

INSTITUTIONAL REVIEW BOARD CHECKLIST FOR MAKING AN AMENDMENT TO AN APPROVED PROJECT

Changes in protocols and/or consent documents **MAY NOT** be implemented until approved by the IRB, **UNLESS** failure to immediately implement the modification would place subjects at risk of harm or injury. The type of review that revisions receive (either full-board or expedited) will depend on the modifications being requested (see IRB Guidelines and Policies Manual 3/2002 page 15 for further explanation).

SUBMIT ONE UNSTAPLED COPY OF THE FOLLOWING TO THE PPHS OFFICE:

- This Completed Checklist
- Memorandum detailing each change being made to the research, the reason for it, and where the change is being made in the application forms. Also document any special issues or circumstances the PI would like to call attention to, particularly if the project consists of more than one project or phase.
- Revised protocol, if change is applicable, with all changes underlined
- IRB form 1 – Revised Protocol Summary (if change applies to document) with all changes underlined
- IRB form 2 – Revised Consent Document (if applicable) with all changes underlined. Note that if a protocol modification necessitates a change in information that should be provided to study participants (past, current, or future enrollees as applicable), a revised consent document must be submitted for review and approval.
- IRB form 2 – Revised Consent Document, if applicable, with all changes, ready to be stamped (not underlined)
- Copy of most recently approved consent document (if consent is being revised)
- Any other IRB/HIPAA form which the modification affects
- Any other relevant documentation (DSMB report, sponsor documentation, etc).
- Receipt Form, optional

Note: Assistance for completion of these forms can be obtained from the IRB Administrators, East Bldg., 4-79, ext. 88980