IRB Boards and Qualitative Research:

Insider Guidance for IRB Forms, Informed Consent

Presented By: Jo Anne Schneider, PhD

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IRB Boards and Qualitative Research: Insider Guidance for IRB Forms, Informed Consent

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Webinar Goals

- Provide an overview of the IRB process for qualitative studies
- Clarify when a qualitative project is exempt or eligible for expedited review
- Outline strategies to write a successful IRB application
- Discuss various forms of informed consent for qualitative methods and ways to present them in an IRB application

Example Projects

- Faith and Organizations Project (www.faithandorganizations.umd.edu): Multi-project study of relationship of faith based organizations to their communities, sectors and people they served
  - Participant observation in organizations
  - Key informant interviews
  - Informal interviews with participants
  - Semi-structured survey
- Disability projects:
  - Qualitative interview study of IDD interviewers
  - Semi-structured interviews of adults with IDD

Qualitative Methods

- Participant observation
- Depth or life history interviews
- Key informant interviews
- Focus groups
- Document analysis
  - Organizational materials
  - Budget data
  - Historical data (board minutes, newspaper articles, etc.)

Key References

- Emerson, Robert, Fretz, Rachel, Shaw, Linda. (1995). *Writing Ethnographic Fieldnotes.* University of Chicago Press.
- LeCompte, Magaret and Jean Schensul. (1999) *Designing and Conducting Ethnographic Research.* Ethnographers Toolkit. Walnut Creek, CA: Altamira Press.
- McCracken, Grant (1988) *The Long Interview*. Qualitative Research Methods Series Volume 13. Thousand Oaks, CA: Sage

Key IRB Definitions

- ***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 the individual can reasonably expect will not be made public Private information must be individually identifiable …to constitute research involving human subjects.
- ***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Exempt Categories

- Research on organizations, not individuals
- Research in schools or other educational settings (including special ed) or evaluations of curricula, educational tests or other educational interventions
- Research using data already collected by others if sources publically available or subjects de-identified
- Research on public benefit programs
- Food taste and quality evaluations (as long as food doesn't contain harmful substances)

Expedited Categories

- Some or all of the research methods are found by the reviewer(s) to involve no more than minimal risk,
- Minor changes in previously approved research during the period (of one year or less) for which approval is needed.

Full Review Required

- Doing research on specially protected populations (children, pregnant women, adults with mental incapacity, incarcerated or institutionalized populations)
- Doing some form of experiment or intervention on special populations
- Asking details about personal experience that may trigger mental health issues (severe trauma, abuse, torture, etc.)

Questions to Determine Appropriate Level of Review

- Does my study fit one of the exempt categories?
- If studying an organization, am I gathering information from individuals that may be confidential and cause them harm if it got out?
- Am I adequately protecting confidentiality?
- Is this study a minimal risk for the people participating in it?

Informed Consent

- Insuring that participants know:
  - They are voluntary participants in a study
  - Their privacy will be maintained
  - How you plan to carry out your research
  - Why you are doing this project
  - How the information you gather will be used

Elements of Informed Consent

- Five points on previous slide
- Information on who to contact for additional information on the study
- Information on who to contact if the participant has concerns about how the research is being conducted (usually a center director or sponsored research official)

Types of Informed Consent

- Project Information Sheet (only for organization focused studies or participant observation studies)
- Verbal consent
- Written consent forms

Exemption Applications

- Description of project and its impact on human subjects
  - Explain why you think project is exempt
- Project benefits
  - Explain why you think project qualifies as minimal risks and benefits exceed risk
- Informed consent
  - Explain, justify and give examples of ways you plan to obtain informed consent
- Measures to protect human subjects
  - Data protection procedures

Expedited Applications

- Covers same general topics as exempt form
- Key involves describing research methods in sufficient detail to assure no harm to subjects
- Must include examples of informed consent forms and justification of forms

Additional Questions?

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IRB Boards and Qualitative Research:

Bonus Handouts #1
Relevant Federal IRB Regulations

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Subpart A	Basic HHS Policy for Protection of Human Research Subjects
	Authority: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b).
	Source: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102, must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

EXEMPTION CATEGORIES

(b) **Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:**

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

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(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 paragraph (b)(2) 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 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.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the

substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[1] Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

KEY DEFINITIONS

§46.102 Definitions.

(a) *Department or agency head* 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.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *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 the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) *Certification* means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

EXPEDITED REVIEW

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

KEY CRITERIA FOR IRB APPROVAL

§46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

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

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not

participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

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

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

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

INFORMED CONSENT

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) 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;

(7) 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; and

(8) 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.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) 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; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for

research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§46.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

IRB Boards and Qualitative Research:

Bonus Handouts #2
Informed Consent

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http://scpp.ubalt.edu/~faithandcommunities

Maintaining Vital Connections Between Faith Communities and Their Organizations: Brief Summary

The Faith and Organizations project has received funding from the Lilly Endowment to assist faith communities in maintaining connections to the non-profits they create. We seek faith communities and organizations to participate in the project. Participation would involve hosting a researcher who would 1) develop a history of the faith community's social welfare, health, senior services and education activities through non-profits, 2) interview key people involved with stewardship of organizations, and 3) observe meetings and events associated with faith community connections to their organizations. We are seeking congregations, higher level religious institutions (Yearly Meetings, archdiocese, synods, conferences, Federations), and faith based organizations to participate in the project. Organizations can also participate in a second phase of the project that would involve testing a self-assessment instrument on stewardship and a small number of interviews and focus groups. For more information, contact Jo Anne Schneider at jschneider@ubalt.edu or 410.837.6145 or see the project website at: http://scpp.ubalt.edu/~faithandcommunities

Background: Scholars of social welfare in the United States have long recognized that much of the U.S. social welfare and health systems was founded by faith communities and religions also played a key role in education. Faith communities continue to have ties to the organizations they founded today, as well as starting new initiatives. However, in some cases the relationship between founding faith communities and organizations have become attenuated or unclear. Despite faith community interest in strengthening the connection between faith and works for religious institutions, few studies have focused on faith community connections to the non-profits they create.

The Faith and Organizations project was created in order to remedy this situation by providing concrete data on the relationship between faith communities and their organizations as well as practical guidance and tools based on this research. The project is unique because it explores the role of specific religion's and denominations' theology and religious culture in service activities, providing concrete products specific both to that religion as well as more general theologically grounded materials. To date, the project has completed a pilot study: home.gwu.edu/~jschneid). This new project continues work on this issue from the perspective of faith communities by exploring ways that practical theology plays out in stewardship of non-profits created by mainline Protestants, Evangelicals, Peace Churches, Catholics, Jews, and African American Christians.

We define stewardship as *the faith community's effort to maintain its practical theology of justice and charity in the activities of the non-profits affiliated with that religion or denomination*. Practical theology means the every day actions that carry out that faith's beliefs regarding justice, charity and social equity. This projects' primary goals

knowledge
that works

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involve 1)documenting ways that faith communities maintain connections to their organizations and 2) providing practical advice on ways to strengthen stewardship or discern appropriate actions regarding organizations no longer practicing the practical theology of that religion. The project explores three questions:

1.How do faith communities understand their practical theology, regarding work in the world, and how does that practical theology play out in stewardship of organizations?

2.How does stewardship differ among the various branches of Christianity (mainline Protestants, Evangelicals, Peace Churches, Catholics, African American churches) and Jews?

3.What strategies can a faith community use to address concerns regarding the faith base in organizations under its care or affiliated with that religion?

