

CHESTNUT HILL COLLEGE  
POLICIES AND PROCEDURES OF THE  
INSTITUTIONAL REVIEW BOARD (IRB)

Guidelines for the Protection of Human Subjects in Research

Judith Marsh, Ph.D.  
Assistant Professor of Professional Psychology  
Chair, Department of Professional Psychology

Scott Browning, Ph.D.  
Associate Professor of Professional Psychology

Patricia O'Donnell, SSJ, Ph.D.  
Associate Professor of Philosophy  
Chair, Department of Philosophy  
Director, Institutional Research

3/07/01  
(Revisions 02/05, 08/06)

## Table of contents

I.	Philosophy of the IRB	1
II	Structure and Functions of the IRB	1
1.	Membership	1
2.	Tenure	2
3	Schedule	2
4	Voting	2
5	Appeals	2
III	Guidelines	2
1.	Studies Requiring Review	2
2.	Definition of Human Subjects	3
3.	Research Review by the IRB	3
	A. Types of Reviews	3
	B. Exempt Protocols.	4
	C. Expedited Review	5
	D. Full Board Review	5
4.	Elements of the Proposed Protocol	6
	A. Cover Sheet	6
	B. Reviewers Comment(s) Form	6
	C. Abstract	6
	D. Methods	7
	E. References	11
	F. Appendices	11
5.	Responsibilities Following Submission of a Protocol	11
	A. IRB	11
	B. Investigator(s)	11
	References	12
	Appendices	
	A. Research Activities That Qualify for Expedited Review	13
	B. Sample Indemnifying Clauses	14
	C. Steps for Submission of All IRB Proposals/Application Checklist	15
	D. Request for Protocol Review/ Cover Sheet/ Application Form	16-17
	E. Request for Protocol Review/ Reviewer(s) Comments Form	18
	F: Concepts and Definitions	19

**CHESTNUT HILL COLLEGE  
POLICIES AND PROCEDURES OF THE  
INSTITUTIONAL REVIEW BOARD (IRB)**

Guidelines for the Protection of Human Subjects in Research

***I. PHILOSOPHY OF THE IRB***

Safeguarding the rights and welfare of all human beings (i.e., human subjects) who participate in research projects conducted under the aegis of Chestnut Hill College is the responsibility of both the College and the investigator(s). The College and the investigator(s) have a duty to protect research participants as well as to comply with the specific requirements established by sponsors of research projects. The following guidelines are based on the standards established by the Declaration of Helsinki Recommendations *Guiding Doctors in Clinical Research* (1964, 1975); U.S. Department of Health, Education, and Welfare *Guidelines* (1971, 1974); *The Nuremberg Code* (1947); *The Belmont Report* (1978); and the *Ethical Principles in the Conduct of Research With Human Participants* (American Psychological Association, 1982). These documents are available for review from the Chair of the Institutional Review Board of Chestnut Hill College.

No one code or set of guidelines is fully adequate to meet all research situations. Concern that the rights and welfare of human beings are safeguarded from individuals who are conducting research requires federally mandated review processes to assure adequate protection of human subjects used in research protocols. The Institutional Review Board (IRB) of Chestnut Hill College has the responsibility to review protocols and represent the best in ethical concerns for safeguarding the rights and welfare of all human subjects used in research protocols.

This document, upon acceptance, will be applied to the Doctoral Program in Clinical Psychology. All other programs within the Chestnut Hill College community may, and are encouraged to, employ these safeguards as a pilot project. The purpose of this project would be to ensure that these guidelines are applicable to any research being conducted with human subjects across the college community.

Data collection and analysis may begin only after the Institutional Review Board has approved the project and a copy of the approval has been placed in the student's academic file. The decision will be communicated to the investigator as soon as possible by the Chair of the IRB.

***II. STRUCTURE AND FUNCTIONS OF THE IRB***

**1. Membership**

The IRB will be composed of eight members. Seven of the members will be voting members, the eighth member of the board will be a college administrator serving in an ex officio capacity. Included on the Board will be at least one faculty member from the Department of Professional Psychology, one person from biology or medicine (may be from outside the college community) and at least one ethics professional (including moral theologians). Members will be appointed by the President of Chestnut Hill College in consultation with the IRB (the first IRB will be appointed by the President). One member must be chosen from outside the college community. Of the seven voting members, two should be people not involved in scientific research. One member may satisfy more than one of these requirements. In accordance with federal guidelines,

no person having an interest in a research protocol may participate in the IRB's initial or continuing review of that protocol, except to provide information requested by the IRB. Board members who are mentors or chairs of a dissertation committee will recuse themselves from the discussion.

## **2. Tenure**

Members of the Board will serve three years on a rotating basis.

## **3. Schedule**

Any proposal for research with human subjects will be submitted to the Board as described above. The Board will meet at least once a semester and these dates will be published well in advance. All materials required must be submitted a **full four weeks** prior to the Board's meeting. Two weeks prior to a board meeting, the Chair of the IRB will notify the investigator(s) that the proposal will be reviewed at that meeting.

## **4. Voting**

A two-thirds majority of the IRB (five of seven votes) is required to approve a protocol.

## **5. Appeals**

Any applicant whose research proposal is rejected by the board will be provided with a written explanation for the reasons for the decision. At that time, the applicant may revise the protocol and resubmit for the next scheduled IRB meeting. If the applicant is a student, she or he must share the letter of rejection with the faculty member who is supervising the research. If the student and/or faculty member disagrees with the recommendation of the Board, the applicant and faculty member may co-submit their written concerns to the Board within ten (10) working days of receiving the letter of rejection. The Board will convene a meeting upon receipt of any appeal, the appeal will be considered, and a judgment will be made. If the response of the Board does not satisfy the applicant, the applicant may appeal to the Vice President for Academic Affairs (VPAA), whose decision is final.

