HARVARD
Human Research Protection Program

Ancillary Review Reference - Faculty Sponsor Review

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The purpose of this document is to provide reference regarding the responsibilities associated with indicating completion of the specified Ancillary Review Type.

By completing the ancillary review activity in ESTR and as the named Faculty Sponsor, I confirm that I will oversee the research and ensure that the Principal Investigator complies with the following (to which the Principal Investigator has already agreed):

1) I will not start Human Research activities until I have obtained all other required institutional approvals, including local ethics committee review for international sites; and approvals of departments or divisions that require approval prior to commencing research that involves their resources.
2) I will ensure that there are adequate resources to carry out the research safely, e.g. sufficient investigator time, equipment, and spacing.
3) I will ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
4) I will update the IRB office with any changes to the list of study personnel.
5) I will personally conduct or supervise the Human Research.
   a) Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB.
   b) When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
   c) Not modify the Human Research without prior IRB review and approval (when required) unless necessary to eliminate apparent immediate hazards to participants.
   d) Protect the rights, safety, and welfare of participants involved in the research.
6) I will submit to the IRB in a timely manner:
   a) Proposed modifications to the previously-approved Human Research, when applicable.
   b) A continuing review application (to avoid a lapse in approval), when applicable.
   c) A continuing review application when the Human Research is closed, when applicable.
7) I will submit to the IRB any reportable new information within five business days.
8) I will personally submit and ensure that Research Staff submit an updated Financial Interest Disclosure within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
9) I will not accept or provide payments to professionals in exchange for referrals of potential participants ("finder's fees").
10) I will not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment ("bonus payments").
11) I will comply with applicable federal and state regulations, ethical guidelines, and Harvard Institutional policies, including (but not limited to) the Institutional conflict of interest, DUA Policy and Guidance, and Harvard Research Data Security Policy.
    - To protect information I must have a strong password for each of my Harvard accounts; including a log in for idle sessions and lock out screen for multiple failed log-in attempts. Log in information will not be shared.
    - Any system storing information qualifying as Level 2 or 'non-sensitive' by the IRB must have updated security patches and virus protection. These systems will only be accessed by those with a current and IRB approved research role.
12) I will maintain adequate and accurate records and make these records available to the IRB or QA/QI Program for review.
13) I will ensure that IRB-approved study documents, including recruitment materials, consent forms, and study tools, are accurately translated in a language understandable to study participants. If applicable, I will submit locally-approved versions of these materials to the IRB when they become available.