



REGIS UNIVERSITY

POLICIES AND PROCEDURES

FOR THE

REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

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I. INTRODUCTION

Regis University, a Jesuit Catholic institution of higher education, has a duty to ensure the protection of the rights and welfare of human subject participating in research. In keeping with its mission, the University will follow the guidelines and policies set forth by the U.S. Department of Health & Human Services Office for Human Research Protections.

Pursuant to the National Research Act (P.L. 93-348§212a) and 45 CFR 46.103, Regis University maintains an Institutional Review Board (IRB) and has created the written policy of this document to govern its actions. At Regis University, the IRB is charged with assuring the protection of the rights and welfare of human subjects participating in research. Therefore, the IRB is required to review all research involving human subjects prior to the conducting of any research. Appendices contain forms, instructions, and other guidelines to assist the researcher, the various academic departments and other units of RU, and the IRB in carrying out the review process.

A. General Distribution of Responsibility

Any undertaking in which an Regis University faculty member, staff member, or student investigates or collects information on living humans for research or related activities may be considered as “involving human subjects.” It is the responsibility of each investigator to seek review by the IRB for any study involving human subjects prior to beginning the project.

Regis University’s IRB is responsible for the review of research or related activities involving human subjects. The respective authorities and duties of the IRB are described in this policy manual.

Consistent with federal regulations, the authorized institutional official (AIO) appoints members to the IRB. At Regis, the AIO is the Provost.

The Human Protections Administrator (HPA) is responsible for managing administration of the application review process, record keeping and reporting, managing IRB directed human subjects research training, and assisting with assurance of compliance with federal regulations. The HPA will assist the chair of the IRB operationally to achieve the administration of all of the above, the IRB process and policy. At Regis, the HPA is the Director of Academic Grants.

B. Abbreviations and Definitions Used in Policy and Procedures

Federal regulations and university policy use the following abbreviations:

CFR	Code of Federal Regulations
FDA	Food and Drug Administration
DHHS	Department of Health and Human Services
OHRP	Office for Human Research Protection
IRB	Institutional Review Board
AIO	Authorized Institutional Official (Provost)
PI	Principal Investigator
OAG	Office of Academic Grants
EAP	Executive, Administrative, and Professional staff
HPA	Human Protections Administrator (Director of Academic Grants)

Federal regulations and university policy define various terms in regard to protection of human research subjects. 45 CFR 46 is the body of regulations promulgated by DHHS. 45 CFR 46 includes the following definitions:

C. Definitions Used by the Department of Health and Human Services and Regis University

(1) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the DHHS to whom authority has been delegated.

(2) *Department or Agency* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(3) *Human subject* means 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.

- *Intervention* includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., cognitive experiment).
- *Interaction* includes communication or interpersonal contact between investigator and human subject (e.g., a telephone interview).
- *Private information* includes 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 which has been provided for specific purposes by an individual and which he or she can reasonably expect will not be made public (e.g., a medical record).

(4) *Minimal Risk* the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the participant's daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR §46.102(i)] In research involving prisoners, minimal risk is also defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. [45 CFR §46.303(d)]

(5) *Vulnerable population* means children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers).

(6) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Prisoners receive additional protections under 45 CFR 46, Subpart C.

(7) *Child* means a person who has not yet attained the age of consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. Children receive additional protections under 45 CFR 46, Subpart D.

(8) *Parent* means a child's biological or adoptive parent.

(9) *Guardian* means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

(10) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(11) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(12) *Adverse effect* means an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (*e.g.*, subject becomes upset following completion of a depression questionnaire, subject experiences intestinal bleeding associated with aspirin therapy) that is directly or indirectly due to participation in a research study.

(13) *Protected health information* or PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. PHI excludes education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g, records described at 20 U.S.C. 1232g(a)(4)(B)(iv), and employment records held by entity in its role as employer.

(14) *Individually Identifiable Health Information* is information that is a subset of health information, including demographic information collected from an individual, and (1) created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of healthcare to an individual; and (a) that identifies the individual; or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Some studies may fall under the regulations promulgated by the FDA (21 CFR 50). These will generally be studies that involve the testing of an investigational medication or a medical device. Refer to 21 CFR 50 for specific definitions regarding these studies. Some FDA definitions differ from the above DHHS definitions.

D. Definitions Used by Regis University

In addition to definitions promulgated by federal agencies, Regis University policy uses the following definitions:

(1) *Principal Investigator (PI)* the individual with signatory power on all documents related to the research project. This person has final authority over the project, is accountable for the overall conduct of a particular research protocol, and is accountable for the overall conduct of a study. The PI accepts responsibility for training all personnel associated with the study in compliance with the human subjects regulations of 45 C.F.R. 46. "Co-principal Investigator" is that individual who co-signs on documents related to the project or who may be designated as a co-principal investigator in grant-related documents. This person has decision making power with regard to the conduct of the research. The co-principal investigator reports to the principal investigator who is ultimately responsible for the conduct of the research.

Others with decision-making power may include such persons as project managers, directors, and trainers. These designations are not all-inclusive. Operationally, these individuals have some oversight responsibility for one or more portions of the project. Individuals in this category are determined uniquely for each project by the principal investigator.

(2) *Key Personnel* include the PI, the faculty sponsor of a student conducting research, and any student conducting research that is not considered a "student project" as defined in Item 4 below.

(3) *Undergraduate Student project* means a study in which an undergraduate student investigator (individually or as part of a group) gathers or analyzes information in a systematic manner, primarily for pedagogical purposes. It is not intended to contribute to the general base of human knowledge and is not to be published (including

publication on the Internet), presented, or archived. Research conducted for a master's thesis or doctoral dissertation does not fall under this definition.

(4) *Institutional research* is a study conducted by RU staff that is designed to obtain information to assist in the administration of the university. Institutional research provides information for administrative planning, policy making, decision making, and includes examinations of institutional effectiveness. It is not intended to contribute to the general base of human knowledge.

(5) *Training* refers to a process approved by RU, and required by federal regulations, to instruct investigators in the conduct of research involving human subjects.

(6) *Research* means a systematic investigation—including research, development, testing, and evaluation—designed to develop or contribute to the general base of human knowledge. Dissemination of findings to a scientific audience is a sufficient (but not necessary) criterion for identifying research that contributes to the general base of human knowledge. Dissemination includes, but is not limited to presentation at a scientific meeting or conference; submission to or publication in a scientific journal (paper or electronic); and Internet postings. Activities that meet this definition constitute research for purposes of these regulations, whether or not they are supported or funded under a program which is considered research for other purposes.

In addition to definitions used by RU the following definitions are used by the IRB and may be helpful:

(1) *Abstain* when an IRB member does not vote upon a protocol under review.

(2) *Agent* a representative who acts on behalf of other persons or organizations.

(3) *Assurance* an agreement between an organization and a federal agency that stipulates that the organization will comply with the agency's regulatory requirements. [45 CFR §46.103]

(4) *Conflict of Interest* a PI or co-PI is said to have a conflict of interest whenever that PI or IRB member, his or her spouse, or dependent child falls under any of the following conditions:

1. Is an investigator or sub-investigator on the protocol (IRB members only, not applicable to PIs);
2. If the IRB member, the member's spouse, or dependent children are involved in the conduct of research;
3. Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest;
4. Acts as an officer, director, or agent of the sponsor; or
5. Has identified him or herself for any other reason as having a conflicting interest.

(5) *Consent* the agreement of a participant or the parent (s) or guardian(s) to the participation of their child or ward in the research/clinical investigation

(6) *Continuing review* the periodic review of a research study by an IRB to evaluate whether the study continues to meet organizational and regulatory requirements. Federal regulations stipulate that continuing review should be conducted at intervals appropriate to the level of risk involved in the study, and not less than once per year. [45 CFR §46.109(e)]

(7) *Data and Safe Monitoring Plan (DSMP)* a process that reviews the integrity, safety and progress of a research protocol with the purpose of protecting participants during the course of study and makes decisions regarding continuance, modification, or stopping of the study for reasons of efficacy or safety. A DSMP may take a variety of forms, such as an investigator reviewing his or her own data, a review by another faculty member not otherwise

involved in the conduct of the research, a committee of investigators, an independent committee, or an independent data and safety monitoring board. The type of safety monitoring that is adequate depends on the specifics of the research.

(8) *Decision making capacity* the ability to understand the choices presented, to appreciate the implications of choosing one alternative rather than another, and to make, and communicate, a choice.

(9) *Engaged in Research* an institution its employees or agents (all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility) (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. Solicitation of consent by performance site staff would be considered engagement.

(10) *Federal Wide Assurance (FWA)* a document that fulfills the requirements of 45 C.F.R. Part 46 and is approved by the Secretary of Health and Human services. Regis University has an approved FWA number as follows: FWA00010784.

(11) *Human Subjects Research* The regulatory definition of research is a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the general base of human knowledge. Contributing to the general base of human knowledge is a goal of most basic research. Even research about the most narrowly defined topic, such as an individual case study or the study of an isolated community, may be intended to contribute to a body of knowledge (45 C.F.R. 46.102(d)).

(12) *Informed Consent* the agreement to participate in research that is made voluntarily by an individual with legal and mental competence and the requisite decision-making capacity, after disclosure of all material information about the research. Informed consent means the knowing consent of an individual or his or her legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Information conveyed in the informed consent procedure must include all essential elements of the appropriate consent form listed in Appendix 3 of this manual.

(13) *Institution* any part of Regis University.

(14) *Institutional Review Board* an independent committee comprised of scientific, non-scientific, and non-affiliated members established according to the requirements of federal regulations. Any board, committee, or other group formally designated by an organization to review research involving humans as participants, to approve the initiation of and conduct periodic review of such research. [45 CFR §46.402(g)]

(15) *Legally authorized representative* an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to that subject's participation in the procedures involved in the research. [45 CFR §46.402(c)]

(16) *Monitoring* may refer to data monitoring or monitoring the conduct of research. Data monitoring means the systematic tracking of data from a research study with the intent to evaluate the harms and benefits that accrue to participants. Monitoring the conduct of research mean the systematic tracking of the implementation of a research study with the intent to maintain compliance with the protocol and regulations, and maintain the integrity of the data.

(17) *Office for Human Research Protections* office that is responsible for regulatory oversight of human subject research.

(18) *Protocol* a formal plan that includes, at minimum, the objectives, rationale, design, methods and other conditions for the conduct of a research study.

(19) *Reporting Requirements* Colorado State Law requires that if you have reasonable cause to know or suspect that a child has been subjected to abuse or neglect or who has observed the child being subjected to circumstances or conditions which would reasonably result in abuse or neglect shall immediately upon receiving such information report or cause a report to be made of such fact to the county department or local law enforcement agency. [Section 19-3-307 and sections 25-1-122 (4) (d) and 25-4-1401 (1z0) (d), C.R.S.]

(20) *Research Staff* individuals who are delegated responsibility by the PI for specific research tasks.

(21) *Serious Unanticipated problem* any event that results in death, a life-threatening situation, hospitalization or prolonged hospitalization, persistent or significant disability/incapacity or a congenital anomaly/birth defect or requires medical intervention to prevent one of the outcomes listed above. Serious unanticipated problems require prompt reporting to the IRB.

(22) *Site* a site whose staff, facilities or private records of identifiable individuals are engaged in the conduct of research; or, a site that receives HHS funds. The performance site is the actual place where the research activity takes place (e.g., clinic or hospital). The performance site's location may be different from the location where the IRB review takes place.

(23) *Undergraduate Student* any individual who is enrolled at Regis University as an undergraduate.

(23) *Class Proxy* a class instructor who has been granted authority by the Regis U IRB to approve exempt graduate and undergraduate student research studies for a specific class of which they are the primary instructor. This requires documentation of approved projects and will include internal audit by the IRB.

E. General Information on Submitting Materials to the IRB

All applications will be submitted electronically through the online application process on the OAG website. PIs should submit their applications electronically through the online application process on the OAG website for review by the IRB. A new application consists of either Form E (exempt research application) or Form F (expedited or full-board review application) and the research grant proposal, if the PI is seeking funding or has received funding. Similarly, any submissions after IRB approval, including protocol modification requests (Form M), protocol continuation reviews (Form C), should be submitted electronically through the online application process on the OAG website. Faculty applications for class related proxy should use Form P. Class Proxies may only approve appropriate exempt protocols. Refer to Appendix 1 for more information on submission materials and for copies of the forms. The IRB chair or one or more designated IRB members will determine the level of review required. The IRB chairperson or designated IRB member will correspond directly with the PI regarding the submission. Correspondence of the PI regarding revisions to the submission materials or questions may be directed to the IRB chairperson, or designated IRB member and may be conducted through e-mail. Communication with the IRB may be initiated by using the email address irb@regis.edu.

Reports of adverse events must be made immediately via phone or e-mail irb@regis.edu to the IRB chair. A written report of the adverse event, using Form A (adverse event report), must then be submitted to the HPA, within 5 working days after first awareness of the situation. Refer to Section G for more information.

II. RESPONSIBILITIES AND ACTIONS OF THE INSTITUTIONAL REVIEW BOARD

A. Composition of the IRB and Appointment of Members

Federal regulations require that the IRB must be composed of at least five members (45 CFR 46.107). At RU, the IRB shall be composed of fourteen (18) voting members.

