EMMANUEL COLLEGE

Committee for the Protection of Human Participants in Research (CPHPR) Policies and Procedures

Mission Statement

Emmanuel College's CPHPR reviews research with human participants. Research is defined as a systematic investigation whose purpose is to contribute to generalizable knowledge. At Emmanuel College, research is not expected to expose participants to any risk of physical danger or psychological distress other than what they would typically encounter as part of daily living.

This Guide incorporates information and language adapted from Department of Health and Human Services (DHHS) documents, the Simmons College IRB Manual, and the Sacred Heart University IRB Guide, and Consent Documents of University of Chicago, Fuller Theological Seminary, Northeastern University and Clemson University.

Thank you to Dr. Diana Stork for founding the IRB at Emmanuel College.

Committee for the Protection of Human Participants in Research
Policies and Procedures

General Policies of the Emmanuel College Committee for the Protection of Human Participants in Research (CPHPR)

Emmanuel College follows the ethical principles regarding research involving human subjects set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. These principles of Justice, Autonomy and Beneficence are set forth in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* and are classified as regulations in *Title 45 Code of Federal Regulations Part 46*.

Emmanuel College has additional requirements that are intended to establish the highest expectations for performance and oversight by investigators of all research activity. The CPHPR uses Bankert, E. A., & Amdur, R. J. (2006) (Eds.) *Institutional Review Board: Management and Function*. Boston: Jones and Bartlett as an additional resource.

The following policies and procedures outline the expectations of the Emmanuel College CPHPR:

1. Any research activity that could expose human participants to an unreasonable risk of harm may not be conducted.
2. The investigator(s) proposing to conduct research involving human subjects must be qualified by experience and/or training that protects the well-being of the human participants in their research.
3. Investigators have primary responsibility for determining whether human participants might be exposed to a risk of harm. Investigators must consult with the CPHPR for a final determination. Investigators also have primary responsibility for protecting human participants from being harmed by their participation in a study. All others involved in the study share this responsibility.
4. The CPHPR is authorized to review and to approve or disapprove, and to state conditions for, the conduct of any research involving human participant(s). In certain circumstances, the CPHPR will consult with others who are especially qualified to represent the views of a particular study or participant population. CPHPR members shall not participate in the approval of projects in which they are involved or have a conflict of interest.
5. Investigators shall explain the objectives of the research, the procedures to be followed, and the potential risks and benefits to participants prior to the start of the study. Investigators shall not use human participants in a study unless satisfied that they, or others legally responsible for their well-being, have consented to participation freely and with understanding of the consequences. Investigators must also obtain the assent of participants who are not legally capable of consenting to participation. The CPHPR may waive some or all of these requirements only when convinced that the research could not practicably be conducted otherwise, that the potential value of the research outweighs the risk to the participant(s), and that the participant(s) risks no other harm in participating. If appropriate, the CPHPR may also require that additional information about the study (a debriefing) be provided to participants after their participation.
6. Investigators shall respect the privacy of participants. They shall protect confidential information given to them, advising participants in advance of any limits upon their ability to ensure that the information will remain confidential.
7. Participants shall not be asked to participate in any way that might affect their ability to decide freely or feel coerced.

8. Participants will be aware that they may withdraw from active participation in the research at any time and without any ramifications. Participants that wish to withdraw will be able to do so quickly.
9. Investigators will share the source of support for the research when asked by a participant.
10. Instructors who assign or supervise research projects and exercises conducted by students are responsible for ensuring that the student is qualified to ensure the safety and well-being of the participants.

Emmanuel College is committed to the pursuit of high quality research and applied scholarship to meet the needs and interests of the academy, the College, and the community.

In accordance with federal regulations set forth by the United States Department of Health and Human Services' Office of Human Subjects Research Protections (OHRP), Emmanuel College requires that any research activity involving human participants be reviewed and approved by the Committee for the Protection of Human Participants in Research (CPHPR) prior to beginning any work on the project.

The CPHPR's purpose is to ensure that each research project involving human participants complies with the highest ethical standards and to protect the rights and welfare of human participants involved in research conducted by the College's faculty, staff, and students. In addition to its mandated review functions, the CPHPR is committed to serving as an educational resource for the Emmanuel College community.