Products: As a research/practice project, this study will produce a combination of applied products for faith communities and organization boards as well as academic and practitioner publications. An advisory committee drawn from hosting faith communities and faith based organizations, the Faith and Organizations Project advisory committee, and dissemination partners will be developed early in the project and meet regularly during the research project to discuss preliminary findings and determine specific products from the project. Products may include a mix of, but are not limited to: 1) a formal report on the study, 2) one dissemination event on the project as a whole, 3) a self assessment instrument for faith communities and organizations on stewardship, 4) a series of brief publications and factsheets with best practices and guidelines for stewardship for faith community members and organizations, 5) webinar and/or seminar curricula on stewardship for specific audiences, 6) one book for practitioners and several applied articles, 7) brief video educational materials, 8) academic articles and presentations.

Informed Consent Examples
Qualitative IRB Webinar
Principal Investigators Association
Jo Anne Schneider, December 2012

Verbal Consent (Maryland Quality of Life Survey)

I am calling to ask you to complete the Maryland Quality of Life survey. You have been chosen to be interviewed to answer questions about _____ who receives services funded under the Maryland Developmental Disabilities Administration. You will have a chance to share what you think about the services _____ receives and provide information that will help us monitor and improve services and supports for people with developmental disabilities. Nothing you say will change _____'s service at all. All answers are kept private. Your participation in the survey is voluntary. There will not be any changes in _____'s services if you decide not to participate. You can stop the survey at any time and you may skip any question.

"If you agree to participate, may I continue?"

Written Consent to Contact and Participate in Interview Study (Ask Me! Peer Interview Study)

Consent for the Survey of Former Ask Me! Interviewers

[Research company] is doing a survey about being an interviewer and how that may have affected my life. I know that I do not have to do the survey, but I want to tell what a job as an interviewer meant to me.

I understand that [Research Company] will be the only one to know that I did the survey, and they will not anyone else. I understand that all of my answers will be voluntary and confidential. Only [Research Company] will know what I say. They will only tell how many interviewers said one thing, and how many said another. I understand that what I say will not affect any job or service I have. What say will also not give me any direct benefit, but it might help future interviewers in Maryland and other places.

I know I can call (research organization executive director) at (phone number) if I have any questions. I voluntary give [Research Company] my name and how I want them to contact me.
__ Call me to set up a face-to-face interview;
__ Call me to interview me by telephone;
__ Email me the URL address so I can click on it and do the Web survey on the Internet.

Signed:
Printed name:
Date:
Telephone number:
Best days to call:
Best time of day to call:
OR
Email address:

http://scpp.ubalt.edu/~faithandcommunities

Consent Form, Phase II, Faith and Organizations Project

Thank you for agreeing on behalf of (insert agency or faith community name here) to participate in Phase II of the Faith and Organizations Project study Maintaining Vital Connections Between Faith Communities and Their Organizations. As outlined on the enclosed summary of the project, the study is designed to assist faith communities and the organizations they create to better understand their relationship in order to develop practical assistance for both founding faith communities and agencies. Additional information is available at http://scpp.ubalt.edu/~faithandcommunities.

Phase II of the project is designed to develop a self-assessment instrument for organizations and faith communities in order to help them understand and potentially improve their relationship. This part of the research follows on a more comprehensive study of organizations that has contributed to creation of the self-assessment and other materials from the project. Organizations that participated in phase one are also participating in Phase II. For organizations just joining the study now, participation will include: 1) interviews with one or two key leaders of your organization and founding faith community; 2) completion of the self-assessment instrument with the assistance of a trained researcher, 3) participation in a focus group regarding the process of filling out the self-assessment instrument in order to help us refine this tool, and 4) a focus group of selected people at your agency and faith community about some other questions related to the project. Agencies and faith communities that participated in phase I will not be asked to do the initial key leader interviews as they have already completed this part of the study.

Participation in the study is voluntary and all information gathered is confidential. (Researcher name) will be your primary contact for the study. S/he can be reached at (phone/email). S/he will work with your agency to determine which individuals should participate in the various parts of the study, determine the best time and place for focus groups, interviews, and discussion of the self-assessment instrument, and otherwise facilitate your participation in the study. All activities associated with the study will be conducted at a time and place convenient to you and your agency/faith community participants.

If you have any other question about the study, please contact the principal investigator, Dr. Jo Anne Schneider, at jschneid@ubalt.edu. The study is hosted by the University of Baltimore. Any questions and concerns regarding confidentiality or the research process that can not be addressed by the PI should be addressed to:

Margarita M. Cardona, MS, CRA
Director of Sponsored Research
University of Baltimore
Office of the Provost
1420 N. Charles St.
Baltimore, MD 21201
(ph) 410-837-6191
(fx) 410-837-5249
mcardona@ubalt.edu

knowledge
that works

Schaefer Center
For Public Policy

University of Baltimore
School of Public Affairs
1420 N. Charles St.
Baltimore, MD 21201

T: 410.837.6188
F: 410.837.6175
http://scpp.ubalt.edu

The project staff hopes to work with you, your organization, and your faith community in completion of this project and development of practical tools and other materials to share its findings. Agency and faith community representatives will be invited to at least one meeting in the spring to share outcomes and we hope to work closely with you to make participation in the project the best possible experience for you.

_____ _____

Agency or Faith Community Head Date

Jo Anne Schneider

11/11/08

Date Principal Investigator Date

Principal Investigator Date

IRB Boards and Qualitative Research:

Bonus Handouts #3
IRB Examples

Presented By: Jo Anne Schneider, PhD

Provided By:

Principal Investigators Association™

Principal Investigators Association

9990 Coconut Road, Ste 316
Bonita Springs, FL 34135
800-303-0129
www.principalinvestigators.org

Geralyn McGovern

From: Merrill Pritchett

Sent: Wednesday, January 23, 2008 9:20 AM

To: JoAnne Schneider; Geralyn McGovern

Professor Schneider,

I behalf of the University of Baltimore IRB have reviewed you research project Maintaining Vital Connections Between Faith Communities and Their Organizations. As this project does not involve human subjects it falls into the exempt category for IRB.

Merrill Pritchett
Institutional Research
University of Baltimore
mpritchett@ubalt.edu

UNIVERSITY OF BALTIMORE

Application for Approval of Research Involving Human Subjects

Faculty Research Project

This form is to be completed by the investigator who will submit it to the committee for Protection of Human Subjects. When the IRB has approved the application, the chair will sign it.

1. Researcher(s):

Jo Anne Schneider	Schaefer Center	6145
Faculty	**Department**	**Phone#**
Faculty	**Department**	**Phone#**

2. Title: Maintaining Vital Connections Between Faith Communities and Their Organizations

3. Proposed Agency Sponsor: Funder Lilly Endowment, no agency sponsor

4. Describe risks or discomfiture to human subjects:
This study examines the relationship between religious bodies (congregations, archdiocese, federations, etc.) and non-profit organizations founded by those religions. This 18 month study, plus 6 months of dissemination activities, is the next phase of the Faith and Organizations project, a national project examining the relationship between faith communities and their organizations (see home.gwu.edu/~jschneid).

As a study of organizations, it does not involve human subjects, nor does the research discuss the activities of individuals in any way. Research methods include participant observation of organization events and meetings, interviews with key leaders regarding organization activity, analysis of historical documents, and focus groups regarding the same issues. Interviews with individuals discuss the policies and practices of organizations, with no reference to the activities of individuals. The study collects public information on agency policies and history, with no reference to any activity that would be considered private. As such, the project does not involve human subjects and falls into the exempt category for IRB. The pilot study for the project, conducted under the auspices of Catholic University of America in 2004-2005, was considered exempt by that institution's IRB review committee.

5. Describe potential benefits:

The project helps faith communities maintain their founding religious values in their organizations, as well as describes best practices to maintain connections between non-profit and its founding religion. Benefits are to the organizations, not individuals.