Representation will include the IRB Chair, Vice Chair, (15) four faculty members from each from Academic Colleges of the University with the exception of CCSI having three due to availability of staff (1) one member from the library, (1) at least one member who is a community member and not affiliated with the University, (1) at least one non-science member from the University at large community. All will serve as voting members. The library will have one alternate. The Chair and Vice Chair will vote on due to the rule of necessity to keep quorum.

In addition, the membership shall include men and women, as well as representation of racial and ethnic minority groups to the fullest extent possible.

In meeting the IRB composition requirements set forth in the previous paragraph, Regis University uses the following methods: The Chair and Vice Chair are appointed by the AIO. IRB members and alternates are appointed by the AIO after consultation with deans or others. The nominees must be confirmed by appointment by the AIO.

All IRB members and any library alternate shall serve three-year terms, which are staggered. They may be reappointed for consecutive terms. Acceptance Letters of Appointment will be kept on file. Additionally, the current membership list is kept on file by the HPA, and is open to inspection by any employee or student of the University. Additionally, a current membership list is posted on the IRB website.

If the IRB chairperson takes a sabbatical or other leave of absence, or leaves the University, the AIO may appoint a replacement for the period of leave or for the remainder of the chair's term, or appoint a new chair.

All members of the IRB are required to complete appropriate CITI training and will work diligently and conscientiously taking any training offered and attend meetings as necessary to understand the process in order to participate in a meaningful manner.

B. Chairperson and Vice Chair(s)

The AIO shall appoint the IRB Chair and Vice Chair (s). IRB Chairs and Vice-Chair(s) will be appointed to operate within the membership of the IRB Committee for three-year terms and are eligible for reappointment at three-year intervals. During the appointment period, an IRB Chair or Vice-Chair may be removed at the discretion of the AIO. In addition to their authorities and responsibilities as IRB Chair and Vice-Chair(s), such individuals serve as members of the IRB and serve as voting members by rule of necessity for the purpose of maintaining quorum. They shall have voting privileges and other authorities and responsibilities of members including the responsibility to review, make motions, participate in discussions and vote on approval/disapproval of studies. The IRB Chair serves as the final decision maker for whether or not a study is referred to full-board review.

Responsibilities of the IRB Chair include but are not limited to those defined in the following three sections. In the absence of the IRB Chair, a Vice-Chair shall assume the responsibilities of the IRB Chair. The Vice –Chair will support and assist the Chair in all the responsibilities of the Chair.

1. Ongoing IRB Chair Responsibilities:

Convene and direct IRB meetings. This includes scheduling reviews, certifying IRB actions, and certifying approval and disapproval of protocols.

- serve as reviewer and router for protocols that do not require Full Board review. (i.e. Exempt, Expedited)
- review and approve, when appropriate, expedited submissions in accordance with regulatory requirements
- determine exempt submissions in accordance with regulatory requirements
- review (or defer to the primary reviewer or other IRB-designee to review) all on-site serious adverse event reports (SAEs) and unexpected problems affecting the safety of subjects and, as necessary, determine if one or more of the following is necessary:
 - (a) immediate action to address the safety of subjects or
 - (b) call an emergency meeting of the IRB
 - (c) schedule for cause audits as needed
- appoint qualified IRB members as IRB-designees with authority for expedited reviews and other actions as defined in these Policies and Procedures
- maintain a thorough understanding of federal regulations pertaining to human subject protections, the Regis University IRB Written Policies and Procedures, and other applicable state, and local regulations. Assure that regulations and policies are applied in all IRB matters with a commitment to foster ethically and scientifically sound human subject research
- respect the diverse backgrounds, perspectives and sources of expertise of all IRB members and foster such respect among the IRB members
- uphold IRB judgments no matter how these are received or perceived by Principal Investigators
- make sure that all IRB procedure is appropriately documented. This includes, but is not limited to , reporting of IRB actions to the Provost, liaison with the staff support, and liaison with faculty in general
- be familiar with (45 CFR 46) especially Common Rule (45 CFR 46.101 through 46.409)
- oversee the development and execution of the educational efforts of the IRB on campus

2. IRB Chair Responsibilities Prior to Each Convened Meeting:

- Establish the IRB meeting schedule and agenda.
- ensure coverage by the Vice-Chair when not able to serve as Chairperson for the meeting and notify the Office of Academic Grants when not able to serve
- provide guidance to the HSRO on the assignment of reviewers to studies requiring convened IRB review
- assist the IRB reviewers and other IRB members with any concerns in preparing for the meeting, as necessary
- recommended consults when appropriate to assist in IRB reviews

3. IRB Chair Responsibilities During IRB Meetings:

- preside over IRB meetings and ensure that meetings are conducted in an efficient, orderly and fair manner with respect given to the opinions of all members. Robert's Rules of Order should be used as a guidebook for conducting the meeting.
- ensure a quorum for each study review and ensure that this quorum is properly documented.
- ensure that all regulatory-required elements of review are addressed during the meeting and that there is meaningful and substantive discussion of relevant matters and/or questions.
- ensure that assigned reviewers present a clear and concise review of study materials including consent documents and recruitment items and process
- ensure that all IRB-required changes to consent and other documents are documented
- ensure that the IRB discusses specific findings, as required by regulations, whenever there is the involvement of vulnerable populations, e.g. children, prisoners, pregnant women and fetuses
- accept appropriate motions from voting members of the IRB.
- as necessary, ensure that the specific elements pertaining to the motion are clearly understood by the IRB and accurately recorded in the meeting minutes
- ensure that IRB decisions are made in accordance with federal, state and local regulations and with the IRB Written Policies and Procedures
- ensure that minutes of IRB meetings and votes of the IRB members accurately reflect discussions and actions

C. Meetings and Quorums

A quorum is required to convene a formal meeting of the IRB. A quorum consists of at least a majority of the 18 members present at the meeting, either in person or via a conference call, (only when necessary). At least one member who is a nonscientist must be present at the meeting. When members are associated with a project being reviewed, they are ineligible to vote on the project. However, such members may provide information about the project or they may excuse themselves from the meeting during the review. Conflicts of interest should be noted in the IRB meeting minutes. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests, early departures, absence of a nonscientist member or alternate), the IRB may not take further actions or votes until the quorum is restored. The Chair and/or Vice Chair may vote by the rule of necessity to maintain quorum.

D. Functions and Operations of the IRB

- Conduct initial and continuing review of research with human subjects and report the findings and actions to the PI in writing.
- Determine and approve any class proxy to act on behalf of the IRB.
- Determine which projects require more than an annual review and which projects require verification (from sources other than the investigators) that no material changes have occurred since the previous IRB review. Considerations used to make these determinations include the absolute risk to the subject, whether the risks outweigh the benefits, and prior conduct of the investigator(s) regarding the protection of human research subjects.

- Review proposed changes in research activities to insure that the protection of human research subjects is maintained.
- Investigate any reported adverse events or incidents of noncompliance.
- Observe project activities at any point to ascertain whether human subject protections are implemented so as to reduce the likelihood of an adverse event or noncompliance.
- Work with the IRB Chair to determine any need for Human Subject Training.

E. Review of Research

In conducting the review of research, the IRB shall follow the regulations stated in 45 CFR 46.109.

F. Approval of Research

Requirements to be met for approval are listed in Appendix 2. Requirements are described in 45 CFR 46.111. In order to approve research covered by stated regulations, the IRB shall determine these requirements have been met.

G. Actions and Authority of the IRB

Action on any of the options listed below requires a majority vote of the quorum. Action to require revision of an application includes the option of empowering the chairperson, or designated IRB member to accept revisions on behalf of the IRB or to require reconsideration of the application as revised at a subsequent meeting.

1. Actions Regarding Approval of Applications

The IRB may reach any of the following determinations with respect to any proposed project:

- Approve application as submitted.
- Approve pending changes. The IRB determines the changes that are required for approval and these are communicated in writing to the PI. The PI submits the changes to the IRB chairperson. The chair, or designated IRB member, may approve the application on behalf of the IRB if the changes meet the requirements described in the written communication with the PI.
- Require modifications and resubmission to the IRB.
 - Request consultant review. At any point, the IRB chairperson, or the IRB may determine that someone not on the IRB with relevant expertise needs to be consulted to address research issues, as they relate to the protection of human research subjects. The consultant shall not be involved in the proposed project. In some cases, the identity of the consultant may need to remain confidential if there is any question that there could be problems should the PI know the identity of the consultant.
 - Disapprove the application as submitted: When a project is disapproved, the PI may revise the proposal in accordance with IRB recommendations; discuss the project with the IRB chairperson or respond in writing; or withdraw the proposal application.

2. Additional Actions and Authority of the IRB

- Consult with the HPA concerning matters of development and implementation of policies and procedures regarding the protection of human subjects and the training of RU employees and students regarding the conduct of research involving human subjects. Suspend or terminate approval of research that is not being conducted in accordance with the requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a written statement of the reasons for the IRB’s action and shall be reported promptly to the HPA and the funding agency (if applicable).

III. RESPONSIBILITIES AND ACTIONS OF THE AUTHORIZED INSTITUTIONAL OFFICIAL (AIO)

A. Administrative Responsibilities of the AIO

- Appoint members to the IRB.
- Appoint the IRB Chair and will also appoint Vice Chair positions as necessary.
- Review research approved by the IRB in accordance with 45 CFR 46.112.

B. Actions of the *Authorized Institutional Official* Upon Receipt of Notice of IRB Action from the Chairperson

- The AIO may review, approve, or disapprove research that has been reviewed and approved by the IRB. The AIO may not approve research covered by these regulations that has not been approved by the IRB (45 CFR 46.112).
- If the AIO does not also approve projects approved by the IRB, he or she will notify the IRB and the PI in writing of his or her action and of necessary subsequent action by the PI.
- Records of these actions will become part of the project file maintained by the IRB.

C. Revisions of Policies and Procedures

The AIO, in consultation with the IRB chair and/or the IRB, may institute any changes of policy and procedure for the review of research involving human subjects as may be consistent with currently applicable regulations, institutional requirements, and IRB experience. As changes occur in 45 CFR 46 and applicable portions of 21 CFR 50, they will be included in Regis University policy and procedures by reference, without requiring separate action by the AIO. The HPA will maintain a current master copy of RU policy, will provide a copy of any changes in Regis University policy to all IRB members and alternates. Additionally, the AIO shall determine the appropriate method of dissemination of policy and procedural changes to the university community.

IV. RESPONSIBILITIES AND ACTIONS OF THE HUMAN PROTECTIONS ADMINISTRATOR

The HPA will be designated by the AIO. The following actions are the responsibility of the IRB administrator (HPA):

- Retain Regis University's federal wide assurance, copies of pertinent federal regulations, policies and guidelines related to the involvement of human subjects, as well as Regis University's policies and procedures.
- Coordinate with grant and contract services regarding compliance on new, continuing, and competing proposals with human subjects regulations and policy.
- Arrange and oversee the training program for IRB members, IRB alternates, PIs, faculty, staff, and students on the ethical conduct of research involving human subjects.
- Educate members of the university research community about the Regis University Human Subjects Policy and changes to the IRB policy and procedures;
- Update the OAG website to assure IRB content is current.
- Maintain a log containing new applications, modification requests, adverse event reports, continuation reviews, and completion reports.
- Ensure that IRB records are being maintained appropriately and that records are accessible upon request, to authorized federal officials.
- Ensure all cooperating research sites in federally supported research have appropriate OHRP-assurances and provide certification of IRB approval of proposed research to the appropriate federal department or agency.
- Report to the IRB, AIO, and appropriate institutional officials any unanticipated injuries or problems involving risks to subjects or others, any serious or continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval of research.

- Delegate responsibilities to an administrative assistant, as appropriate.

V. RESPONSIBILITIES AND RIGHTS OF THE PRINCIPAL INVESTIGATOR

A. Responsibilities

The PI has primary responsibility for all aspects of the protection of human subjects on a given project, including:

- Consult with the IRB Chair or an IRB member if unsure whether a study meets the definition of research with human subjects.
- Submit applications for review and approval prior to initiating research, and in accordance with Section F of Regis University policy.
- When a full review is required, provide additional information and/or documentation to the IRB prior to any meeting at which the application is reviewed. Conduct the study in accordance with the ethical standards described in the Belmont Report, federal regulations, Regis University policy, and the protocol as approved by the IRB.
- Begin research activities only after written approval by the IRB.
- If changes are needed in an approved protocol, submit the proper application to modify the protocol and wait to receive written approval before implementing any changes.
- Submit requests for continuing review in accordance with the timeframe established by the IRB at the time of approval of the protocol.
- Report any unanticipated risks, physical or psychological harm, or other problems to the IRB Chair or Vice Chair immediately upon becoming aware of them. Section G of this policy provides definitions and examples of problems that should be reported.
- Retain signed informed consent forms and research materials for at least three years after the completion of the research project. Some funding agencies may have different retention requirements, and the PI is responsible for understanding and complying with those policies.
- Make accessible all records for inspection and copying by a designated IRB member or the department or agency supporting the research.

