

Procedures for the MOC Human Subjects Review Committee

REGULATORY REQUIREMENTS

The Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b) (4) and (5) require that institutions have written Institutional Review Board (IRB) procedures for each of the following:

(1) Procedures for conducting the initial review of research (HHS regulations at 45 CFR 46.103(b) (4) and (5))

a. The initial contact

The request for faculty or student research is usually in the form of question: “Is this research and do I need approval to proceed?”

These inquiries are directed to the Human Subjects Review Committee (HSRC) Chair for review and resolution. This person gathers enough information to decide whether this project is research and needs to be reviewed by the Human Subjects Review Committee (HSRC) and, if so, by which committee. While it is basically a yes/no decision, there may need to be additional information gathered. The investigator (the individual submitting the request) does not make the decision about review, and the decision is not made by negotiation over the telephone. The initial “official” response is to seek more information. This action usually occurs, apart from the telephone conversation, via postal or e-mail communication.

The HSRC Chair makes the determination whether a proposal may be exempt from further IRB review (that it is **not** research), qualifies for expedited IRB review, or is subject to full IRB review. The HSRC Chair will also conduct a pre-review of the project. This may include working with the investigator on suggested changes.

b. The Information Packet

The information packet will be available to all investigators online at www.moc.edu . The following materials will be available online and are necessary for IRB review:

1. the application form
2. a sample informed consent statement
3. a link to the CITI human subjects training which must be completed prior to submitting application materials to the IRB
4. a document describing the application process for human subjects research

*There will also be additional information and links to outside sources regarding human subjects research on the web page.

c. The Human Subject Review Committee Folders and Database Entries

All projects are organized by a numeric system that provides a unique identifier. The last two digits of the year and the month of project approval are the first four digits. The last two digits (there's a hyphen in between digits 4 and 5) represent the number of that proposal for that month. 0201-06 is the first proposal approved for January, 2006. Following the digits should be the Principal Investigator's name.

The numeric code identifies the month of IRB approval, not time of review.

Each project requires two file folders: a paper copy and a copy in Word document folders within the Human Subjects Review Committee (HSRC) database. The Word document should contain a brief summary of information. A paper copy of all paperwork generated will be placed in a folder and filed in a locked cabinet in the IRB Chair's office.

The folders are labeled with the numeric identification code number, the last name of the PI and one-word title, academic affiliation, and topic area. For example, a folder labeled "0101-06, Smith, A & S, Escapes" indicates that the project was approved in January, 2006 is the first project of that month, was initiated by Smith from the School of Arts and Sciences in the topic area of escapes.

Data entries are made into the Human Subjects Review Committee (HSRC) database (maintained by the IRB Chair) for all projects, regardless of the eventual decision as to whether the project qualifies as research.

d. The Initial Application Review

The HSRC School Subcommittee Administrator or HSRC Chair (distinction described below) will review the file for completeness to spot obvious deficits. The School Administrator or Chair will not submit an incomplete proposal for official review. The School Administrator or Chair will contact the investigator if the project application is not complete.

The following items are necessary to complete the packet:

- A completed application form
- A copy of all tests, interview questions, surveys, etc.
- An Informed Consent statement
- Certificate of completed on-line CITI human subjects training

The agenda deadline for the submission of materials is 10 working days prior to the meeting. The HSRC School subcommittee meetings will be held on the 2nd Monday of every month. A full IRB review will be held on the 3rd Monday one time per quarter in August, November, February, and May. Proposals for expedited review are submitted to the appropriate HSRC School Subcommittee Administrator (i.e. Arts and Sciences, Tillman School of Business, or School of Professional Studies). Proposals that require full board review are submitted directly to the IRB Chair. Any proposals deemed necessary for full IRB review by the School Subcommittee Administrator will be re-submitted to the IRB Chair 10 working days prior to a scheduled full board meeting. The School Subcommittee Administrator will also notify the primary investigator of the need for full review. The School Subcommittee Administrators and HSRC Chair (in the case of full review) will review the applications for completeness and distribute materials to the subcommittee members 5 working days prior to the meeting. Incomplete

proposals will be returned to the investigator indicating what is missing and the next deadline for submission.

Primary (First) Reviewer

Expedited Review:

The School Subcommittee Administrator will designate a Primary Reviewer. This individual will present the study at the School Human Subjects Review Subcommittee meeting. This individual will have read the study and be able to explain it to the other committee members. The School Subcommittee Administrator serves as the Second Reviewer on all projects. If either has questions, they should discuss it among themselves and/or call the Principal Investigator.

The Primary Reviewer will receive the following items to conduct the review:

- A completed application form
- A copy of all tests, interview questions, surveys, etc.
- A revised Informed Consent statement
- A copy of the certificate of completed on-line training

It is permissible, and may be desirable, to request the Principal Investigator to come to the meeting to explain the project to the other committee members and answer any questions.