Application for Approval of Research Involving Human Subjects
Page Two

6. Describe Informed Consent Procedures: (Attach Informed Consent statement)

The project obtains permission from organizations to participate in the study. The form of permission varies depending on the organization from oral agreement to a formal MOU regarding research activities and agency rights to review products for public dissemination. The project has produced an information sheet (see attached) that describes its purposes and the research methods. Interviews with individuals obtain oral consent on tape at the beginning of the interview, giving the interviewee the option that their material be considered confidential. Material is generally not quoted for attribution and is used to create an aggregate portrait of mechanisms to maintain a relationship between organizations and founding religion. The subject of interviews is the organization, not the individual, which is made clear at the beginning of the interview.

7. Describe any additional procedures for protecting the rights of human subjects:

NA, no human subjects

NOTE: Additions or changes in procedures involving human subjects after the proposal has been approved must be brought to the attention of the Committee.

I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human subjects are properly protected

Student Signature _____ **Date** _____

Faculty Signature Jo Anne Schneider **Date** 1/18/2008

We are familiar with and approve of the procedures that involve human subjects in this project.

_____ 1/22/08
Chair, IRB Committee **Date**

_____
Dean **Date**

UNIVERSITY OF MARYLAND, COLLEGE PARK
Institutional Review Board
Initial Application for Research Involving Human Subjects

Name of Principal Investigator (PI) or Project Faculty Advisor *(NOT a student or fellow)* Jo Anne Schneider **Tel. No** 410-747-2644

Name of Co-Investigator (Co-PI) _____ **Tel. No** _____

E-Mail Address of PI jschneid@gwu.edu (UMCP email pending) **E-Mail Address of Co-PI** _____

Name and address of contact to receive approval documents Jo Anne Schneider(campus address pending)/Sybil Paige,Anthro Dept, 1111 Woods Hall

Name of Student Investigator _____ **Tel. No.** _____

E-Mail Address of Student Investigator @

Check here if this is a student master's thesis ☐ or a dissertation research project ☐

Department or Unit Administering the Project Anthropology

Project Title ____ Maintaining Vital Connections Between Faith Communities and Their Organizations

Funding Agency: Lilly Endowment

ORAA Proposal ID Number:

Names of any additional Federal agencies providing funds or other support for this research project: None

Target Population: The study population will include (Check all that apply):

- ☐ pregnant women
- ☐ minors/children
- ☐ human fetuses
- ☐ neonates
- ☐ prisoners
- ☐ students
- ☐ individuals with mental disabilities
- ☐ individuals with physical disabilities

Exempt or Nonexempt (Optional): You may recommend your research for exemption or nonexemption by checking the appropriate box below. For exempt recommendation, list the numbers for the exempt category(s) that apply. Refer to pages 6-7 of this document.

☒ **Exempt----List Exemption Category(s)** ***Or*** ☐ **Non-Exempt**

If exempt, briefly describe the reason(s) for exemption.

This is a study of organizations, not individuals

6/22/09 Jo Anne Schneider

Date **Signature of Principal Investigator or Faculty Advisor**

Date **Signature of Co-Principal Investigator**

Date **Signature of Student Investigator**

Date **REQUIRED** Departmental Signature
Name _____, **Title**_____
(Please also print name of person signing above)

(PLEASE NOTE: The Departmental signature block should not be signed by the investigator or the student investigator's advisor.)

For Internal Use Only (to be completed by the IRB Office) Application #:

Instructions for Completing the Application

The Departmental Signature block should be signed by the IRB Liaison or Alternate IRB Liaison unless there is a conflict of interest. If the Department or Unit does not have an IRB Liaison, the Department Head, Unit Head or Designee should sign the application.

Please provide the following information in a way that will be intelligible to non-specialists in your specific subject area.

1. **Abstract:** Provide an abstract (no more than 200 words) that describes the purpose of this research and summarizes the strategies used to protect human subjects. For HHS sponsored or funded research, you must submit a copy of your grant application for review.

2. **Subject Selection:**

   a. Who will be the subjects? How will you recruit them? If you plan to advertise for subjects, please include a copy of the advertisement.

   b. Will the subjects be selected for any specific characteristics (e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications)?

   c. State why the selection will be made on the basis or bases given in 2(b).

   d. How many subjects will you recruit?

3. **Procedures:** What precisely will be done to the subjects? Describe in detail your methods and procedures in terms of what will be done to subjects. How many subjects are being recruited? What is the total investment of time of the subjects? If subjects will complete surveys and/or other instruments on more than one occasion, state this in the procedures section. If you are using a questionnaire or handout, please include a copy within each set of application documents. If you are conducting a focus group, include a list of the questions for the focus group. If you plan to collect or study existing data, documents, records, pathological specimens or diagnostic specimens, state whether the sources are publicly available and if the information will be recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. If you are collecting or studying existing data, describe the dataset and list the data elements that you will extract from the dataset.

4. **Risks and Benefits:** Are there any risks to the subjects? If so, what are these risks including physical, psychological, social, legal and financial risks? Please do not describe the risk(s) as minimal. If there are known risks, please list them. If not, please state that there are no known risks. What are the benefits? If there are known risks associated with the subject's participation in the research, what potential benefits will accrue to justify taking these risks?

5. **Confidentiality:** Adequate provisions must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information. Explain how your procedures accomplish this objective, including such information as the means of data storage, data location and duration, description of persons with access to the data, and the method of destroying the data when completed. If the research involves audio taping, videotaping or digital recordings, state who will have access to the tapes or recordings, where the tapes or recordings will be kept, and state the final disposition of the tapes or recordings (i.e. Will the tapes or recordings be destroyed? If so, when will the tapes or recordings be destroyed?). Please note that as per the University of Maryland policy on records retention and disposal, all human subject files, including work done by faculty, staff, and students, must be retained for a period of no less than 10 years after the completion of the research and can then be destroyed. Human subject files include IRB applications, approval notices, consent forms, and other related documents. For more information on records retention, go to: http://www.dbs.umd.edu/records_forms/schedule.php (Faculty and Academic Records) or contact Michelle Solter Evers, Assistant to the Director of Business Services at 301.405.9277 or mevers@mercury.umd.edu.
6. **Information and Consent Forms:** State specifically what information will be provided to the subjects about the investigation. Is any of this information deceptive? State how the subjects' informed consent will be obtained. Will you obtain informed consent in a language other than English? If so, list the language(s) in which you will obtain informed consent. Provide consent forms in all languages that will be used. Refer to the attached consent form template, sample consent form and additional consent form guidance on pages 9 to 18. If a consent form has more than one page, please add a signature and date line and the number of pages (*e.g.*, "1 of 2," "2 of 2") to each page. Please allow a 2-inch bottom margin to accommodate the IRB approval stamp. If you plan to obtain consent over the telephone (e.g. consent for a telephone survey), include a copy of the consent script.
7. **Conflict of Interest:** Describe the potential conflict of interest, including how such a conflict would affect the level of risk to the study participants. Please consult the University of Maryland policy on conflict of interest as defined by the University of Maryland Policies and Procedures III-1.11and II-3.10. These may be viewed at: http://www.usmh.usmd.edu/Leadership/BoardOfRegents/Bylaws/SectionIII/III111.html. If there is no anticipated conflict of interest, please state "No conflict of interest." This section must be included in your application.
8. **HIPAA Compliance:** State whether you are using HIPAA protected health information (PHI). Currently, researchers employed by the University of Maryland Center or who are working within or under the auspices of the University Health Center are subject to specific HIPAA requirements regarding the creation, use, disclosure, or access of PHI. Please consult the University of Maryland's Summary of HIPAA's Impact on University Research. For more information on HIPAA, go to: http://www.hhs.gov/ocr/hipaa/ If you are not using HIPAA protected health information, please state "Not Applicable." This section must be included in your application.

