

**CLARION UNIVERSITY OF PENNSYLVANIA**  
**Policy and Procedures**  
**for the Protection of Human Subjects of Research**

**Frequently Asked Questions**

- 1. Complete Application Package:** Use the applications found on the web site [www.clarion.edu/admin/facres/irb](http://www.clarion.edu/admin/facres/irb). Find the document you need, highlight it, copy and paste it into the Word document your computer has. At that point you can type on the “form.”
- 2. Consent documents:** Always submit the consent form currently in use - even when renewing. Omission of the consent form(s) will delay the processing of your application.
- 3. How Do Changes Affect the Consent Document/Risks to Subjects?:** If a change occurs, specify whether or not the change will necessitate an amendment to the consent form. Submit the revised proposed document(s).
- 4. How Do I Report a Change in Protocol?:** Most changes of protocol can be made by memo. Indicate the name of your study, the name of the principal investigator, and the file number assigned to your study. State the changes and new wording to be used. The IRB Chair, and Committee if necessary, will review the changes, and you will be notified by letter of approval.
- 5. Renewal Application and Injury Reporting:** Injury reports should be made to the IRB Administrative Office and Chair. On renewal applications, if injury has occurred, specify if and when the adverse events have been previously reported.
- 6. Change in Investigatorship:** Report this occurrence to the IRB Administrative Office and Chair as an amendment to your study. This may be done by memo and again, make reference to the name of the study, the original principal investigator, file number and the name of the new investigator.
- 7. What If I Only Have a Draft of My Instrument?:** Submit your draft as a “DRAFT” instrument. This will give the Committee an idea of what you intend to ask. After you have finalized the instrument, send a copy of it to the IRB Administrative Office to be placed in your file.
- 8. Is It Necessary to Have A Consent Form For a Survey?:** Yes. Even though the completion and return of a survey implies consent, policy requires that a statement be made on the survey stating: 1) that the completion of the survey is voluntary; 2) that the subjects may skip over any question(s) that may them feel uncomfortable; 3) and the length of time needed to complete the survey.
- 9. How Do I Report an Injury?:** Contact the IRB Administrative Office at (814) 393- 2337. Information and reporting forms will be made available to you.