B. Rights

- Applications shall be reviewed by the IRB in accordance with the ethical principles described in the Belmont Report, federal regulations, and Regis University policy.
- When protocols are submitted, the IRB shall review the application within 10 to 15 working days, barring any unforeseen and insurmountable problems.
- All decisions of the IRB shall be conveyed to the PI in writing.
- The PI may consult with the IRB chairperson if he or she is unclear about the rationale for its decisions or if any questions arise at any time.

C. Responsibilities of the PI upon Leaving Regis University

When a PI plans to leave Regis University and continue the research activities at another institution, he or she must notify the IRB in writing. This will allow the IRB to close the active research file. The PI is responsible for obtaining IRB approval at the new institution. If the research project will continue at Regis University under another investigator, the PI must submit Form M, and the IRB will follow the review guidelines set forth in this policy.

VI. PROCESS FOR IRB REVIEW AND APPROVAL OF RESEARCH

A. Levels of Review

This section describes the three possible levels of IRB review for studies that involve human research subjects.

1. Exemption Certification Review

(a) New Application

Research activities in which the involvement of human subjects constitutes no more than minimal risk and falls within one or more of the exemption categories described in 45 CFR 46.101 (see Form E) may be eligible for exemption certification. The PI may request that the research application receive exemption certification by submitting Form E and with justification for the exemption. Only the IRB or an approved IRB approved class proxy may certify that the proposed research meets the exemption criteria. Exempt review is conducted by the IRB chair, designated IRB members, or IRB approved class proxy who will verify level of review through the categories listed in Form E (exempt research application) and consider the issues delineated in the reviewer checklist (Appendix 2), and local context issues.

If the IRB Chair is involved with the study or has a conflict of interest with the protocol under review, the IRB chair will designate another IRB member, who is not involved with the project, to review the study for exemption certification.

The IRB Chair, or designated IRB member, may take one of the following actions:

- Certify the research project as exempt and requiring no further IRB review, unless modifications are proposed which are outside the exemption categories. The PI is sent an exemption certification letter.
- Require additional information or modification(s). The IRB Chair or designated IRB member will contact the PI to request the required additional information or modification(s). If the IRB Chair, or designated IRB member, is satisfied that the protocol meets the exemption criteria, the research project is certified as exempt and an exemption certification letter is sent to the PI.
- Deny exemption certification. If the protocol does not fall within one or more of the exemption categories, as deemed by the IRB Chair, or designated IRB member, the PI is contacted in writing or via e-mail and the application is considered for expedited or full review.

(b) Modification Request

If a study is certified as exempt, the PI must request approval for any proposed modifications (see Form M) to the research project's protocol or informed consent or assent forms that do not fall within the exemption categories. The modifications must be approved by the IRB prior to implementation.

(c) Continuation Request

Once a study is certified as exempt, continuation reviews are not required.

2. Expedited Review

(a) New application

Research activities in which the involvement of human subjects involve no more than minimal risk and fall within one or more of the expedited review categories (see Form F) may be eligible for expedited review. The PI may request that the research application receive expedited review by submitting application Form F and justifying the criteria for expedited study approval. Only the IRB may decide whether the proposed research meets the expedited review criteria requirements. Expedited review is conducted by the IRB Chair (or Vice Chair in the absence of the Chair) and a designated IRB member who will verify level of review through the

categories listed in Form F (expedited review application checklist) and evaluate for consistency with the issues delineated in the reviewer checklist (Appendix 2), the informed consent information (Appendix 3), and local context issues. If there is a conflict of interest for the chair, the Vice Chair and a designated IRB member will conduct the review. Prior to sending the application for review the IRB Chair, or designated IRB member, may ask the PI to make revisions to the protocol or informed consent procedures.

Under the expedited review process, the reviewers may take one of the following actions:

- Approve the research application and decide on the length of time the study is approved (one year or less).
- Require additional information or modifications. The IRB Chair or a designated IRB member will contact the PI to request the required additional information or modifications. The reviewer(s) may decide additional information or modifications are needed. If the reviewer(s) are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less and a letter of approval is sent to the PI.
- Require a full review of the application. If the protocol does not fall within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the subjects, the reviewer(s) will forward the application for a full review. The PI will be notified via e-mail that a full review is required and will be informed of the reasons for this decision. Additionally, the PI may be asked to revise the application prior to distribution of the application to the full IRB committee.

(b) Modification Request

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

Modification requests to the protocol or informed consent or assent forms for research projects that were previously approved through the expedited review process may be reviewed under the expedited review process. The PI will submit Form M for review. For minor modifications that do not change the substance of the project, the level of risk to the subjects, or the level of review required, the IRB chair, or a designated IRB member may conduct the review. For more than minor modifications, the review process is the same as for a new application. The reviewers may take one of the following actions:

- Approve the requested modifications. The PI is sent a letter of approval of the requested modifications.
- Require additional information or modifications. The IRB chairperson or designated IRB member will contact the PI to request the required additional information or modification(s). If the reviewer(s) are satisfied that the requested modifications meet the IRB review criteria, the modifications are approved and a letter of approval is sent to the PI.
- Require a full review of the modification request. If the modifications change the study protocol such that the study no longer falls within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the subjects, or the additional information or modifications are extensive, the reviewers will forward the modification request for a full review. The PI will be notified in writing that a full review by the IRB is required and will be informed of the reasons for this decision. Additionally, the PI may be asked to revise the modification request prior to distribution of the modification request to the full IRB.

(c) Continuation Request

Research projects which are approved under the expedited review process will require continuation review at a specified interval, which will not exceed one year.

A continuation request for a research project that was approved under expedited review procedures may be reviewed under the expedited review process. The PI will submit Form C. The IRB chairperson or a

designated IRB member will verify the appropriate level of review for the continuation request, and will inform the PI in writing or via e-mail if a full review is needed. The expedited review process, and review actions are the same as for a new application.

If the PI fails to request a continuation or submit requested information, IRB approval may be terminated on the approval expiration date. All research activities, including data analysis, must cease, unless the IRB finds it is in the best interest of the individual subjects to continue participating in the research interventions or interactions. A notification letter will be sent by the IRB Chair to the PI and, if appropriate, the IRB Chair will inform the HPA. The HPA will contact the funding agency.

(d) Informing IRB members of Expedited Reviews

At each regular IRB meeting, the IRB Chair will provide the IRB with a list of new research applications, modification requests, and continuation requests that have been submitted or approved through the expedited review process.

3. Full Review

(a) New application

Research activities in which the involvement of human subjects involves more than minimal risk does not fall within one or more of the exemption categories (see Form E) or expedited review categories (see Form F), or involves certain vulnerable populations (e.g., prisoners) must undergo a full IRB review. Prior to distribution to the IRB members, the IRB Chair, or a designated IRB member will review the application and may ask the PI to make revisions to the protocol or informed consent procedures. Once revisions, if needed, are received, a full review will be scheduled for the next regular IRB meeting or a special meeting may be called. The application materials will be distributed to the IRB members at least seven working days before the meeting. The application materials must be received at irb@regis.edu at least 14 prior to the meeting.

The PI is responsible for submitting the required materials to the IRB Chair by the deadline, 14 working days prior to a scheduled meeting. The meeting schedule is posted on the OAG website. Submission of materials by the deadline does not guarantee the full review will be conducted at the next meeting. Reasons for delaying review until the next meeting may include an incomplete protocol, student protocol missing advisors approval, already full agenda or the protocol requires revisions prior to review. Therefore, the IRB recommends that the PI submit the materials as early as possible. If a full board review of an application is approved or requires changes the PI will be notified within 2 days of the IRB meeting. The IRB may vote to conditionally approve an application dependent upon required changes being made. In this case an application would not have to wait a month for the next meeting for another full board review.

Under the full review process, the IRB will discuss issues delineated in the reviewer checklist (Appendix 2) and the informed consent form information (Appendix 3), as well as issues related to the local context. The IRB may take one of the following three actions:

- Approve the research application and decide on the length of time the study is approved (one year or less from the date of the convened meeting at which the IRB reviewed and approved the proposal).
- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information available at the meeting, the PI will forward this information, in writing, to the IRB chairperson, as soon as possible. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
 - The IRB Chair, or designated member may review the additional information or modifications to ensure that they meet the IRB requirements and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB Chair, or designated IRB member

- may continue to work individually with the PI until the IRB requirements are met or request that the IRB continue its review at the next meeting, or
 - The IRB may require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.
- Disapprove the research application. The PI is sent a letter describing the reasons the research application was not approved. The PI may revise the research application in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB Chair or a designated IRB member; or withdraw the research application.

(b) Modification Request

The PI must request approval for any proposed modifications to the research project’s protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

Modification requests to the protocol or informed consent or assent forms for research projects that were previously approved through the full review process may be reviewed under the expedited review process if the requested modifications are minor (see Modification Request under the discussion of Expedited Reviews, above); otherwise, a full review process will be used. The PI will submit Form M and the IRB chairperson, or a designated IRB member will decide the appropriate level of review for the modification request. The PI will be informed of the level of review required. For modification requests, which can be reviewed under the expedited review process, see the modification request section (Section F.1.2.1) under expedited review process (Section F.1.2). For modification requests that require a full review, prior to distribution to the IRB members the IRB chairperson or a designated IRB member will review the application and may ask the PI to make revisions to the protocol or informed consent procedures. Once revisions, if needed, are received, a full review will be scheduled for the next regular IRB meeting or a special meeting may be called. The modification request will be distributed to the IRB members at least 5 working days before the meeting. The PI must attend the meeting in which his or her modification request will be reviewed. If the PI is a student, the faculty sponsor must attend, and the IRB strongly recommends that the student attend, as well.

The IRB may take one of the following actions:

- Approve the requested modifications. The PI is sent a letter of approval of the request modifications.
- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information, the PI will forward this information, in writing, to the IRB chairperson. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
 - The IRB Chair, or designated IRB member may review the additional information or modifications to ensure they meet the IRB requirements and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB chair, or designated IRB member may continue to work individually with the PI until the IRB requirements are met or request that the IRB continue its review at the next meeting, or
 - The IRB should require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.
- Disapprove the modification request. The PI is sent a letter describing the reasons the modification request was not approved. The PI may revise the modification request in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB chairperson, IRB vice chairperson, or designated IRB member; or withdraw the modification request.

(c) Continuation Request

Research projects that are approved under the full review process will require continuation review at a specified interval, which will not exceed one year.

A continuation request for a research project that was approved under the full review procedures may be reviewed under the expedited review process if the research project meets the requirements listed in Form F; otherwise a full review will be required. The PI will submit Form C and the IRB chairperson, or a designated IRB member will decide the appropriate level of review for the continuation request. The PI will be informed of the level of review required. For expedited reviews, see Continuation Review in Section F.1.2.2 under Expedited Review (Section F.1.2). For full reviews, the review process and review actions are the same as for a new application.

If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the approval expiration date. All research activities involving human participants must cease. A notification letter will be sent to the PI and, if appropriate, the funding agency.

B. Length of IRB Approval

Typically, the IRB approves a research study or continuation request for one year. However, approval may be granted for less than one year in some circumstances, which may include, but are not limited to, high-risk protocols, projects involving unusual types of risk to subjects, projects involving vulnerable subjects (e.g., prisoners), and projects conducted by a PI who has previously failed to comply with IRB requirements.

C. Verification of Sources other than the PI

Some projects may require verification from sources other than the PIs that no material changes have occurred since previous IRB review. The criteria for determining which studies may need outside verification include, but are not limited to complex projects involving unusual levels or types of risk to subjects; projects conducted by PIs who previously failed to comply with 45 CFR 46 or the requirements or determinations of the IRB; and projects where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

VII. PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, AND NONCOMPLIANCE

A. Guidelines for Defining Problems to be Reported

Unanticipated problems involving risks to subjects or others and adverse effects need to be reported to the IRB. Adverse effects may be directly or indirectly related to the research and may be expected or unexpected.

The following examples illustrate what needs to be reported:

Unanticipated problem involving risk to subjects: The laptop computer which has identifying information about research subjects is stolen.

Unanticipated problem involving risk to others: The research assistant involved in the project is inadvertently exposed to a low level of radiation.

Expected adverse effect: Subject A becomes upset when asked about feelings regarding prior sexual abuse. The subject is referred for counseling.

Unexpected adverse effect: Subject B becomes agitated and angry when asked general non-invasive questions about the appropriateness of corporal punishment of children. The subject is referred for counseling.

The last two scenarios are examples of direct effects. An example of an indirect effect is if Subject A or B misses class or work due to the psychological conditions described.

In general, the PI must report the following adverse events to the IRB chairperson:

- Situations related to the protection of study data, such that there is an inadvertent breach of confidentiality
- Negative outcomes from unintentional or intentional deviations from research protocol or informed consent process (e.g., loss of privacy, loss of rights, damage to reputation, legal problems, academic failure)
- Unforeseeable events that occur during or after a research intervention, even if it is unclear whether they were actually caused by the intervention
- Known side effects of an intervention
- Allergic reactions (or other adverse reactions to medications, devices, or procedures)
- Complications from procedures (e.g., infection, abnormal EEG, psychological change)
- Complications from research-related tests (medical and psychological)
- Increase in seriousness of a primary condition or situation

B. Guidelines for Defining Serious Noncompliance

Noncompliance includes, but is not limited to:

- Breaking confidentiality, unless required by law (e.g., child abuse)
- Unapproved subject recruitment activities
- Failure to secure confidential records in the required manner
- Failure to report problems involving physical or psychological injury to subjects or others
- Failure to report risks to subjects or others that exceed the protocol as approved
- Report from a subject of abuse by the PI or research staff

Even though these types of events must be reported, the PI is encouraged to contact the IRB chairperson if anything occurs that causes concern regarding the protection of human subjects.

