When Should I Submit an Amendment?

After a study has been approved by the IRB, an Investigator should submit an Amendment Application when planning to implement any changes. Regardless of how minor or benign the proposed change might seem any change in a protocol must be approved by the IRB BEFORE the Investigator implements it.

Common examples requiring an Amendment Application:
- Changing or adding an instrument/measure to the protocol
- Changing or adding recruitment methods or recruitment materials
- Changing or adding informed consent documents
- Adding or removing a Co-Investigator or research personnel
- Adding a research site
- Increasing the sample size
- Adding planned research activities not included in the previously approved proposal

An Investigator should not wait until it is time to submit a Continuing Review Application to submit an Amendment. An Amendment can be submitted at any time.

A direct, online submission link to the amendment application is available on the “Forms” section of the IRB website:

http://www.utexas.edu/research/rsc/humansubjects/forms.html

Also available on this page is the Amendment Summary Form, which is now required for all amendment submissions.

If the initial application was determined to meet the criteria for exemption from the regulations, contact your Program Coordinator or ORS to verify if an Amendment Application is required.

ORS Educational Sessions & Workshops 2014

The following course is available:

RC 201 – IRB Intro
July 9, 2014
10:00 - 11:30 AM
POB 3.408

Please check the ORS news page and TXClass for future offerings.

A Friendly Reminder on Continuing Review Applications

For Expedited and Full Board studies, in order to renew approval for another year, PIs must complete the following steps:

1. Submit a Continuing Review Application at least 30 days in advance of the expiration date (or 60 days in advance for a full board study).
2. Submit the currently approved version of ALL the required documents.

All research personnel must also have updated training (human subjects AND Conflict of Interest) and have a current Financial Interest Disclosure (FID) form on file. Contact your IRB Program Coordinator if you require assistance.