Documents required for the submission of an application via ROAM

The DSRB relies solely on the documentation submitted by the Principal Investigator for review. Therefore, the Principal Investigator is strongly encouraged to submit their application well before the deadline for submission to allow the DSRB time to assess if there any missing documentation or information that is required for review.

A submitted research proposal will be scheduled for DSRB review only when the DSRB has determined that the information and materials submitted provides adequate description of the proposed research.

Click here for DSRB Submission deadlines <hyperlink to Ethics & Quality DSRB, meeting dates>

List of documents required for a new application must include the following, but is not limited to:

- A duly completed ROAM online DSRB Application.
- Informed consent form Study Protocol (this is mandatory for clinical trials involving drugs, medical devices and surgical procedures)
- Questionnaires, surveys, videotapes and other such related tools (if used).
- Copy of the approved grant application (including DHHS-approved study protocol and sample consent form, if one exists).
- Investigator's Brochure and other available safety information (for industry sponsored clinical trials).
- Recruitment materials intended to be seen or heard by potential subjects, including email solicitations (if used).
- Written information intended to be provided to subjects (if used).
- Curriculum vitae (CV) of Principal Investigators and co-investigators, updated within the last one year.

Additional documents which may be requested by the DSRB for submission:

- Data collection forms
- Financial disclosure statements
- Clinical trial agreement (for industry-sponsored research)
- Documentation relating to non-approval of study by another institutional review board (IRB)
- Translated informed consent form and translation certificates, or main English informed consent form accompanied by the translated short consent form
- Any other relevant documentation that the DSRB may specifically request
- Any other documentation to be given to subjects when in the judgement of the DSRB, the additional information would add meaningfully to the protection of the rights, safety and well-being of the subjects.