9. Research Outside of the United States: Provide responses to the following questions. Separate responses are required for each country where the research will be conducted. If you are not conducting research outside the U.S., please state "Not Applicable." This section must be included in your application.

a) Did the investigator(s) previously conduct research in the country where the research will take place? Briefly describe the investigator's knowledge and experience working with the study population.

b) Are there any regulations, rules or policies for human subjects research in the country where the research will take place? If so, please describe and explain how you will comply with the local human subject protection requirements. The United States Department of Health and Human Services, Office for Human Research Protections (OHRP) has an International Compilation of Human Subject Research Protections with a listing of the laws, regulations and guidelines of over 50 countries. This compilation can be accessed on the OHRP website: http://www.hhs.gov/ohrp/international/HSPCompilation.pdf

c) Do you anticipate any risks to the research participants in the country where the research will take place, taking into account the population involved, the geographic location, and the culture? If so, please describe, including any physical, psychological, social, legal and financial risks. Do you anticipate that subjects who participate in this research will be placed at risk of criminal or civil liability? If so, please describe.

10. Research Involving Prisoners: Provide responses to the following additional IRB criteria for research involving prisoners. If you are not conducting research involving prisoners, please state "Not Applicable." This section must be included in your application.

a) the research under review represents one of the categories of research permissible described below;

i. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

ii. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

iii. research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or

iv. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

b) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

c) the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
d) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
e) the information is presented in language which is understandable to the subject population;
f) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
g) if there is a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

SUPPORTING DOCUMENTS

Each copy of the application must include the IRB application cover sheet, the information required in items 1-10 above, and all relevant supporting documents including: consent forms, letters sent to recruit participants, questionnaires completed by participants, and any other material germane to human subjects review.

For research funded by the Department of Health and Human Services (DHHS), submit a copy of your HHS grant application. If there are discrepancies between the research proposed in your IRB application and your grant application, include a memo listing these discrepancies and the rationale for them.

NUMBER OF COPIES

Please send 1 original application including the signed cover sheet and 1 copy of the signed, original application unless your research requires full Board Review. For applications which will require review of the full Board, please submit 1 signed original application and seventeen (17) copies. Full Board reviews are required for initial applications involving greater than minimal risk to the subjects (i.e. more risk than subjects would generally encounter in their routine daily activities).
IRB Campus Mailing Address: 2100 Lee Building, Zip -5125.

IRB MEETING DATES AND APPLICATION SUBMISSION DEADLINES

To view the dates for upcoming meetings and the final date for submission of applications to be considered for each meeting, please check the following URL: http://www.umresearch.umd.edu/IRB/IRBdates.html.

STATUS OF THE IRB APPLICATION

You may send an e-mail to irb@umd.edu or call the IRB Office at 301-405-4212 to inquire about the status of an IRB application.

EXEMPTION CATEGORIES

(PLEASE NOTE: Exempt research must be approved by the IRB Manager, Assistant Manager or an IRB Co-Chair before data collection may begin.)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods. **Research involving surveys or interviews with children does not qualify for exempt review. Also, this exempt category does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of 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.**

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subject's 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. **Exemption category #2 does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed. Also, this exempt category does not apply to research involving the collection of person identifiable data in which any disclosure of the data outside of 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. 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 paragraph (2) if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. **E.g. the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g and the research conducted for the National Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.**

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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

If the research is funded by the United States Department of Health and Human Services, the following criteria must be met:

- **a) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).**
- **b) The research or demonstration project must be conducted pursuant to specific federal statutory authority.**
- **c) There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).**

The project must not involve significant physical invasions or intrusions upon the privacy of participants.

6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed or (b) 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 U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

NOTE: The 6 exemption categories do not apply to research involving prisoners.

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Initials _____ Date _____

CONSENT FORM

[Instructions: Please use this template to prepare your consent form. Bolded, italicized text found throughout this document offers guidance and suggestions. Replace this text with the appropriate wording for your project.]

Project Title	***[This title should be the same as the project title used in the IRB application.]***
Why is this research being done?	*This is a research project being conducted by _____ at the University of Maryland, College Park. We are inviting you to participate in this research project because you _____.* ***[describe why the person reading the consent form is a possible research subject for your project]*** *The purpose of this research project is _____.* ***[describe the knowledge or information that is being sought and explain why you are seeking the knowledge or information]***
What will I be asked to do?	*The procedures involve __.* ***[Describe the procedure(s) chronologically using lay language and short sentences. State the location where the study will be conducted. Explain medical and other technical terminology using simple language. State the overall duration for the subject's participation and, if appropriate, how long each procedure will take. If the research involves surveys or interviews, include a detailed description of the questions. Identify experimental procedures. Describe alternative procedures or courses of treatment, if any that might be advantageous to the subject.]***

Project Title	***[This title should be the same as the project title used in the IRB application.]***
What about confidentiality?	*We will do our best to keep your personal information confidential. To help protect your confidentiality, _____* ***[Include a description of the procedures to maintain the confidentiality of the data, e.g. having locked filing cabinets and storage areas, using identification codes only on data forms, and using password-protected computer files. For anonymous surveys, state that "the surveys are anonymous and will not contain information that may personally identify you". For coded identifiable information, state the following, if applicable (1) your name will not be included on the surveys and other collected data; (2) a code will be placed on the survey and other collected data; (3) through the use of an identification key, the researcher will be able to link your survey to your identity; and (4) only the researcher will have access to the identification key.]*** *If we write a report or article about this research project, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law.* ***[If there is a possibility that you will collect information on child abuse or neglect, abuse or neglect of the developmentally disabled or other vulnerable adults, danger to the subject or others, or similar types of information that may need to be disclosed to comply with legal requirements, professional standards, etc., the possibility of such disclosure must be included in the consent form. Use the following example, and modify it to include all applicable types of information. If there is a possibility that you will collect such information, but you do not intend to disclose it, you must provide an explanation and any justification for non-disclosure in your IRB Application. If you have a Certificate of Confidentiality, refer to the Appendix.]*** *In accordance with legal requirements and/or professional standards, we will disclose to the appropriate individuals and/or authorities information that comes to our attention concerning child abuse or neglect or potential harm to you or others.*

What are the risks of this research?	*There may be some risks from participating in this research study* ***[Describe any known risks including physical, psychological, social, emotional, legal and financial risks that may result from participating in the research. Some studies include risks that may be better described as things that could make the subject feel uncomfortable such as fear, embarrassment or fatigue. These are also examples of risks that should be included. If you will be asking the subject any sensitive questions (e.g. drug abuse, criminal activity), please indicate this and provide information on the topics that will be covered. Do not describe risks as minimal and do not state that there are no risks beyond everyday life. Risks should be consistent with the risks described in the protocol. If applicable include a statement that the research (or a particular procedure) may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant) that are currently unforseeable. OR if applicable, state the following:*** *There are no known risks associated with participating in this research project.*
What are the benefits of this research?	*The benefits to you include* ***[only list the direct and reasonably expected benefits to the subject. Monetary compensation and extra credit for courses are not benefits and should be described in the procedures section]*** *_____* ***or*** *This research is not designed to help you personally, but the results may help the investigator learn more about _____. We hope that, in the future, other people might benefit from this study through improved understanding of ___.* ***Describe the anticipated benefits to science or society expected from the research, if any.***
Do I have to be in this research? May I stop participating at any time?	*Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.* ***[If applicable, include an explanation of any circumstances under which a subject's participation may be terminated by the investigator without regard to the subject's consent. If applicable, include an explanation of the consequences of a subject's decision to withdraw from the research and any procedures for orderly termination of a subject's participation.]***
Is any medical treatment available if I am injured?	***[Include this section for research involving more than minimal risk]*** *The University of Maryland does not provide any medical, hospitalization or other insurance for participants in this research study, nor will the University of Maryland provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law.*