It is the responsibility of all members of the Emmanuel College research community to observe the CPHPR policies and procedures for themselves and on behalf of students. Furthermore, failure to comply with the CPHPR's rules could impugn an investigator's own name and the reputation of the College and could lead to restrictions on the research activity of the individual and the College. Non-compliance with CPHPR rules by investigators or research staff may also lead to disciplinary actions by Emmanuel College.

Goals of the Committee for the Protection of Human Participants in Research (CPHPR)

- Protect the rights of human participants who participate in research conducted by faculty, staff, and students at Emmanuel College.
- Assess the risks and benefits of the proposed research in order to ensure that risks to human participants are minimized and are justified by potential benefits of the research.
- Ensure that information collected from research participants is kept confidential to the extent allowed by law.
- Protect participants by ensuring that an Informed Consent is obtained when appropriate.
- Support high quality research at Emmanuel College.
- Create a supportive process, encouraging discourse with researchers.
- Comply with applicable state and federal privacy laws.

CPHPR Membership and Authority

Emmanuel College's CPHPR typically reviews research in psychology, sociology, political science, business, and other social and behavior sciences, as well as research conducted by staff members of the Emmanuel community designed to improve collegiate services. Researchers also include

individuals from outside the Emmanuel community who conduct research with members of the Emmanuel community.

Emmanuel College's CPHPR consists of a Chair and Vice-Chair who are faculty members with experience reviewing research with human participants. The CPHPR Administrator is a member of the administration of the College, and the CPHPR Administrative Coordinator organizes the operations of the CPHPR. CPHPR members at Emmanuel College are chosen by the CPHPR Administrator based on their experience in reviewing research, their expertise in areas of research expected to come before the board, and their diversity, consistent with federal regulations http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.107. In addition, at least one member of the CPHPR comes from outside the College. At present, CPHPR members consist of the following individuals (link to CPHPR website - members):

The College's CPHPR has the authority to approve or disapprove any research involving human participants. No human participants' research may be conducted without the approval of the CPHPR. The CPHPR may require modifications in proposals for research with human participants as a condition of approval. The CPHPR also has the authority to suspend or terminate its approval of human participants' research that is not being conducted in accordance with the CPHPR's requirements or that has been associated with unexpected serious harm to participants. The College may disapprove research that the CPHPR has approved, but it may not approve research that the CPHPR disapproved.

Required Training for Researchers

- Emmanuel College requires completion Human Subjects Research through CITI www.citiprogram.org. The training provides the necessary information that investigators must know regarding the ethical principles of research for all human subject research, regardless of whether or not investigators have received funding to support their project. **This training is mandatory for all faculty, staff, and students who conduct/supervise research involving human subjects whether on campus or off-campus, whether funded or unfunded.**
- Once you have completed the online training course, please forward a copy of your training certificate to the CPHPR. The certificate can be sent as an email attachment or web link.

Responsibilities of an Investigator

The primary responsibility of the investigator in human participants' research is to ensure that the rights and welfare of the participants are protected. Keeping the participants from unnecessary risk is the ethical responsibility of each person who is involved, either directly or indirectly, in conducting research at Emmanuel College.

Investigators must assure that each member of the research team carries out all research procedures in accordance with ethical principles of research. These principles of Justice, Autonomy and Beneficence are set forth in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* and are classified as regulations in *Title 45 Code of Federal Regulations Part 46*. Investigators are strongly encouraged to read these and other relevant documents available at the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP) web site.

The Review Process

Federal guidelines require an independent review of protocols involving human subjects before an investigator can begin the study as a basic part of ethical conduct in research. This independent review process must provide an unbiased evaluation of the risks; promote the safety of research participants and documents that the research will follow federal regulations if approved. The CPHPR review will determine that the following requirements are satisfied in order to approve a study:

1. Risks to participants are minimized: (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk, and (b) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the CPHPR considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The CPHPR should not consider possible long-range effects of applying knowledge gained from the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of participants is equitable. In making this assessment, the CPHPR takes into account the purposes of the research and the setting in which the research will be conducted, paying particular attention to the special issues of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by DHHS regulation (45 C.F.R. § 46.116 and summarized below).

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by DHHS regulation (45 C.F.R. § 46.117 and summarized below).

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

7. When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

8. When some or all of the participants are likely to be vulnerable populations, additional safeguards have been included in the study to protect the rights and welfare of these participants.