C. Reporting of Problems or Noncompliance by the PI

The PI must contact the IRB chairperson via phone or e-mail immediately following an incident of injury, increase in risk, unanticipated risk, other adverse effects experienced by subjects or others involved in research, or incident(s) of serious noncompliance. Additionally, the PI must submit Form A to the IRB Chair, as soon as possible thereafter, after first awareness of the problem. The report will be reviewed by the IRB chairperson, designated IRB member(s), or the full IRB. If the incident is severe or increases the risk to subjects or others, the PI may be asked to suspend research activities pending further review by the IRB or AIO for application of the Regis Non-Compliance Policy. In cases of non-compliance not considered serious and not endangering participants the IRB Chair may request they be handled by the Regis Non-Compliance Policy.

D. Investigations of Problems and Noncompliance

If any member of the IRB receives information about injuries to subjects, unanticipated problems involving risk to subjects or others, or serious noncompliance, through a source other than the PI or co-PI, he or she will immediately inform the IRB Chair. The IRB Chair may temporarily suspend IRB approval for a study, pending an investigation, after

learning of the problem, adverse effect, or serious noncompliance. In cases of non-compliance not considered serious and not endangering participants may be handled by the Regis Non-Compliance Policy.

If the IRB Chair determines it necessary, due to federal regulation, a subcommittee of the IRB consisting of the IRB Chair, and two IRB members, members must be outside the PI's department, will investigate the allegation of a problem involving risk to subjects or others, an adverse effect, or noncompliance. The IRB Chair will request an interview with the individual(s) alleging the problem, adverse effect, or noncompliance, unless the allegation was received in writing. The IRB Chair will share the results of this interview or written correspondence with the other members of the ad hoc committee, and they will decide how to proceed. The IRB Chair will notify the PI in writing within five working days that an allegation of problem, adverse effect, or noncompliance was received. Following the interview or upon receipt of a written allegation, the IRB Chair will request an interview with the PI and any other researchers involved, in order to assess the situation, require changes in the protocol, if necessary, and resolve the issues without further official action. The ad hoc committee members will decide if both need to be present at the interview with the PI and other researchers involved. If the ad hoc committee members are not satisfied with the results of the initial interview with the PI, they may expand the investigation. The ad hoc committee members may interview the research staff and any other persons who have relevant information, including research subjects. The ad hoc committee will produce written summaries to the interviewed parties for comments, and written comments received will be included in the record of the investigation.

The ad hoc committee will prepare a report which includes a description of the investigative activities, how and from whom information was obtained about the problem(s), a list of those interviewed, a summary of records obtained, finding, basis of findings, and actions taken. Before the report is shared with the IRB and AIO, identifying information which may put the individual making the allegation at risk may be removed. The final report, which contains all identifying information, will be filled with confidential project records.

Appropriate institutional officials, OHRP and funding agency officials (if applicable) will be notified if problems are confirmed by the ad hoc committee.

E. Suspension or Termination of Approval of Research Activities

At any point, the IRB may vote to suspend a study under either of two conditions: (1) The IRB finds that unacceptable and uncorrectable levels of risk or harm to the subjects or others exist; or (2) serious disregard on the part of the researcher to the policies and directives of the IRB has occurred. The IRB Chair will promptly notify the PI(s), as well as the HPA and AIO, in writing of this decision and the reason(s) for suspension of approval. The AIO will, if appropriate, notify OHRP and funding agency (if applicable) of the suspension or termination of approval.

F. Reporting by RU of Problems or Noncompliance

The IRB Chair or HPA will make the reports by PIs or others of unanticipated problems involving risk to subjects or others, adverse effects, serious or continuing noncompliance, and suspension or termination of IRB approval available to the AIO. The AIO or an appropriate AIO delegated individual will notify appropriate institutional officials, OHRP (if appropriate), and the Department or Agency head of the funding agency (if the study is funded) of unanticipated problems involving risk to subjects or others, unanticipated adverse effects, serious adverse effects that may have been expected, serious or continuing noncompliance, and the IRB suspension or termination of approval for research activities. In cases of non-compliance not considered serious and not endangering participants may be handled by the Regis Non-Compliance Policy.

VIII. Conflicting Interests

Several types of conflicting interests may arise in conducting research. Project personnel must report all such real or potential conflicts to the PI. The PI is responsible for making certain that no project personnel perform research tasks if there is likely to be a conflicting interest.

Conflicting interests apply to both funded and non-funded research. 45 CFR 46 does not directly address conflicts of interest, but the IRB is required to determine that information provided to potential and actual subjects regarding the research is objective regarding the risks and benefits. It is also required to determine whether risks of the research have been properly addressed in the protocol. If conflicting interests exist, then such objectivity and handling of risks can be compromised.

Such potential conflicting interests include, but are not necessarily limited to those discussed below.

A. Financial Conflict of Interest

Disclosure of any such conflicts must be made in writing. Federal policy covers Financial Conflicts of Interest in Research that is funded by DHHS, FDA, and NSF, among others.

The AIO has final responsibility to assure compliance with university policy and state and federal law regarding financial conflicts of interest.

B. Intellectual Property

All investigators must adhere to RU's policy regarding intellectual property claims.

C. Conflicts of Commitment

Conflicts of commitment arise when an investigator's time or other commitments to a project cannot be honored because of existing commitments to the University. All investigators must avoid such conflicts that may arise due to the conduct of a research project.

D. Dual Relationships

Dual relationships exist whenever one role of the investigator calls into question his or her ability to be objective about fulfillment of another role. While such dual relationships may involve financial conflicts of interest, many do not. At RU, the most common situations are likely to be those in which faculty recruit students for research projects. Faculty must not recruit students from their classes, unless the IRB grants approval for doing so. See Section P of this policy for a detailed discussion of students as research subjects.

IX. COOPERATIVE RESEARCH

Cooperative research projects are those projects which involve more than one institution. The official relationship between the two institutions is not relevant. Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal and institutional policies. See 45 CFR 46.114 for more information.

Regis University faculty, staff, and students who are conducting research at another institution are required to abide by university requirements, as well as the requirements of the other institution. If the other institution has an IRB, the PI

may be required to seek its approval as well, or file a request to designate one of the institutions' IRB to review the research (e.g., IRB authorization agreement). For studies funded by DHHS the PI is responsible for ensuring all data collection sites within the cooperative research protocol have an approved DHHS assurance (e.g., federal wide assurance), and each will review the research separately or designate one of the institutions' IRBs to review the research (e.g., IRB authorization agreement).

When Regis University is considered to be "engaged in research" (see OHRP guidance document "Engagement of Institutions in Research," January 26, 1999) but the PI is not associated with Regis University, the PI generally must submit the following for review by the IRB: an application (Form E or F). The IRB may opt to use the format of the cooperating institution for their review. The IRB will then complete the appropriate review process, based on the nature of the research project. RU may choose to rely on the review of the PI's IRB, in which case both institutions would need to complete the IRB authorization agreement. When RU is not "engaged in the research," the unaffiliated PI needs to obtain IRB approval at his or her institution and secure permission from the Regis University IRB to conduct the study at Regis University.

X. INFORMED CONSENT

A. Informed Consent Requirements

Informed consent is an ongoing process, not just a form that is signed. Informed consent assures that potential subjects understand the nature of the research project and their participation and can make an informed, voluntary decision about participating or not participating in a research study. The language used to present the information needs to be appropriate for the targeted subject population. Researchers should keep in mind that individuals have the right to participate or not participate in a study and those who decide to participate may withdraw their consent from the study at any time for any reason, without incurring negative consequences.

The process of obtaining informed consent must comply with the requirements of 45 CFR 46.116. Documentation of informed consent must comply with 45 CFR 46.117. Unless changes to the informed consent process are approved by the IRB, the PI is responsible for ensuring that informed consent is obtained in writing from the subject or the subject's legally authorized representative (e.g., parent), is understandable to the subject (or representative), is obtained in circumstances that are not coercive and that offer the subject (or representative) sufficient opportunity to decide whether he or she will participate. If any subjects are members of certain vulnerable populations, 45 CFR 46 Subpart B, Subpart C, and Subpart D describe additional informed consent requirements.

The informed consent form delineates the basic elements that must be included in an informed consent form. The checklist also provides additional elements that may need to be included in the informed consent form, depending on the nature of the research study. Informed consent forms should be written in second person (e.g., "You are invited to participate..."), with the exception of the signature section, which may be written in first person. Use of first person in the body of the informed consent may be interpreted as suggestive or coercive. The informed consent form may not include exculpatory language in which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the PI, sponsor, or institution (or its agents) from liability for negligence. The person who signs the informed consent form should be given a copy as a reference.

Informed consent procedures must be delineated in the research description portion of the application to the IRB (Form E or F). Any waivers to the procedure or documentation must be requested, as well. For studies in which the documentation of informed consent is waived, a letter of invitation to participate, which includes the elements of informed consent, may be appropriate. Additionally, informed consent forms and assent forms, if applicable, must be submitted to the IRB for review.

B. Alterations to the Informed Consent Procedure

Federal regulations on informed consent do allow for modifications in the consent procedures and, under certain circumstances, informed consent may be waived entirely if the research meets certain conditions [see 45 CFR 46.116(c)(d)]. Note that such modifications and waivers are not allowed under FDA regulations. See 45 CFR 46.116(c)(d) and Appendix 3 for more information.

C. Alterations in the Documentation of Informed Consent

Typically, informed consent must be documented through the use of a written informed consent form that has been approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy should be given to the individual signing the form. However, documentation of informed consent may be waived in some circumstances. See 45 CFR 46.117(c) and Appendix 3 for more information.

D. Research Involving Children

Research projects involving children as subjects typically require the written permission of one or both parents [see 45 CFR 46.408(b)] or guardian in accordance with the informed consent procedures delineated in the informed consent requirements (Section J.1). In addition to parental or guardian permission for a child to participate in a research study, the assent of the child may be solicited, assuming the child is capable of providing assent. To make this judgment, the IRB will consider the age, maturity, and psychological state of the targeted child population. Even if the children are capable of providing assent, the IRB may waive the assent requirement when consent requirements are waived (see CFR 46.116).

Typically, parental or guardian permission must be documented. However, a PI may request a waiver of the documentation of informed consent based on 45 CFR 46.117(c) (see Appendix 3 for information). Additionally, the IRB may determine that parental or guardian permission is not a reasonable requirement to protect subjects (e.g., neglected or abused children) and it may waive the consent requirements, provided that an appropriate mechanism for protecting the children who participate as subjects in the research is substituted and the waiver is not inconsistent with federal, state, or local law [45 CFR 46.408(c)].

XI. PROTECTION OF CONFIDENTIAL INFORMATION

The PI is responsible for ensuring the privacy and confidentiality of all personally identifiable information from research subjects, except as required by law (e.g., child abuse) or allowed with written permission of the research subject. This information may be contained in either electronic or hard copy formats. When appropriate, the informed consent document should outline those conditions under which data are not considered confidential (e.g., child abuse). Data collection and storage, and safeguards to ensure confidentiality must be delineated by the PI in the research description portion of the application to the IRB.

A. Storage and Retention of Confidential Records

The PI must store confidential hard copy information gathered from or about any research subject in a secure (locked) facility to which only the PI and authorized project staff have access. Electronic data shall be password-protected at the workstation or file level. If this level of protection is not feasible, electronic data should be stored on removable media which can be locked and protected. Records (e.g., signed informed consent forms, data) relating to the research project must be retained for at least three years after completion of the research (five years for FDA studies). All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner [45 CFR 46.115(b)].

B. Certificate of Confidentiality

For studies, whether funded or not funded, in which data are being collected about sensitive issues, the PI may obtain from the appropriate Federal agency an advance grant of confidentiality, known as a Certificate of Confidentiality that will provide protection of research data against subpoena. Sensitive issues include, but are not limited to, the collection of information falling into one or more of the following categories:

- information relating to sexual attitudes, preferences, or practices;
 - information relating to the use of alcohol, drugs, or other addictive products;
 - information pertaining to illegal conduct;
 - information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
 - information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
 - information pertaining to an individual's well-being or mental health;
 - other information that is not listed here may also be considered sensitive, given specific cultural or other factors.
- Sensitive information may exist in a number of forms, including, but not limited to, survey responses, medical or other records, results of medical or psychological tests, or responses to experiments.

Student research or surveys involving the sensitive information above will only be approved by the IRB under special circumstances.

For information on how to apply for a Certificate of Confidentiality, contact the IRB Chair.

