NEW JERSEY DEPARTMENT OF HEALTH
INSTITUTIONAL REVIEW BOARD

APPLICATION TO MODIFY HUMAN SUBJECTS RESEARCH

INSTRUCTIONS

- If requesting multiple modifications, each modification must be submitted on a separate application.
- All documents (protocol, recruitment documents, questionnaires, informed consent documents, etc.) must include in the footer of each page the 1) version date, 2) page numbers in the form of "X of Y" and 3) document title (e.g., "Informed Consent Document for Controls", "Recruitment Letter for Cases", "Questionnaire", etc.).
- Send one copy of each document.

Modifications to add investigators or research personnel:

- For each person you are requesting to add, provide a 1) curriculum vitae/resume, 2) current CITI research ethics training certificate, and 3) signed original *Agreement for the Ethical Conduct of Human Subjects Research* (OC-41 or OC-45).
- The response to Question #1 must include a detailed description of the activities to be conducted by the person to be added, including who will be responsible for supervising them.
- The response to Question #2 must include a detailed description of how the person is qualified to perform their assigned activities (e.g., experience, training, education, etc.)

Modifications to Recruitment Materials or Informed Consent/Assent Documents

- Provide one copy of the 1) currently approved version of the document with the deletions, additions and changes marked and highlighted and 2) new document without the deletions, additions and changes marked and highlighted.

Requirement to Re-Consent Currently Enrolled Research Subjects

- Research subjects must be re-consented if the proposed modification 1) creates a new risk, 2) increases the likelihood, magnitude or duration of a previously identified risk or 3) is inconsistent with the current informed consent/assent document or recruitment materials.

Email the application materials to: "*irb.dhss@doh.state.nj.us*".