What if I have questions?	*This research is being conducted by **[Principal Investigator's name and department]** at the University of Maryland, College Park. If you have any questions about the research study itself, please contact _____ **[Principal Investigator's name]** at: _____ _____ [**Address, telephone number, and (if appropriate) e-mail address of principal investigator.]*** *If you have questions about your rights as a research subject or wish to report a research-related injury, please contact:* **Institutional Review Board Office, University of Maryland, College Park, Maryland, 20742; (e-mail) irb@deans.umd.edu; (telephone) 301-405-0678** *This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.*	
Statement of Age of Subject and Consent	*Your signature indicates that:* *you are at least 18 years of age;,* *the research has been explained to you;* *your questions have been fully answered; and* *you freely and voluntarily choose to participate in this research project.*	
Signature and Date	**NAME OF SUBJECT**	
	SIGNATURE OF SUBJECT	
	DATE	

*******Please note: When the consent form requires more than one page, please include a space for the subject to initial and date at the top right-hand corner of each page. The corner should appear as: Initials_____ Date_____***
Also, each page must display a page range such as: Page 1 of 2, then Page 2 of 2. This additional information would confirm that the subject agreed to the entire contents of the consent form. ****

(SAMPLE)

Page 1 of 3
Initials _____ Date _____

CONSENT FORM

Project Title	*Prolonged Sleep Loss*
Why is this research being done?	*This is a research project being conducted by John Doe at the University of Maryland, College Park. We are inviting you to participate in this research because you are at least 18 years of age and you are not currently experiencing any sleep loss problems. The purpose of this research is to measure the effects of prolonged sleep loss.*
What will I be asked to do?	*The procedures involve three sessions, four weeks apart, during which you will be asked to go without sleep for periods of 24 to 48 hours. The total time for your participation will be 72 to 144 hours. At various times during the sleepless period, you will be asked to perform simple tasks and to respond to sound by pushing a button. The research will take place at the Sleep Lab at the University of Maryland, College Park.*
What about confidentiality?	*We will do our best to keep your personal information confidential. To help protect your confidentiality: (1) your name will not be included on the surveys or other collected data; (2) a code will be placed on the survey and other collected data; (3) through the use of an identification key, the researcher will be able to link your survey to your identity; and (4) only the researcher will have access to the identification key. If we write a report or article about this research project, your identity will be protected to the maximum extent possible.* *Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law.*
What are the risks of this research?	*There are some risks from participating in this research study. As a result of sleeplessness, you may experience extreme tiredness and sleep disturbances over a short period of time. There are risks associated with driving while tired. Therefore, you should not drive while tired and you must make arrangements for someone to pick you up after each session. Normally, there are no long-term effects associated with the periods of sleeplessness involved in this experiment.*

Page 2 of 3
Initials _____ Date _____

Project Title	*Prolonged Sleep Loss*
What are the benefits of this research?	*This research is not designed to help you personally, but the results may help the investigator learn more about sleep loss and the ability of persons to perform tasks for the safe operation of machinery and cars. We hope that, in the future, other people might benefit from this study through improved understanding of how sleep loss affects the ability of a person to safely operate machinery and cars.*
Do I have to be in this research? **Can I stop participating at any time?**	*Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.*
Is any medical treatment available if I am injured?	*The University of Maryland does not provide any medical, hospitalization or other insurance for participants in this research study, nor will the University of Maryland provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law.*
What if I have questions?	*This research is being conducted by John Doe at the University of Maryland, College Park. If you have any questions about the research study itself, please contact John Doe at: The University of Maryland, 123 Lee Building, 301-555-1212 or johndoe123@umd.edu* *If you have questions about your rights as a research subject or wish to report a research-related injury, please contact:* **Institutional Review Board Office, University of Maryland, College Park, Maryland, 20742; (e-mail) irb@deans.umd.edu; (telephone) 301-405-0678** *This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.*
Statement of Age of Subject and Consent	*Your signature indicates that:* *you are at least 18 years of age;,* *the research has been explained to you;* *your questions have been answered; and* *you freely and voluntarily choose to participate in this research project.*

Page 3 of 3
Initials _____ Date _____

Project Title	*Prolonged Sleep Loss*	
Signature and Date	**NAME OF SUBJECT**	
	SIGNATURE OF SUBJECT	
	DATE	

******Please note: When consent form requires more than one page, please include a space for the subject to initial and date at the top right-hand corner of each page. The corner should appear as: Initials_____ Date_____**
Also, each page must display a page range such as: Page 1 of 2, then Page 2 of 2. This step would confirm that the subject agreed to the entire contents of the consent form. ****

APPENDIX
UNIVERSITY OF MARYLAND, COLLEGE PARK
CONSENT FORM TEMPLATE
ADDITIONAL GUIDANCE FOR SPECIFIC ISSUES

Informed Consent

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. Therefore, informed consent language and its documentation must be written in language that is understandable to the people being asked to participate. The University of Maryland, College Park Consent Form Template and Sample Consent Form contain the basic elements of informed consent as identified in and required by the Federal Policy for the Protection of Human Subjects, 45 CFR 46.

Research Involving Minors

For research involving individuals under the age of 18, include a Parental Permission Form to ask parents for consent to the participation of their child and an Assent Form to ask the minors if they agree to participate in the research, depending on whether the children are capable of assenting. The Parental Permission form should contain all of the elements of the sample consent form and the consent form template provided with the IRB application. However, the parental permission form should be written in language appropriate for parents granting permission for their child's involvement rather than as though they themselves will be participating (e.g. we are inviting your child to participate the risks to your child's participation include). When determining whether the children are capable of assenting, take into account the ages, maturity, and psychological state of the children involved. Assent forms should be written in age-appropriate language.

Research Involving Individuals with Impaired Decision-making Capacity

Using the Informed Consent Form Template, prepare a consent form to ask the research subject's authorized representative for consent to the participation of the research subject. Prepare an assent form to ask the research subjects if they agree to participate in the research, depending on whether the subjects are capable of assenting. When determining whether the subjects are capable of assenting, take into account the decision-making capacity of the research subjects.

SUGGESTED WORDING

Instructions: You should cut and paste these paragraphs, where applicable, into the appropriate area of the Informed Consent Form. However, the suggested wording below should be modified appropriately for the specifics of your study.

Audio taping/Videotaping/Photographs/Digital Recordings

[Include the following information in the What about confidentiality? section]
This research project involves making **[*audiotapes/videotapes/photographs*]** of you. **[Then explain why the tapes/photos are being made, who will have access to them, where they will be stored, and when (or if) they will be destroyed]**

___ I agree to be **[**videotaped/audiotaped/photographed**]** during my participation in this study.
___ I do not agree to be **[**videotaped/audiotaped/photographed**]** during my participation in this study.

Research Projects Involving Data Collection in a Classroom

[Include the following information in the Do I have to be in this research? Can I stop participating at any time? Section]

Participation is not a course requirement. You and your class members have non-research options for earning the same amount of credit **[describe the options for earning the same amount of credit. The options must not be more difficult than participation in the research.]**

Research Projects Involving Prisoners

[Include the following information in the Do I have to be in this research? Can I stop participating at any time? Section]

Your decision to participate or not participate in this research project will not affect or influence the length of your sentence, your parole, or any other aspect of your incarceration. Also, if you decide to participate and then leave the study before it is over, that will not affect or influence the length of your sentence, your parole, or any other aspect of your incarceration.

Certificate of Confidentiality

[Replace the What about confidentiality? section with the following information.] We will do our best to keep your personal information confidential. To help protect your confidentiality, _____ _____ ***[Include a description of the procedures to maintain the confidentiality of the data, e.g. having locked filing cabinets and storage areas, using identification codes only on data forms, and using password-protected computer files. For anonymous records, state those names and other identifiers will not be placed on surveys or other research data. For coded identifiable information, state the following, if applicable (1) your name will not be included on the surveys and other collected data; (2) a code will be placed on the survey and other collected data; (3) through the use of an identification key, the researcher will be able to link your survey to your identity; and (4) only the researcher will have access to the identification key.]*** If we write a report or article about this research project, your identity will be protected to the maximum extent possible.

