Instructions for Completion of Form: Protocol Amendment

Federal regulations require that the Institutional Review Board (IRB) must have written policy for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject. This means that an investigator must submit an amendment form to the IRB of proposed changes to the research and must obtain written approval from the IRB before initiating any of these changes. The Protocol Amendment form is the method by which an investigator provides the necessary information to the IRB about the proposed changes so that the IRB can make a determination as to whether or not the changes can be approved or whether additional changes need to be made to make the amendment approvable.

First, complete the date the form was completed. If the IRB asks for revisions during the review process and you make changes to the amendment form originally submitted to the IRB, enter the date the form was revised.

Next complete the PI name and contact information, and if applicable, the name and contact information of the Faculty Sponsor. If you are changing the Faculty Sponsor as part of this amendment, provide the name and contact information for the new Faculty Sponsor on the Form: Co-Investigators and Key Research Personnel.

Section I: Enter the protocol number, title of the research, and the current level of review for the protocol.

Section II: This section lists many of the common types of amendments. Indicate what type of amendment you are submitting. Take note of any instructions after the amendment descriptions which provide guidance on additional forms or materials that may need to be included in the amendment with your submission.

Section III: In this section, if there are any new Conflicts of Interest (COI) to report related to personnel already listed on the protocol you should report them here. If you are adding new personnel, just as you completed a COI disclosure at the time that you submitted the protocol initially, you should indicate whether the new personnel have any conflicts of interest that need to be reported.

Section IV: In this section summarize the amendment changes and indicate why the changes are being made. For example, maybe you have had some subject complaints that your questionnaires are too long or are difficult to understand, so the reason you are revising them is to simplify the language and shorten the questionnaires. It is important to remember that since the initial IRB

application is your research protocol, if the amendment changes the information in that protocol document, you should revise the originally approved application so that it is an accurate and up-to-date description of how you will conduct the research.

Section V: In this section, answer the questions as to whether the amendment changes alter the risk or benefits of the research. Sometimes changes to the research add new risks or remove prior risks, and even sometimes changes the level of review required for the protocol. The IRB must assess the changes to the risks, and when necessary, ensure that the subjects are informed of any new information.

Section VI, Informed Consent, Parent/Guardian Permission, Assent, HIPAA Authorization and Broad Consent: In this section the questions ask about whether or not subjects have been already enrolled in the research and whether or not the information in the consent, parent/guardian permission, assent, HIPAA Authorization or broad consent is changed or altered. This is important because the IRB regulations require that new information be provided to subjects, if necessary. For example, if an investigator becomes aware of new risks to the research during the course of conducting the research and subjects were still participating in the research, these subjects must be informed of the newly discovered risks. Depending upon the research and the type of new information that becomes available, even if subjects are have already completed the research, it may still be necessary to provide them with the new information.

Section VII: This section is asking for signatures from the PI, and if applicable, the Faculty Sponsor indicating the information provided is complete and accurate and the research with the described changes will be conducted in compliance with federal regulations, DePaul policy, and state or local laws.