the active links to our various IRB submission forms on our website. Now, users will need to use the ESTR Library to access the forms. Why did we do this?

Our forms are stored in an online Wiki that is not accessible from our website. Therefore every time that a form is updated, we must download the form and then save it to our website library. What this has created is an outdated website library that is not able to keep up with our revisions. We always want our research community to have the most up-to-date forms available, so we cut out the website middleman.



IRB Administrator Job Opening

Intrigued by the work that an IRB does? Want to get involved in a fast-paced yet supportive environment? Are you looking for a career that is rewarding and contributes to research by ensuring ethical practices?

The Harvard University Area IRB is seeking candidates for the recently posted IRB Administrator position (requisition 46975BR). If interested, please see our job posting [here](#).

Do you speak IRB?



When does compensating subjects undermine informed consent or parental permission?

You may have received correspondence from your IRB staff reviewer that asks about the amount of money that you are paying research subjects. Why? Well, our friends at OHRP (Office of Human Research Protections, our federal regulators) provide good information on how compensation may be considered an undue influence:

“The HHS regulations require that “An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence” (45 CFR 46.116).

Paying research subjects in exchange for their participation is a common and, in general, acceptable practice. However, difficult questions must be addressed by the IRB. For example, how much money should research subjects receive, and for what should subjects receive payment -- their time, inconvenience, discomfort, or some other consideration -- IRBs must be sensitive to whether any aspect of the proposed remuneration will be an undue influence, thus interfering with the potential subjects' ability to give voluntary informed consent.

Remuneration for participation in research should be just and fair. However, the specifics of each protocol will influence how those determinations are made. Both researchers and IRBs need to be familiar with the study population and the context of the research in order to make reasonable judgments about how compensation might affect participation. Wherever the remuneration is set, it will influence the decisions of some more than others. In particular, it will be more important to those for whom it will make a significant financial difference. Thus, IRBs should be cautious that payments are not so high that they create an “undue influence” or offer undue inducement that could compromise a prospective subject’s examination and evaluation of the risks or affect the voluntariness of his or her choices.

Information submitted to IRBs should indicate and justify proposed levels and purposes of remuneration, which also should be clearly stated in the accompanying consent forms. Some institutions have adopted policies regarding the recruitment and payment of volunteers. IRBs and investigators should ensure that the consent process includes a detailed account of the terms of payment, including a description of the conditions under which a subject would receive partial or no payment (e.g., what will happen if he or she withdraws part way through the research or the investigator removes a subject from the study for medical or noncompliance reasons).

Finally, in studies of considerable duration or that involve multiple interactions or interventions, OHRP recommends that payment be prorated for the time of participation in the study rather than delayed until study completion, because the latter could unduly influence a subject’s decision to exercise his or her right to withdraw at any time. For example, if the study is conducted over a period of 6 months, there might be a monthly or bi-monthly payment. Or, if the study involves 12 sessions, there might be payment after every two sessions.”

For more information and guidance on paying research participants, please refer to “WORKSHEET: Payments (HRP-316)” found in the ESTR Library, as well as the [Harvard University Financial Policy on Human Subject Payments](#).

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<http://calists.harvard.edu/mailman/listinfo/huairb>

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