



EMMANUEL COLLEGE

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

(Revised Jan 12, 2012)

Mission: 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, and Clemson University. We thank Dr. Diana Stork for founding the IRB at Emmanuel College.

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I. Purpose of the Committee for the Protection of Human Participants in Research (CPHPR) of Emmanuel College

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. At the same time, the College is committed to protecting the welfare of every person who may be involved in research and training projects. Members of the College community, while upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers for competence, for objectivity, and for the welfare of every human participant in a project.

The College has provided a formal, legally-binding guarantee to the U.S. Department of Health and Human Services (DHHS) that it will comply with the DHHS Regulations for the Protection of Human Research Subjects (45 C.F.R. part 46, as may be amended from time to time) (available at <http://www.hhs.gov/ohrp/humanhumansubjects/guidance/45cfr46.htm>). This guarantee, known as the Federal wide Assurance, applies to *all* human participants' research, regardless of the source of funding, conducted by anyone on the premises of Emmanuel College or elsewhere by individuals who are representing the College in the conduct of such research, including faculty, students, and staff.

As required by the Federal wide Assurance, the College has established a Committee for the Protection of Human Participants in Research (CPHPR) competent to review research that involves human participants. 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.

II. Purpose of this CPHPR Guide

This CPHPR Guide serves to establish Emmanuel College's CPHPR policies and procedures for the benefit of the Administrator, Chairman, and members of the College's CPHPR and other institutional officials, and to assist Emmanuel College investigators in the preparation and submission of research proposals for review by the CPHPR. *All "research" involving "human subjects/participants" (as these terms are defined in the federal regulations – see the Glossary contained in this CPHPR Guide) conducted by the College's representatives must be submitted prospectively to the CPHPR for review.* Submission and review procedures are described in this Guide.

The CPHPR policies and procedures set forth in this guide are based on the rules and procedures mandated by the DHHS Regulations for the Protection of Human Research Subjects (45 C.F.R. part 46). An excellent book that describes these rules and procedures is Bankert, E. A., & Amdur, R. J. (2006) (Eds.) *Institutional Review Board: Management and Function*. Boston: Jones and Bartlett, which can be obtained in the

Emmanuel library.

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 their students. Furthermore, failure to comply with the CPHPR's rules could impugn the 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.

III. Statement of Principles of Emmanuel College's CPHPR

Emmanuel College affirms the value and dignity of the individual person. The value of the person supersedes and anchors all other values. The doctrine of the supreme worth of the person is reflected in American political society in the theory of human rights that underlies the legal system. It is also articulated in such statements as the United Nations' *Universal Declaration of Human Rights* (1948), the World Medical Association's *Declaration of Helsinki* (2008), and the U.S. Department of Health, Education and Welfare's *Belmont Report* (1979).

In addition to conforming to applicable laws and regulations, Emmanuel College's CPHPR research policies and procedures reflect the basic ethical principles first expressed in the *Belmont Report*: respect for persons, beneficence, and justice in the conduct of all research.

“Respect for persons embodies at least two ethical convictions: first, those individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and capable of acting freely under the direction of his or her deliberations. Respect for persons demands that autonomous participants enter into the research voluntarily and with adequate information.

Not every person is capable of self-determination or of acting freely. Some persons are immature and others have become incapacitated due to illness, mental disability, or circumstances that restrict their liberty.

Among vulnerable populations in need of protection are the mentally disabled, the terminally ill, prisoners, and children under eighteen. Additional vulnerable populations include the patients of physicians conducting research, the students of professors conducting research, and pregnant women whose fetus is considered a human participant in need of protection.

- “Beneficence” demands that foreseeable risks and costs to individual human participants be minimized and that foreseeable benefits be maximized.

- “Justice” is carried out by ensuring that the selection of research participants is fair and equitable. Research populations should be included or excluded only for reasons directly related to the research project itself, and they should not be selected based upon their easy availability or compromised position.

Moral principles not only serve as a basis of social unity but also provide guidance for individual decision-making. Cases of perplexity arise in various contexts, including that of research involving human participants. Moral principles, such as those described in the *Belmont Report* and summarized above, express ways of resolving perplexities that are well established in scientific and medical practice. An examination of these principles provides insight into morally sound decisions.

IV. Online Resources for CPHPRs and Investigators

Helpful resources regarding human participants’ research are listed here. As additional resources are identified, they can be added and posted on the Emmanuel College CPHPR website:

- <http://www.hhs.gov/ohrp/> (Office of Human Research Protections; links to other resources)
- <http://vwww.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.msrmr.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)

V. CPHPR Members at Emmanuel College

The types of research typically reviewed by Emmanuel College’s CPHPR include 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. The research generally reviewed by Emmanuel's CPHPR involves administering questionnaires or interviews to human participants in person or online; cognitive or non-invasive biological assessments, ethnographic and other qualitative studies; and focus groups.

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 (45 C. F. R. 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 (see the Emmanuel CPHPR website for recent updates):

CPHPR Administrator: Dr. Joyce De Leo, Vice-President of Academic Affairs email: deleoj@Emmanuel.edu

CPHPR Chair: Prof. Geraldine Chalykoff (Nursing) e-mail: Chalykge@Emmanuel.edu

CPHPR Vice-Chair: Prof. Joyce Benenson (Psychology) e-mail: Benensjo@Emmanuel.edu

CPHPR Administrative Coordinator: Ms. Ellen Mendonca (ADM 326B) e-mail: mendoncae@Emmanuel.edu

CPHPR Non-Scientists: Prof. Ray Devettere (Philosophy), Fr. Tom Leclerc (Religion)

CPHPR Scientists: Prof. Linda Lin (Psychology), Prof. Kimberly Sofronas (Education), Prof. Bette Weiss (Biology)

CPHPR Community Representative/Member: Susan Keane (e-mail: Skeane929@aol.com)

VI. CPHPR Review Process

A. What Is the Definition of Research Involving Human Participants?

Emmanuel College's CPHPR reviews research involving human participants:

- "Research" is defined as (1) a systematic investigation (2) whose purpose is to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this CPHPR Guide, whether or not they are conducted or supported under a program which is considered research for other purposes. Under this definition some demonstration, service, and training projects may constitute research activities. 45 C.F.R. § 46.102(d).

- “Human subject (participant)” is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable, private information. 45 C.F.R. § 46.102(f).

B. Authority of the CPHPR

The College’s CPHPR has the authority to approve or disapprove any research involving human participants covered by this CPHPR Guide. No human participants’ research described in this CPHPR Guide 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 – see also Section VI.I (Review by Emmanuel College).

C. Criteria for CPHPR Approval

Each investigator proposing to conduct research involving human participants must submit a project proposal for review and approval by the CPHPR before he or she can commence the proposed research – see Section VIII (Project Proposals) for additional detail.

In order to approve the research, the CPHPR must determine and document that all of the following requirements are satisfied:

- 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.
- 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.
- 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.

- 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).
- 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).
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- When appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- 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.

D. CPHPR Risk Assessment

To determine whether a human participant will be harmed in any way as a result of his or her participation in a research project, the CPHPR will make a decision based on sound professional judgment and common sense as to whether or not the proposed research places the human participant "at risk."

1. What Constitutes "Risk"

A human participant is considered to be "at risk" if s/he may be exposed to the possibility of harm or discomfort (whether physical, psychological, sociological, or other) that is greater than the possibility of harm or discomfort encountered in daily life. The CPHPR will consider the fact that certain human participant populations (*e.g.*, minors, pregnant women, prisoners, mentally disabled, culturally or socioeconomically disadvantaged individuals) may be vulnerable and thus at greater risk than others. See also Section IX.A (Research with Vulnerable Populations) for specific regulatory requirements for children, pregnant women, and prisoners.

Certain risks are inherent in life itself, but the CPHPR process does not address the ordinary risks of public or private living. Risks that are subject to DHHS regulation and CPHPR review are most evident in medical and behavioral science research projects involving procedures that may induce a potentially harmful altered physical state or psychological condition. Obvious examples include surgical procedures, the administration of drugs or radiation, strenuous physical exertion, and interventions that precipitate an emotional disturbance. There is also a wide range of medical, social and behavioral research which may not include physical risk but may subject the individuals to discomfort, anxiety, harassment, invasion of privacy, or constitute a threat to the human participant's dignity.

The CPHPR also will assess the risks involved in those studies that are dependent upon

existing information or stored data that have been obtained for quite different purposes but that, when used in a research context, may present risk to the human participant. For example, there are medical and biomedical research projects concerned solely with organs, tissues, body fluids and other materials previously obtained in the routine performance of medical services that have been stored or banked. If an investigator desires to use any of these stored materials for research purposes and, in the process, would have access to identifiable, private information about the individual donors, then such research would meet the definition of human participants' research and would be subject to DHHS regulation and the College's CPHPR policies and procedures. Although the use of these materials for certain research purposes introduces no new element of physical risk to the human participant, their use for these purposes may present psychological, sociological, or legal risks to the human participant or his or her authorized representatives.

