**IRB Procedures for Investigators**

Any member of the York College community who wishes to engage in research on human subjects must submit an application to the College IRB, and wait to receive approval from the Board before commencing with their research.  If you have questions, feel free to contact the Chair of the IRB.

**Contact Information**

Questions, applications, and general correspondence relating to York's IRB should be directed to the Chair of the IRB.  He will route materials to the appropriate party.  Currently (2015-16) the Chair is:

>   Carl Seaquist, Associate Dean of Academic Affairs
>   cseaquis@ycp.edu
>   717-815-2084  (office)

**Overview of the IRB Process**

The website of the YCP IRB will provide current forms, directions, guidance, and other documentation necessary for investigators to follow the IRB process.  Investigators should familiarize themselves with these documents and check the website before commencing with a new or revised application.

A note on terminology:  we use the term "modification" to refer to changes to applications that have been previously approved by the IRB, and "clarification" to additions to an application made during the consultation process but before approval.  Clarifications may be in the form of additional information provided in response to questions from the IRB, or alterations to procedures that were described in the original application.  Final clarifications should be collected in one formal document and submitted to the IRB as an appendix to the original application, or in an updated application; but they may result from a process of informal communication between the PI and the IRB.

Below are the steps to be followed in seeking IRB approval of human subject research:
1. Principal Investigator (PI) submits an initial application to the Chair of the IRB by email.
    a. When a new version of the application form is distributed through the website, investigators may continue to use the previous version for two months.

2. The Chair of the IRB will acknowledge receipt of the application by email, and will provide the PI with an application number that will serve to track the project throughout the life of its research, including any subsequent modifications to the originally submitted draft.
    a. This is more than just acknowledgement that the application was received.  At this point the Chair will have either given the application a first read or sent the application to a Board member for initial review, and the PI will receive some kind of status report.
3. If there are concerns regarding the initial application, the Chair will relay them to the PI informally (through email rather than a separate memo, and/or by voice).  The IRB will work with the PI to find solutions to these concerns, and if necessary bring additional parties into the conversation who may provide useful advice or specialist knowledge.
    a. While many IRBs issue formal statements of conditional approval or rejection, the YCP IRB will generally only issue such statements at the request of the PI.  Our goal is to work with investigators to find a solution that meets your research needs while protecting the rights of research subjects, and we view outright rejections as inconsistent with this vision.
    b. Occasionally, for the sake of time, we will issue approval conditional on small changes that we believe the PI will find unobjectionable.  Feel free to object to these conditions.  Such conditional approvals should be viewed as part of the communication process and not as definitive judgments.  However, acceptance of these conditions mean that you do not have to send us a further clarification but rather can move straight into your research.
4. If necessary, investigators will submit *clarifications* to the original application.
5. Once the Board is satisfied that the proposed research meets appropriate standards, the Chair will send a memo to the PI indicating that the project has been approved, and providing additional or summary information as necessary.
6. If, after a project has been approved, investigators find it necessary to modify their research, they should consult with the Chair about whether a formal *modification* needs to be submitted to the Board in order to continue with research.
7. IRB approval lasts only for a calendar year, and research projects lasting more than a year will have to be resubmitted to the Board.  We will attempt to track projects that we know will last more than a year and send you timely reminders, but the ultimate responsibility for completing or ceasing research, or renewing approval, rests with the PI.

The Chair will mediate between the Board and investigators, unless he delegates this task to a member of the Board.  The Chair may read a large portion of applications and is authorized to approve proposals on behalf of the Board.  He may also forward applications to members of the Board and either solicit their feedback or authorize them to oversee the rest of the steps outlined above for that project.  When special expertise is needed to properly evaluate a research proposal, an application will be forwarded to a Board member with the relevant expertise, or an outside reviewer may be solicited.  The IRB does not currently have funds to pay outside reviewers for their help, so such assistance must be provided *pro bono*.  The entire

IRB will only be asked to weigh in on a project when necessary, and this will be done electronically when possible. The entire Board will meet together in person rarely.

Applications requiring full review must be reviewed by the entire Board. The Chair or another single reader from the Board may deem a project to be exempt, or may approve a project that is deemed exempt from further review or subject to expedited review.

**Timeline**

Applications and modifications to applications will be acknowledged within a week of receipt, and generally PIs will receive either approval or requests for further clarification within this time span. If an application requires additional time for review, PIs will be informed of this fact.

The IRB will not give approval to proceed with research until it is convinced all relevant issues have been adequately addressed. Our goal is to facilitate research and not to hold it up, but our chief obligation is to the subjects of research and we cannot compromise this in order to meet investigators' timelines. That said, if you are under strict time pressure, let us know and we will do what we can to help you meet your deadlines.

Most of the applications we receive are fairly straightforward and easy to process; when delays occur, it is generally because initial applications were incomplete or missing necessary attachments. When we encounter highly complex or technical research projects, or those that entail greater risks to subject safety or privacy, or involve special or vulnerable populations, we may have to seek outside consultations and this can slow our response time. If you anticipate pursuing research along these lines, you are encouraged to make contact with the Chair as soon as possible, even before submission of application materials, so that we can begin planning for your submission.

Investigators are encouraged to check in with the Chair if an application or modification has not been acknowledged within a week, or if, in further stages of the process, they have not heard back from the IRB in what they consider a reasonable time.

**Acceptable Formats for Documentation of IRB Processes**

All formal documentation of IRB processes and deliberations will be in the form of Word or PDF files, and these will be sent and stored electronically. Communications between the Primary Investigator (PI) in the body of emails or by voice will not constitute official records of Board decisions or elements of the research project. This requirement that all official documents be in Word or PDF format is designed to facilitate documentation of the actions of the IRB. The Chair can be of assistance should investigators have difficulty with the electronic submission of documents.

**Application Materials**

For initial applications, please submit a completed application form along with all additional documentation (informed consent documents, surveys, descriptions of research or debriefing protocols, letters from relevant third parties, etc.), preferably in a single pdf file.  Submissions will be deemed incomplete even if they are missing just one necessary attachment, so please double check that you have included everything that you need to provide.

If we realize that a document is missing, you can simply submit that at a later time:  you do not need to resubmit the entire package.  However, please be aware that careful review of application materials takes time, and we may have to review the entire application when a new attachment arrives.  Thus piecemeal submission can (and generally does) slow our response time.

All of the above comments also apply to revisions of previously approved applications.  There is a separate document that describes the formatting of revisions.


**Review Categories**

IRB applications can fall into three categories:  exempt, expedited, and full.  There are strict guidelines that determine whether an application can be reviewed by exempt or expedited means.  This does not depend, as is frequently assumed, just on the level of complexity of the research, or on whether there is material risk involved in participation.

Few IRB applications received at York College meet the standards for exempt review, but as a practical matter this makes little difference since it does not affect the amount or type of information that we request.  If on your application you seek exemption from further review, please read the document that describes the criteria for exempt review; and explain in the corresponding field which criterion is relevant and how your research meets this criterion.  Note that "exempt" does not mean a project can avoid all IRB review:  it just means that certain requirements can be avoided.

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