FAQ's ABOUT HUMAN SUBJECTS RESEARCH AT ODU

When should projects involving human subjects be reviewed?
All research involving human subjects must be reviewed and approved **before** data collection can occur to assure that subjects are being treated ethically.

Should I submit my proposal to the Institutional Review Board (IRB) or to a College Committee (CC)?
If you think that your study is exempt and the study is not federally supported, submit the proposal to your CC.
Use the Application Form For Exempt Research.
http://www.odu.edu/ao/research2/forms/exempt_application.doc

If your study is not exempt or if the study is federally supported, submit your proposal to the IRB.
Use the Human Subjects Research Review Application Form.
http://www.odu.edu/ao/research2/forms/irbapplication.doc

What are the deadlines for submission to the IRB?
The researcher shall submit at least ten (10) copies of the entire proposal and at least ten (10) copies of the proposed informed consent document to the Office of Research in 4111 Monarch Way, Suite 203. All submissions are due in the Office of Research by 5 p.m. on Monday one week prior to the IRB meeting.

How often does the IRB meet?
The responsible project investigator (RPI), or a member of the research team familiar with the project, should attend the Institutional Review Board (IRB) meetings regarding the project. The IRB meet monthly except for the month of July. For dates, go to the Office of Research's Human Subjects website,
http://www.odu.edu/ao/research2/compliance/humans.shtml

How long will it take to get a response from the IRB?
The IRB reviews proposals at each meeting. Studies are approved, approved with modifications, or disapproved. The Chair of the IRB will notify you within a few days of the IRB meeting regarding the IRB vote and whether any modifications to your proposal are necessary. Researchers are encouraged to attend IRB meetings to answer any questions the committee may have.

What is a Responsible Project Investigator (RPI)?
A RPI is a faculty or full-time staff member who assumes the responsibilities below. A student may not serve as a RPI.
- Submission of all required forms to the IRB or College Committee
- Conduct of the research
- Compliance with IRB/College Committee decisions
- Submitting proposed changes to previously approved research

How do I complete IRB/CC application forms?
- Answer every question fully
- Be sure to enter a brief but accurate description of the procedures in item #11; do not say "see attached."
- Type the application. Handwritten applications will be automatically rejected.
- Append to the application form:
  - research protocol (for funded proposals)
  - data collection instruments
  - surveys/questionnaires
  - recruitment materials
  - other pertinent information

How do I write an informed consent document?
- Use the ODU template http://www.odu.edu/ao/research2/forms/consent.doc
- Write in language understandable to the subject
- Include timeline for procedures – duration of each visit, total duration of study
- Use proper grammar
- Spell check
- Make sure that information in the informed consent matches the application
- Include local phone number for subjects to call with questions

What projects receive expedited review?

The IRB Chair performs expedited reviews in 2 instances:

- a collaborative project has already been approved by a separate IRB
- a revision is being made to a project already approved by the ODU IRB

What is the application process for studies that have been approved by another IRB?
The IRB Chair can perform an expedited review, since the research is already approved by another IRB. The RPI must send the IRB Chair a copy of the IRB approval and application. If the project utilizes an informed consent document, the informed consent will need to be modified to include references to ODU, the IRB Chair, and the Office of Research.

A researcher from off campus wishes to perform a study at ODU without an ODU collaborator. What type of review is needed?
The only action needed by the RPI is to submit the IRB approval from another institution to the Office of Research. The Office of Research will then check to see if there is any obvious problem with allowing the study to proceed. If there are no problems, then the Office of Research will inform the RPI that he or she may proceed.

What type of training is required for investigators?

- All RPIs, proposing non-exempt research must document on-line training within the past 12 months from http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp
- A copy of the RPI's Human Participant Protections Education for Research Teams certificate must accompany proposal applications to the IRB.
- RPI's must ensure training of all personnel, but certificates are not required by the IRB.

When can I start collecting data?
You cannot start collecting data until you have an approval letter in hand! You must conduct the study according to the approved protocol and IRB and/or College Committee conditions.

What happens if I want to make a change to the protocol after the study is approved?
Submit **ANY** proposed changes directly to the IRB Chair for review and approval before implementing them. Such changes include:

- Alteration of study design, methodology, or recruitment methods
- Changes to any instruments, including surveys and questionnaires
- Changes to informed consent documents
- Addition/deletion of investigators
- Alteration of Project Title
- Addition of research sites

Changes to exempt studies do not need review unless the change makes the study non-exempt.

What is an adverse event (AE)?

- An adverse event is any illness, injury, trauma experienced by a subject during the course of a study that required medical or psychological treatment. Such events may occur during data collection or outside of data collection, at the research site, or away from the research site.
- A serious AE is one that resulted in death, life threatening situation, inpatient hospitalization, significant disability, or a birth defect.
- An unexpected AE is an adverse event that is not currently listed in informed consent.

What type of adverse events should be reported and how?

- All adverse events should be reported, even those that do not appear to be related to the study.
- Serious or Unexpected: Report to IRB within 5 days; AE form (If serious, physician comment required)
- Neither Serious nor Unexpected: Report to IRB within 1 month; AE form

http://www.odu.edu/ao/research2/forms/adverse_events.doc

Can I do a study for more than a year?
Submit a progress report if a non-exempt project is to last longer than the approval period, which is typically 1 year. Submit 10 copies of the Progress Report to the Office of Research 2 months prior to the study's expiration. The study must be reviewed and re-approved by the IRB for research to continue.
http://www.odu.edu/ao/research2/forms/progress_report.doc

When is a study complete?
Non-exempt studies are considered complete when data collection and data analysis are complete. Submit 1 copy of the Close Out Report to the Office of Research 1 month after your study is complete.
http://www.odu.edu/ao/research2/forms/closeout_report.doc

If you have additional questions, please contact:

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