2. *When Is Risk Acceptable?*

If the CPHPR concludes that a proposed research project will expose a human participant to risk, then the CPHPR must assure itself that each of the following requirements is satisfied before approving a project proposal: (a) the rights and welfare of the human participant are adequately protected by the introduction of appropriate safeguards, (b) the methods used to obtain informed consent are adequate and appropriate, (c) the risks to the human participant are reasonable in relation to the potential benefits to the human participant and to the importance of the knowledge that is reasonably expected to be gained, and (d) the risks to human participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose human participants to risk. Any study carrying more than minimal risk will be considered by the full CPHPR, and decisions recorded in the minutes regarding calculations of acceptable level of risk.

E. Levels of CPHPR Review

1. *Overview*

Project proposals will receive one of three levels of CPHPR review:

- Exempt from review
- Expedited review
- Full review

Investigators should submit their proposals for the level of review they believe is most appropriate based on the criteria listed below. The Chair of the CPHPR or his or her designee will make the final decision. Whether a research proposal ultimately is designated as exempt from CPHPR review, or receives an expedited or full review, depends on the CPHPR's assessment of the risks involved in the project proposal.

2. *Exempt from Review*

There are certain categories of research that meet the definition of "human participants"

research” but that have been specifically exempted from CPHPR review. ***Only the CPHPR, not the investigator, has the authority to determine whether a proposed research project comes within one of these categories and is exempt from CPHPR review. Thus, investigators are required to submit the Request for Exemption from Review form (see Appendix A) to the CPHPR, even if they believe the proposed research project is “exempt”. Note that the Chair has the right to ask for additional information or to request completion of the full Proposal Submission form.***

A research project is exempt from CPHPR review if it is in one or more of the following categories, established by DHHS regulation:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices;
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior where human participants cannot be identified, directly or indirectly, and no disclosure of human participants’ responses could place them at risk civilly, criminally or financially, or damage their financial standing, employability or reputation.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the bullet above, if:
(a) the human participants are public officials or candidates for public office;
or (b) federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Research involving data, specimen or other information already collected, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or indirectly (but see medical-HIPAA and educational-FERPA regulations regarding privacy).
- Research and demonstration projects that are conducted by or subject to the approval of public department or agency heads, and which are designed to study public benefit or service programs.
- Taste and food quality evaluation and consumer acceptance studies, but only if wholesome foods without additives, or contaminants below minimum acceptable levels, are consumed.

Emmanuel College’s CPHPR generally does not exempt from review research that falls into the last two categories. Because it is difficult to know whether a research project meets these criteria, an investigator must submit a Request for Exemption from Review form (see Appendix A) to the CPHPR Chair.

Any investigator who believes that his or her project is exempt from review is encouraged to discuss the project with the CPHPR Chair before submitting a Request for Exemption from Review form. The CPHPR Chair can then assist the investigator as how to proceed, including questions regarding how informed consent will be obtained. The CPHPR Chair

will review the Request for Exemption from Review form and attachments and determine whether further CPHPR review is warranted. The CPHPR Chair may consult other CPHPR members or institutional officials before making this determination.

If the CPHPR Chair determines that the project proposal is exempt from CPHPR review, the investigator will be notified. However, the investigator has not received approval to begin the study until two hard copies of the Request for Exemption from Review form and associated documents have been provided to the CPHPR office, consistent with the process set forth in “CPHPR Determinations and Administrative Requirements,” below. If the CPHPR Chair determines that the project does not qualify for exemption, the investigator will be notified and advised whether the project can be evaluated through expedited review, or whether full review is required.

In each case in which the CPHPR Chair decides that a particular project qualifies for exemption from CPHPR review, the CPHPR will document the determination and the specific category justifying the exemption.

3. *Expedited Review*

Expedited review by the CPHPR is permitted for (a) certain kinds of research involving no more than minimal risk and (b) for minor changes to pre-approved research.

Research Involving No More than Minimal Risk

Certain research may qualify for expedited review on the basis that it involves no more than minimal risk, but only if it falls within one of the categories specified in a list published by DHHS and titled “Categories of Research that May Be Reviewed by the Institutional Review Board through an Expedited Review Procedure.” This list is available at <http://www.hhs.gov/ohrp/humansubjects/guidance/> and may be amended from time to time). Of particular note, the expedited review procedure may not be used unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The types of research typically reviewed at Emmanuel College under the Expedited Review Procedure conform to the following categories of expedited review as determined by federal guidelines:

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Minor Changes to Pre-Approved Research

The CPHPR also may use the expedited review procedure to review minor changes to previously- approved research provided that the changes are requested during the period

for which the CPHPR's approval is authorized (*i.e.*, within one year of the CPHPR's last approval, unless the CPHPR has required more frequent review consistent with Section VI.J (Continuing Review). These minor changes include addition of researchers, small wording changes in the consent document, modifications to the title; supplementary recruiting materials, and other minor modifications. They may be approved through completing the online Amendment form (see Appendix B). Because small modifications may be made from time to time, the CPHPR recommends investigator's download the latest version which is available online.

Process

Even if an investigator believes that his or her study qualifies for expedited review, the investigator nonetheless must submit a complete project proposal, which includes such documents as instruments that will be used, approval letters from relevant institutional officials, consent forms, and other required attachments, to the CPHPR. Expedited review may be carried out by the Chair of the CPHPR (or designee), with or without consultation with other CPHPR members. The CPHPR Chair is responsible for ensuring that all CPHPR members are advised of research proposals that have been approved under the expedited procedure. Once per month, a description of all research proposals that have been approved in the prior month by expedited review is read to all CPHPR members for approval by the full board. Under an expedited review procedure, the CPHPR reviewer(s) may exercise all of the authorities of the CPHPR, except that they may not disapprove the proposed research. Rather, a research activity may be disapproved only after a full review procedure is conducted, consistent with the processes described below.

4. *Full Review*

All proposals that do not qualify for exemption or expedited review, including all research that involves more than "minimal risk," must be submitted for review by the full CPHPR. For a full review procedure, a quorum must be present. A majority of the members of the CPHPR, including at least one member whose primary concerns are in non-scientific areas, constitutes a quorum. In order for research to be approved, it must receive approval by the majority of the present CPHPR members.

F. Consultations with Investigators or Outside Experts

Investigators may be invited to CPHPR meetings to clarify parts of the proposal, if so requested by the CPHPR. The CPHPR also 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.

G. 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.

H. CPHPR Determinations Regarding Project Proposals

The CPHPR will notify the investigator and Emmanuel College in writing of its decisions concerning project proposals. The Emmanuel College CPHPR makes every effort to evaluate proposals requiring exempt and expedited review within two weeks after their receipt. Full reviews generally occur one month after receipt. Exceptions occur only when an unusually high volume of proposals is received or when the CPHPR cannot be convened for a full review due to absence of a quorum. In these cases, proposals will be reviewed at the next scheduled CPHPR meeting. 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 – and described herein at Section VI.C (*Criteria for CPHPR Approval*) – are satisfied. The investigator will be notified of the CPHPR's approval. The investigator may not begin the study until all required forms have been submitted to the CPHPR Administrative Coordinator, consistent with the process set forth in "CPHPR Determinations and Administrative Requirements" below.

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 all required forms have been submitted to the CPHPR Administrative Coordinator, consistent with the process set forth in "CPHPR Determinations and Administrative Requirements" below.

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 all required forms have been submitted to the CPHPR Administrative Coordinator, consistent with the process set forth in "CPHPR Determinations and Administrative Requirements", below.

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 Administrative Coordinator, consistent with the process set forth in "CPHPR Determinations and Administrative Requirements," below.

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.

I. Review by Emmanuel College

The CPHPR Administrator is informed monthly of final decisions on all research proposals. Consistent with DHHS regulations, project proposals that have been approved by the College's CPHPR may be subject to further review or disapproval by officials of Emmanuel College. However, Emmanuel College officials may not approve the research if it has been disapproved by the CPHPR.

J. Continuing Review or Project Renewals

Federal regulations require that research involving human participants receive continuing review at least once per year. At Emmanuel College any project that exceeds a period of one year in duration must be reviewed by, and receive CPHPR approval prior to, the beginning of the second and any successive years of the research project. Furthermore, Emmanuel College's CPHPR will conduct continuing review of research

at intervals appropriate to the degree of risk and shall have authority to observe or have a third party observe the consent process and the research, consistent with 45 CFR 46.109(e). CPHPR determination of the review interval and the need for additional supervision is made on a project by project basis, as necessary to ensure the continued protection of the rights and welfare of research participant. Consequently, any project that contains more than minimal risk or that has produced adverse effects may be reviewed more frequently than once per year. Continuing review requires submission of the Request for Continuing Review (see Appendix C) 11 months after obtaining initial approval. A request for continuing review in most cases will be approved by the CPHPR Chair provided no adverse events occurred during the project. If the request for continuing review is not submitted within 11 months of the initial approval, then it is considered a new proposal. The CPHPR Administrative Coordinator will make every effort to contact all investigators 11 months after they obtained initial approval to determine whether the project is closed or continuing review is required. However, it is ultimately the investigator's responsibility to ensure that a request for continuing review is submitted within 11 months of initial approval date.