To help us further protect your privacy, we have obtained a Certificate of Confidentiality from _____ **[Name of agency issuing the Certificate of Confidentiality]**. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding. We may, however, release identifying information in some circumstances. For example, the Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should also understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality also does not prevent the researchers from voluntarily disclosing identifying information, and the researchers may notify appropriate individuals and/or authorities if information comes to their attention concerning child abuse or neglect or potential harm to you or others. **[Modify as needed to include any other conditions under which disclosure would be made (e.g., abuse or neglect of the developmentally disabled or vulnerable adults, reportable communicable diseases, etc.). If no such disclosures will be made, the researchers should provide an explanation in the IRB Application.]**

Rev. Oct. 6, 2008

University of Maryland, College Park
Institutional Review Board
Request for Determination of Non-Human Subject or Non-Research
(Adapted from Vanderbilt University IRB)

1. **Principal Investigator's Name, Email-Address, Telephone Number and Mailing Address** (Please note that a student cannot serve as a Principal Investigator)
__Jo Anne Schneider (UMCP contact information pending, c/o Anthropology department, UMCP 1111 Woods Hall), jschneid@gwu.edu, 410-747-2644
2. **Co-Investigator's Name, Email-Address, Telephone Number and Mailing Address**
_____
3. **Student Investigator's Name, Email-Address, Telephone Number and Mailing Address**
_____
4. **Department Name**
Anthropology_____
5. **Project Title** Maintaining Vital Connections Between Faith Communities and Their Organizations
_____
6. **ORRA Proposal Number**
_____

7. **Study Information:**

   A. **Give a brief description of the project. (**Describe the specific objectives, including background information and rationale for the proposed project. This summary should be written in a way that will be intelligible to non-specialists in your specific subject area).

This study examines the relationship between religious bodies (congregations, archdiocese, federations, etc.) and non-profit organizations founded by those religions. This 18 month study, plus 6 months of dissemination activities, is the second phase of the Faith and Organizations project, a national project examining the relationship between faith communities and their organizations (see http://scpp.ubalt.edu/~faithandcommunities/). The study focuses on faith based organizations and their founding faith communities in order to understand the various strategies that different religions use to guide organizations associated with that religion.

This IRB application covers the last two months of research activities which involve testing a self-assessment instrument with organizations in the Washington DC metropolitan area. We anticipate that only 4-10 interviews will remain to be completed when the project transfers effective July 1, 2009. Earlier research was covered under IRB approval through University of Baltimore (attached) which covers research through the point of transfer of the project to UMCP. Research is also being completed through subcontracts to partner universities in expansion sites in Chicago (IUPUI) and South Carolina (USC). Both of these institutions have received IRB

approval from their university IRB committees. The Chicago and South Carolina research should be completed by July 1, with perhaps 1 or 2 interviews remaining.

B. Describe the subject population/type of data/specimens to be studied.
(Identify who your subjects will be and indicate the type of data or specimens you will collect. Describe the methods in which the data or specimens will be collected, stored, and how confidentiality will be maintained.)

As a study of organizations, it does not involve human subjects, nor does the research discuss the activities of individuals in any way. Interviews with individuals discuss the policies and practices of organizations, with no reference to the activities of individuals. The study collects public information on agency policies and history, with no reference to any activity that would be considered private. As such, the project does not involve human subjects and falls into the exempt category for IRB. The project was classified as exempt by the IRB committee at University of Baltimore, which was its original sponsor. The pilot study for the project, conducted under the auspices of Catholic University of America in 2004-2005, was also considered exempt by that institution's IRB review committee.

The remaining organizations to be studied have been selected as matches or contrasts to organizations in the more intensive phase 1 study. They include an assisted living facility sponsored jointly by a synagogue and mainline Protestant church, two mainline Protestant social service, immigration or emergency services organizations, and an independent Jewish community development organization.

The self-assessment instrument came out of the initial ethnographic research phase of the project and is designed to serve as a planning or problem solving tool for organizations and faith communities to better understand their current relationship and supporting ties between non-profit and sponsoring faith community. Agency and faith community representatives are given copies of the self-assessment instrument appropriate for their religion in advance of the study (see attached). A researcher then schedules time for a tape recorded interview that includes 1) some general background information on the organization's history and its relationship to its founding faith, 2) going through the self-assessment instrument with the agency or faith community representative, 3) asking the agency representative for feedback on the this pilot instrument, insights on how such a self-assessment tool might be used by the agency, and suggestions on the kinds of guidelines and other supporting materials an agency might need in order to administer the instrument without a researcher assisting. In addition to the taped interviews, researchers also often collect agency annual reports and fliers, all public information.

All taped interviews are confidential, with transcriptions kept on a password protected site. Individual informants for phase two self-assessments are not identified in project documents unless they specifically ask that their name be used. Organizations are given the option to have their own names used in project documents or use a pseudonym. In situations where pseudonyms are requested, the names of any individuals affiliated with the organization are also changed in all transcriptions and other data. About 1/3rd of participating organizations have chosen to use pseudonyms.

Agencies were given a project information sheet as an introduction to the project as well as the link to the project website when recruiting them for the study. For phase 2, agencies are also asked to sign a consent form that explains the project and provides IRB information on the sponsoring university. I have enclosed the consent form given to most of the agencies already involved in the study, including a few that remain to be interviewed. We will update this form with UMCP data once contact information for project key staff has been determined.

8. Determination of "Research."

45 CFR 46.102 (d): ***Research*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

A. For existing specimens, was the data/specimen(s) obtained in a systematic manner?
□ No □ Yes X Not Applicable, research does not involve the collection of existing specimens

B. For future data collection, will the data/specimen(s) be obtained in a systematic manner?
□ No X Yes □ Not Applicable, research does not involve future data collection

C. Is the project designed to develop or contribute to generalizable knowledge?
□ No X Yes

D. Is the intent of the project to create an archive for the purpose of providing a resource for others to do research?
□**X** No □ Yes

E. For research only involving coded private information or specimens, was the private information or specimens collected specifically for the currently proposed research project through an interaction or intervention with living individuals?
□ No □ Yes X Not Applicable, research does not only involve coded private information or specimens

9. Determination of "Human Subject"

45 CFR 46.102(f):

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

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

Interaction includes communication or interpersonal contact between investigator and subject.
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 the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

A. Does the study involve intervention or interaction with a "human subject"?
□ No X Yes

B. Does the study involve access to identifiable private information?
□**X** No Yes (not for individuals, yes for organizations)

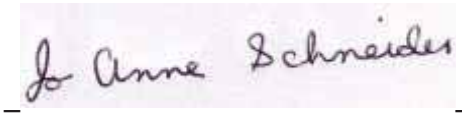
C. Are data/specimens received by the investigator with identifiable private information?
□**X** No □ Yes

D. Are the data/specimens coded such that a link exists that could allow the data/specimen(s) to be re-identified?
X□ No □ Yes

If "Yes,":
Is there a written agreement that prohibits the Principal Investigator, Co Investigator, student investigator(s), and any other members of the research team from access to the link?
□ No □ Yes

Are there other legal requirements that prohibit the release of the key to the investigators, until the subjects are deceased?
□ No □ Yes (If Yes, please explain on a separate sheet of paper.)

10. Signatures



Principal Investigator **Date** **6/22/09**

Student Investigator **Date**

1. Abstract

This study examines the relationship between religious bodies (congregations, archdiocese, federations, etc.) and non-profit organizations founded by those religions. This 18 month study, plus 6 months of dissemination activities, is the second phase of the Faith and Organizations project, a national project examining the relationship between faith communities and their organizations (see http://scpp.ubalt.edu/~faithandcommunities/). The study focuses on faith based organizations and their founding faith communities in order to understand the various strategies that different religions use to guide organizations associated with that religion.

