## **Standard Research**

The UC IRB must review and approve all human research activities conducted at the University of Cincinnati or conducted by UC faculty, students, and staff. In order to approve research, the IRB shall determine that all of the following requirements are satisfied:

- 1. Risks to subject are minimized: by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, <u>and</u> whenever appropriate, by using procedures being performed on the subjects for diagnostic or treatment purposes.
- 2. Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.
- 3. Selection of subjects is equitable.
- 4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- 5. Informed consent will be appropriately documented.
- 6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards must been included in the study to protect the rights and welfare of these subjects.

If an investigator is conducting human research activities that involve interaction or intervention with human subjects and/or the analysis of individually identifiable specimens or data that will be collected prospectively, then a Standard Research Project must be submitted through the electronic Protocol Administration System (ePAS) using this link: <u>electronic Protocol Administration System (ePAS)</u>.

**Note**: All investigators will need to gain access to ePAS in order to submit through the electronic system. Click <u>here</u> for instructions on how to gain access.

## **Scientific Pre-Review**

A scientific review must be completed prior to submission to the IRB for all non-exempt medical human research protocols, except those solely involving pre-existing records and/or specimens is required prior to submission to the IRB. Please <u>click here</u> for more details on this process.

## **Initial Submission or Amendment Review Process**

1. After the investigator gains access to the ePAS system, please select "My Home" from the upper right corner.

- 2. Select either "New IRB Application" or "New Amendment" from the left margin and answer the questions presented to you. For new submissions, please ensure that "Standard Research Project" on the Research Classification page (4th screen) is selected.
- 3. Select "Finish" at the end of the submission.
- 4. Select "Submit Study" from the "My Activities" list in the left margin of the screen.

You will receive an email notification from ePAS with comments/questions or your submission will be forwarded to an IRB member for review within 2 weeks of submission.

## **Continuing Review Process**

- 1. After the investigator gains access to the ePAS system, please select "My Home" from the upper right corner.
- 2. Select "New Continuing Review" from the "My Activities" list in the left margin and answer the questions presented to you.
- 3. Select "Finish" at the end of the submission.
- 4. Select "Submit Study" from the "My Activities" list in the left margin of the screen.

You will receive an email notification from ePAS with comments/questions or your submission will be forwarded to an IRB member for review no later than one month prior to expiration.

If an investigator is collecting or studying existing data, documents, records, pathological specimens, or diagnostic specimens, then a "Use of Existing Records and/or Specimens" submission must be submitted through the <u>electronic Protocol Administration System (ePAS)</u>.