### **III. GUIDELINES**

#### **1. STUDIES REQUIRING REVIEW**

To assure the protection of human subjects and to comply with federal law, Chestnut Hill College requires that, prior to initiation, all research projects involving human subjects or human materials be reviewed and approved by the IRB. This policy applies to funded and non-funded research, and to all biomedical and behavioral research involving human subjects or human materials conducted by faculty, administrators, staff, and students of Chestnut Hill College. Questions regarding research involving animals should be directed to the Chair, Chestnut Hill College IRB.

#### **2. DEFINITION OF HUMAN SUBJECTS**

Research involving human subjects is defined as research involved with any living individual about whom any investigator (whether faculty, administrator, staff, or student) conducting research obtains

data through an intervention or an interaction with that individual or acquisition of identifiable private information. Surveys conducted by the college such as alumnae and accreditation surveys and learning outcome surveys will be excluded from IRB review. Intervention includes both a manipulation of the human subject's environment or a physical acquisition of data performed for research purposes. Interaction includes any communication or interpersonal contact between the investigator and the subject for research purposes. Private information includes all information about an individual or the behavior of an individual that occurs in a context in which an individual can reasonably expect that such information would not be made public.

### 3. RESEARCH REVIEW BY THE IRB

Human research is defined as any activity initiated by Chestnut Hill College faculty, administration, staff, or students that has the intent of securing information from humans for the purpose of advancing knowledge. The IRB expects that the investigator has included in the submission of the research protocol explicit objectives and formal procedures of the research so suitable review can be undertaken. The IRB has the responsibility of reviewing, and the authority to approve, require modification in, or disapprove any or all activities or proposed changes in previously approved research activities. The IRB approves human research based on the IRB's determination that the following requirements are satisfied.

#### A. Types of Reviews

According to Federal Guidelines, there are three types of reviews: those that meet criteria for exemption from the review process, those that meet criteria for an expedited review and those that require full board review.

Protocols will undergo different levels of scrutiny depending on a number of considerations. These considerations have to do with a few key issues including whether human subjects will be involved in a project and if so, who those subjects are (i.e. children vs. adults); the potential for stress, discomfort, or harm to subjects, and issues of deception, privacy and confidentiality. Table I summarizes the criteria by which protocols submitted to the Chestnut Hill College IRB will be evaluated.

Table 1. Criteria for Determining Type of Review

<i>A Proposal will be exempt if</i>	<i>A Protocol will be expedited if</i>	<i>Full board review is required if</i>
it involves minor changes to a protocol that has prior CHC IRB approval, or is a new protocol which:	it involves <u>major changes</u> to a protocol that has prior CHC IRB approval, or is a new protocol and:	the proposal involves major changes to a protocol that has prior CHC IRB approval, or is a new protocol and:
it poses no risk of physical or psychological harm to subjects	there is <u>minimal risk</u> of physical or psychological harm to subjects and	a clear potential for more than minimal physical or psychological harm to subjects exists and/or
it does not involve deception of subjects	there is no deception of subjects	the protocol involves deception of subjects and/or

it does not infringe on the privacy of subjects	it does not infringe on the privacy of subjects and/or	the protocol has the potential to infringe on the privacy of subjects and/or
It involves an interview or procedures where there is no potential for subjects to be identified	It involves an interview or procedures where there is no potential for subjects to be identified and/or	The protocol involves an interview or procedures where there is the potential for subjects to be identified and/or
It has no potential for disruption of a subject's daily routine	there is no potential for disruption of a subject's daily routine	there is potential for disruption of subject's daily routine and/or
the study does not include subjects who are minors or who are selected from vulnerable populations	the study does not include subjects who are minors or who are selected from vulnerable populations	the study includes subjects who <i>are</i> minors or who are selected from vulnerable populations

Specific definitions of the terms contained in this table including "deception," "physical or psychological harm," "confidentiality," "privacy," etc. can be found in Appendix F. In depth discussion of these terms and concepts is also provided in *Ethics in Research with Human Participants* (Sales & Folkman, 2000) which is available in the Chestnut Hill College Library and from the Chair of the Chestnut Hill College IRB. Additional resources are listed in the reference list of this document. It is the responsibility of investigator(s) to know, understand and be able to apply these concepts and definitions to the research being proposed and conducted.

**B. Exempt Protocols\***

The Chair of the IRB, in consultation with the IRB, is responsible for conducting a preliminary review of all submitted research protocols to determine whether they qualify for exemption. Therefore, the researcher must submit to the IRB a proposed research protocol so that a determination for exemption can be made. The following categories of research are normally exempt from full board IRB review but must be reported to the IRB for determination of exempt status:

- 1 . Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving educational tests (i.e., cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior. No research will be exempted if the information obtained is recorded in a way that the subject can be directly identified or indirectly identified through identifiers linked to the subject; or, any disclosure of the human subject's responses outside of research could reasonably place the subject at risk of criminal liability, civil liability, or damage financial standing, employability, or reputation. Further, no human research involving elected or appointed public officials or candidates for public office can be exempted.

3. Research involving existing data or documents that are publicly available or if the investigator records the information in a manner that human subjects cannot be directly identified or through identifiers linked to the subjects.

\*Note: Studies using minors or special populations are ineligible for exempted review.