If the continuing review is requested for a project that required full review, the following information must be included in the renewal request: the description of the study; the consent form; the number of participants already included, the number of participants who withdrew already and the reason for withdrawal; a summary of any adverse events or unanticipated problems that arose that involved risks to participants or complaints received from participants; any other information pertaining to risks associated with the research; and a detailed description of any proposed changes. If the continuing review is requested for a project that required expedited review, the following information must be included in the renewal request: the description of the study; the consent form; a summary of any adverse events or unanticipated problems that arose that involved risks to participants or complaints received from participants; any other information pertaining to risks associated with the research; and a detailed description of any proposed changes. The form for requesting Continuing Review of a project is located in Appendix D. Because small modifications may occur from time to time, the latest version should be downloaded from the CPHPR website. The CPHPR will approve a project at the time of continuing review only if that project meets all of the approval criteria set forth in Section VI.C (Criteria for CPHPR Approval).

As described in Section VIII.C (Informed Consent, Permission, and Assent Forms), the informed consent form likewise is valid for a maximum of one year after its approval. In cases where a project is continuing beyond one year, permission to continue use of an CPHPR-approved informed consent form must be applied for at least 30 days in advance of the one-year anniversary date, in conjunction with the investigator's application for continuing review, and permission to continue using the informed consent form would be granted in conjunction with approval of the application for continuing review.

K. Suspension or Termination of CPHPR Approval

1. Non-compliance and Protocol Violation Policy

Non-compliance is the failure to follow federal regulations or the failure to

comply with requirements of the Emmanuel CPHPR.

Serious non-compliance is non-compliance that includes, but is not limited to, the following:

- Failure to obtain CPHPR approval for a study that includes research activities either by not submitting the study to the CPHPR, or by proceeding with a submitted study without CPHPR approval, or by continuing an approved study beyond one year without additional CPHPR approval;
- Failure to obtain voluntary and fully informed consent of participants before enrolling them in any study that includes research activities;
- Enrolling participants who do not meet CPHPR approved eligibility requirements;
- Failure to observe special federal requirements for research involving vulnerable populations which includes children (persons not yet 18), prisoners, pregnant women, and neonates;
- Failure to report to the CPHPR in a timely manner problems that emerge during research involving risks to participants, or other adverse events;
- Alterations to the Emmanuel Proposal Submission Form or other required CPHPR documents submitted in hard copy or electronically to the CPHPR;
- Failure to report financial or other conflicts of interest on the part of any investigators;
- Any intentional non-compliance (serious or minor) that continues after the CPHPR has instituted appropriate corrective action or remedial education. This is known as “continuing non-compliance” and is considered serious even if the original non-compliance was minor.
- Failure of the principal investigator to report to the CPHPR within 10 days known instances of serious non-compliance or major protocol violations that occur in the research.

Minor non-compliance is non-compliance that is not serious or continuing. It includes, but is not limited to, the following:

- Missing an original signed and dated informed consent form;
- Faulty documentation of informed consent;
- Using an outdated informed consent form;

- Failure of an investigator to have completed successfully the CITI course within the past three years.

Protocol violation is any deviation from an approved protocol that is not approved by the CPHPR prior to its initiation. Protocol violations can be major or minor. Major protocol violations are any violations that may affect the participant's willingness to participate in the research, or the participant's safety, or the scientific integrity of the research.

Protocol violations include, but are not limited to:

- Failure to obtain CPHPR approval for any changes to an approved protocol, including personnel changes (adding or subtracting named investigators), before initiating the changes. CPHPR approval for changes is sought by filing with the CPHPR an amendment explaining the proposed changes. Multiple amendment proposals should be numbered (amendment #1, amendment #2, and so forth).
- Failure to obtain CPHPR approval for changes to the approved informed consent form;
- Failure to obtain CPHPR approval for changes in participant recruitment;
- Failure to notify the CPHPR of changes in the title of the research protocol.

2. *Review of Non-compliance*

Any person affiliated with Emmanuel College who becomes aware of apparent non-compliance with federal regulations or with CPHPR requirements in connection with studies that include research activities on human participants has the responsibility to report the apparent non-compliance to the Chair of the CPHPR within 10 days.

Co-investigators have the responsibility to report apparent non-compliance connected with their research to the principal investigator within 10 days. The principal investigator is required to report in writing to the Chair of the CPHPR apparent non-compliance within 10 days of his or her discovery of the apparent non-compliance. Failure to do so is an additional instance of non-compliance.

If the CPHPR Chair becomes aware of an event that appears to be a non-compliance issue the Chair will appoint 2 tenured members of the CPHPR to join him or her in an *ad hoc* fact-finding committee that will gather additional facts to better ascertain the nature and scope of the alleged non-compliance. The *ad hoc* committee will review all documents and may interview appropriate parties and consult with college Counsel. At any point in the fact gathering the Chair may suspend the research in whole or in part.

The *ad hoc* committee will make one of the following determinations within 45 days:

No non-compliance. The Chair will dismiss the report of non-compliance and send a written report to the principal investigator.

Minor non-compliance. The Chair will report the alleged minor non-compliance finding to the CPHPR at the next scheduled meeting which will then determine by majority vote whether minor non-compliance has occurred. If so, the CPHPR will then determine by majority vote whether one or more of the following corrective actions should be taken:

- Minor modifications in the research and/or consent form;
- Repeat the informed consent process;
- Remedial education for investigators;
- Any other action deemed appropriate to minor noncompliance.

Serious or continuing non-compliance. The Chair will bring the *ad hoc* committee's finding of serious or continuing non-compliance to the CPHPR at the next scheduled meeting. By majority vote the CPHPR will determine whether serious or continuing non-compliance has occurred as defined by this policy or by the CFR. If serious or continuing non-compliance has occurred the CPHPR by majority vote will take one or more of the following actions.

- Accept the *ad hoc* committee's report and approve its proposed changes;
- Require additional fact-finding by the *ad hoc* committee;
- Terminate the research;
- Suspend the research;
- Restrict the research privileges of investigators;
- Require remedial education;
- Require that the participants enrolled in the research be notified of the non-compliance;
- Require current participants to re-consent to the research;
- Require oversight by an experienced investigator;
- Require modifications to the protocol and/or the consent form.

Protocol violations will be treated as minor non-compliance issues unless the protocol violation is major; that is, unless it may affect the participant's willingness to participate, or the participant's safety, or the integrity of the data. Major protocol violations will be treated the same as serious non-compliance issues.

3. *Reporting Serious or Continuing Non-compliance*

Whenever the CPHPR determines that an incident of serious or continuing non-compliance or a major protocol violation has occurred, the Chair will prepare a report that details the nature of the event and the corrective actions taken by the CPHPR. The Chair will send copies of the report within 30 days to:

- The CPHPR
- The investigators named in the protocol
- The department heads of the investigators
- The Institutional Official designated in the Federal Wide Assurance (FWA)
- The Academic Vice President
- The President of the College
- The Office for Human Research Protections OHRP

L. CPHPR Recordkeeping

The CPHPR Administrative Coordinator will record minutes at all CPHPR meetings which will be sent to all CPHPR members and the CPHPR Administrator within 2 weeks of each meeting. Minutes of CPHPR meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the CPHPR; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution. Minutes will document all concerns regarding a proposal evaluated under the full review procedure as well as the vote on the proposal. The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

The CPHPR Administrative Coordinator also will be responsible for maintaining all records relating to the submission of proposals for 3 years following the expiration date of a research project. These records shall include copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants, as well as approval from any external or internal directors of the institution or department where the research will be conducted (such as departments within Emmanuel College, or institutions such as schools or hospitals outside Emmanuel).

VII. Investigator’s Responsibilities

A. Training Requirements

Investigators must comply with the federally-mandated educational training requirements. This may be accomplished by taking an online course offered by the Collaborative Institutional Training Initiative (CITI), titled “*Course in the Protection of Human Research Human Subjects*,” which is found at www.citiprogram.org. The CITI program includes courses in the protection of human research participants for biomedical researchers, social/behavior/educational researchers, and student researchers and their research advisors. Investigators are required to submit evidence of course completion with their project proposals.

B. Prepare and Submit Project Proposals for CPHPR Review

Any potential investigator proposing to conduct research involving human participants must prepare a Proposal Submission form (see Appendix D) or if the investigator believes the project might be exempt from review, a Request for Exemption from Review form (Appendix A) for review by the CPHPR. Regardless of the level of review, the proposed project must be described in sufficient detail so that the CPHPR can understand the research purposes, procedures, potential risks (including potential violations of privacy) and benefits, and measures taken to protect against risks. The description of the project will enable the CPHPR to assess whether adequate protection of the rights and welfare of prospective human participants is provided in accordance with all pertinent laws, regulations, and policies.

A complete project proposal contains all of the materials listed in the chart below, as applicable. A complete project proposal must be submitted to the CPHPR regardless of the level of CPHPR review being requested by the investigator (*i.e.*, exempt, expedited, or full).

Form	Comments
1. Proposal Submission Form	Required for all research projects.
2. Protocol	Required
3. Informed Consent, Permission, or Assent Forms	<u>Informed Consent Form</u> : Required for all research projects, unless the CPHPR waives the requirement. <u>Permission and Assent Forms</u> : Required only if certain participant populations are involved.
4. Research Instruments	Required if investigator intends to use instruments for data collection in the course of the study.
5. Recruitment Materials	Required if investigator intends to use materials to recruit study participants.
6. Authorization(s) from cooperating institutions or organizations. Financial disclosure form if needed.	Required only if applicable.
7. CITI completion signatures (evidence that investigator/s has completed the requisite research ethics training courses ethics training courses)	Required for all research projects.