C. Access to Confidential Records

The University has the right of access to the supporting records for all research at the University or supported by University-sponsored funds, provided such access to the records shall be for reasonable cause, at reasonable times, and after reasonable notice. The university's right of access to the data shall continue regardless of the location of the responsible investigator. Extramural sponsors providing support for research at RU may also have the right to review the data and records resulting from that extramural support. Co-investigators and trainees who are an integral part of a research project have the right to review all records and data which are part of that project.

D. Other Regulations Related to Privacy, Confidentiality, and Consent

In addition to 45 CFR 46 and FDA regulations (21 CFR 50), other federal regulations may apply to research involving human subjects.

(1) Privacy Rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Public Law 104-191, 104th Congress

The Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, regulates the way covered entities handle individually identifiable health information known as protected health information (PHI). The Privacy Rule itself applies only to covered entities, not to research itself; however, the Privacy Rule may affect researchers because it establishes the conditions under which covered entities can use or disclose PHI for research.

When the Privacy Rule is or may be involved in a research project the PI should consult both (1) University policy regarding HIPAA and (2) the Chair of the IRB prior to preparing an IRB application.

XII. INTERNET RESEARCH

Research using the Internet has unique characteristics that are not directly addressed by the Federal regulations. Currently, the Internet is used primarily for two research activities – recruitment of subjects and survey administration. Most human subjects protection issues that arise in conducting research activities on the Internet concern privacy and consent. For a thorough discussion of the pertinent issues, refer to “Ethical and Legal Aspects of Human Subjects Research on the Internet,” prepared for DHHS by The American Association for the Advancement of Science (<http://www.aaas.org/spp/dspp/sfrr/projects/intres/main.htm>)

The ability to consent is difficult to ascertain over the Internet. Generally, this ability is related to age, but may be relevant to other vulnerable populations (e.g., decisionally impaired, incarcerated). Also, email-based activities are far less secure than website-based activities. Software exists to enhance the privacy of both types of activities. RU strongly recommends that researchers work with a vendor that specializes in Internet-based research to minimize risks in these areas.

Internet-based studies may not include minors as subjects unless the IRB waives written parental permission and informed consent.

Generally, Internet-based surveys do not require written documentation of consent, but the IRB strongly encourages the use of a cover statement or letter of consent/assent.

In all Internet-based surveys, individuals must be able to easily print a readable copy of information about the study and the informed consent documentation (if required) for their own records.

XIII HUMAN SUBJECTS PROTECTION IN FIELD RESEARCH

Field research typically involves observation of and interaction with individuals and groups in their own environment, often over long periods of time. It also includes other types of generally qualitative activities that fall under the definition of research, such as interviews conducted for historical or biographical research and archival research on identifiable living individuals. Interviews by journalists conducted solely for the purpose of writing an article in a newspaper, magazine, or other media outlet are not considered research and do not require IRB review.

It may not be possible to specify in an informed consent statement the detailed description of the research protocol, as the research itself may involve interactions between the researcher and subjects that evolve over time. Likewise, differences in language, culture, or the nature of the subjects or topic may preclude the use of a written informed consent document. If appropriate justification is given, the IRB may waive the requirement for some or all of the informed consent requirements or the requirement to obtain signed informed consent in certain situations; 45 CFR 46.116(c) and (d) describes the circumstances in which waiver is possible (also see Appendix 3 of this policy for more information). The investigator should request such a waiver if he or she determines that it is appropriate. The IRB will make the final determination. In addition, the sensitive nature of some field research may make it advisable for the investigator to consider obtaining a Certificate of Confidentiality (see Section K.2 of this policy for more information).

Investigators conducting field research should consider guidelines developed by a relevant professional association, such as the American Anthropological Association, the American Historical Association, or the American Sociological Association, when designing their protocols.

XIV. OTHER STUDIES INVOLVING HUMAN SUBJECTS

This section sets out policy for conducting other types of studies that include human subjects, but do not meet the Federal definition of research.

A. Undergraduate Student Projects

Undergraduate Student Projects involving human subjects are considered non-conventional research. Regis University has guidelines created by the Human Subjects IRB outlining appropriate subjects for student research with human subjects. Students will be guided by the advice of their Regis University faculty sponsor, faculty advisor, or class instructor when designing research projects with human subjects. Faculty approval will be necessary for the Human Subject IRB to approve the research to be conducted. All student research involving human subjects will only be done under the supervision of a Regis University Faculty Member.

(1) Distinguishing Student Projects from Conventional Research

Generally undergraduate student research involving human subjects is either in the form of class projects or independent directed research projects. The type of review required is determined by whether the research projects are intended to contribute to general base of human knowledge.

Dissemination of findings to a scientific audience is a sufficient (but not necessary) criterion for identifying when a study contributes to the general base of human knowledge. Dissemination includes (but is not limited to) presentation at a scientific meeting or conference; submission to or publication in a scientific journal (paper or electronic); and Internet postings. If the project falls under this definition of research, review and approval of a human participants research protocol by the IRB is always required.

Instructors are advised to discuss protection of human subjects with students before the instructional assignment or project begins so that informed decisions can be made about whether IRB review is needed. If even the slimmest likelihood exists that an instructional assignment or project may fall under the definition of research outlined in this document, instructors are advised to submit the appropriate human participants research protocol to the IRB for review and approval. Please remember that IRB approval of a research protocol cannot be granted retroactively under any circumstances.

(2) Sponsor Responsibilities in Student Projects

All student projects must have a Regis University faculty sponsor. For class projects, this is usually the instructor. The sponsor/ instructor will be responsible for the supervision of the student researcher sufficiently to assure the protection of human research subjects in accordance with ethical standards of the relevant discipline.

B. Institutional Research

Data collected or studies conducted for purposes of providing information to the university, any unit within the university, or any other organization (e.g., accrediting agency), with the purpose of addressing issues deemed important to university operations is considered to be institutional research. Studies of this nature do not require IRB review. If information collected is intended for further dissemination, publication (including Internet), or involves more than minimal risk, it requires IRB review.

When IRB review is not required, institutional research projects or other activities must still communicate applicable elements of informed consent (e.g., purpose, risk, benefit, voluntary participation, permission to withdraw) and include appropriate anonymity and confidentiality protections.

C. Other Projects

Projects such as program evaluation, policy analysis, or quality assurance studies conducted for the purpose of providing information only to the organization studied do not require IRB review, provided they meet the following conditions: (1) They are not intended to produce knowledge that contributes to the general base of human knowledge or publishable; (2) They involve no more than minimal risk as defined in Federal regulations and RU policy; (3) They do not involve vulnerable populations.

XV. TRAINING

Training is critical to the successful operation of an institution's human subjects' protection program. The following describes how faculty, staff and students at the University may become involved with the one of the best training systems available. For specific information regarding these programs individuals should contact the Office of Academic Grants.

A. CITI: The Collaborative IRB Training Initiative

The Institutional Review Board (IRB) at Regis University recognizes the value of the multiple methodological approaches taught and employed at Regis University. Central to all these methods is the rights and protection of human subjects who participate in our research and learning. Based on Federal guidelines and, moreover, the basic grounding principle of Regis University, "How ought we to live?" the IRB Committee at Regis University outlines the following as mandatory:

- (1) All Regis University Faculty teaching research method classes, capstone classes, and allied coursework that involves data gathering from primary research with human subjects be CITI certified.*
- (2) All faculty and students at Regis University participating in research method classes, capstone classes, and allied coursework that involves data gathering from primary sources or engaging in primary independent research that involves human subject participation other than exempt protocols must be CITI certified.*CITI certification must renewed every three years.
- (3) All Regis University Faculty who wish to obtain an authorized class proxy (formerly omnibus approval qualification) and thus serve as a class proxy for a specific class at Regis University must be CITI certified.* Proxies or a college/school/department designee will retain all required paper work for human subject approval and will be under the oversight of the IRB.

Once completed, the faculty or student will print copies of the certificates for their records. The following CITI modules will be required:

- (1) Introduction (no quiz)
- (2) History and Ethical Principles-SBR
- (3) The Regulations and The Social and Behavioral Sciences-SBR
- (4) Assessing Risk in Social and Behavioral Sciences-SBR
- (5) Informed Consent-SBR
- (6) Privacy and confidentiality-SBR

*These modules are necessary but not necessarily sufficient. Training other than the Social Behavioral Research modules may be required (e.g., Biomedical modules). Additionally, other Social Behavioral Research modules may be required depending on the type of research being conducted. For example (but not limited to), a person working with children

would be required to complete the Research with Children module; a person working with the prison population would be required to complete the Research with Prisoners module; as person working in the public school system would be required to complete the Research in Public Elementary and Secondary Schools module; a person doing international research would be required to complete the International Research module.

B. Class Proxy Training

All Regis University Faculty who wish to obtain an authorized class proxy (formerly omnibus approval qualification) and thus serve as a class proxy for a specific class at Regis University must apply to be a class proxy for each different class they would like to serve as class proxy for using Form P and must be CITI certified. Class Proxies will only approve exempt qualified Proposals. Those requiring higher levels of review must send appropriate application to irb@regis.edu. Class Proxies will be appointed by the IRB. Proxies must be faculty. Proxies will have class proxy authority for the approved class until the curriculum or research requirement for the class changes. The class proxy will be responsible for the protection of human subjects for all research they review and approve. This is all reviews and approvals they do not pass on to the IRB for review. Proxies will be given a handout and web resources to assist them in decision making processes. Proxies will be given individual guidance by the IRB on an ongoing basis. Requests for guidance, information or training will be made to the IRB Chair. The HPA will assist the IRB in training on an administrative and cooperative level.

XVI. STUDENTS AS RESEARCH SUBJECTS

Students are often used as subjects in research studies, both by RU student, faculty, and staff researchers as well as researchers from other universities and organizations. Because of their unique position, RU policy addresses several issues pertaining to the use of students in research projects.

A. Recruitment of Students for Research Studies

Faculty should think very carefully about the implications of using students as participants in research. Although students often provide a ready source of potential participants, they are not always as representative or appropriate to the research as other subject pools, and many research proposals and manuscripts have been rejected for funding or publications, respectively, on those grounds. If students are determined to be appropriate participants, then several key issues need to be considered.

(1) Coercion : If the instructor of the course is also the PI on the project, recruitment of students into the project by the instructor could be viewed as coercive. Students may fear that their grades would be jeopardized by their non-participation in the research, especially since the instructor could identify who has participated and who has not. Therefore, it is important that measures are built into the research to ensure students that their participation is strictly voluntary and that they may withdraw their participation at anytime without penalty.

(2) Consent : Even though potential participants are enrolled in the PI's class, informed consent is still required. The PI must explain the procedures; disclose all the risks and benefits, and any other information, which may influence the potential participant's decision to willingly participate. Signed_informed consent is required, except under the following conditions:

- a. Anonymous (no means of identifying participants) mailed questionnaires or telephone interviews; and

- b. The only record linking the subject and the research would be the signed consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Please note: Although signed informed consent may be waived, participants must still receive the standard consent information.

If credit is offered in exchange for participation, an alternate means of earning equivalent credit for an equivalent commitment of time and effort should be made available to the entire student pool. (Please note that extra credit should be awarded only in addition to the base amount of points to be earned for the course, rather than being figured in to the base amount of points to be earned.)

XVII. Protected Health Information (PHI)

Regis University researchers may engage in human subjects research in which PHI, patient care records, or data protected by the Health Information Portability and Accountability Act of 1996 (HIPPA) of the research subjects is ultimately disclosed with permission patient if possible and provided:

- A. All Regis University guidelines and regulations involving PHI are followed.
- B. PHI is de-identified by researchers fully so that no links may be made between collected data and human subjects.
- C. Researchers have obtained valid approval of the research project from the Regis IRB.
- D. Researchers have obtained authorization from the research subjects to use the PHI and that authorizations have been approved by the Regis IRB.

Regis University researchers may also engage in human subjects research in which PHI, patient care records, or data protected by the Health Information Protection Act of subjects is ultimately disclosed provided:

- E. The Regis IRB has reviewed the research and, in accord with relevant federal regulation, has waived the subject's authorization for the use of their PHI.

Appendices

Appendix 1—Instructions for submissions and forms

Instructions for Submitting Materials for Review by the University Institutional Review Board

Form A—Adverse Incident Report

Form C—Continuation Request

Form E—Exempt Application to the Institutional Review Board for Review of Research Involving Human Subjects

Form F—Expedited/Full Board Review Application to the Institutional Review Board for Review of Research Involving Human Subjects

Form M—Proposed Modifications to Study Protocol or Informed Consent/Assent Form(s) after IRB Approval

Form P – Application to be Designated for a Class Proxy of Class for IRB Exempt Studies Review

Appendix 2—Reviewer Checklist

Appendix 3—Informed Consent Information

Informed Consent Form Checklist

Conditions for waiver of some or all informed consent requirements

Conditions for waiver of requirement to obtain signed informed consent

Appendix 4—Reference Material

The Belmont Report

The Nuremburg Code

The Declaration of Helsinki

Appendix 1—Instructions for Submissions and Forms

Instructions for Submitting Materials for Review by the University Institutional Review Board

Form A—Adverse Incident Report

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Form F—Application to the Institutional Review Board for Expedited/Full Board Approval of Research Involving Human Subjects

Form M—Proposed Modifications to Study Protocol or Informed Consent/Assent Form(s) after IRB Approval

Form P—Certification/Recertification of Class Proxy

Instructions for Submitting Materials for Review by the Institutional Review Board

New Application—Checklist of materials required for review

Submit electronic copy to the irb@regis.edu with attached separate supplemental files.