### **C. Expedited Review**

Federal regulations (1979, 1985, 1991) have established a list of categories of research that may be reviewed by the IRB using an expedited review process. The IRB uses the expedited review process to review either or both of the following:

1. some or all of the research appearing in Appendix A and found by the reviewers to involve no more than minimal risk.
2. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

The expedited review process is as follows: After receipt of a protocol, the Chair of the IRB will review and categorize the protocol based on type of review being requested (Exempt, Expedited, Full). The Chair of the IRB and one member (reader) of the Board will review the protocol and render a decision as to whether it meets criteria for expedited review outlined in these guidelines. If a protocol meets criteria for expedited review, the Chair and reader will sign the cover sheet indicating approval. The protocol is returned to the investigator(s) and the proposed research may begin. The IRB members conducting the expedited review have all of the authority of the IRB except that the reviewers may not disapprove a research protocol. The reviewers will refer any research protocols which they do not accept for expedited review to the full board for review.

When the expedited review procedure is used, the IRB Chair and member conducting the review shall inform the full board in writing of research protocols that have been approved. At a convened IRB meeting, any member may request that any research protocol that has been approved under the expedited procedure be reviewed by the IRB in accordance with full board review procedures. For full review, a two-thirds majority vote of the members of the IRB is required to conduct a full board review of a protocol previously approved by the expedited review process.

### **D. Full Board Review**

Full board review is required for all protocols that involve human subjects and do not meet the above criteria for an exempt research proposal or an expedited review. The purpose of the IRB is to *"evaluate the strengths and weaknesses of the research as it relates to the ethics of research on human subjects."* It is not the role of the IRB to raise questions about research methodology or to expect the investigator to justify the validity of measures used unless these issues in some way compromise the protection of human subjects.

The Chair of the IRB will review a protocol and select two readers who are responsible for reading the proposal thoroughly, evaluating the strengths and weakness of the research as it relates to the ethics of research on human subjects, and preparing to present the research and a critique and recommendations to the full board at the next IRB meeting. Students will not be permitted to begin to collect research data until the critique and recommendations are presented to the full board for approval. Copies of the protocol will also be distributed to all other Board members for their review.

The board will meet at least once a semester and any protocols received by the published deadline will be presented to the full board by the primary reviewer(s). If the number of proposals received exceeds the number which can reasonably be considered, additional meetings will be scheduled. Once a board meeting is convened, board members will be given time to ask questions and discuss specific issues pertaining to each protocol that is presented. The investigator(s) will be invited to the board meeting in order to have the opportunity to discuss their protocol and to ask questions. Investigators will join the meeting after their protocol is presented to and discussed by the board. An investigator will be invited to the board meeting to provide the committee with information. The board will reach a decision outside the part of the meeting when the investigator is present. The decision and a detailed review will be sent to the investigator(s) by the Chair of the IRB within three weeks.

#### **4. ELEMENTS OF THE PROPOSED PROTOCOL**

##### **A. Cover Sheet**

A completed copy of the "cover sheet" that is found in the appendix to this document must be submitted with all protocols. All questions on this form must be answered before a protocol will be considered by the IRB. If a research project is seeking grant funding, the target funding program/agency may require a particular form or format for a cover sheet. Agency required cover sheets should be completed in addition to the Chestnut Hill College IRB cover sheet.

##### **B. Reviewers Comment(s) Form**

Included with the protocol should be a copy of the Reviewer(s) Comments Form which is found in Appendix E. It is the responsibility of the investigator(s) to provide the information requested in the top two lines, "Name of Investigator(s)" and "Project Title." The rest of the form should be left blank. Reviewer(s) comments will be returned to investigator(s) on this form.

##### **C. Abstract**

The abstract is a summary of the major elements of the protocol. The purpose of the abstract is to provide the reader(s) with the highlights of the protocol in order to give a context with which to review the proposal. Included in the abstract should be:

1. An introductory sentence or two discussing the purpose(s) or overall goal(s) of the proposed research.
2. One to three sentences summarizing the major findings of the literature review.
3. Four to six sentences delineating the research problem(s) and the major hypotheses to be investigated as well as a summary of the specific objectives of the proposed project.
4. One to six sentences summarizing the methods to be employed in conducting the research, including a description of subjects and methods of subject selection.
5. One to six sentences summarizing the statistical methods to be used to analyze data.
6. One to three sentences summarizing the potential significance and/or utility and/or impact of expected results of the proposed project.



The maximum recommended length of the abstract is two pages containing approximately three to five paragraphs (in 12 point font). However, it is recommended that the abstract be limited to one or two paragraphs, single spaced. For those doing research in the field of psychology, it is strongly recommended that the guidelines for preparation of abstracts described in the *Publication Manual of the American Psychological Association (5th ed.)* (APA, 2001) be followed.

## **D. Methods**

### 1. Characteristics and Selection of Potential Subjects

Describe the number of subjects to be used in the research protocol, method of subject selection (e.g. random sampling, stratified random sampling, etc.), and the rationale for selecting that number.

Describe the potential subjects in terms of gender, age-range, ethnic group, economic status, and any other significant descriptors.

Indicate whether subjects belong to a "vulnerable population." Research involving subjects that are particularly vulnerable will require full board review. Vulnerable groups may include (this is not an all-inclusive list):

Minors	Mentally impaired persons
Pregnant women	Prisoners
Individuals in nursing homes	Chronically disabled persons
Terminally ill patients	Single parents (including minors)
Impoverished persons	Armed forces personnel
Battered adults	People with medical illness
Persons who are HIV positive or who have AIDS	Abused children
	Students

Indicate any special subject characteristics. If the subjects are children, mentally or emotionally challenged, or legally restricted, please explain why it is necessary to use these persons as subjects. The investigator(s) must document why such persons are necessary for the research.