Full Review:

The above primary reviewer system will be used for protocols requiring full IRB review with the IRB chair designating a Primary Reviewer and serving as second reviewer.

a. Meeting Agenda

The School Subcommittee Administrator, or IRB Chair in the case of full review, will construct the agenda. The agenda will list all of the proposals to be considered (each to follow the format below) and will attach all the relevant supporting materials. These materials, in Word format, will be emailed to all members 5 days prior to the meeting.

Below is the presentation style:

Proposal 0301-06, Smith

Title: *The effects of CBI program participation on infractions by adult male inmates*

Principal Investigator: Troy Smith, student, MOC School of Arts and Sciences

MOC Sponsor: Dr. John Smith, School of Arts and Sciences

Outside Sponser: (if grant funded, etc)

First Reviewer: Foster

All materials will be sent out to the members 5 days in advance. Ideally, materials will be sent via electronic mail (Word documents are attached to the email). In some cases where the relevant material is on paper (a copy of test or literature), the two reviewers should get these. Printed material of all projects will be available at the meeting.

f. The Meeting

The Chair or Subcommittee Administrator depending on the level of review convenes the meeting when quorum is achieved. Both the Chair and the Subcommittee Administrator will take detailed notes to prepare the minutes and memos to the investigators. The Chair will review the previous minutes and call for a vote. If approved without change, the Chair will sign the minutes. In the case of an expedited Subcommittee review, the Subcommittee Administrator will sign the minutes and send them to the IRB Chair for review and second signature. If there are changes, the Subcommittee Administrator will make these, correcting the copy and have these signed by the Chair (there is no need for the full committee to re-approve these minutes).

The Chair / Subcommittee Administrator will review other business, and introduce the education section. (This is a 10 – 15 minute presentation along with a handout on an issue relevant to the protection of human subjects in research.)

The Chair / Subcommittee Administrator will initiate and facilitate the presentation, discussion, and voting on each of the proposals. S/he will recognize the Primary Reviewer. After this individual is finished, the Chair / Subcommittee Administrator will add comments. The Chair / Subcommittee Administrator will ask for discussion and appropriately call for a vote until the meeting materials are finished.

The Chair / Subcommittee Administrator is responsible for documenting who is present or absent, and how each person voted on each proposal.

The HSRC can take the following actions:

1. Approve
2. Disapprove
3. Defer or table
4. Review stopped / Approve pending modification:
 - a. Substantive changes requiring it to come back to full or subcommittee, or
 - b. Minor changes allowing for the HSRC Chair to review these minor changes.

Both the minutes and the memo to the Investigator will indicate the status of the project using one of the four categories above. The status also applies to the informed consent document. If either is found unacceptable, the deficiencies and the suggested corrections will be listed. The memo will state clearly whether the Full Board or Subcommittee wants to review the corrections or if the HSRC Chair will conduct an administrative review.

The memo to the Investigator for Category 4 (Review stopped / Approvable pending modification) needs to state clearly that the study may not be undertaken until the revisions have been submitted to the full committee or the Chair, and that appropriate approval is granted. This memo elaborates the list of stipulations and suggestions, and needed action on the part of the Investigator.

Statutory Note:

(5) Contingent Approval of Research with Substantive Changes and no Additional Review by the Convened IRB. OPRR finds that the IRB frequently approves research contingent upon substantive modifications or clarifications without requiring additional review by the convened IRB. OPRR recommends the following guidelines in such cases: (i) When the convened IRB requests substantive clarifications, protocol modifications, or informed consent document revisions, IRB approval of the proposed research must be deferred pending subsequent review by the convened IRB of responsive material. (ii) Only when the convened IRB stipulates specific revisions requiring simple concurrence by the investigator may the IRB Chair or designated reviewer subsequently approve the research on behalf of the IRB." "OPRR Compliance Activities: Common Findings and Guidance" (11/29/99)

g. The minutes

The Subcommittee Administrator, or HSRC Chair in the case of full board review, is responsible for the first draft of the minutes. The subcommittee will review these for completeness. The minutes will be written in a manner to fully explain the committee's decisions and rationale for those decisions.

The minutes will be completed by the Subcommittee Administrator, or HSRC Chair in the case of full board review, and sent out within 5 working days after the meeting to committee members and HSRC Chair for review. Corrections may be incorporated at the time they are received although the minutes will not be approved until the next Committee meeting.

h. The memo to the Investigator

The HSRC Chair, using the content of the minutes, will construct the memo to the Investigator. This memo will be written in a manner to fully explain the committee's decisions and rationale for those decisions.

The memo to the Investigator will be completed within 5 working days of the meeting. It will be sent out via e-mail and, if necessary, supporting papers sent out via postal mail.

Human Subjects Review Committee (HSRC) membership

The Human Subjects Review Committee (HSRC) Chair will maintain a roster of all standing and alternate members of the Human Subjects Review Committee (HSRC) according to procedures established by the IRB Chair and the VPAA. The list will be in the format prescribed by OHRP.