- _____ Submit Exempt Application or Expedited/Full Board Application including answers to all research description items
 - If you are submitting your proposal for external funding or your project has been externally funded, submit a copy of your grant proposal
- _____ Questionnaires, surveys, tests, or other materials that will be administered to subjects
- _____ Written permission from other institutions or agencies involved in the research (e.g., school board, hospital, agency, prison)
- _____ Informed consent form or written request for waiver of an informed consent form
- _____ Advertisements, letters, or flyers that will be used, if any

Do Not Embed Documents or Files in Forms!

If you embed them the information will be lost. Prepare supplemental files for all additional information or documents and submit them electronically with the application as attachments.

******Send all applications to irb@regis.edu ******

Modification Request—Checklist of materials required for review

Submit 1 copy of the following:

- _____ Form M and documentation requested on the form

Continuation Request—Checklist of materials required for review

Submit 1 copy of the following:

- _____ Form C and required documentation requested on the form
- _____ Protocol summary, including approved modifications since last review and/or proposed changes
- _____ Informed consent forms, permission forms, and assent forms, if applicable

Adverse Incident Report—Checklist of materials required for review

Call or e-mail the IRB Chair immediately and complete and submit Form A and documentation requested on the form to OAG within 20 working days

Submit 1 copy of the following:

- _____ Form A

For IRB use only IRB File No.: _____ Date received: _____ Approval expires: _____
--

Form A (Adverse Incident Report)

Regis University
 Institutional Review Board
 for Review of Research Involving Human Subjects
 Adverse Incident Report
 PI REPORT OF PROBLEMS INVOLVING RISK, ADVERSE EFFECTS, OR NONCOMPLIANCE

irb@regis.edu

Institutional Review Board
 Regis University
 3333 Regis Blvd.
 Mail Code H4
 Denver, Colorado 80221-1099
 Telephone: 303-458-4206

All problems involving risk to subjects or others, injury or other adverse effects experienced by subjects in research, and incidents of noncompliance must be reported to the IRB immediately. This report should be submitted as soon as possible, but NO LATER THAN 5 WORKING DAYS after first awareness of the problem.

1. Date of Report: _____

2. Title of Project: _____
IRB File Number: _____

3. Principal Investigator*: _____

*Note: Students engaging in research are required to have a faculty sponsor or executive, administrative, or professional (EAP) staff sponsor. List sponsor below.

Status: Faculty Student* EAP Staff Other—specify: _____

Mailing address: _____

Phone: _____ E-mail: _____

Department or Unit _____

Co-Investigator or Sponsor: _____

Status: Faculty Student EAP Staff Other—specify: _____

Mailing address: _____

Phone: _____ E-mail: _____

Department or Unit _____

List additional co-investigators, including above information, on a separate sheet.

4. Description of problem involving risk to subjects or others, adverse effect, or noncompliance

Date: _____

The problem, adverse effect, or noncompliance was: mild moderate severe fatal

Was the event related to the research procedure? Yes No Maybe Unknown

Provide a brief description.

5. Treatment provided to the subject or other

Was treatment provided to the subject or other?

Yes—Date of treatment: _____

Describe the treatment provided to the subject or other.

No —Explain why treatment was not provided.

6. Changes necessitated by the problem involving risk to subjects or others, adverse effect, or noncompliance

A. Change in Protocol: In your judgment is a change in your protocol necessary to reduce or eliminate risk?

Yes—Provide revised protocol with changes highlighted. Note that data should not be collected until the revised protocol is approved by the IRB.

No —Provide a brief rationale.

B. Change in Informed Consent/Assent Document(s): Are any changes required in the informed consent/assent document(s) to better inform and protect the rights and welfare of the subjects?

Yes—Attach the revised consent/assent form with changes highlighted. Note: No new subjects may be enrolled in the study until the revised consent/assent form(s) is approved by the IRB.

No —Provide a brief rationale.

C. Enrolled Subjects: Is it necessary to inform presently enrolled subjects or legal representatives of the adverse event?

Yes—Describe how subjects or legal representatives will be informed and if necessary, attach a revised consent or assent form.

No—Provide a brief rationale.

7. Additional Comments:

Principal Investigator's Signature

Date

Faculty or EAP Staff Sponsor's Signature
(required when a student is the PI)

Date

for Review of Research Involving Human Subjects

RESEARCH CONTINUATION REQUEST

Federal guidelines (45 CFR 46.109e) require that Institutional Review Boards (IRB) “conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.” In conducting the continuation review, the IRB will review, at a minimum, a protocol summary and informed consent/assent forms, as well as a status report on the progress of the research.

1. Title of Project: _____

IRB File Number: _____

2. Principal Investigator*: _____

Status: ___ Faculty ___ Student* ___ PSS ___ Other—specify: _____

*Note: Regis University students or personnel external to Regis University engaging in research under the purview of Regis University are required to have a faculty sponsor or approved professional staff sponsor (PSS). List sponsor below.

Mailing address: _____

Phone: _____ E-mail: _____

Department or Unit _____

Co-Investigator or Sponsor: _____

Status: ___ Faculty ___ Student ___ PSS ___ Other—specify: _____

Mailing address: _____

Phone: _____ E-mail: _____

Department or Unit _____

List additional co-investigators, including above information, on a separate sheet.

3. Project begin date: _____ Estimated project end date: _____

4. Approximate total number of subjects who will be enrolled: _____

Number of subjects actually enrolled as of this date: _____

Number of subjects who have dropped out: _____

Number of subjects who have formally withdrawn: _____ (If subjects have withdrawn, please summarize reason(s) for withdrawal)

5. Since the last IRB review, have any injuries or adverse events occurred?

___ Yes—summarize injuries or events

___ No

Details:

6. Since the last IRB review, have any unanticipated problems involving risks to subjects or others occurred?

Yes—summarize problems

No

Details:

7. Since the last IRB review, have any complaints about the research been received?

Yes—summarize complaints

No

Details:

8. Are there any changes in the protocol requested?

Yes—describe proposed changes to the protocol and attach a protocol summary. Include amendments or modifications to the research since the last review.

No—attach a protocol summary. Include amendments or modifications to the research since the last review.

Details:

9. Are there any changes to the informed consent/assent form(s)?

Yes—describe changes and attach new consent/assent form(s) with changes highlighted.

No—attach informed consent/assent forms

Details:

10. Are there any additions and/or changes in sites where data are being collected?

Yes—list additional sites or changes. Attach approval letters (See location of study in Research Description of the New Application packet—Form A).

No

Details:

* A **professional staff sponsor (PSS)** may be any Regis University staff member authorized by the IRB to sponsor research studies. A PSS will have the appropriate CITI certification(s) for supervision of the study. Qualifications for a PSS will include, but not be limited to, a working knowledge of research methods, data analysis, and the responsible conduct of research.

For IRB use only

IRB File No.: _____

Date received: _____

Approval expires: _____

Approved by:

Name IRB Position

Signature Date

Form E. (Exempt Application)

APPLICATION FOR EXEMPT APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS (Word Version, EXEMPT FORM)

IRB, Regis University
Main Hall, Room 452, Mail Code H4
Denver, CO 80221
Email: irb@regis.edu

Applicants, please fill in the following information:

Project Title:
Proposal Submission Date: Time:
Principal Investigator(s):
Contact Address:
Telephone: - - ext. **Email:** (Regis email)
Academic Department or School:
Faculty Advisor (student projects):

Note: Research must be resubmitted for approval if changes are made in the research plan that significantly alter the involvement of human subjects from that which is described by this application. **Applicants, please read the “special notice” on the Table of Contents page.**

The following table is for IRB use only. Each person in the approval process has a maximum of 10 working days to process the application.

Approval Process	Date Reviewed	Review(er) Determination	Signature Code	Comments
Faculty Advisor (student projects)		<input type="checkbox"/> Returned to student for correction/addition <input type="checkbox"/> Forwarded to next review		
Class Proxy (student projects)		<input type="checkbox"/> Returned to student for correction/addition <input type="checkbox"/> Recommend student resubmit as expedited study <input type="checkbox"/> Recommend student resubmit as full board review <input type="checkbox"/> Approved exempt study		
IRB Reviewer (as necessary)		<input type="checkbox"/> Returned to researcher(s) for correction/addition <input type="checkbox"/> Recommend researcher(s) resubmit as expedited study <input type="checkbox"/> Recommend researcher(s) resubmit as full board review <input type="checkbox"/> Approved exempt study		
IRB Chair (as necessary)		<input type="checkbox"/> Returned to researcher(s) for correction <input type="checkbox"/> Recommend researcher(s) resubmit as expedited study <input type="checkbox"/> Recommend researcher(s) resubmit as full board review <input type="checkbox"/> Approved by IRB vote pending mandated changes <input type="checkbox"/> Approved exempt study <input type="checkbox"/> Denied by IRB vote		

Table of Contents

I. Basis for Exempt Request

II. Projected Timeline

III. Research Design/Problem Abstract

IV. Outside Approval

V. Institutional Considerations

VI. CITI Certification

****Special Notice: For students, please have your faculty advisor certify your proposed research topic as acceptable before starting the IRB research proposal submission process.****

I. Basis for Exempt Request

I understand that exempt studies will not involve members of vulnerable populations; data collection related to Federal Departments, their employees, nor eligible beneficiaries; nor international studies. I request that my study be exempt from the Regis University IRB human subjects protection board review process based on one of the following exempt study categories from 45CFR46.101.b (**please check the appropriate box**):

(1) My research will be 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. Personal identifiers will not be collected linking individuals to the collected data.

(2) My research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. The information obtained will not be recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) no 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.

(3) My research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of 45CFR46.101 but the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) My research will involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. The sources for data collection are publicly available or the information will be recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) My research or demonstration project will be conducted by or subject to the approval of Federal department or agency heads, and are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) My research involves taste and food quality evaluation and consumer acceptance studies where (i) wholesome foods without additives will be consumed or (ii) food to be consumed contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug

Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Even if a study is determined to be exempt from formal IRB review application, letters of approval must be submitted with this application if the study intends to target military, Federal, or State records/data, employees, or beneficiaries. Letters of approval must also be submitted if no formal research agreement exists between Regis University and the host site for the study.

II. Projected Timeline

- Projected start date: (Please allow a 30 day lead for the request.)
- Projected finish date: (Studies longer than 1 year require recertification on an annual basis—approval anniversary.)

III. Research Design/Problem Abstract

Please provide a brief overall description of the research project. Include enough information about the background and rationale for the study; the purpose, hypothesis, research question, and objectives; and the research methodology to justify its approval as an exempt study. Sections A through F must be completed.

A. *Background and rationale (no more than 2 pages):*

B. *Purpose (no more than 2 pages):*

C. *Methodology (no more than 2 pages):*

D. *Target population (no more than 2 pages):*

E. *Briefly justify the choice of the exemption criteria selection in Section 1 (no more than 1 page):*

F. *Provide the complete text of any test, interview, or survey instrument to be used as a data collection tool; recruitment tools; and/or any consent statement or letter of consent to be given participants (no page limit):*

IV. Outside Approval

- Will you be recruiting participants from an organization outside, or conducting the study at an institution other than, Regis University? Yes No
- If **YES**, your proposal must also be approved by the appropriate authorit(y/ies) within that organization/institution. Paste a copy (jpeg) of the approval letter(s) here:

V. Institutional Considerations

- Does the proposed research have any potential conflicts with Roman Catholic teachings

(i.e., Ethical and Religious Directives)? Yes No

- An example of a conflict with Roman Catholic teaching is research testing the effectiveness of condom use for preventing the spread of sexually transmitted disease.
- If **YES**, what are those potential conflicts and what justification can be given for pursuit of this research?

- Does the proposed research have potential negative implications for Regis University? Yes

Yes No

- An example of potential negative effect on the university is a study design that violates university policy such as observation of individual responses to intentional sexual harassment of students, staff, or faculty.
- If **YES**, what are those potential negative implications and what justifications can be given for pursuit of this research?

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VI. CITI Certification

What is the expiration date of the CITI certification for each

investigator? Name: CITI expiration date:

Name: CITI

expiration date: Name:

CITI expiration date: Name:

CITI expiration date: Name:

CITI expiration date: Name:

CITI expiration date: Name:

CITI expiration date:

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 Email: irb@regis.edu

Form F (Expedited/Full Board Review Application)

APPLICATION FOR REVIEW/APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

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 Main Hall, Room 452, Mail Code H4
 Denver, CO 80221
 Email: irb@regis.edu

Applicants: Please fill in the following information.