This IRB application covers the last two months of research activities which involve testing a self-assessment instrument with organizations in the Washington DC metropolitan area. We anticipate that only 4-10 interviews will remain to be completed when the project transfers effective July 1, 2009. Earlier research was covered under IRB approval through University of Baltimore (attached) which covers research through the point of transfer of the project to UMCP. Research is also being completed through subcontracts to partner universities in expansion sites in Chicago (IUPUI) and South Carolina (USC). Both of these institutions have received IRB approval from their university IRB committees. The Chicago and South Carolina research should be completed by July 1, with perhaps 1 or 2 interviews remaining.

2. Subject selection

The subjects for the self-assessment phase of the study, and the study as a whole, are faith based non-profits and their affiliated faith communities. Human subjects are not the focus of this research. We have selected non-profits from five religions (Mainline Protestant, Catholic, Jewish, Evangelical, Quaker, African American) and four organization types (schools, health care/senior services, community development, social services). The attached organizational matrix for phase 1 provides examples of the types of organizations in the study. In most cases, the self-assessment gathers information about various aspects of the relationship between the non-profit and its founding religious body from 1) a representative of the organization (usually the agency executive director or a key board members) and 2) a representative of the founding faith community (pastor, key board member, representative of Jewish federation, archdiocese, religious order or other key leader in the founding religion). In cases where the organization is no longer sponsored by a religious community or the religious leader and non-profit heads are the same person, data is only collected from the agency head.

The remaining organizations to be studied have been selected as matches or contrasts to organizations in the more intensive phase 1 study. They include an assisted living facility sponsored jointly by a synagogue and mainline Protestant church, two mainline Protestant social service, immigration or emergency services organizations, and an independent Jewish community development organization.

3. Procedures

The self-assessment instrument came out of the initial ethnographic research phase of the project and is designed to serve as a planning or problem solving tool for organizations and faith communities to better understand their current relationship and supporting ties between non-

profit and sponsoring faith community. Agency and faith community representatives are given copies of the self-assessment instrument appropriate for their religion in advance of the study (see attached). A researcher then schedules time for a tape recorded interview that includes 1) some general background information on the organization's history and its relationship to its founding faith, 2) going through the self-assessment instrument with the agency or faith community representative, 3) asking the agency representative for feedback on the this pilot instrument, insights on how such a self-assessment tool might be used by the agency, and suggestions on the kinds of guidelines and other supporting materials an agency might need in order to administer the instrument without a researcher assisting. In addition to the taped interviews, researchers also often collect agency annual reports and fliers, all public information.

Taped interviews are used for two purposes: 1) to provide data on a larger pool of non-profits and faith community sponsors than the approximately 60 that participated in the intensive phase 1 of the study, and 2) to provide evaluation of the current pilot self-assessment instrument that will be used to create a final document and supporting materials.

4. **Risks and Benefits.**
There are no risks to human subjects as they are not the focus of this study. The project helps faith communities understand their founding religious values in their organizations, as well as describes best practices to maintain connections between non-profit and its founding religion. Benefits are to the organizations, not individuals. We have found that the self-assessment has been most helpful to organizations that have experienced some tensions with their founding community as the instrument provides an opportunity to reflect in a structured way on that relationship.

5. **Confidentiality.**
All taped interviews are confidential, with transcriptions kept on a password protected site. Individual informants for phase two self-assessments are not identified in project documents unless they specifically ask that their name be used. Organizations are given the option to have their own names used in project documents or use a pseudonym. In situations where pseudonyms are requested, the names of any individuals affiliated with the organization are also changed in all transcriptions and other data. About 1/3rd of participating organizations have chosen to use pseudonyms.

6. **Information and Consent forms.**
Agencies were given a project information sheet as an introduction to the project as well as the link to the project website when recruiting them for the study. For phase 2, agencies are also asked to sign a consent form that explains the project and provides IRB information on the sponsoring university. I have enclosed the consent form given to most of the agencies already involved in the study, including a few that remain to be interviewed. We will update this form with UMCP data once contact information for project key staff has been determined.

7. **Conflict of Interest.**
None that we are aware of.

8. **HIPAA compliance:** N/A no medical data collected.

UNIVERSITY OF MARYLAND
INSTITUTIONAL REVIEW BOARD

2100 Lee Building
College Park, Maryland 20742-5125
301.405.4212 TEL 301.314.1475 FAX
irb@deans.umd.edu
www.umresearch.umd.edu/IRB

July 06, 2009

MEMORANDUM

Application Approval Notification

To: Jo Anne Schneider
Anthropology

From: Joseph M. Smith, MA, CIM
IRB Manager

University of Maryland, College Park

Re: **IRB Application Number:** 09-0426

Project Title: "Maintaining Vital Connections Between Faith Communities and Their Organizations"

Approval Date: July 06, 2009

Expiration Date: July 06, 2010

Type of Application: Initial

Type of Research: Non-Exempt

Type of Review for Application: Expedited

The University of Maryland, College Park Institutional Review Board (IRB) approved your IRB application. The research was approved in accordance with the University IRB policies and procedures and 45 CFR 46, the Federal Policy for the Protection of Human Subjects. Please include the above-cited IRB application number in any future communications with our office regarding this research.

Recruitment/Consent: For research requiring written informed consent, the IRB-approved and stamped informed consent document is enclosed. The expiration date for IRB approval has been stamped on the informed consent document. Please keep copies of the consent forms used for this research for three years after the completion of the research.

Continuing Review: If you intend to continue to collect data from human subjects or to analyze private, identifiable data collected from human subjects, after the expiration date for this approval (indicated above), you must submit a renewal application to the IRB Office at least 45 days before the approval expiration date. If IRB approval of your project expires, all human subject research activities including the enrollment of new subjects, data collection, and analysis of identifiable private information must stop until the renewal application is approved by the IRB.

Modifications: Any changes to the approved protocol must be approved by the IRB before the change is implemented, except when a change is necessary to eliminate apparent immediate hazards to the subjects. If you would like to modify the approved protocol, please submit an addendum request to the IRB Office. The instructions for submitting a request are posted on the IRB web site at : http://www.umresearch.umd.edu/IRB/irb_Addendum%20Protocol.htm

Unanticipated Problems Involving Risks: You must promptly report any unanticipated problems involving risks to subjects or others to the IRB Manager at 301-405-0678 or jsmith@umresearch.umd.edu.

Student Researchers: Unless otherwise requested, this IRB approval document was sent to the Principal Investigator (PI). The PI should pass on the approval document or a copy to the student researchers. This IRB approval document may be a requirement for student researchers applying for graduation. The IRB may not be able to provide copies of the approval documents if several years have passed since the date of the original approval.

Additional Information: Please contact the IRB Office at 301-405-4212 if you have any IRB-related questions or concerns.

Faith and Organizations Project

http://scpp.ubalt.edu/~faithandcommunities

Consent Form, Phase II, Faith and Organizations Project

Thank you for agreeing on behalf of _____ to participate in Phase II of the Faith and Organizations Project study Maintaining Vital Connections Between Faith Communities and Their Organizations. As outlined on the enclosed summary of the project, the study is designed to assist faith communities and the organizations they create to better understand their relationship in order to develop practical assistance for both founding faith communities and agencies. Additional information is available at http://scpp.ubalt.edu/~faithandcommunities.

Phase II of the project is designed to develop a self-assessment instrument for organizations and faith communities in order to help them understand and potentially improve their relationship. This part of the research follows on a more comprehensive study of organizations that has contributed to creation of the self-assessment and other materials from the project. Organizations that participated in phase one are also participating in Phase II. For organizations just joining the study now, participation will include: 1) interviews with one or two key leaders of your organization and founding faith community; 2) completion of the self-assessment instrument with the assistance of a trained researcher, 3) participation in a focus group regarding the process of filling out the self-assessment instrument in order to help us refine this tool, and 4) a focus group of selected people at your agency and faith community about some other questions related to the project. Agencies and faith communities that participated in phase I will not be asked to do the initial key leader interviews as they have already completed this part of the study.