Once completed, the Proposal Submission Form along with all relevant documentation must be sent electronically in one attachment to

CPHPR@Emmanuel.edu.

C. Schedule for Submitting Project Proposals

In general, project proposal submissions (including addenda) are due to the CPHPR on Thursday before 5 pm, the week prior to a scheduled CPHPR meeting. If, however, the investigator anticipates that his or her research is exempt from CPHPR review (see the CPHPR's policy regarding exempt research, above), he or she may submit that project proposal to the CPHPR on or before any Thursday. The schedule for all CPHPR meetings will be posted on the Emmanuel College CPHPR website in August for the upcoming academic year and in May for the summer months. ***It is critical that professors preparing to submit multiple proposals for research courses take these deadlines into consideration when preparing their courses.***

D. CPHPR Determinations and Administrative Requirements

It is the responsibility of the investigator to comply with all CPHPR decisions, conditions, and requirements.

Research involving human participants cannot begin until the proper forms have been filed. If the investigator's project proposal receives CPHPR approval, then it is the investigator's responsibility to bring two hard copies of the approved project proposal, including all forms related to the project with the investigator's signature, to the CPHPR's Administrative Coordinator (ADM 326B). Both copies of the project proposal must be stamped by the Administrative Coordinator. One copy will be filed in the CPHPR office and the investigator must retain the second copy.

E. Reporting Proposed Changes in Research Activity

If the investigator wishes to make a small modification to a research procedure during the period for which CPHPR approval has already been given, the investigator must submit an Amendment Form. The Amendment Form can be found in Appendix B. Because small modifications may occur to the form, the latest version should be downloaded from the website. The investigator may not proceed with the proposed changes without written approval of the CPHPR, except if necessary to eliminate apparent immediate hazards to the human participant(s).

In cases where an investigator seeks approval for more than a small modification to a project proposal, the expedited review process described in Section VI.E (Levels of CPHPR Review) should be used. However, full CPHPR review is required where an investigator submits a previously approved proposal to other funding agencies, or where the proposed changes are determined by the CPHPR to be more than "minor" in nature.

F. Inquiries and Other Correspondence with the CPHPR

Investigators with (a) questions concerning the development, submission, or status of their project proposals, (b) revisions to their pending project proposals, or (c) other relevant information to share with the CPHPR should contact the CPHPR Chair, Dr. Geraldine Chalykoff, at CPHPR@Emmanuel.edu, or the CPHPR Administrative Coordinator, Ms. Ellen Mendonca, at mendoncae@Emmanuel.edu. Dr. Geraldine

Chalykoff generally responds to queries on Thursdays, unless the correspondence raises serious concerns, in which case it will be addressed promptly.

G. Reporting of Adverse Events, Unanticipated Problems or Serious or Continuing Non-Compliance

Investigators must report adverse events in the course of CPHPR-approved research within one week of such event(s) to the CPHPR Administrative Coordinator, Ms. Ellen Mendonca. If the adverse event is **unexpected and serious**, specifically those in which unanticipated problems arise involving risks to participants or others, the investigator must (a) notify the CPHPR **immediately** by contacting the CPHPR Administrative Coordinator, who will inform the CPHPR Chair that day; and (b) suspend research involving human participants until further notified by the CPHPR. Serious or continuing non-compliance will be treated in accord with the procedures described previously. Any adverse events or unanticipated problems or serious or continuing non-compliance will be reported to all CPHPR members and the CPHPR Administrator as soon as possible, but no later than 48 hours after the CPHPR Chair has been informed of the problem. The CPHPR Chair and Vice-Chair and the CPHPR Administrator will meet with the investigator as soon as possible to discuss remedial action. The CPHPR Chair and Vice-Chair will make a recommendation to the CPHPR Administrator regarding immediate action to reduce imminent risk to others. At the next CPHPR meeting, the entire CPHPR will vote on appropriate action to take regarding the future of the research project. The investigator cannot continue work on the project until the entire CPHPR votes to allow continuation with potential modifications to the procedure.

VIII. Project Proposals

This section describes in detail each component of the project proposal to be prepared by the investigator and submitted to the CPHPR for review.

A. Proposal Submission Form for Expedited and Full Review

The proposal submission form is the investigator's primary opportunity to explain the study's purpose and other details to the CPHPR. A complete and clear proposal submission form provides the CPHPR with an overview of the investigator's proposed study, including hypothesis, design, demographic information, foreseeable risks and benefits, and any safeguards to be implemented.

A sample proposal submission form is included in Appendix D for your reference, but note that the form may be changed from time to time, thus the investigator must download the form from in order to ensure that the current form is being used.

B. Informed Consent, Permission, and Assent Forms

1. Purpose of Obtaining Informed Consent, Permission, and Assent

Obtaining the informed consent of an individual before enrolling him or her in a research study is a vital element in the protection of human participants. The ability to have human participants be part of research is a privilege granted to the investigator, not a right.

Although there are DHHS and state regulations that require individuals, or their legally authorized representatives, to give informed consent prior to participating in a study, the principal reason for informing human participants about a study is that they have a moral and ethical right to know what is to be done to them and what consequences this might entail, before they give their consent. An experiment or other forms of research entails something that is done *to* the human participant, and, therefore, differs from usual clinical practice where something is done *for* the person.

Before a person participates in an investigation with foreseeable risks, including the likelihood of stress or discomfort, the nature of these hazards and the procedures to be followed are to be carefully explained and informed consent obtained.

Three types of acquiescence to participate in a research project can occur. First, persons who are 18 years of age or older have the capacity to *consent* to participate in research themselves, as long as they understand the research project and can voluntarily choose whether to participate. Second, in cases in which a person is under 18 or cannot be expected to understand the research proposal, or cannot voluntarily choose whether to participate (typically a minor or cognitively impaired person), a legal guardian can provide *permission* for that person to participate in the study. Third, if a legal guardian provides permission for a person to partake in the research project, the investigator is expected to obtain the *assent* of the person who would be participating in the research study before enrolling him or her as a participant. Assent is the prospective research participant's personal permission to participate in the research. The assent process generally requires a simplified description of the research proposal, followed by the person's giving his or her permission to participate in the study. The person's assent may be given in writing (if he or she is able), orally, or, if the person cannot communicate orally, by an affirmative cue such as a nod. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Because the informed consent, permission, and assent processes are a critical component of the respect for the dignity of human participants, the CPHPR will carefully review these and any informed consent, permission, and assent processes and forms proposed by the investigator in the project proposal. For purposes of the CPHPR review, the assent process should be described in a separate document included in the project proposal. In a few simple paragraphs, the investigator should explain what he or she will say to each prospective participant; including everything that the participant will be asked to do as part of the study, and that the participant can stop participating in the study at any time. When working with young children, the assent documentation must describe how ongoing assent will be assessed – that is, what behavioral or oral cues will be used to determine whether continuing is appropriate or not for a particular participant.

2. *Informed Consent Process*

The “informed consent” requirement in research involving human participants refers to a process, not merely a form. There must be a process that provides potential human participants with enough information for them to make an informed decision and does so in a way that is free from pressure and undue influence. Informed consent forms generally are required as part of the informed consent process, but, as further explained below, this requirement may be waived by the CPHPR in specific circumstances. The

CPHPR will carefully review an investigator's proposed informed consent process, as described in the project proposal, to ensure that human participants will be adequately informed and free to make a decision about their participation in the study. The CPHPR also will review the investigator's informed consent form to determine if it contains all appropriate elements of informed consent.

Investigators must seek consent under circumstances that provide the prospective human participant or the legally authorized representative sufficient opportunity to consider whether or not to participate (*i.e.*, participation in projects must be voluntary) and that minimize the possibility of coercion or undue influence. An individual does not abdicate any rights by consenting to be a research participant. A human participant has the right to withdraw from a research project at any time or to refuse to participate without loss of benefits to which the human participant would otherwise be entitled. Further, a human participant has the right to receive appropriate professional care, to enjoy privacy and confidentiality in the use of personal information and to be free from undue embarrassment, discomfort, anxiety, and harassment.

Unless the CPHPR issues a specific waiver of the informed consent process or of documentation of informed consent (consistent with Section VIII.C.4 (CPHPR Waiver of Informed Consent Requirements), below), then documented written informed consent of human participants through the use of a consent form is required for all research projects reviewed by CPHPR. If a human participant is not legally or physically capable of giving informed consent, a legally authorized representative may give permission for the human participant to partake in the research. Careful consideration will be given to the representative's depth of interest in and concern for the human participant's rights and welfare.

3. *Contents of the Consent/Permission Form*

An informed consent form must convey all of the following information, at a minimum. It should also be simply written and easily understood.

- A statement that the study involves research, a readily understood explanation of the purposes of the research and the expected duration of the human participant's involvement, a description of the procedures to be followed, including identification of any procedures which are experimental.
- A description of how data will be handled (who will have access and for what purposes).
- A description of how and to whom data and results will be disseminated (intentions to present or publish, share with colleagues, and at what level of aggregation, etc.).
- A description of any reasonably foreseeable risks or discomforts to the human participant.
- A description of any benefits to the human participant or to others which may reasonably be expected from the research and/or findings (if no direct benefit, this should be stated).
- A statement describing the extent, if any, to which confidentiality of records that

identify the human participant will be maintained. (If signed informed consent forms are used, regulations require they must be kept for 3 years.)