An alternate may serve for multiple Human Subjects Review Committee (HSRC) members but the roster needs to denote members for who alternates will serve. The meeting minutes should document when an alternate member replaces a primary member.

Consultants are not alternate members. Should the Human Subjects Review Committee (HSRC) believe that it needs to add special expertise to its review, the Chair or Subcommittee Administrator may bring a person on board as a consultant (45 CFR 46.107(f) and 21 CFR 56.107(f)). A consultant is not counted toward the quorum and cannot vote but can otherwise

participate in all deliberations of the IRB. A consultant could also provide a written report in addition to or instead of participating in the convened meeting.

Conflict of Interest

HHS regulations at 45 CFR 45.107 stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. OHRP recommends that except when requested by the IRB to be present to provide information, IRB member absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such should be noted in the IRB meeting minutes.

Database Research

Research with all and any staff or student records that contain identifiable confidential information (in any official database, personnel files, medical records, quality assurance databases, etc.) needs to be submitted to the Human Subjects Review Committee (HSRC) for review for each research question that is going to be addressed with data from the database/registry. There are no blanket approvals for a researcher to conduct various, yet-to-be-specified, studies using database/registry data.

A retrospective chart review is "exempt" if the data collection sheet that the investigator uses to record his/her data on has no provisions for any identifying information. Recording an identifier and then not giving it to the data entry person doesn't qualify.

ASQ (Automated System Query) searches do not meet this criterion and are exempt from review. All information deemed to be public record does not meet this criterion.

(2) Procedures for conducting continuing review of research (HHS regulations at 45 CFR 46.103(b) (4) and (5))

a. Approval timeframe

All research involving human subjects is subject to continuing IRB review at intervals appropriate to the degree of risk, but at least once per year. Before the end of that year, the Human Subjects Review Committee (HSRC) must review and approve the project's continuation.

The date is one year from the last review and approval. The memo to the Investigator needs to state the date upon which the approval expires.

The tracking database should be set to notify the IRB Chair 3 months in advance of the approval expiration. The Chair should contact the Principal Investigator as a reminder of the impending expiration, and that the request needs to be in the office the month prior to the project expiration date.

The Principal Investigator will submit the IRB application for approval of research involving human subjects cover page and a status report summarizing the progress made to this point to the HSRC Chair. According to OHRP guidelines the status report should include: (i) the number

of subjects accrued; (ii) a summary of adverse events and any unanticipated problems involving risks to subjects or others, or any withdrawal of subjects from the research or complaints about the research since the last IRB review; (iii) a summary of relevant recent literature, interim findings, and amendments or modifications to the research since the last review; (iv) any other relevant information, especially information about risks associated with the research; and (v) a copy of the current informed consent document and any newly proposed consent document.

The IRB minutes will document separate deliberations, actions, and votes for each protocol undergoing continuing review.

Conducting human subject research without current IRB approval is a violation of federal and institutional regulations. If IRB approval of a project expires, no new subjects may be enrolled and all ongoing research activities must stop.

(3) Procedures for notifying Investigators and the Institution about its findings and actions (HHS regulations at 45 CFR 46.103(b) (4) and (5))

a. Institution notification

Both the agenda and the minutes are sent to the following institutional officials. These staff represent the interest of the College.

- IRB Chair
- Vice President for Academic Affairs
- Vice President for Institutional Research and Planning

The role of these staff is to review the projects for possible administrative concerns from within their division that might affect the decision to implement.

The IRB has the responsibility to make final decisions regarding the implementation of any research project involving human subjects. In accordance with HHS regulations at 45 CFR 46.112, no other institutional office or official may approve human subjects research that has not been approved by the IRB.

b. Investigator notification

The memo to the Investigator will be completed within 5 working days of the meeting. It will be sent out via e-mail and, if necessary, supporting papers sent out via postal mail. The memo will highlight the status of the project (see the 4 possible actions) and needed actions.

The memo to the Investigator needs to state the date upon which the approval expires, one year from the date of the last review and approval, and a description of what steps must be taken to ensure that the investigator does not implement any protocol changes without prior IRB review and approval.

(4) The procedures for determining which projects require review more often than annually (HHS regulations at 45 CFR 46.103(b) (4) and (5))

This decision is made during the discussion of the project at the meeting. If there is reason to deviate from the annual review, this is noted in the minutes and in the memo to the Investigator.

(5) The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review (HHS regulations at 45 CFR 46.103(b) (4) and (5))

There is no procedure at this point.

(6) The procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (HHS regulations at 45 CFR 46.103(b) (4) and (5))

There are no specific procedures other than a reminder to the Principal Investigator to do so.

(7) The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of: (a) any unanticipated problems involving risks to subjects or others; (b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and (c) any suspension or termination of IRB approval (HHS regulations at 45 CFR 46.103(b) (4) and (5))

There are no specific procedures other than a reminder to the Principal Investigator to do so.