Describe how you will gain access to these potential subjects. Please be precise as to the methods used to gain access to potential subjects. If advertisement(s) are to be used, please include a copy of the advertisement in the appendix section.

A summary paragraph containing specific inclusion criteria is required. If subjects are to be excluded because of age, gender, economic status, ethnic origin, etc., reasons for exclusion must be documented by the investigator(s) as well.

If subjects are from an institution other than Chestnut Hill College, please indicate the name of the office responsible for granting access to the subjects. The IRB has the responsibility of assuring that cooperating institutions and/or research sites have appropriately reviewed and approved applications for the use of human subjects. Once students have finalized their plan to complete a research project at an agency or site, the student must submit a copy of that institution's IRB policy along with a letter indicating approval for the student to conduct the research at that site.

## 2. Experimental or Research Procedures

Describe the intended experimental or research procedures. This should include a description of the design, research setting and duration of the project as well as a clear summary of what the subject will experience or be required to do. Describe the experimental procedures in sufficient detail so that the IRB will have a clear understanding of the experimental design and procedures.

Indicate if subjects will be deceived in any way. If so, describe how the subjects will be deceived. Research using deception will require full board review. Justification and documentation as to why deception must be used must be provided by the investigator(s) to the IRB.

Indicate to what extent routine activities of the subject will be interrupted during the course of the study. Justification for significant disruption of the subject's daily routine must be documented by the investigator(s).

Explain how and when subjects will receive compensation or inducements for participation in the research. Compensation is not required. If subjects are to be compensated, describe any inducements to be provided to the subjects whether monetary or prizes, gifts, or provided services or benefits. Compensation for subjects that are excluded by the investigator or by withdrawal must be clarified.

## 3. Confidentiality

Describe the procedure(s) you will use to insure confidentiality of the data. You must communicate to the IRB how you will preserve subject anonymity. The IRB of Chestnut Hill College requires that confidentiality be maintained for subjects. The IRB must be informed of the steps that will be taken to assure confidentiality especially when personally identifiable information is being recorded. Specifics concerning the coding of data, storage of data, and access to data must be documented by the investigator(s). In some cases, sponsoring agencies may have access to data for review. If such review is mandated, the IRB must be notified. Limits to confidentiality must be addressed in the informed consent process.

## 4. Informed Consent

### (a) Consent and Assent Procedures

The specific procedures that will be followed by the investigator(s) to obtain informed consent must be described in this section. Further, a description of assent procedures for minors, mentally challenged persons, persons with significant emotional disturbance, or subjects belonging to any vulnerable group must also be included. For minors, a consent form written for and signed by the guardian must be submitted to the IRB. Whenever possible, provide an assent form written in lay language understandable by the minor, mentally challenged person, or person with significant emotional disturbances. If non-written assent is to be used, provide a statement describing the procedures that will be followed to obtain assent and what the subjects will be told. The goal of assent is to involve the person in the process of agreement to participate, to the extent possible, in a manner tailored to the person's level of comprehension.

### (b) Consent Form

The consent form should be a succinct statement which gives reasonable information about the study including the purpose, procedures, benefits, risks, and discomfort to the subject, duration of the study, and alternative therapy if applicable so that the subject may make a meaningful decision about

participation. The consent form must be titled "Consent Form" and should be subtitled with the name of the study. The name(s) and phone number(s) of the responsible investigator(s) should appear under "Consent Form." It should be written in clear, understandable English or appropriate language that explains the purpose of the study and precisely states what will be done to the subject. For a consent form in language other than English, a translation must be provided to the IRB. The consent form must provide adequate information concerning the study in order for the subject to be able to decide whether or not to participate. It should not contain language whereby the subject is asked to waive, or appears to waive, any of his/her legal rights or to release Chestnut Hill College or its agents from liability for negligence. Each adult subject must receive a signed copy of the consent form. Legal guardians signing for minors or those individuals who cannot provide informed consent must receive a signed copy of the consent form. The principal investigator must retain in his/her confidential files copies of the consent forms signed by each subject for at least five (5) years following the completion of the research study or longer if required by the sponsoring agency.

The following information must be included on the consent form. A copy of the consent form must appear as an appendix of the proposed research:

Purpose of research. The purpose of the research should be expressed in lay terms clearly indicating the purpose and nature of the research.

Selection of subjects: The subject must be informed of the reasons why he/she is being asked to participate in the research. Inclusion and exclusion criteria must be made known to the subject.

General experimental procedures: The subject must be informed of the general experimental procedures and exactly what his/her participation will involve. Information concerning the duration of the research procedures, place where the experimental procedures will be performed, pre- and post-evaluations of subjects, types and number of tests, randomization procedures, photographing, video-taping, or audio-taping requirements, amount of blood, urine, or saliva to be taken, and follow-up studies, must be clearly stated in the consent form. The disclosure of inherent and/or unforeseen hazards, discomforts, and inconveniences must be clearly stated in the consent form. Procedures for debriefing subjects and provisions for therapeutic assistance should the subject experience discomfort must also be stipulated.

Confidentiality: The subject must be informed of the steps that will be taken to assure confidentiality, particularly when personally identifiable information is to be recorded. Procedures for coding of data, maintaining files, and access to data must be included in the consent form.