- An explanation of whom to contact for answers to pertinent questions about the research and research human participants' rights, and whom to contact in the event of a research-related problem or injury to the human participant.
- For research involving more than minimal risk, an explanation as to whether any medical or psychological treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- A statement that participation is voluntary, that deciding not to participate will involve no penalty or loss of benefits to which the human participant is otherwise entitled, and that the human participant may discontinue involvement at any time without penalty or loss of benefits to which the human participant is otherwise entitled.
- A statement concerning costs or compensation to the human participant, if any.
- A statement disclosing alternative treatment courses that may be available to the human participant.
- A statement similar to this in the consent document: *If you have questions or concerns about the research you may contact [name and contact information of investigator and/or the Chair of the Committee for the Protection of Human Participants in Research] at 617-264-7616.* Students should also include name of and contact information for their research advisor or course instructor.

The CPHPR may require additional information to be included in the consent process and/or included in the informed consent form.

4. *CPHPR Waiver of Informed Consent Requirements*

Waiver of the Informed Consent Process Requirement

The CPHPR may waive the requirement that the investigator undergo the informed consent process, in accordance with the DHHS regulations (45 C.F.R. § 46.116), if it finds that:

- (a) The research involves no more than minimal risk to the participants;
- (b) The waiver (or alteration of certain of the informed consent requirements) will not adversely affect the rights and welfare of the human participants;
- (c) The research could not practicably be carried out without the waiver or alteration;
AND
- (d) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Waiver of the Informed Consent Documentation Requirement

The CPHPR may waive the requirement that the investigator obtain a signed consent form for some or all participants, in accordance with DHHS regulations (45 C.F.R. § 46.117), if it finds that one of the following scenarios exists:

- (a) The only record linking the participant and the research would be the consent document, and the principal risk involved in the study would be potential harm resulting from a breach of confidentiality. In this scenario, each human participant must be asked whether s/he wants to be linked with the research; **OR**
- (b) The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context; **OR**
- (c) The human participant never signed an informed consent form, because the informed consent process requirement was waived.

For example, if the only record linking the human participant to the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, the consent form could be provided to the human participant but not signed and returned to (or otherwise documented by) the investigator.

Waiver of the informed consent documentation requirement does not necessarily waive the requirement that potential human participants be provided all information required to make an informed decision about whether to participate in the study. In the event of (a) or (b) above, the CPHPR may still require an informed consent process – that is, providing human participants with a written or oral description of the research and making sure they are freely choosing to participate.

If an investigator believes that his or her study qualifies for a waiver of any of the informed consent requirements, reasons for this belief should be given in the Proposal Submission Form.

The basis for and decisions regarding waivers will be included in the minutes.

5. *Instructions for Preparing the Informed Consent Form*

Language, style, and level: The consent form should be ***written in the second person*** (e.g., “you are being asked to participate in a research study”). When combined with conditional language and the invitation to participate, use of the second person communicates that the investigator believes there is a choice to be made by the prospective human participant. Use of the first person may be interpreted as presumption of human participant consent before consent has been legally obtained.

******The information that is given to the human participant or legally authorized representative shall be in language understandable to the human participant or the legally authorized representative. Keep in mind that terms commonly used by members of a profession are a part of the professional’s language, a language many people outside that profession do not understand. If there is any doubt that a term may not be understood, a definition should be added. If some of the anticipated human participant population does not understand English, appropriate translation should be provided. Researchers are

commonly advised to write consent materials for about an *8th grade reading level*.

The informed consent form must not contain any exculpatory language through which the human participant or legally authorized representative is made to waive or appear to waive any of the human participant's legal rights, or through which s/he releases or appears to release the investigator, the sponsor, the institution, or their agents from liability for negligence.

Length: The informed consent form should be long enough to explain consent factors adequately but not so long or detailed as to lose the attention of the human participant or to cause confusion. If a separate project description is given to human participants; the actual informed consent form will not need to exceed one page.

Submission to the CPHPR: Investigators must include copies of any proposed informed consent form(s) with the project proposal for review and approval by the CPHPR. Informed consent forms cannot be used unless and until the CPHPR has approved the form. Investigators must also submit copies of any written or oral explanation of the project that will be given to prospective human participants. Once approved by the CPHPR, the informed consent form is valid for a maximum of one year. In cases where a project is continuing beyond one year, the investigator must apply for the CPHPR's permission to continue use of the informed consent form at least 30 days in advance of the one-year anniversary date. Such permission is granted in conjunction with the application for continuing review.

Stationery: The informed consent form must include the official Emmanuel College emblem.

Note: If the research study will include individuals with linguistic backgrounds other than English, the CPHPR will generally require that the investigator translate the informed consent form into the appropriate other language. The translated informed consent form must be submitted with the other materials the investigator includes with the Proposal Submission form. An English "back translation" of the Form should be submitted as well. In cases where an individual may be unable to read – whether it is English or another language – or has impaired vision, appropriate arrangements must be made to orally convey the contents of the informed consent form. Arrangements must also be made for the individual to give or withhold his or her willingness to participate in the research project.

6. *Recordkeeping*

Informed consent forms must be approved by the CPHPR prior to use in a study. Any proposed changes or amendments to a CPHPR-approved informed consent form must be resubmitted to the CPHPR for advanced approval. In addition, since CPHPR approval of a research project is valid for no more than one year, investigators must submit their informed consent forms in conjunction with the continuing review process, at least annually. In light of the potential for different versions of informed consent forms, all informed consent forms should include a version number and a date, in order to ensure that a current informed consent form is being used and to serve as a reminder to the investigators of the need for continuing review.

Investigators must ensure that anyone signing a written informed consent form is given a copy of that form before participating in the project.

Investigators are responsible for safeguarding informed consent documents signed by human research human participants. Faculty supervisors must maintain the informed consent documents for student investigators. Signed copies of informed consent forms must be stored in a secure manner. Unless otherwise specified by federal and/or state regulations, retention shall be for a period of at least three years beyond the termination of the study. If the faculty member with responsibility for safeguarding the informed consent forms resigns before the end of the designated period, the informed consent forms must be submitted to the CPHPR unless otherwise specified.

7. *Informed Consent Form Template*

The template shown in Appendix E is designed to help investigators as they design the informed consent process and prepare an informed consent form for their studies (see Appendix E). All researchers are required to make use of this template. If this template is not appropriate for a particular study or if you have any consent questions, contact the CPHPR Chair. Remember that what is included here relates to consent, designed for competent adults. For children, incapacitated adults, or other individuals physically or mentally unable to provide their consent, assent needs to be obtained from the prospective research participant as well as permission from the parent, guardian, or legally authorized representative. See also Section VIII.C (Informed Consent, Permission, and Assent Forms).

Because small modifications may be made to update the form, the latest version should be downloaded from the website:

C. Research Instruments

Research instruments include, but are not limited to, the following: surveys, interview guides, observation tools, psychometric tests, or any data collection tool. Submit copies of your research instrument(s) if possible. If not, describe them in detail in the project proposal.

D. Recruitment Materials

Any proposed flyers, recruitment advertisements (including those listed on the Psychology Subject Pool website), Survey Monkey descriptions, or other recruitment materials must be submitted to the CPHPR with the project proposal.

E. Authorization(s) from Cooperating Institutions, Organizations, or Agencies

If the investigator intends to conduct research on the premises of another institution, he or she must provide written documentation to the CPHPR Administrative Coordinator that the other institution approves of the research project before beginning to collect data. Investigators may include this documentation as an Appendix to their project proposal if they have contacted the institution before submitting their project proposal to the CPHPR. However, the CPHPR has authority to approve or disapprove all project proposals, so it is reasonable to obtain formal CPHPR approval before obtaining approval from an

institution, then to submit the approval forms from outside institutions before beginning to collect data.

Investigators cannot begin to collect data until appropriate authorizations from any applicable institutions are filed with the CPHPR Administrative Coordinator.

IX. Important Additional Considerations

A. Research with Vulnerable Populations

For research with vulnerable populations, additional protections are required. The DHHS regulations contain specific rules for research involving minors (45 C.F.R. §§ 46.404-407), pregnant women (45 C.F.R. §§ 46.204-207), and prisoners (45 C.F.R. §§ 46.305-306). In addition, vulnerable populations include physically disabled or mentally disabled persons, economically or educationally disadvantaged persons, elderly individuals, patients of a doctor who is conducting the research, and students of a professor who is conducting the research. Any study that includes vulnerable populations will be reviewed by the full CPHPR and documented in the CPHPR minutes.

Investigators who intend to conduct research that involves vulnerable populations should review materials in the CITI training modules and consult with the CPHPR to assist with the development of their project proposals and informed consent forms in order to ensure that appropriate safeguards are in place.

1. Research Involving Minors (Persons under 18 Years of Age)

No human participant can provide consent unless he or she is at least 18 years of age. If human participants are under 18 years of age, they will require a parent or guardian to provide permission for them to participate. Accordingly, Emmanuel College students under 18 years of age cannot participate without the permission of a parent or guardian.