Project Title:

Proposal Submission Date: Time:

Principal Investigator(s):

Contact Address:

Telephone: - - ext. **Email:** (Regis email)

Academic Department or School:

Faculty Advisor (student projects):

Note: Research must be resubmitted for approval if changes are made in the research plan that significantly alter the involvement of human subjects from that which is described by this application. **Applicants, please continue the application process on Page 2. Please read the “special notice” on Page 2.**

*The following table is for IRB use only. Each person in the approval process has a **maximum** of 10 working days to process the application.*

Approval Process	Date Reviewed	Review(er) Determination	Signature Code	Comments
Faculty Advisor (student projects)		<input type="checkbox"/> Forwarded to next review <input type="checkbox"/> Returned to student		
Class Proxy (student projects)		<input type="checkbox"/> Approved exempt study <input type="checkbox"/> Recommend expedited <input type="checkbox"/> Recommend full board <input type="checkbox"/> Returned to student		
IRB Reviewer		<input type="checkbox"/> Approved exempt study <input type="checkbox"/> Recommend expedited <input type="checkbox"/> Recommend full board <input type="checkbox"/> Returned to PI		

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IRB Chair		<input type="checkbox"/> Approved expedited <input type="checkbox"/> Approved by full board <input type="checkbox"/> Returned to PI		
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- I. Projected Timeline**
- II. Categories for Expedited Review**
- III. Research Design/Problem Abstract**
- IV. Research Participants**
- V. Risks and Benefits**
- VI. Consent Process**
- VII. Privacy Protection**
- VIII. Institutional Considerations**
- IX. Support Documentation**
 - A. Informed consent documents.
 - B. Study questionnaires/surveys.
 - C. Data collection forms, checklists, instruments.
 - D. Study interviews/focus groups interview schedule(s)/instruments.
 - E. Recruitment flyers or recruitment email texts.
 - F. Letters of support from the instructor, school, or department.
 - G. Approval documents for studies conducted off-site from, or with populations from institutions other than, Regis University.
 - H. Award letters from funding agencies.
 - I. Thesis or dissertation prospectus.

****Special Notice: For students, please have your faculty advisor certify your proposed research topic as acceptable before starting the IRB research proposal submission process.****

I. Projected Timeline

- Projected start date: (Please allow a 30 day lead for the request.)
- Projected finish date: (Studies longer than 1 year require recertification on an annual basis—approval anniversary.)

II. Categories for Expedited Review (Optional)

The following are the research categories eligible for expedited review/approval (OHRP Categories of Research & 63 FR 60364-60367).

Please **check the box** next to the research category under which you are requesting expedited review.

1. I am conducting a clinical study of a drug/medical device under condition (a) or (b).
 - a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. I am collecting blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. I am conducting prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. I am collecting data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. **Note:** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5. My research involves materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
6. I am collecting data from voice, video, digital, or image recordings made for research purposes.

7. I am conducting 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
8. This is a continuing review of research previously approved by the convened IRB as follows:
 - a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. where no subjects have been enrolled and no additional risks have been identified; or
 - c. where the remaining research activities are limited to data analysis.
9. This is a continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

If this is an expedited review request, please justify the request (no more than 2 pages):

III. Research Design/Problem Abstract

Please provide an overall description of the research project. Include information about the background and rationale for the study; the purpose, hypothesis, research question, and objectives; and the research methodology. Include sufficient detail that the Committee can assess any potential hazards. A brief literature review should be part of the *Background and rationale* section.

A. *Background and rationale (no more than 3 pages):*

B. *Purpose (no more than 3 pages):*

C. *Methodology (no more than 3 pages):*

- Are investigational drugs to be used? Yes No
- Are medical devices to be used? Yes No (NOTE: medical devices must be FDA approved for the study.)
- Is this a multicenter or collaborative study? Yes No

D. *Justification for inclusion of vulnerable populations (if included)(no more than 2 pages):*

IV. Research Participants

- Please provide a general description of the target population.
- Does the study target participants from (a) vulnerable population(s)?
 - Yes No (If **YES**, justify the inclusion of these participants in the *Research Design* section, and specifically identify risks and benefits to vulnerable population participants in the *Risks and Benefits* section.)
- Describe the method of selection and recruitment of participants.
- Inclusion criteria for participant recruitment:
- Exclusion criteria for participant recruitment:
- Will you be recruiting participants from an organization outside, or conducting the study at an institution other than, Regis University?
 - Yes No (If **YES**, after approval by this Committee your proposal must also be approved by the appropriate authorit(y/ies) within that organization/institution. Paste a copy (pdf/jpeg) of the approval letter(s) into Support Documentation, section G at the end of this form.)

- Will you be recruiting participants for an international study?
 - Yes No (If **YES**, after approval by this Committee your proposal must also be approved by the appropriate authorit(y/ies) of the countries in which the study will be conducted according to the laws/regulations of those countries. Paste a copy (pdf/jpeg) of the approval letter(s) into Support Documentation, Section G at the end of this form.)

V. Risks and Benefits

- Risks and benefits to research participants should address any physical, emotional, psychological, financial, academic, employability, and/or reputation risks and/or benefits. Other areas of potential risk or benefit may be addressed as deemed proper for the study.
- What relationship, if any, exists between the researcher(s) and the study participants/subjects?
- Describe any potential direct benefits to the participants.
- Describe the broader benefits of the project to society.
- Describe any potential risks that the participants could encounter through their participation in this study.
 - *Current risks:*
 -
 - *Future risks:*
 -
- Describe any efforts to minimize risks to the subjects.
- Describe any costs (financial) to the participants.
- Will the participants be offered compensation or incentives for participation in the study? Yes No
 - If **YES**, please describe the compensation/incentives.

- - Describe any planned follow-ups with study participants.
 -

*Please ensure that specific risks and benefits, if any, for vulnerable populations are identified.

VI. Consent Process

- Describe process for obtaining participant consent.
 -
- Is a waiver of the consent process required? Yes No
 - If **YES**, justify the waiver of consent request.

▪

VII. Privacy Protection

- Describe the procedures to be used that will ensure collected study information will be kept secure. All collected data and consent forms for expedited or full board approval, or if consent forms are used for exempt studies, **MUST BE SECURELY STORED FOR 3 YEARS AFTER COMPLETION OF THE STUDY, 5 YEARS FOR FDA APPROVED CLINICAL TRIALS.**
- Do you plan to maintain personal identifiers (names, addresses, birth dates, phone numbers, etc.) after your project is completed? Yes No
 - If yes, explain why.
- Describe your plans for the destruction of linkages to personal identifiers and the time frame.

- Will photographs, audio, or video recordings of participants be made? Yes
No
 - If yes, describe whether you will maintain, destroy, or return them to participants.
- Will personal identifiers will be revealed in your study (i.e., not kept confidential)?
Yes No
 - If yes, provide justification and describe how the subjects will be informed that this information will be disclosed.
- Will your study involve the collection of data that might produce a regulatory mandate or duty to inform authorities about potentially harmful or illegal activities?
Yes No
 - If yes, what is your plan for dealing with this information?
 - Will you apply for a Federal exemption to reporting? Yes No Paste a copy (pdf/jpeg) of the approved exemption under Support Documentation, Section A at the end of this application form.

VIII. Institutional Considerations

- Does the proposed research have any potential conflicts with Roman Catholic teachings (i.e., Ethical and Religious Directives)? Yes No
 - An example of a conflict with Roman Catholic teaching is research testing the effectiveness of condom use for preventing the spread of sexually transmitted disease.
 - If **YES**, what are those potential conflicts and what justification can be given for pursuit of this research?
- Does the proposed research have potential negative implications for Regis University?
Yes No

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- An example of potential negative effect on the university is a study design that violates university policy such as observation of individual responses to intentional sexual harassment of students, staff, or faculty.
- If **YES**, what are those potential negative implications and what justifications can be given for pursuit of this research?

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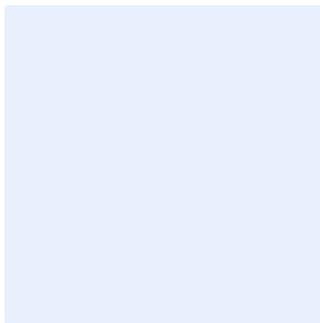
IX. Support Documentation

Copy and paste or insert appropriate documentation into the following areas as applicable.

A. Informed consent documents:

Text:

Or .jpeg:

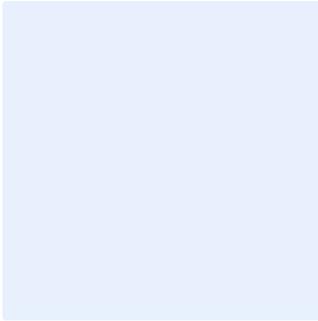


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B. Study questionnaires/surveys:

Text:

Or .jpeg:

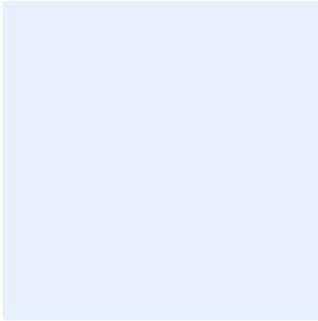


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C. Data collection forms, checklists, instruments:

Text:

Or .jpeg:

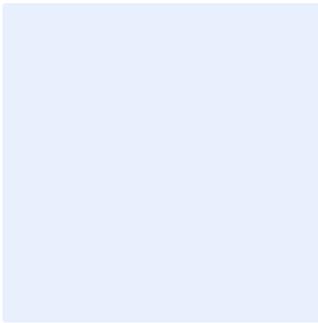


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D. Study interviews/focus groups interview schedule(s)/instruments:

Text:

Or .jpeg:

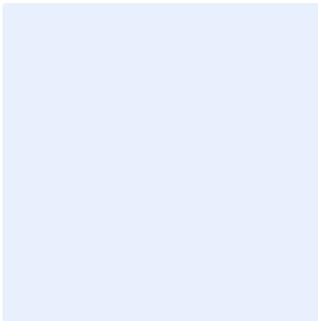


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E. Recruitment flyers or recruitment email texts:

Text:

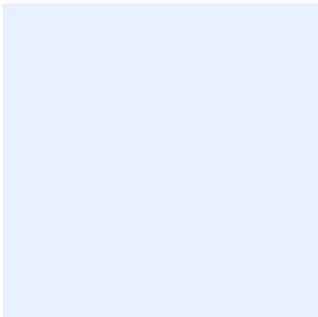
Or .jpeg:



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F. Letters of support from the instructor, school, or department:

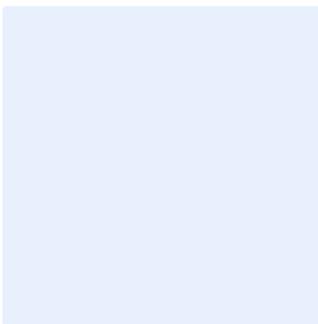
.jpeg:



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G. Approval documents for studies conducted off-site from, or with populations from institutions other than, Regis University:

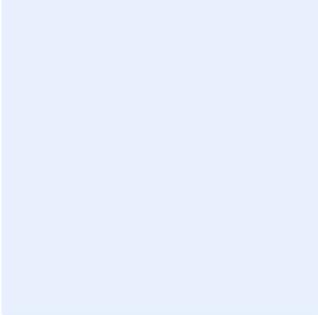
.jpeg:



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H. Award letters from funding agencies:

.jpeg:

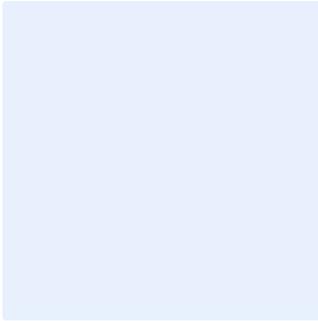


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I. Thesis or dissertation prospectus:

Text:

Or .jpeg:



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For IRB use only IRB File No.: _____ Date received: _____ Approval expires: _____
--

Form M (Proposed Modification)

PROPOSED MODIFICATIONS TO PROTOCOL OR
INFORMED CONSENT/ASSENT FORM(S) AFTER IRB APPROVAL

1. Title of Project: _____
IRB File Number: _____

2. Principal Investigator*: _____

Status: ___ Faculty ___ Student* ___ PSS Staff ___ Other*—specify: _____

*Note: Regis University students or personnel external to Regis University engaging in research under the purview of Regis University are required to have a faculty sponsor or approved professional staff sponsor (PSS). List sponsor below.

Mailing address: _____

Phone: _____ E-mail: _____

Department or Unit _____

Co-Investigator or Sponsor: _____

Status: ___ Faculty ___ Student ___ PSS Staff ___ Other—specify: _____

Mailing address: _____

Phone: _____ E-mail: _____

Department or Unit _____

List additional co-investigators, including above information, on a separate sheet.

3. Are there any proposed changes in the protocol requested?
___ Yes—describe proposed changes to the protocol and submit protocol with revisions incorporated.
___ No

Changes:

4. Are there any proposed changes to the informed consent/assent form(s)?
___ Yes—describe changes and attach new consent/assent form(s) with changes highlighted.
___ No

Changes:

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5. Are there any additions and/or changes in sites where data are being collected?
___ Yes—list additional sites or changes. Attach approval letters (See location of study in Research Description of the New Application packet—Form A).
___ No

Additions/Changes:

6. Are there changes in key personnel assisting in the research project?
___ Yes—list changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, and responsibility in project.
___ No

Changes:

7. Describe any proposed changes, not listed above:

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the study's protocol and/or consent forms and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB in writing within 5 days of occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

Principal Investigator's Signature

Date

Faculty or PSS Assurance (required when a student is the PI)

This is to certify that I have reviewed this proposed modification request and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. I assure that the investigator(s) is knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator on a regular basis to monitor study progress and compliance with IRB policy for the conduct of ethical research.