#### Limits of confidentiality

In conversations and forms whose purpose is to assure informed consent or assent, research subjects must be informed that there are limits to confidentiality. For example, a statement such as the following should be included in consent processes:

You need to know that there are a few exceptions to the rules of confidentiality that we just discussed. If, for example, you are ever involved in a court action in which the judge orders me to produce any and all data that I collected regarding you during this study, I would have to turn the information over to the judge. In addition, if you indicated in any way that you may be a danger to yourself or others, I would have to take steps to ensure your safety and/or the safety of anyone else who may be involved. Do you have any questions?

If issues of immediate clinical risk should arise in the process of working with subjects in research projects, the researcher will judge how best to bring the interview to a conclusion, and then immediately

take action appropriate to the researcher's qualifications. If the researcher is not a licensed psychologist in the state of Pennsylvania, he or she must identify in advance a licensed psychologist who will be willing to consult with him or her when questions of clinical risk arise. An unlicensed researcher should consult with the identified psychologist to decide if any further action is needed.

Benefits of the Study: The benefit(s) to the subject, if any, should be explained. If there is no benefit to the subject this should also be explained. A study that has no benefits to the subject and places the subject under risk will be critically reviewed by the IRB. If relevant, describe how society will benefit from the conduct of this study. If there is no benefit to society this should also be explained. The IRB is reluctant to approve research that has no benefit to the subject or society and puts the subject at risk.

Risks/Discomforts to Subjects: The investigator must provide a detailed rationale for exposing the subjects to risks, discomforts, inconveniences, and physical danger. The IRB cannot make a decision concerning approval of the protocol without such detail. Describe any aspect of the research project that might cause discomfort, inconvenience, or physical danger to the subjects. The investigator must provide documentation of short-term risks, discomfort, inconveniences, and physical danger that may occur to a subject participating in the research protocol. Documentation of emergency or debriefing procedures should be included where appropriate. Any long-range risks must also be described.

Injury/ Compensation : If applicable, subjects should be advised as to availability of medical or psychological treatment or compensation for injury incurred as a result of participating in the research. For research involving more than minimal risks, there may be obligations by Chestnut Hill College to cover, in part, medical treatments, etc. In studies where threat of injury exists, subjects should be advised of these potential injuries.

Disclaimer/Withdrawal: The subject must be informed that he/she is free to decide whether or not to participate in the study, or to withdraw from the study at any time during his/her participation. The subject must be informed that nonparticipation in the research or withdrawal from the research will not prejudice future interactions with the investigator or Chestnut Hill College. There must be assurances that the subject is not coerced to participate and is not coerced not to withdraw from the research.

Subject rights: The following statement (appropriately worded) regarding the rights of research subjects must appear in all consent forms:

*'I understand that if I wish further information regarding my rights as a research subject, I may contact the IRB Chair by phoning 215-248- 7???. "*

Questions: The subject should be encouraged to ask questions. The consent form should state that the subject can ask questions and these questions will be answered.

Indemnifying Clauses: Some types of research will require indemnifying clauses. Please refer to appendices for examples of indemnifying clauses.

Certification by the IRB: The IRB will stamp and date the approved consent form prior to its use. The approval will be for one year following the date of certification. If at any time the investigator(s) alters the IRB approved research protocol, the IRB must be notified and the consent form may have to reflect the alterations of the research protocol. Once appropriate changes have been made to the

revised consent form, the IRB will stamp and date the revised form.

### E. References

This section should contain only those references that are cited in the body of the protocol and should be written in accordance with the *Publication Manual of the American Psychological Association*, (5<sup>th</sup> ed.,APA 2001).

### F. Appendices

Additional or supplementary information that is too detailed or technical for inclusion in the body of the proposed protocol should be included as attachments in this section. Each document should be entitled Appendix A, Appendix B, and so on. Copies of all consent forms, questionnaires, data forms to be used by the researchers, letters of permission to use off-campus sites, letters of agreement of participation from off-campus co-investigators are examples of items often included as appendices.

## **5. RESPONSIBILITIES FOLLOWING SUBMISSION OF A PROTOCOL**

### **A. IRB**

If Full Board Review is required, copies of the protocol are sent to each member of the IRB. It is the responsibility of the primary reviewers to lead the discussion concerning the protocol being reviewed at the scheduled meeting of the IRB. Following discussion of the Proposal by the Board and with the investigator(s), the IRB determines whether human subjects are or are not at risk, and decides to (a) approve the protocol as submitted; (b) approve the protocol contingent on specific revisions; (c) table the protocol for substantive changes and/or resubmission to the IRB; or (d) disapprove the protocol. Actions of the IRB will be recorded in the minutes of scheduled meetings. The Chair of the IRB will notify the investigator of the decision within three weeks after the meeting.

Chestnut Hill College policy and federal regulations require that all research studies involving human subjects be reviewed within twelve months of approval and every twelve months thereafter. The Chair of the IRB will be responsible for tracking yearly reviews and for assuring that they are placed on the IRB agenda. In some cases, depending upon the risks to human subjects, the IRB may review research studies on a more frequent schedule. If the IRB becomes aware at any time of investigator abuse of human subjects in Chestnut Hill College sponsored research, it is responsible to immediately revoke the IRB's approval of the research protocol.

### **B. Investigator(s)**

It is the responsibility of the investigator(s) to immediately inform the IRB of any changes in the research protocol, injuries and/or untoward responses of human subjects, and/or termination of the research. The IRB will review most protocol changes by expedited review. Changes in research protocols may mandate changes in the consent form. The approved revised consent form will be stamped and dated by the IRB. The consent form will be certified for use for one year following the date of certification. If changes in the research protocol are instituted, the process for research protocol approval and the certification of the consent form will be immediately initiated by the investigator(s) as previously described. Any and all injuries and untoward response(s) that occur during a research protocol must be immediately reported to the IRB Chair, and followed with detailed documentation of the events. Actions taken to remedy either the injuries or untoward responses must also be included. Investigators must inform the Chair of the IRB in writing when a project is terminated.