At Emmanuel College, the CPHPR serves this independent review function. *It is the policy of Emmanuel College that no activities involving human subjects be undertaken until those activities have been reviewed and approved by the CPHPR*.

Go to FAQs for information on:

Q: What are the different **levels of review** and how is the level of review determined?"

Q: What is the **timeline for submitting protocols and obtaining approval** from the CPHPR?

Q: How does the CPHPR **assess risk** to participants?

Investigators are responsible for allowing a minimum of 3 weeks for the review process regardless of the level of review. Please carefully edit and proofread all application materials before submission to CPHPR as incomplete and missing information will cause delays in the protocol application review process.

The Emmanuel College CPHPR meets regularly to review protocols. Depending upon the nature of the research, some studies may be reviewed and approved independently by a smaller subgroup or by the Chair of the CPHPR. Other studies may require review by the full committee.

Protocol reviews are always prospective and never retrospective. Performing research with human subjects without prior CPHPR approval is unethical, illegal, and may jeopardize the rights and welfare of participants in research. A project that is conducted without CPHPR approval is subject to termination or other action by Emmanuel College.
-Link to CPHPR meeting dates and deadlines on the website

Investigators are responsible for adhering to the guidelines provided prior to submitting an application for review.

Protocol reviews are prospective. No retrospective approvals can be granted. *Performing research with human subjects without prior CPHPR approval is unethical, illegal, and may jeopardize the rights and welfare of participants in research*. A project that is conducted without CPHPR approval is subject to termination or other action.

In order to receive federal funding for research with human participants, Emmanuel College must have a *Federal Wide Assurance* (FWA) approved by the United States Department of Health and Human Services. In this signed agreement, Emmanuel College assures the federal government that all university research will be conducted in accordance with federal regulations for research. Any violation of research guidelines by the university or an investigator jeopardizes this agreement and threatens the College's federal funding.

These federal regulations are the minimal standards for research. State laws or college policies may impose additional requirements as deemed appropriate, but may not decrease requirements.

External Consultants/Outside Experts

The CPHPR may consult with someone knowledgeable in the investigator's field of study. If no one on the CPHPR meets this criterion, investigators may request that a particular person who is an expert in the area and who is willing to act as a consultant to the CPHPR be involved in the review. Although that person will not be able to vote on a proposal, his or her recommendations will be documented and considered by the CPHPR in making its decisions. If the CPHPR declines to adopt the recommendations

of the consultant, the CPHPR will document the rationale for taking an alternative course of action.

Conflicts of Interest

A CPHPR member is not permitted to participate in the CPHPR's review of a particular project proposal if that member has a conflicting interest, except to provide information requested by the CPHPR. Conflict of interest includes instances where a CPHPR member is collaborating with an investigator, supervising a student, or holds any type of intellectual, emotional, or financial interest in the outcome of a review. Should this occur, the CPHPR member with the conflicting interest will leave the room, and the minutes will reflect that this individual was absent during discussion due to a conflict of interest.

What Research Requires Review?

If you are conducting research with human participants, as defined below, your research requires review and approval for use of human subjects.

The Code of Federal Regulations 46.102f defines a *human subject* as a living individual about whom an investigator obtains:

- data through intervention or interaction with the individual, (such as, interviews, surveys, clinical testing, or any other physical intervention or personal interaction), or
- identifiable private information.

Legal requirements to protect human subjects apply to a broader range of research than many investigators realize. Protections are required for research that uses:

- Bodily materials, such as cells, blood or urine, tissues, organs, hair or nail clippings, *even if you did not collect these materials.*
- Residual diagnostic specimens, including specimens obtained for routine patient care that would have been discarded if not used for research.
- Private information, such as medical information, which can be readily identified with individuals, even if the information was not specifically collected for the study in question. Research on cell lines or DNA samples that can be associated with individuals fall into this category.

These policies apply to research conducted by faculty, staff or students of Emmanuel College on-campus or off-campus. Research that uses any Emmanuel property or non-public information to identify or contact prospective participants must be reviewed and approved prior to recruiting participants or collecting data.

Procedures for Submitting Proposals for Review

- Read the FAQS and *Policies and Procedures for Protecting Human Participants in Research* to understand the procedures for which you are responsible as an investigator and to assist you in completing the *Proposal Summary Form (PSF)*.
- Complete the PSF. *This must be signed by the Investigator and the department chair when applicable.*
- Other forms, as described in the PSF, may be necessary.

