**Institutional Review Board Tips Sheet**

**Continuing Reviews:**

* Be sure to breakdown enrollment by gender and ethnicity. If you don’t have such figures, be sure to include a statement as to why

* If your enrollment exceeds the number the study was approved for, be sure to include either a revision request seeking an increase in the number of subjects (and update all applicable study documents, such as the informed consent), or a statement that the study is now closed to enrollment.  Also, be sure to state why enrollment figures were exceeded. If enrollment was exceeded a protocol deviation must be submitted to the IRB explaining why.

* If you submit a continuing review after a protocol has expired, please include an assurance that no research activities have taken place or will take place between the date of expiration and the date the continuing review is approved.

* If the protocol migrated from paper to eCAP and has a waiver of informed consent and/or a waiver of HIPAA authorization, please submit such documentation with each continuing review submission.  All requests for waivers must be signed and dated by the PI each year.

* Conflict of interest forms must be completed by all listed investigators each year as portfolios/financial relationships can change year to year.

* Response to Stipulations Continuing Review:  If you submit a response to stipulations to a continuing review after the protocol has expired, be sure to include an assurance that no research activities have taken place or will take place between the date of expiration and the date the continuing review is approved.

**Amendments:**

* When submitting a revision to the protocol, please detail all proposed revisions in the Description of Changes section of the eCAP Amendment application. Please highlight all changes/revisions in yellow for revised documents to facilitate the review process. Please note which sections have been revised in the Description of Changes section of the eCAP Amendment application. In addition, please also provide a clean copy of any revised documents for IRB stamping upon approval of the Amendment.

**General submission:**

* All IRB forms can be downloaded from this [link](http://intranet.hss.edu/research/IRB/62.htm).

**SCIENTIFIC PRE-REVIEW**

**Completion of Parts I & II:**

* Answer **all** the questions.
* There can only be **one primary outcome. It must be defined and operationalized:** State how often it will be measured, when the final outcome measurement will be taken, and what difference between baseline and final measurement will be considered a good outcome.
* Background Information – include what is important for the reviewers to know in considering the proposal and provide a reference list with full citations.
* Attach questionnaires and data collection sheets.
* Set up a consultation with the Biostatistics Core for assistance with controls, randomization, sample size determination and statistical analysis of data. Download and complete the study intake form which can be found at this [link](http://www.hss.edu/epi-biostats-intake). A statistician will be assigned to assist you within 48 hours of receipt of the intake form.
* Only the Principal Investigator can submit the protocol via eCAP. The Research Service Chief must review and approve the protocol before it can be reviewed by a CRP or the IRB.

Download and begin writing the consent form for your protocol while it is being reviewed by the CRP. This way you will have it ready when you complete Part III for submission to the IRB.

**If you have any questions, please contact:**

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