## References

- American Psychological Association. (1982). *Ethical principles in the conduct of research with human participants*. Washington, DC: Author. (see most recent version)
- American Psychological Association. (1992). Ethical principles of psychologists and code of conduct. *American Psychologist*, 47(12), 1597-1611.
- American Psychological Association. (2001). *Publication Manual of the American Psychological Association*, (5th ed). Washington, DC. Author.
- National Institutes of Health (1994). Guidelines on the inclusion of women and minorities as subjects in clinical Research. *Federal Register*, 59,14508-14513.
- National Research Act, P.L. 93-348, 88 Stat.342 (1974).
- Office for Protection From Research Risks, Protection of Human Subjects. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research (QPO 887-809)*. Washington, DC: U.S. Government Printing Office.
- Office for Protection From Research Risks, Protection of Human Subjects. (199 1, June 18). Protection of human subjects: Title 45, Code of Federal Regulations, Part 46 (GPO 1992 0-307-551). *OPRR Reports*, pp. 4-7.
- OMB Circular A- 110 (1999). Uniform administrative requirement for grants and agreements with insitutions of higher education, hospitals, and other non-profit organizations. *Federal Register*, 64, 5492654930.
- Sales, B.D. & Folkman, S. (2000). *Ethics in research with human participants*. Washington, DC: American Psychological Association, 188.

**APPENDIX A**  
**CHESTNUT HILL COLLEGE INSTITUTIONAL REVIEW BOARD**  
**RESEARCH ACTIVITIES THAT QUALIFY FOR EXPEDITED REVIEW\***

**\*Source:** Sales, B.D. & Folkman, S. (2000). *Ethics in research with human participants*. Washington, DC: American Psychological Association.

Federal guidelines stipulate that research activities that qualify for expedited review include protocols involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods).

Collection of hair and nail clippings, in a nondisfiguring manner, deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

Collection of escreta, and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week from subjects 18 years of age or older and who are in good health and not pregnant.

Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

Voice recordings made for research purposes, such as investigations of speech defects.

Moderate exercise by healthy volunteers.

The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

**APPENDIX B**  
**CHESTNUT HILL COLLEGE INSTITUTIONAL REVIEW BOARD**  
**SAMPLE INDEMNIFYING CLAUSES**

The following statement (amended as appropriate) must be included in informed consent only if the study could affect women of childbearing age, the unborn fetus, or a woman breast-feeding a child.

**PREGNANCY:** Due to the effects of this drug/device, there could be serious harm to unborn children (or children who are breast-feeding) and it could also jeopardize the health of the mother. In addition, it is possible that harmful side effects that are not yet known could occur to both the mother and unborn or breast-feeding child. For this reason, if you are pregnant, we want you to tell us and we will not include you in the study. If you are capable of becoming pregnant, you will be given a pregnancy test prior to entry into the study. Further, you understand that while you are taking this drug/device you should not become pregnant, and if you do become pregnant, you must discontinue the drug/device and notify your physician immediately.

The following statement (amended as appropriate) must be included in the consent form only if a sponsoring agency reviews the data.

**CONFIDENTIALITY:** Any information obtained in connection with this project and which could be identified with you will be kept strictly confidential. However, representatives of the United States Department of Health and Human Services, or the United States Food and Drug Administration (or the appropriate sponsoring agency) may inspect the research records to assess the results of this research. The information obtained in this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

The following statement (as amended as appropriate) may need to be included in the consent form if the research intervention could result in untoward physical, psychological, or medical responses.

**INJURY:** If you are injured as a result of your involvement in this study, only physician fees and medical expenses in excess of your medical and hospital coverage or other third party coverage will be paid with no additional cost to you. No financial compensation for such injury is available.



**APPENDIX C**  
**CHESTNUT HILL COLLEGE INSTITUTIONAL REVIEW BOARD**

**Steps for submission of all IRB proposals:  
exempt, expedited, and full review**

1. Write your **Proposal**: two sections/ chapters: 1- literature review substantial enough to support your methodology and 2- methodology. It is very important to submit a final version of your methodology to the IRB, since any changes in methodology after IRB approval would require resubmission.
2. Complete an IRB **Application Packet**:
  - a. Refer to sample IRB applications in the library.
  - b. Obtain IRB Application Forms: download pdf versions - from the Graduate Division section of the Chestnut Hill College web page, go to Academics (on the left), then to the Institutional Review Board at the bottom of the list.  
([http://www.chc.edu/page\\_template.asp?section=3&file=institutional\\_review\\_board](http://www.chc.edu/page_template.asp?section=3&file=institutional_review_board))  
Or contact the IRB secretary to have a paper version mailed or an Excel version transmitted to you.
  - c. Include all of the following components:
    - i. Cover sheet (application form)
    - ii. Reviewer's comment form (application form)
    - iii. 250-word summary/abstract of the project
    - iv. Methodology for the project, addressing all points noted in Guidelines
    - v. Instruments to be used, if any, with attached examples, if the instrument has been created for the project under review
    - vi. All "Consent to Participate" and "Assent to Participate" forms \*
    - vii. Complete debriefing script, if applicable
    - viii. Process for dealing with data storage and disposal
    - ix. References (selected for relevance to methodology) - As per APA style
    - x. Any additional information that relates specifically to the welfare or activities of the human subjects
3. Present the completed proposal and completed application packet to your advisor or dissertation chair for approval and signature.
4. Submit three copies of your **application packet**, complete with your signature and *signature(s) of all members of your dissertation committee (PsyD students Approval of Dissertation Proposal form) or advisor*, to the IRB secretary.
5. Submit one copy of the entire **proposal** to the IRB secretary. This document should also have the signature of our advisor or dissertation chair, verifying that he or she has approved this version. This document includes the Literature Review.