Only one copy of the *Proposal Summary Form* and the appropriate attachments are necessary for the initial review submission. Please contact CPHPR@emmanuel.edu with any questions on completing the PSF and about relevant regulations.

Review Process

Initial Review and Timeframe

Upon receipt of the *PSF*, the CPHPR Chair conducts a preliminary review. Investigators are responsible for allowing a minimum of 3 weeks for the review process - you should apply at least 4 weeks before your anticipated start date for the project.

As part of the initial review, CPHPR assigns protocols to a review level – link to FAQ "**What are the different levels of review and how is the level determined?"**

Protocols are reviewed in the order in which they are received. Link to "**What is the timeline for submitting protocols and obtaining approval from the CPHPR?"**

Classroom Research

Professors who assign a research project to be conducted by students within the time frame of an academic course should complete a Human Subjects Research Classification form and submit it to the CPHPR prior to the start of the course when possible. Link to "**If my students are doing research projects assigned through my course, what do I need to do?**

Using Students as Research Study Participants

Faculty members at Emmanuel College may not recruit students from their classes for personal research projects as this could be viewed as coercion. Postings on general information boards may be used to recruit students.

In general, if students are directly recruited to participate in research, it is of the utmost importance to avoid undue influence or coercion (or even the appearance of coercion). It must be explicitly stated that the decision of a student to participate or not will have no effect on their class standing or any relationship with the faculty member or the College.

Investigators should consider their reasoning for recruiting students and ask themselves if students are a convenient sample or are they a representative sample of the target research population.

Research Involving Children

Children are more vulnerable as research participants due to their limited capacity to understand and make responsible decisions concerning participation. Therefore, special attention is required in the preparation and review of protocols involving children as participants/subjects cfr46.401-409.

Obtaining parental permission/child assent

Written *permission* from the parent or guardian is required for a child to participate in research, including surveys and interviews, unless otherwise determined by the CPHPR.

A child cannot provide legal *consent* to participate in research. Provisions should be made by the Investigator to obtain *assent* from all children who are capable. Assent means a child's affirmative agreement to be in the study. Failure to object is not considered assent. Children have the right to refuse to participate.

Assent is to be obtained from the child unless there is a clear, written justification for not obtaining assent, e.g., age, maturity, psychological state.

Assent may be oral if the Investigator provides sufficient explanation that written assent is not feasible.

Judgments about the capability of providing assent may be made for each child or for all the children. This must be clearly specified.

There must be a clear means of documenting how assent is obtained, and by whom. When appropriate, a separate assent form should be drafted with language appropriate to the child's developmental level.

Explanation of and process for quitting or withdrawal from the research

Since children tend to be agreeable to the direction of an adult and may be reluctant to speak up when uncomfortable, special care and attention must be given to processes for discontinuing and withdrawing from research. Along with the usual statements in the informed consent, the researcher is advised to:

- Be aware of signs of discomfort shown by the child throughout the interview or testing procedures and periodically inquire about the child's reactions or feelings.
- Include procedures for withdrawal that address the above considerations.

Other Vulnerable Populations

Individuals who are elderly, prisoners 46.301-306, pregnant 46.201-211, mentally-disabled, ill, economically or educationally-disadvantaged, do not speak English, etc., are likely to be vulnerable to coercion or undue influence and therefore require special precautions in research procedures 46.111(7b). Include additional safeguards in the protocol, recruitment and consent procedures to ensure that the rights and welfare of these participants are being protected adequately.

CPHPR Determinations and Approvals

The CPHPR will notify the investigator and Emmanuel College in writing of its decisions concerning project proposals. CPHPR decisions regarding expedited and full reviews will be assigned to one of four categories:

1. *Approved*
   The CPHPR may approve a project proposal so long as all criteria set forth in the DHHS regulations at 45 C.F.R. § 46.111 are satisfied. The investigator may not begin the study until it has been approved and all required forms have been submitted to the CPHPR.

2. *Approved Contingent upon Specific Modifications*
   The CPHPR may conditionally approve a project proposal, requiring that certain modifications be

made before commencement of the study. If the CPHPR conditionally approves a project proposal, it will notify the investigator in writing as to the nature of the required modifications. The investigator must resubmit a revised project proposal to the Chair of the CPHPR incorporating the modifications. If the Chair of the CPHPR, acting on behalf of the entire CPHPR, determines that all required modifications have been adopted in the revised proposal and approves the modified project proposal, the investigator will be notified. The investigator may not begin the study until it has been approved and all required forms have been submitted to the CPHPR.