2. Permission and Assent Processes

As described in Section VIII.C (Informed Consent, Permission, and Assent Forms), investigators conducting research involving minors or other individuals who do not have the capacity to give their informed consent must obtain **both** permission from a parent, guardian or legally authorized representative and assent from the prospective human participant.

When submitting a project proposal to an CPHPR, investigators must include copies of informational materials to be sent home to parents, guardians or legally authorized representatives, a clear description of the procedures for obtaining permission and gaining and maintaining a human participant's assent, and copies of the permission forms (and any assent forms, if applicable) to be signed. For example, teenagers under 18 require parental permission, but they themselves must also provide **assent** to participate in a study. Obtaining the assent of teenagers can be accomplished by providing them with a written description of the study. The assent is similar to the permission form. Researchers must obtain the teens' signatures prior to the commencement of the study.

But for younger children, or individuals with diminished mental capacity, the CPHPR may determine that assent can be obtained orally or behaviorally and may require that assent be sought not only before the research commences but also periodically throughout the course of the research.

B. Privacy and Safeguarding Information

Safeguarding information about an individual that has been obtained in the course of an investigation is a primary obligation of the investigator. When the investigator is a student, responsibility for the conduct of the research and the supervision of human participants lies with the faculty sponsor. Such information shall not be communicated to others unless explicit permission for the release of identifying data is provided by the individual, or unless such disclosure is required by law. Information about individuals may be discussed only for professional purposes and only with persons involved with the project. Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy.

Provisions must also be made for the maintenance of confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the CPHPR in the project proposal and carried out by the investigator until the records are destroyed. Records containing personal information shall be destroyed as soon as possible in keeping with the long-range goals of the project and any applicable rules established by the research sponsor (*e.g.*, federal government).

One exception to provisions of confidentiality, however, concerns the federal government. Unless the investigator files a form with the federal government requesting confidentiality before data is collected, federal officials concerned with protection of human participants are allowed to request data collected by an investigator.

C. Approval by an Outside IRB or CPHPR

An Emmanuel College representative (*e.g.*, student, faculty member, or administrator) may be involved in a research project that has been approved by another institution's IRB or CPHPR. In such cases, the College representative takes complete responsibility for obtaining IRB/CPHPR approval from the other institution for the project. The College representative does not have to attain approval from Emmanuel College's CPHPR except when the representative is a student who is receiving Emmanuel College course credit for the project.

Emmanuel College students receiving course credit for a research project conducted at another institution also must submit the project for review to Emmanuel's CPHPR using an abbreviated procedure. To receive approval from Emmanuel College's CPHPR for a project conducted at another institution, the student must be supervised by an individual at the institution at which the project is being conducted. In addition, the student's and the supervisor's names must be listed on the IRB/CPHPR approval form (or an amendment to that form) at the institution where the project is being conducted. The student then must submit the following information to Emmanuel College's CPHPR before beginning to work

on the project: (1) a brief description of the project and the student's role in the project (2) the supervisor's name and contact information, and (3) the host institution's CPHPR approval form containing the student's name. The CPHPR reserves the right to disapprove the research if it does not comply with Emmanuel College's CPHPR policies and procedures.

X. Student Research Not Otherwise Subject to this CPHPR Guide

Any research that fits the definition of "human participant research" under this CPHPR Guide must be submitted to the CPHPR for a determination of whether the research requires full or expedited review, or is exempt from review. In addition, all research courses in which students are expected to conduct a formal research project – including research internships, senior research projects, individual student research projects – require approval from Emmanuel College's CPHPR, whether such research will be conducted at the College or at another institution (*e.g.*, another university, a hospital, etc.). (Note: A professor may bundle all students' research projects into a single submission, or students in the course may submit individual or small-group proposals to the CPHPR.) As stated above however, Emmanuel College's CPHPR will accept the IRB/CPHPR approval of an outside institution where the student is working, provided the standards of Emmanuel College's CPHPR are upheld.

However, student projects in non-research courses may involve collecting data from humans but not meet the definition of "human participants' research". This research is not subject to CPHPR review but nonetheless must be evaluated for its ethical implications and submitted to a representative of Emmanuel College (*e.g.*, the professor of a course) for approval. If the researcher or professor is in doubt as to whether a project constitutes "research"; the proposal should be submitted to the CPHPR for review.

The following examples illustrate research that may not constitute "human participants research" under this CPHPR Guide and the means by which ethical approval may be obtained at Emmanuel College for such research.

- *Collection of data within the confines of an Emmanuel College course* – If, as part of a course offered at the College, a professor wishes to demonstrate how to create and distribute questionnaires, give interviews, collect observations, or run an experiment by having the students in the course serve as human participants for one another, the professor may proceed without CPHPR review if the particular project does not meet the definition of "research". The professor must obtain consent from all members of the course to collect data. Data collection must pose no risk to the students or human participants; human participants must have the right to refuse to participate without penalty; confidentiality must be maintained to the greatest extent possible; extra precautions must be taken with vulnerable populations; and the data may not be published.
- *Collection of data for a non-research course* – If, as part of a course, a professor requires students to collect data with human participants from outside the course, the project may proceed without CPHPR review if it does not meet the definition of "research". In addition, the data collection must pose no risk to either the

students or human participants and must involve only a few human participants. For example, observing a few individuals in public places, interviewing several individuals, holding a focus group, conducting a completely physically and psychologically harmless experiment, or providing a harmless intervention within a service learning course with a few individuals are acceptable. Human participants must have the right to refuse to participate without penalty; confidentiality must be maintained to the greatest extent possible; extra precautions must be taken with vulnerable populations; and the data may not be published.

In the scenarios described above, the professor of the course assumes legal liability and will not be protected by the College should a legal complaint arise. If a professor is uncertain whether a project is subject to CPHPR review, then he or she should err on the side of submitting the project to the CPHPR.

XI. Glossary

Human participant or human subject: a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable, private information.

Interaction: includes communication or interpersonal contact between investigator and human participant.

Intervention: both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the human participant or the human participant's environment that are performed for research purposes.

Private information: information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (*i.e.*, the identity of the human participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

Committee for the Protection of Human Participants in Research (CPHPR): the committee at Emmanuel College given the authority to approve or disapprove research projects involving human participants.

Investigator: either a person affiliated with Emmanuel College (faculty, staff, or student) conducting human participants' research on or off campus, or a person unaffiliated with the University who wishes to conduct research involving human participants affiliated with Emmanuel College.

Legally authorized representative: an individual or other body authorized under applicable law to consent on behalf of a prospective human participant to the human

participant's participation in the research procedure(s).

Minimal risk: risks of harm anticipated in the proposed research that are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research: systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Under this definition some demonstration, service, and training projects may be considered to include research activities.

Vulnerable populations: categories of participants, such as children, prisoners, pregnant women, disabled, elderly, mentally disabled persons, or economically or educationally disadvantaged persons, who are entitled to additional safeguards in the study

Appendix A

Emmanuel College

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

Request for Exemption from Review

Name _____ e-mail _____

Faculty Sponsor's Name (if student) _____

Department _____

Proposal Title _____

I. Exemption from Review at Emmanuel College is permitted when the study meets one of the criteria listed below. Please check which criterion your study falls under.

____ (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

____ (2) (Non-Vulnerable Adults only) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. (If i and ii are true, then exemption will not be granted.)

____ (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the paragraph above if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

____ (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Existing data means that the data were collected prior to the start of this study. No information recorded by the investigator can include identifiers.

II. Please describe in a paragraph your participants and methods.

III. Please attach all instruments (e.g., surveys, interview questions).

IV. Please attach your consent document or information sheet or state how participants will be otherwise informed that they are part of a research study and can choose not to participate.

V. If applicable, please attach recruitment materials (e.g., letter of invitation, flyers), HIPPA authorization, and letters of permission from internal departments or external agencies.

Signature _____ Date _____

Signature of Faculty Sponsor (for students) _____

***Please note that the IRB may request additional information concerning the proposal. The IRB will make a determination as to whether the proposal is exempt from review or it is necessary to complete the proposal submission form.**

CPHPR Office Use only (please file)

Action Taken:

Exempt _____

CPHPR Chair

DATE

Not Exempt _____

Further action Taken:

CPHPR Chair

DATE

Appendix B

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

Amendment Form

Principal/Overall Investigator:		Email:	
Research Study Title:			
Protocol Number:		Amendment Number (circle): 1 st 2 nd 3 rd 4 th	
		Amendment Date:	
Please check the box on the left for all applicable items that are being changed in the protocol:			
<input type="checkbox"/>	Consent Form	<input type="checkbox"/>	Recruitment Procedures
<input type="checkbox"/>	Consent Procedures	<input type="checkbox"/>	Duration of Study
<input type="checkbox"/>	Investigator	<input type="checkbox"/>	Questionnaires
<input type="checkbox"/>	Co-Investigator(s)	<input type="checkbox"/>	Eligibility Requirements
<input type="checkbox"/>	Project Staff	<input type="checkbox"/>	Compensation
<input type="checkbox"/>	Protocol Version	<input type="checkbox"/>	Research Related Use of Medical Records
<input type="checkbox"/>	Sponsor	<input type="checkbox"/>	Research Related Use of Discarded Material
<input type="checkbox"/>	Number of Participants	<input type="checkbox"/>	Use of Specimens
<input type="checkbox"/>	Source of Participants	<input type="checkbox"/>	Required Tests
<input type="checkbox"/>	Protocol Title	<input type="checkbox"/>	Other (please describe):
Protocol amendments frequently require revising documents used to guide and/or recruit participants. Please attach all documents that have been revised as a result of this amendment. Indicate by checking the box to the left below all documents appended.			
<input type="checkbox"/>	Revised Protocol (New Version) Protocol Version: Version Date:	<input type="checkbox"/>	Sponsor Letter with Description of Changes
<input type="checkbox"/>	Revised Consent Form	<input type="checkbox"/>	PI Memo Describing Changes
<input type="checkbox"/>	Revised Advertisement	<input type="checkbox"/>	Other (please describe):
Please fully describe your amendments below. List the current item followed by the new or revised item including a reason or justification for the change. Include a discussion of how the change might affect the integrity of the protocol and the risk/benefit ratio.			