Type or use a word processor to complete the forms. Incomplete cover sheets will be returned to the investigator(s) along with proposed protocols and will not be approved for review until a completed cover sheet is provided.

\* Some Exempt research projects may not need consent forms. In such cases the appropriate details should be covered in the material subjects received (i.e. in the wording of a survey).

Investigator(s) May Not Begin The Proposed Research Until It Is Approved By The Chestnut Hill College IRB.





**APPENDIX E**  
**CHESTNUT HILL COLLEGE INSTITUTIONAL REVIEW BOARD**  
**REQUEST FOR PROTOCOL REVIEW/ REVIEWER(S) COMMENTS FORM**

Name of Investigator(s) (As it appears on cover sheet):

Project Title (As it appears on cover sheet):

**(RESEARCHERS DO NOT WRITE BELOW THIS LINE)**

---

**Reviewer's Comments** (continue on back if necessary):

**Recommendations of the IRB:**

Exempt

Full Review

Expedited

Approve

Conditionally Approve

Do Not Approve

Primary Reviewer's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Secondary Reviewer's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of IRB Chairperson \_\_\_\_\_ Date: \_\_\_\_\_

**APPENDIX F**  
**CHESTNUT HILL COLLEGE INSTITUTIONAL REVIEW BOARD**  
**CONCEPTS AND DEFINITIONS**

(Adapted, with permission, from: 1) Guidelines, Policies, and Procedures for the Safeguarding of the Rights and Welfare of Human Beings of the Research Ethics Review Board of Immaculata College, and 2) Protection of Subjects Used in Research- General Guidelines, Policies, and Procedures of the Temple University Institutional Review Board Subcommittee B for the Safeguarding of the Rights and Welfare of Human Beings Participating in Funded and Non-Funded Research)

**I. SOME GENERAL CONSIDERATIONS WHEN PLANNING RESEARCH WITH HUMAN SUBJECTS**

1. The investigator and the IRB are responsible for the important task of weighing *the risks and benefits* of carrying out the research in question, and particular emphasis must be placed on safeguarding the welfare of human participants.
2. Special concern is given when participants are considered to be at more than "*minimal risk*" in participating in the study.
3. Entering into a *dual relationship* as part of a research study raises concerns and considerations.

**II. ETHICAL RESPONSIBILITIES OF INVESTIGATORS/ RESEARCHERS**

Investigators are responsible for

1. the ethical treatment of all research participants, and
2. their own actions as well as those of any researchers, collaborators, assistants, students, employees, and employers (all of whom share ethical responsibility); for example:
  - the actions of research assistants, as well as their safety and welfare;
  - guarding against the potential influence of a dual relationship with research assistants;
  - honoring all promises and commitments included in the consent agreement;
  - protecting all participants from physical and mental discomfort, harm, and danger that may arise from research procedures. If these risks exist, the investigator informs the participants of these risks.
  - (1) When undesirable consequences do result, the investigator is responsible for detecting, monitoring, and removing or correcting any harm (i.e. emotional or physical).
  - (2) The participant should be informed of how to contact the investigator for a reasonable amount of time following completion of the study.
  - (3) The participant is invited to report any stress, harm, concerns, or questions to the investigator.
3. In cases where research is being conducted as part of a course of study, such as, a thesis or dissertation, the faculty advisor shares the responsibility for case study research.

### **III. INFORMED CONSENT**

1. Investigators must enter into a signed informed consent agreement with the subject prior to the subject's participation in the research study.
2. The informed consent should include all aspects of the research that may reasonably be expected to influence the subject's willingness to participate.
3. The investigator is especially sensitive to potential concerns, given the nature of the dual relationship, and is open to answering questions posed by the subject.

### **IV. DECEPTION**

Deception is failure to make full disclosure of the nature of the study prior to participant's consent and requires additional safeguarding of the welfare of subjects. Therefore,

1. the investigator assures that participants are at no more than "minimal risk."
2. These safeguards and others are highlighted and magnified for the participant, given the nature of the dual relationship with participant.
3. If deception is used, the investigator is obligated to determine that the deception is necessary and justified by the value of the study.

#### **Debriefing:**

4. When deception is used, the investigator must ensure that participants are provided with an explanation of the study as soon as possible.
5. When deception is used, participants should be given the opportunity to withdraw any data that has been collected regarding themselves.

#### **Concealment of Participation:**

6. Studying some phenomena is confounded if the individual is aware of being observed or studied.
7. Observation of *public* data, which is recorded in a way that ensures confidentiality, is often acceptable in circumstances in which there is no direct effect on the subject.
8. Covert recording of participants using cameras, microphones, or other technology is typically considered personally objectionable and would not be included within this situation.
9. Covert or participant observation of private data is problematic and often objectionable.

#### **Action Research:**

10. Adding research procedures and/or manipulation to existing non-research programs and operations in institutional or action research is a common form of research in *workplace* settings. For purposes of these guidelines, *workplace* will be defined as any setting in which the investigator

may be entering into a dual *relationship* with participants. For example, if the investigator and participant have a previous relationship as defined by a role other than participant-investigator. This definition would apply when the investigator is an employee, volunteer, trainee/intern, healthcare provider, student, church/organization member at the research setting, or fulfills any other role that shares the spirit of those listed.