3. *Deferred Due to Serious Concerns*
   The CPHPR may defer reaching a determination on grounds that it is uncertain whether the investigator can address adequately its concerns. The investigator will be notified in writing as to the nature of the CPHPR's concerns and any required modifications. If the investigator believes he or she can address the CPHPR's concerns and comply with all of its required modifications, the investigator then may resubmit a revised proposal incorporating the modifications. If the entire CPHPR determines that all required modifications have been adopted in the revised proposal and approves the modified project proposal, the investigator will be notified. The investigator may not begin the study until it has been approved and all required forms have been submitted to the CPHPR.

4. *Withdrawn*
   If the CPHPR does not receive a response from an investigator in within one month (unless other arrangements have been made with the Chair); the CPHPR can inform the investigator that the project is withdrawn from review. Should this occur the investigator will have to re-submit the proposal for a new review.

5. *Disapproved*
   Project proposals may be disapproved only upon full review by the CPHPR. If the CPHPR decides that the investigator may not proceed with the project, it will notify the investigator of such decision in writing and explain the reasons for its decision. The investigator will be given an opportunity to respond in person or in writing.

Note: If the CPHPR determines that a research proposal is exempt from review, the investigator may not begin the study until all required forms have been submitted to the CPHPR.

After any of the above decisions are communicated by the CPHPR to the investigator, the investigator can contact either the Chair of the CPHPR or another CPHPR member designated by the Chair to discuss the proposal and the CPHPR's decision.

Compliance and Non-compliance

All Investigators are required to conduct research projects in accordance with the CPHPR policies and procedures, federal regulations, state law, and College policy in order to be in compliance. Non-compliance can be minor, serious or continuing as defined below:

Non-compliance: Any action or activity associated with the conduct or oversight of research involving human participants that fails to comply with the research plan as approved by the

CPHPR, federal regulations or institutional policies governing such research. Non-compliance may range from minor to serious, be unintentional or willful, and may occur once or several times.

Minor non-compliance: Any action or omission in the conduct or oversight of research involving human participants that differs from the approved research plan, federal regulations or institutional policies but because of the nature of the change, research project or participant population does not place, or have the potential to place, participants at greater risk than previously anticipated. Examples of minor non-compliance include, but are not limited to:

- Changing investigator, co-investigators or student research assistants without notification/approval by the CPHPR
- Changing the wording in surveys, interviews or questionnaires without CPHPR approval

Serious non-compliance: Any action or omission in the conduct or oversight of human research that impacts the rights and welfare of participants, increases risks to participants, decreases potential benefits of the research or compromises the integrity or validity of the research. Examples include, but are not limited to:

- Conducting non-exempt research that requires direct interaction or interventions with human subjects without first obtaining IRB approval;
- Enrolling subjects who fail to meet the inclusion or exclusion criteria in a protocol that involves greater than minimal risk and that in the opinion of the IRB Chair, designee, or convened Committee, places the participant(s) at greater risk;
- Failure to adequately provide informed consent as described in the IRB approved protocol;
- Inadequate supervision in research involving experimental drugs, devices or procedures;
- Failure to follow recommendations made by the Committee to ensure the safety of subjects;
- Failure to report appropriate adverse events, unanticipated problems, or proposed protocol changes to the Committee or
- Serious protocol deviations that place, or have the potential to place, participants at increased risk from the research.

Continuing Noncompliance: A pattern of non-compliance that, in the judgment of the IRB Chair, designee, or a convened Committee, indicates a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants, compromises the scientific integrity of a study such that important conclusions can no longer be reached, suggests a likelihood that non-compliance will continue without intervention, or frequent instances of minor non-compliance. Continuing non-compliance may also include failure to respond to a request from the IRB to resolve an episode of non-compliance.

Renewing or Closing Your Study: Continuing Review and Annual Renewal

The purpose of continuing review is to analyze a study and to determine if the anticipated risks and benefits are reflected in the actual experience of the human participants. Additionally, this process ensures that the intended safeguards are indeed adequate to protect the participants from any harm.