Current Item	Revision	Reason
i.e.: eligibility age 30-50	i.e.: eligibility age 30-60	i.e.: insufficient recruitment

Principal Investigator's Signature: _____ Date: _____

CPHPR USE ONLY		
This Amendment was reviewed on the following date:		
This Amendment was:		Approved
		Approved Pending Revisions
		Deferred
		Not Approved
This Amendment was reviewed by:		Full CPHPR Review
		Expedited Review
Signature of the CPHPR Chair:		
Date:		
<p>CPHPR PROCEDURE FOR NOTIFYING INVESTIGATOR OF APPROVAL OF AMENDMENTS: The CPHPR will return a date-signed PDF copy of this form to you by e-mail. You will receive no further notification of CPHPR review <i>unless</i> changes to the protocol or consent form are required.</p>		

Appendix C

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

Request for Continuing Review

DATE
Title of Study:
Principal Investigator:
Co-Investigator

I. INSTRUCTIONS

If study initially required a full review- complete sections II through

If study initially required an expedited review- complete sections III and V

II. CUMULATIVE SUMMARY OF PARTICIPANTS ENROLLED TO DATE

A. Number of Participants Signed Consent Form/Enrolled	
B. Number Found Ineligible	
C. Number Withdrew Consent	
D. Number Currently Active/On Study	
E. Number Completed (without events leading to early termination)	
F. Number Terminated Due to Adverse Events	
G. Number Terminated Due to Other Reasons (provide detail in progress report)	
H. Number Lost to Follow-up	
I. Number of Other (participants not accounted for above, provide details in progress)	
Total of B through I should equal A: (number of participants signed consent form)	

III. PROGRESS REPORT

(Complete all sections in sufficient detail to assess current risk/benefit ratio)

The primary purpose of continuing review is to re-assess the risk-benefit ratio at intervals appropriate to the degree of risk associated with the study procedures, but not less the once per year. At the time of continuing review, the CPHPR must ensure that the regulatory criteria for CPHPR approval at 45 CFR 46.111, and when applicable, at 21 CFR 56.111, continue to be satisfied. Please answer the following questions so that both you and the CPHPR can determine whether any new information has emerged, either from the research itself or from other sources that could alter the CPHPR's previous determinations, particularly with respect to risk to participants.

UNANTICIPATED PROBLEMS INVOLVING RISKS TO PARTICIPANTS OR OTHERS

ADVERSE EVENTS

Since the last CPHPR review, have any unexpected adverse events occurred that were considered more likely than not related to participation in the research? ___YES ___NO

If YES, please provide a summary of the unexpected events that occurred, and any changes made to the protocol and/or consent form as a result.

NOTE: All unexpected adverse events that, in the opinion of the investigator, are more likely than not related to the study procedures must be reported to the CPHPR.

MAJOR PROTOCOL VIOLATIONS

Since the last CPHPR review, have any major protocol violations involving risks to participants or others occurred? ___YES ___NO

If **YES**, please provide a summary of protocol violations involving risks to participants or others, and any changes made to the protocol and/or consent form as a result.

Have all of these major protocol violations been reported previously to the CPHPR? ___YES ___NO

NOTE: All unanticipated problems, including protocol violations or deviations, must be reported to the CPHPR.

COMPLAINTS ABOUT THE RESEARCH

Since the last CPHPR review, have any participants or others complained about the research? ___YES ___NO

If **YES**, please provide a summary of the complaints and how they were resolved.

OTHER UNANTICIPATED PROBLEMS

Since the last CPHPR review, have any other unanticipated problems involving risks to participants or others occurred, for example, medication or laboratory errors, loss or unintended disclosure of confidential information, investigator suspension or termination? ___YES ___NO

If **YES**, please provide a summary of the other unanticipated problems involving risks to participants or others, and any changes made to the protocol and/or consent form as a result.

Have all of these unanticipated problems been reported previously to the CPHPR? ___YES ___NO

If **NO**, describe the unanticipated problem.

NOTE: All unanticipated problems, including protocol violations or deviations, must be reported to the CPHPR.

IV. PROGRESS REPORT AND INTERIM FINDINGS**PROGRESS REPORT AND FINDINGS TO DATE**

Provide a brief general summary of the progress of the study.

Has there been an interim analysis or are there any interim findings to report? ___YES ___NO

If **YES**, please provide results of interim analysis or a summary of any findings to date.

OTHER INFORMATION RELEVANT TO THE RESEARCH

Since the last CPHPR review, have there been major advances which would alter the risk/benefit assessment of the study? ___YES ___NO

If **YES**, please provide a summary of relevant information. Provide key references if desired, and interpretation/commentary.

AMENDMENTS / PROPOSED CHANGES TO THE RESEARCH

Are any changes to the research proposed at this time? ___YES ___NO

If YES, please attach Amendment Form detailing proposed changes.

NOTE: The CPHPR must approve all changes to protocols and consent forms and other study documents (questionnaires, recruitment letters, advertisements, and changes in study staff) prior to implementation.

V. ATTACHMENTS

___ **Proposal Submission Form:** Current dated version of the detailed proposal form, which must incorporate CPHPR approved changes to date (highlight any changes proposed with this continuing review submission, if applicable) Version:

___ **Research Consent Forms:** Copy of most recent CPHPR approved consent forms.

CERTIFICATION:

I certify that this protocol is being conducted with strict adherence to the federal and state regulations, and institutional policies governing the protection of human participants of research, including applicable institutional credentialing requirements.

Print Name of Principal/Overall Investigator: ___
Signature of Principal/Overall Investigator: ___
Date:

Appendix D

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

Office Use Only
PROPOSAL CODE

CPHPR Proposal Submission Form

(Send to CPHPR@emmanuel.edu)

Submission Date:	<i>Click here to enter a date.</i>
Principal Investigator (<i>must be a faculty member</i>):	<i>Click here to enter text.</i>
E-mail:	<i>Click here to enter text.</i>
Position of Principal Investigator	<i>Choose an item.</i>
Student Co-Investigator(s):	<i>Click here to enter text.</i>
Name of Course that Student Co-Investigator(s) Enrolled in for this Research Study (if applicable):	<i>Click here to enter text.</i>
Anticipated Start Date:	<i>Click here to enter a date.</i>
Anticipated End Date:	<i>Click here to enter a date.</i>
Anticipated Level of Review:	<i>Choose an item</i>
If more than one Investigator, names of other Investigators and their positions: <i>Click here to enter text.</i>	

1. Proposal Title: <i>Click here to enter text.</i>
2. Briefly describe the questions/hypotheses you will address: <i>Click here to enter text.</i>

3. In two or three paragraphs, briefly provide a rationale for your research project based on prior literature. Write so non-specialists will comprehend your project:

Click here to enter text.

4. Describe in detail the design of your project, or how you will analyze your data:

Click here to enter text

5. Describe in detail all methods including the procedures and measures you will employ. Please attach appendices with the precise instruments, if applicable.

Click here to enter text

6. Are you planning to use deception in your study? If so, justify its use:

Note: The CPHPR discourages the use of active deception in research.

Click here to enter text

7. Are you planning to include a debriefing session at the conclusion of your study? If so, provide a rationale for using a debriefing and a precise description of the debriefing.

Choose an item

8. Describe in detail all demographic information (age, gender, ethnicity, etc.) that you will collect:

Click here to enter text.

9. Describe the population that you will include in your research proposal and why you chose that population. Indicate whether you have any special knowledge of or experience with this sample population:

Click here to enter text.

10. Estimate the approximate number of participants you expect to include. [Please include a power analysis (if appropriate) and rationale for your N (number of participants) Please be cognizant of your colleagues and the students at Emmanuel College in asking for large numbers of participants]:

Click here to enter text.

11. Describe in detail how you will recruit your participants. Participating Emmanuel students must be 18 years of age or older. Describe the process you will use to ensure this age restriction is met. Indicate if you are using students in the Psychology Department Participant Pool. Please write verbatim the information you will post to recruit your participants: *Note: If you are recruiting participants from another institution, you may need to get approval from that institution's CPHPR or IRB, as well as from the Emmanuel College CPHPR. If the institution does not require its own IRB review, you may be asked to provide written documentation of the institution's support for your project.*

In most circumstances it is inappropriate for an investigator to use their own students as participants because of the possibility of coercion. Exceptions may be allowed, but the investigator would have to substantiate the need to use their own students as participants and propose an acceptable plan in accordance with CPHPR requirements and policies.