11. To the extent that the research aspect has little or no effect on what participants actually experience, and to the extent that the procedures are indigenous to the environment in which the research is carried out, the question arises whether informing participants of the research is necessary. In this case, the researcher should balance between the desirability of informing subjects, and the probability that doing so will bias the validity of the study; balance the feasibility and practicality of attaining informed consent; examine whether the only form of identity of the subjects would actually be on the consent form; determine if the risk is more than minimal to the subjects, and if so, get written informed consent; determine if the research involves *reasonable* variations in operations and programming of the organization, and if so, informed consent from participants is not required. In such a case the investigator bears a special obligation to ensure the procedures are ethically acceptable and the welfare of the subject is safeguarded.

## **V. RISKS/BENEFITS**

Investigators are obligated to weigh and evaluate the risks and benefits of completing a research project. The essential ethical question is whether the potential risk to the welfare of participants is warranted by the importance of the research. Investigators must consider the following questions as they weigh the potential risks and benefits of their proposed research project.

1. Is the study being conducted for the benefit of the specific, chosen setting or is it for the benefit of general knowledge/theory within a field of study?
2. Could the study be equally and effectively conducted in another setting, and if so would the risks be any different?
3. Are the subjects being chosen in part because they are a captive population, or are they the specific group of interest?
4. How practical or feasible would it be to complete the study in a different setting?
5. Are the subjects being asked to do anything different from what they would have done if they had not been involved in this research?
6. Does anyone have access to information they would not have if this research were not being conducted?
7. Is deception of participants involved in the design and/or conduct of this study?
8. Is the study being conducted using existing data?
9. Is the data already accessible to the researcher even if the study is not conducted?

## **VI. FREEDOM FROM EXPLOITATION: DUAL RELATIONSHIP**

1. Investigators should be sensitive to a subject's obligations and loyalties to the organization.
2. Given the dual nature of the relationship, sensitivity to the impact of this relationship on the ability of subjects to feel free to decline or withdraw participation is necessary.
3. The investigator should examine and reveal any actual or implied penalties or risks that a participant may face if declining or withdrawing from participation.
4. Investigators who are conducting research with patients or clients should be careful not to exploit their willingness to take risks, or give the impression that continued services are contingent upon research participation.
5. The investigator must make explicit which services are by necessity contingent upon research participation.
6. One possible resolution to some of these problems is to protect the potential participant's right to refuse by having a third party, who is not involved in the relationship, recruit participants and conduct the data collection.

## **VII. CONFIDENTIALITY**

1. Given the nature of the relationship, particular safeguards against identification of subjects would be needed to guarantee anonymity.
2. Given the dual relationship, identifying information may extend to handwriting, reports of certain experiences, rare facts, etc. Therefore:
  - access to the data should be assessed and disclosure made clear regarding who would have access to the data and other information;
  - if the investigator indicates that the information will remain confidential, the parameters of this confidentiality should be made clear;
  - if the information will be placed in the participant's personal file (i.e. medical or personnel files) this should be made explicit.
3. The investigator should explore ways in which participation may impact the nature of the relationship once the study is completed.
4. Investigators are often asked to give specific data to the organization since the organization has supported the research and its representatives may feel that they have the right to the information. Nonetheless,
  - disclosure of individual data is not permitted without the participant's permission. Otherwise, the investigator **MUST** keep the data confidential.
  - When research is commissioned or supported by an organization that may request the data, the investigator should include this limitation of confidentiality in the consent form.



5. Whenever possible, participant data should be recorded anonymously, with identifying information removed from the research protocol as soon as possible. When the name of a participant must be available, the records may be coded and the key to the code stored where it is only accessible by the investigator.

6. The law does not safeguard the confidentiality of all research data, even when confidentiality has been promised to the participant by the investigator. Therefore,

- when an investigator collects data that may be court ordered, the investigator is obligated to inform the potential participant of the limits of confidentiality, possible risks involved with the revelation of the data to the courts, and steps taken to safeguard the information against such disclosure.
- The investigator may protect the participants by storing the sensitive data in a way that makes identification of individual data impossible.
- Confidentiality may be compromised when information is obtained regarding a serious threat of harm to the participant or another person.

7. Confidentiality may be compromised when data is collected on a sample that is very small or very unique, or when details are given that may reveal the identity of a participant. Therefore, the extent of this risk should be revealed to participants and included within an informed consent, both at the outset of the research and after seeing the specific report. The identity of these participants should also be disguised as much as possible without jeopardizing the research.

## **VIII. SENSITIVITY TO INFLUENCE ON DATA**

Investigators maintain an ethical responsibility to consider fully the potential threats to validity, which are encountered when subjects have an additional investment in the relationship with the investigator. These threats to validity should be minimized through research design and then addressed fully within any presentation/ publication of the research.

## **IX. IMPACT OF THE INVESTIGATOR'S RELATIONSHIP WITH THE ORGANIZATION**

An organization typically has a vested interest in the research process and outcome, particularly as it reflects upon its mission. Investigators should therefore:

- ensure that the scientific integrity of the research process and the welfare of participants are not compromised by these influences; and
- be aware of the mission, policies, and intentions of the organization prior to conducting the research. For example, investigators should know the following: how the organization will apply or publish the findings and how particular findings will impact the willingness of the organization to use, or to immediately or completely publish the results.