The initial CPHPR approval is based on the researcher's estimation of the anticipated risks and benefits to the participants. After the research begins, often this can shift and be understood more concisely. As such, it is important for the researchers to engage in continuous re-evaluation of their projects.

The continuing review process for the CPHPR is done by completing progress reports on a project. The investigator submits regularly scheduled reports at least annually and sometimes more frequently if there are concerns about risk to participants. This will be decided by the CPHPR when the original CPHPR approval is granted.

Ongoing monitoring

It is also expected that researchers will monitor the progress of the project on an ongoing basis in order to address any adverse events or changes to the intended effects to participants. Investigators need to ensure that procedures are in place for the continuous monitoring of the research activity before they begin data collection.

Annual/Continuing Review

All protocols regardless of where they are in the research stage (i.e., data collection, data analysis or dissemination) must be renewed annually until the study is completed and closed. Since federal regulations require that research be discontinued if the CPHPR protocol approval has expired, it is important the annual/continuing review form be submitted prior to the expiration date of the protocol approval.

Closing your study

In order for a study to be complete, publication or presentation must be completed. If the researcher indicates that the project is still underway or is 'incomplete' on the renewal paperwork, a progress report or summary of the status of the study must be submitted. This is indicated on the Annual Renewal form (link).

Projects that do not receive written notice of renewed approval from the CPHPR may not continue past the expiration date.

Modifying/Changing an Approved Protocol

After receiving the written approval from the Emmanuel CPHPR to begin a research project, investigators must follow the protocol procedures and use only the versions of the recruitment materials, consent and assent forms and study instruments as approved. When it becomes necessary to make changes to the study, you may request an Amendment to modify/change the approved protocol 45 CFR 46.110 (b2). **The amendment must be approved by the Emmanuel CPHPR before you initiate the change.**

Modifications that require approval include, but are not limited to, changes of Investigator(s), inclusion/exclusion criteria for subjects, sites of study, recruitment strategy, consent and authorization process, informed consent document, questions on survey/interview/focus groups, testing procedures, confidentiality measures, or safeguards for participants. **Conducting a study with unapproved procedures invalidates the approval status.**

To request approval for a change or modification, complete the Amendment form and submit it to the CPHPR (link to form).

Minimal changes are approved by expedited means and involve little time. Most changes fall in this category. However, if modifications are significant, they will be reviewed by the full by the CPHPR .

Reporting Adverse Events

Any adverse events involving human subjects must be promptly reported in writing to the Emmanuel CPHPR in addition to other sites or institutions that might be involved 46.103(b5).

On Site Monitoring

Federal regulations [46.109e] authorize Emmanuel College to observe all human participants research procedures and the process of obtaining informed consent, and to conduct audits of research records and ensure that confidentiality is being maintained according to stated procedures.

Audits may also be conducted by external agencies and sponsors such as the Office for Human Research Protections (OHRP) and the National Institutes of Health (NIH).

Audits may be unannounced, so records should be readily available.

Suspension or Termination of CPHPR Approval

The Emmanuel CPHPR has the authority to suspend or terminate approval of research that is not being conducted in accordance with the CPHPR requirements or that has been associated with unexpected serious harm to participants 46.113.

Investigators performing research that is not in compliance with CPHPR policies may not receive CPHPR or other review or approval for any other research activities until the compliance issues have been resolved.

Regulations require that the CPHPR report violations of policies or federal regulations to the appropriate officials.

Important Links

- http://www.hhs.gov/ohrp/ (Office of Human Research Protections; links to other resources)
- http://vvww.apa.org/science/rcr/homepage.html (American Psychological Association research ethics page; links to other resources)
- http://ori.dhhs.gov/education/products/rcrHumans.shtml (Office of Research Integrity; links to other resources)
- http://www.ed.gov/about/offices/ist/ocfo/humansub.html (Department of Education, Protection of Human Subjects in Research; links to other resources)
- http://www.CPHPRforum.org/ (CPHPR Forum, with announcements, events; links to other

resources)

- http://www.msmr.org/CPHPRResources.html (Massachusetts Society for Medical Research; links to other resources)
- http://www.aapor.org/additionalCPHPRresources (American Association for Public Opinion Research; links to other resources)
- http://bioethics.gov/ (The Presidential Commission for the Study of Bioethical Issues)