Click here to enter text.

12. Please describe how you will obtain participants' approval. If you are obtaining consent/permission/assent, please attach the form(s) as appendices. The CPHPR is federally mandated to ensure that the consent process is free of coercion or undue influence. For research involving permission and assent, a complete description of the process must be included. The consent/permission form should be written at the level of an 8th grader.

Please see the consent form template and sample consent form provided at the back of the guidebook.

Click here to enter text.

13. If you believe the CPHPR should waive the requirement of a signed consent form and you are not going to collect the form, please justify your decision here. If you are not going to distribute consent forms at all, please justify your decision here:

Click here to enter text.

14. Please describe any foreseeable risks that your research project could pose and assess their likelihood and seriousness. *Note: Risk is a very broad concept for which Principal Investigators should seek counsel from the CPHPR, if there are any questions. The CPHPR will examine the project to ensure that a wide range of risk issues are addressed- from the risk of information and identity disclosure to feelings of discomfort generated by questions on a survey to physiological discomfort or danger. There are other risks, but the preceding is intended to underscore the breadth of the concept.*

Click here to enter text.

15. If risks are involved, describe procedures for protecting against or minimizing any potential risks identified above and assessment of likely effectiveness and seriousness:

Click here to enter text.

16. Describe any benefits that will accrue to participants themselves or to society:

Click here to enter text.

17. Will you be recording or collecting any identifiable, private information about individual participants that would allow an individual to be identified (for instance unusual ethnicity, birthdate, etc.)? Choose an item

17.1 Will you be collecting audiotapes, videotapes, or still photography in your research?

Choose an item.

17.2 If you answered yes to either question, describe a.)which media will be used and b.) how you will protect the privacy of your participants and maintain confidentiality, including provisions for secure storage of data after the completion of your research. (On the consent/permission form, you will need to inform participants or guardians of your intent to record, and you will need to describe what will happen to these records).

Click here to enter text.

17.3 If you answered yes, please read and sign below:

I understand that I am obligated to protect and keep confidential any identifiable, private information gathered about individual participants through the conduct of my research. I agree to keep such information confidential, unless I obtain the participant's express written permission to do otherwise or unless I am legally compelled to provide the information.

Signed: _____ Date: _____

17.4 If you answered no, you will need to ensure that you protect the privacy of your participants and maintain confidentiality, including provisions for secure storage of data. Please describe how you will accomplish this: Click here to enter text.

17.5. Does this proposal involve any of the following populations:

Choose an item.

18. Is this project being reviewed by any other review board? If yes, provide name and location of other institution.

Choose an item.

19. Are you going to collaborate with any Emmanuel department or external agency or organization. If yes, please attach a letter of approval from the Emmanuel department or external agency.

Choose an item.

Completed Proposal Submission Forms must be sent **via email to CPHPR@emmanuel.edu**. Please do not send items related to the CPHPR to individual emails of the CPHPR Chair or Administrative Coordinator. Proposals are **due 3 weeks PRIOR to the CPHPR meeting**. Meeting dates are found on the website. Go to “Offices and Services” :: click on “Committee for the Protection of Human Participants in Research”.

After the CPHPR has approved a project, two hard copies of all forms related to the project with the investigators’ signatures must be brought to Ellen Mendonca (ADM 326b). Both copies must be stamped by Ellen Mendonca. One will be filed in the CPHPR office and the investigators must retain the second.

Note: All correspondence must be deposited in the CPHPR office files. A study cannot begin until this correspondence has been filed.

Investigators with questions concerning the development, submission, or status of their proposal should contact Geraldine Chalykoff, CPHPR Chair or Ellen Mendonca, CPHPR Administrative Coordinator.

Assurances:

If a Consent Form is used, it is understood that it must be kept on file for three years. Participants must be given a copy of the consent Form. The CPHPR may request copies of signed Consent Forms for all participants participating in this research.

It is understood that Emmanuel College students should be initially recruited as participants by public announcement and not by personal solicitation.

If any project exceeds a period of one year in duration, it must be reviewed and receive CPHPR approval before the beginning of the second and any successive years of the project.

It is understood that Investigators must comply with the federally mandated educational training requirement. This is done by taking the online “Course in the Protection of Human Research Participants,” which is found at <https://citiprogram.org>. There are CITI modules for Biomedical researchers, Social/Behavior/Educational researchers, and a module for student researchers and their research advisor.

It is understood that any required financial disclosure documents must be signed before the project is approved.

In signing this statement, **I certify that I have already completed the CITI training**. I also certify to the accuracy of the information provided in this document and in any attachments or other supporting documents, and I reassert my intention to abide by the College’s policies and procedures governing research involving human participants.

Signature: _____ Date: _____

Signature: _____ Date: _____

Signature: _____ Date: _____

Signatures of all project investigators are required.

Prior to submission to the CPHPR, all proposals must be reviewed by the Departmental Chair or other suitable person/s for scientific merit and feasibility.

Department Chair Signature: _____ **Date:** _____

(for CPHPR use only)

___ Proposal Submission Form

___ Consent/Permission/Assent Form

___ Research Instruments

___ Recruitment Materials

___ Authorizations

Signature of CPHPR Chair: _____ Date: _____

Geraldine Chalykoff, RN, PhD

Email: chalykge@emmanuel.edu

Recorded at CPHPR Full Meeting on Date: _____

Appendix E

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

Informed Consent Form

**Emmanuel
College**
Department of [] [Names of Researchers]

Informed Consent

**[Title of
Study]**

[
D
a
t
e
]

Dear X:

You are invited to participate in a research study entitled [name of study] conducted by [insert the Principal Investigator’s name here; with student research, insert both the student name and the faculty sponsor’s name]. You must be 18 years or older to participate [omit if this study is not conducted with students at Emmanuel College] and [list any other prerequisites for participation.]

A. Purpose and Procedures

- The purpose of this research is [explain the purpose of the study in easily understood language].
- In this study, you will [describe the procedures to be followed in easily understood language; describe the tasks that the participant will be engaging in. If you will be asking any personal or sensitive questions, state as much here.] This study will take place [specify location]. The time to complete this study is approximately [add expected time; indicate how time is divided – *e.g.* two sessions, a week apart]. The number of people who will participate is approximately [add expected number].
- [If participants will be compensated, state the amount and terms of compensation. If payments will be prorated if a participant withdraws from the study, state the terms. Course credit for participation is considered compensation and must be described, along with the reminder that an alternative way to earn credit is available.]

B. Risks and discomforts

- There are no known risks to participating in this study.

OR

- There may be some risks or discomforts if you participate such as [describe any reasonably foreseeable risks or discomforts to the participant. You should also describe the measures you will take to minimize these risks and discomforts. When appropriate, be sure to include specific information regarding referral(s) to professional consultation if your project has potential for causing strong feelings in participants (*i.e.*: questions regarding sexual orientation, physical abuse, drug use, suicidal thoughts, etc.).]

[For studies involving more than minimal risk, add the following statement: If you believe you have been injured as a result of your participation in this study, you may contact {name/service} at {telephone number and e-mail address}.]

C. Potential benefits

- There are no direct benefits to you from participating in this research. [If appropriate, you can add: This research may help us to understand...(limit to a brief statement).]

OR

- [Describe any benefits to the participant and to others that may reasonably be expected from the research.]

D. Protection of confidentiality

- Your name or other identifiers will not be attached to your answers so that your confidentiality can be maintained. Your privacy will be ensured in that all data resulting from this study will be analyzed, written, and published in summary form. [State conditions for exactly how you will protect the confidentiality of data here.]

E. Voluntary participation

- Your participation in this research study is voluntary; you may choose not to participate. You also have the right to stop participating at any time for any reason. You will not be penalized in any way should you decide not to participate or if you withdraw from this study.

F. Contact information

- If you have any questions or concerns about this research, please contact [list researcher's contact information, including name, mailing address, telephone number, and email address; include a faculty contact on student research].
- If you have any questions about your rights as a participant in this research or if problems arise, please contact Dr. Geraldine Chalykoff, Chair of the Emmanuel College Committee for the Protection of Human Participants in Research (CPHPR) at 617-264-7616 (e-mail: CPHPR@Emmanuel.edu) or Ms. Ellen Mendonca, Administrative Coordinator of Emmanuel's CPHPR at 617-735-9788 or mendoncae@emmanuel.edu. The CPHPR is a group of people who review research proposals and may also review study records to ensure that research is designed and conducted in an ethical and safe way.

G. Consent (choose one of the following endings)

- By completing the [questionnaire/interview/focus group participation — select appropriate activity, you are agreeing to participate in this study. You may keep a copy of this document for future reference.

OR

- I have read this consent document and have been given the opportunity to ask questions. I have been given a copy of this document for future reference. I agree to participate in this study.

Participant's signature: _____

Date: _____

Sincerely,

Your Name

Your title, address, telephone, and e-mail contact information.