Faculty or PSS Signature

Date

A professional staff sponsor (PSS) may be any Regis University staff member authorized by the IRB to sponsor research studies. A PSS will have the appropriate CITI certification(s) for supervision of the study. Qualifications for a PSS will include, but not be limited to, a working knowledge of research methods, data analysis, and the responsible conduct of research.

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Form P (Application for Class Proxy)

APPLICATION FOR CERTIFICATION/RECERTIFICATION OF CLASS PROXY

COLLEGE:

CPS RC RHCHP CCIS DAYTON MEMORIAL LIBRARY

School/Division/Department: Class Designation: Class Title:

A. The research that students in my class will do may involve work with a government agency, its employees, or beneficiaries; or involves an organization separate from Regis University. Yes No

If “Yes”, the proper letters of approval must be attached to each relevant exempt student research application. All governmental (federal/state/local) laws, rules, and regulations must be followed in obtaining such letters of approval. It would be best for students to avoid research with military or Federal subjects as the approval process is lengthy and adds a definite layer of administrative complexity. Exempt studies DO NOT require a consent form. It is suggested that a letter or statement of consent be given prior to participation.

B. The research that students in my class will do meets the federal definition of research with human subjects. Yes No

If the answer to the above is “Yes” check the appropriate category or categories in which that research will fall (listed below) and proceed to the next page. Fill out the “Application for Exemption of a Class from IRB Review” form. If the answer to the above question is “No” proceed immediately to the next page and fill out the form.

C. ONLY research activities in which involvement of human subjects will be in one or more of the categories specified below are eligible for exemption certification. If the research study involves a vulnerable population, such as children, prisoners, pregnant women, refer to 45CFR 46 subparts B, C, and D for protections afforded these groups.

Please check all the appropriate categories that might apply to your classes research projects:

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. **No personal identifiers will be collected from participants.**
2. 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 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.** *Note: According to 45 CFR 46.401, if the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do(es) not participate in the activities being observed.*
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 #2 (above) of this section 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.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or

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services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Appendix 2—Faculty Class Proxy Frequently Asked Questions

Class Proxy FAQ Sheet

1. What is a Class Proxy?

A Class Proxy is an affiliate or ranked faculty member who has IRB permission to approve students' classroom or individual human subjects research projects as Exempt. Class Proxies can only make decisions relevant to the current class in which they are the class facilitator. They cannot approve Expedited or Full Board Review research.

2. What requirements do I need to meet to be a Class Proxy?

To be a Class Proxy, affiliate or ranked faculty members must have CITI training certification, which is achieved by completing the CITI training course.

If you have not completed CITI training, the link can be found on the Regis Academic Research and Grants webpage, under "Required CITI Training." The required CITI training for Class Proxies typically includes completion of 6 modules listed within the "CITI Social Behavioral Research (SBR) Investigators" course. Additional modules may be required depending on the type of research being conducted. Contact the IRB for more detailed instructions.

<http://www.regis.edu/Academics/Academic-Research-and-Grants/Regis%20Review%20Boards.aspx>

To act as a Class Proxy, faculty must be the class facilitator for a class that requires human subjects research activities as part of the class (i.e., Research Methods, Capstone, and other classes). Some examples of such activities include: informal surveys, interviews, and field experiments. Class Proxies also review and approve Exempt research that does not involve human subjects, such as archival research, for the students in their class.

3. How long does it take to become a Class Proxy?

The turnaround time for Class Proxy approvals by the IRB is usually about 5 business days.

4. Where do I find the Class Proxy application?

The Class Proxy application can be found on the Regis Academic Research and Grants webpage, under "IRB Resources."

<http://www.regis.edu/Academics/Academic-Research-and-Grants/Regis%20Review%20Boards.aspx>

5. What is my job as a Class Proxy?

Your job is to review student (or class) human subjects research proposals and decide if they can be classified as Exempt. After careful review, if you believe they are Exempt, fill out the cover form of each proposal, indicating your decision and including your signature.

Your next step is to email the completed proposals to the IRB (irb@regis.edu) with a memo indicating that you reviewed and approved them as Exempt.

Human subjects research proposals that are **not** Exempt (i.e., are classified as needing Expedited or Full Board Review) must be emailed to the IRB (irb@regis.edu) for committee review after you have reviewed and signed them as the faculty advisor.

6. How often do I have to apply to be a Class Proxy?

Once your Class Proxy application has been accepted, your status as a Class Proxy is valid until the expiration of your CITI training certificate. At the beginning of each new academic year (end of August), please send an email to your school Dean indicating that you will be a Class Proxy and the relevant class(es) you will be teaching for the upcoming year. The Dean will compile a Notification List and send it to the IRB.

7. How do I decide if research is Exempt?

If you are uncertain about whether a research proposal would be classified as Exempt, there are resources to help you. Exempt Research Qualifications can be found under “IRB Resources” on the Regis Academic Research and Grants webpage.

<http://www.regis.edu/Academics/Academic-Research-and-Grants/Regis%20Review%20Boards.aspx>

8. Who do I contact if I need additional help while reviewing a student’s IRB proposal?

The members of the IRB committee are always willing to assist you in being an exceptional Class Proxy. If you have questions, call or email the IRB representatives in your college.

You can find a list of the current IRB members on the IRB webpage.

<http://www.regis.edu/Academics/Academic-Research-and-Grants/Regis%20Review%20Boards.aspx>

Appendix 3—Submission Checklist

Regis IRB Submission Checklist

Preliminary Steps

- Primary investigator or sponsoring faculty (if investigator is a student) has completed mandatory online CITI training.
- Primary investigator has made revisions under supervision of faculty.
- Sponsoring faculty has reviewed and signed the student's IRB application and provided contact information.

Proposal

IRB application includes the following information:

- Who the participants are
- How participants will be recruited
- What participants will be asked to do
- The instruments, tests, materials and/or devices that will be used
- Risks and benefits of the study
- Procedures used for maintaining confidentiality or anonymity
- Date of CITI training expiration

Informed Consent

- Consent Form (or Information Sheet for Exempt study), on Regis University letterhead, is included.
- Consent form includes all sections illustrated in sample consent form on Regis IRB Website:

- Statement that the study involves research
- Explanation of the purpose of the study
- Description of procedures to be followed
- Statement that the study includes procedures which are experimental
- Expected duration of subject's participation
- Description of foreseeable risks or discomforts to the subject
- Description of any benefits expected from the research
- Statement that confidentiality will be maintained
- Explanation of whom to contact for questions about the study
- Explanation for whom to contact regarding research subjects' rights
- Statement that participation is voluntary and that refusal to participate will involve no loss or penalty
- Statement that a subject may discontinue participation at any time *Materials*

- Copies of **all** data instruments and other materials to be distributed to participants (e.g. questionnaires, surveys, interview questions) are attached.

Supporting Documents (If Applicable)

- Original Letter of Agreement from outside institutions or agencies where you are conducting the research.
- Letter of Agreement includes: written permission on company letterhead, title of study, dates for which permission is granted, title and type-written name of permission-granting authority, and authority signature. (Template available on IRB website).

Supporting Documents (If Applicable)

- Translations of consent forms and all materials to be distributed to participants.
- A letter of verification signed by a translation authority is included that verifies accurate translation of materials by an individual who is fluent in all applicable languages. An example of a Verification of Translation Accuracy Form can be found at http://www.sjsu.edu/gradstudies/docs/irb_translation_verification.pdf

Organization of Support Documentation

- All supporting documents have been combined into a single file using the order specified in *Section IX. Support Documentation* of the IRB application.

Signatures

Primary Investigator _____ Sponsoring Faculty _____

Final Steps

- A completed copy of this checklist has been included with your IRB application.
- Your IRB application, .pdf file of supporting documents, and checklist have been completed and emailed to irb@regis.edu.

Appendix 4—Informed Consent Information

Informed Consent Form Checklist

Conditions of waiver of some or all informed consent requirements

Conditions for waiver of requirement to obtain signed informed consent

**Regis University
Institutional Review Board
for Review of Research Involving Human Subjects
Informed Consent Form Checklist**

Informed consent/assent forms should be written in second person (e.g., You are being asked to participate...).

Basic elements to include

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them
	A description of any benefits to the subject or to others which may reasonably be expected from the research. Monetary compensation is not a benefit. If compensation is to be provided to research subjects or healthy volunteers, the amount should be stated in the consent document
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. Include a description of whom may have access to research records
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled

Additional elements, as appropriate

	An explanation as to why subject is eligible to participate
	The approximate number of subjects involved in the study
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	Payment for participation—give amount and if/how it will be prorated if subject does not complete study
	A statement that the collection of data will be audio taped or videotaped
	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study
	If the subject is or may become pregnant, a statement that the particular treatment may involve risks, which are currently unforeseeable, to the subject or to the embryo or fetus

Conditions for Waiver of Some or All Informed Consent Requirements

The IRB may approve a waiver of some or all of the informed consent requirements provided that:

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practically be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation. [see 45 CFR 46.116 (d)]

Additionally, for research studies that are designed to evaluate or demonstrate possible changes in (or alternatives to) provision of benefits or services provided under federal, state, or local programs, an IRB may approve alteration or waiver of informed consent requirements providing the research could not be practically carried out without such waiver or alteration. [See 45 CFR 46.116 (c)]

Conditions for Waiver of Requirement to Obtain Signed Informed Consent

Federal regulations [45 CFR 46.117 (c)] allow the IRB to waive the requirement to obtain a signed informed consent for some or all of the subjects providing that the IRB finds either of the following:

- the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; or
- the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Additionally, the IRB may decide to waive written documentation of informed consent (i.e., signature of subjects) for research that falls within one or more exemption categories (see categories listed in Form E). For example, a PI who is using a survey may include the elements of informed consent in a letter of invitation to participate and by completing the survey subjects are consenting to participate in the research study.

Appendix 5—Reference Materials

Reference documents representing historical significant societal statements for change bringing about what we know today to be Human Subject Research Protection.

The Belmont Report
The Nuremburg Code
The Declaration of Helsinki

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

The Belmont Report Office of the Secretary Ethical Principles and Guidelines for the Protection of Human Subjects of Research The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research April 18, 1979

AGENCY: Department of Health, Education, and Welfare.

ACTION: Notice of Report for Public Comment.

SUMMARY: On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: **(i)** the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, **(ii)** the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, **(iii)** appropriate guidelines for the selection of human subjects for participation in such research and **(iv)** the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare.

Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

Members of the Commission

Kenneth John Ryan, M.D., Chairman, Chief of Staff, Boston Hospital for Women.
Joseph V. Brady, Ph.D., Professor of Behavioral Biology, Johns Hopkins University.
Robert E. Cooke, M.D., President, Medical College of Pennsylvania.
Dorothy I. Height, President, National Council of Negro Women, Inc.

Albert R. Jonsen, Ph.D., Associate Professor of Bioethics, University of California at San Francisco.

Patricia King, J.D., Associate Professor of Law, Georgetown University Law Center.

Karen Lebacqz, Ph.D., Associate Professor of Christian Ethics, Pacific School of Religion.

**** David W. Louisell, J.D., Professor of Law, University of California at Berkeley.*

Donald W. Seldin, M.D., Professor and Chairman, Department of Internal Medicine, University of Texas at Dallas.

****Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania.*

**** Robert H. Turtle, LL.B., Attorney, VomBaur, Coburn, Simmons & Turtle, Washington, D.C.*

**** Deceased.*

Ethical Principles & Guidelines for Research Involving Human Subjects

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes(1) intended to assure that research involving human subjects would be carried out in an ethical manner. The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

Part A: Boundaries Between Practice & Research

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not carefully defined.

For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals.(2) By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to the general base of human knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project. (3) Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Part B: Basic Ethical Principles

The expression "basic ethical principles" refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice.

1. Respect for Persons. -- Respect for persons incorporates at least two ethical convictions: first, that 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 of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. Beneficence. -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children -- even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. Justice. -- Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are **(1)** to each person an equal share, **(2)** to each person according to individual need, **(3)** to each person according to individual effort, **(4)** to each person according to societal contribution, and **(5)** to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available. Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

The Nuremberg Code

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.
7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Reprinted from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Vol. 2, pp. 181-182.. Washington, D.C.: U.S. Government Printing Office, 1949.

The Declaration of Helsinki

Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, and the 35th World Medical Assembly, Venice, Italy, October 1983.

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration, "and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient. "

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects. In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the law of their own countries.

I. Basic Principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who isn't engaged in the investigation and who is completely independent of this official relationship.
11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.
12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present declaration are complied with.

II. Medical Research Combined with Professional Care (Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
3. In any medical study, every patient- including those of a control group, if any- should be assured of the best proven diagnostic and therapeutic method.
4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).
6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.

2. The subjects should be volunteers- either healthy persons or patients for whom the experimental design is not related to the patient's illness.
 3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.
 4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.
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Cite as:

World Medical Organization. Declaration of Helsinki. *British Medical Journal* (7 December) 1996;313(7070):1448-1449.