Participation in the study is voluntary and all information gathered is confidential. _____ will be your primary contact for the study. S/he can be reached at _____ S/he will work with your agency to determine which individuals should participate in the various parts of the study, determine the best time and place for focus groups, interviews, and discussion of the self-assessment instrument, and otherwise facilitate your participation in the study. All activities associated with the study will be conducted at a time and place convenient to you and your agency/faith community participants.

If you have any other question about the study, please contact the principal investigator, Dr. Jo Anne Schneider, at jschneider@anth.umd.edu. The study is hosted by the University of Maryland College Park. Any questions and concerns regarding confidentiality or the research process that can not be addressed by the PI should be addressed to:

Institutional Review Board Office
University of Maryland
College Park, Maryland, 20742;
(e-mail) irb@deans.umd.edu
(telephone) 301-405-0678

The project staff hopes to work with you, your organization, and your faith community in completion of this project and development of practical tools and other

materials to share its findings. Agency and faith community representatives will be invited to at least one meeting in the spring to share outcomes and we hope to work closely with you to make participation in the project the best possible experience for you.

Agency or Faith Community Head _____ Date _____

Jo Anne Schneider

Principal Investigator _____ Date _____

IRB APPROVED
EXPIRES ON
JUL 06 2010
UNIVERSITY OF MARYLAND
COLLEGE PARK

IRB Boards and Qualitative Research:

Bonus Handouts #4
Ethics, Confidentiality and Informed Consent

Presented By: Jo Anne Schneider, PhD

Provided By:

Principal Investigators Association™

Principal Investigators Association

9990 Coconut Road, Ste 316
Bonita Springs, FL 34135
800-303-0129
www.principalinvestigators.org

Ethics, Confidentiality and Informed Consent

Summary for Student Researchers

Sociology and Anthropology Department, University of Wisconsin-Parkside

Jo Anne Schneider

Students working on research projects need to follow the same guidelines of ethical behavior as their teachers and other professional researchers. This includes making sure that information collected remains confidential and that people whom you work with understand that they are part of a research project. This summary is meant as a short outline of ethical issues for Sociology and Anthropology. It is meant to accompany copies of the ethics statements for both disciplines.

What are the major points of ethics for sociologists and anthropologists?

Ethical statements set the standards of good conduct for a researcher. These principals come out of the experiences that researchers face when conducting studies. In general, social science researchers observe the following standards in their work:

Do no harm to the people, organizations or communities who participate in research projects

Get permission or *informed consent* from the people or organizations who are the subjects of the research before doing a study. This includes sharing the goals and procedures of the research that you intend to do with the people who will be the subjects of the research. If the project is funded by an agency looking for particular information, you also need to share those goals and objectives.

Maintain the privacy or *confidentiality* of the people and organizations participating in the research project.

Be honest about the limits of your training and what you can learn through a particular research project.

Not falsify or make up data on a research study. To report accurately and completely research findings-

Report your research findings to the communities involved in your study, the scientific community , and the general public as appropriate in ways that further the public good and scientific knowledge-

Develop and maintain a working relationship with the communities that you study so that you can benefit them and so that other researchers can continue work with these people.

In many cases, the right way to behave may not be obvious. When this happens, researchers should check with their teachers and, when appropriate, share their experience with their classmates or other students working on the same project. But this sharing must happen during a class or other structured context and maintain the privacy of the research participants.

What does "do no harm" mean?

Social scientists try to be neutral observers of the communities and people that they study. The goal is to understand the behaviors and attitudes of a research population or a community or agency involved in a study, not to judge the people in the research project or do anything which may hurt them in any way. For example, social scientists do not report criminal behavior in research settings to the police or try to change the behavior or values of their research subjects.

In some cases, the researcher may find situations which he or she clearly think require action. For example, an organization may run a program in a way that keeps some eligible people from getting benefits. In cases like this, the

researcher first must carefully document this information, understand the context for the behavior, and work with the agency to share those findings. He or she may report the research results to a wider audience or work with members of the community to advocate for change. **In all cases, the researcher must maintain the privacy of those who participated in the research unless they give clear permission to use their names.**

How do I get informed consent?

Informed consent means that the people and organizations involved in a research project understand that 1) they are voluntary participants in a study, 2) that their privacy will be maintained 3) how you plan to carry out your research, 4) why you are doing this project, and 5) how the information you gather will be used. The only time that you do not need to get informed consent is when you are observing a public place like a shopping mall or a public meeting. When the research project involves ongoing activity -like observing a school, the researcher needs to continue to make sure that people in the setting consent to be part of the project.

Researchers get informed consent through a written or oral statement which briefly outlines the

answers to the five points above. For example, in a questionnaire study, the researcher might ask the participant to sign a consent form which states the person volunteers to participate in a research study. The next sentence in the consent form should state that all information given is completely voluntary , that the subject can refuse to answer any set of questions, and that the researcher will not reveal the person's name or the information given to anyone without the participant's permission. Then the researcher should briefly outline what is in the questionnaire, why he or she is doing the project and how that information will be used. For example:

*I would like to ask you to answer a questionnaire that asks about your experience inschool and some questions about your education and work experience. Participation is completely voluntary and you can refuse to answer any question. Your information will be combined with others and no-one will know your name or what you said. It shouldtake about 1*5 *minutes. I am doing this research because I am interested in how students like school. The information will be used for my class paper.*

The researcher should ask if the potential participant has any questions before they sign

Qualitative studies often get consent orally. When a project involves studying an organization like a school or community based agency, permission to do the research is often obtain d the agency head, principal or teacher. In these cases, the researcher does not need to get permission from every student or person they meet in the agency. However, you need to tell everyone that you are doing a study and why. You also may not include someone if they do not want to be part of your research.

How do I maintain confidentiality?

In most cases, researchers keep the identities of the people and organizations they work with secret. Maintaining the privacy of research study participants is the main way that social scientists do no harm. In a questionnaire study, basic confidentiality procedures include making sure that the names of the study participants are kept separate from the data collected about them. Usually, researchers do this by assigning a number to identify research subjects on a questionnaire. These numbers may be put on the consent form signed by the study participant so that the researcher can find the person again if they need additional information. However, the consent forms and any list which links study participants to identifying numbers are e separate place from the data. This identifying information is often kept in a locked cabinet.

In qualitative studies, researchers usually make up names for participating agencies and people. Any public document or discussion of the fieldsite uses the false names. These pseudo sometimes used in fieldnotes if they are shared in a class or among members of a project . However, in most research projects which involve teams of researchers, other researches know the identity of places and some of the participants. In these cases, the researcher sure that nothing shared among project team members is revealed outside of research discussions. The researcher must not share information in their research study with family, friends or outsiders in any way which could identify their study participants.

In a study of an agency, the researcher must also be careful to keep information gathered from one person or setting secret from others in the setting. For example, a teacher might as u interview with a student. Unless the researcher has permission to share information with the teacher from the student, or information on students is shared as part of more general findings and the identity of anyone student is kept confidential, the researcher should tell the tea the information is confidential.

In some cases, agencies or individuals want their names used in research reports. When this

happens, the researcher should check with the agency to make sure information is factually accurate.

What does it mean to he honest about my training and the limits of the study?

Since many people do not understand the methods and limitations of social science research, it is important to be clear about these limits. For example, a small study on why people like c can not solve the problems of the school system. The researcher must be clear about what he or she can learn in this project. A researcher who only knows how to do basic statistics can claim that he or she will do sophisticated multivariate analysis.

Why is it important to collect accurate data and report all findings?

The accuracy of the research findings depends on the quality of data. If students make u data, collect incomplete information or falsify information the findings win be useless. Likewise, research should seek to present all data on a particular topic. While most research reports support a particular point of view, the researcher can not deliberately leave something out because it contradicts his or her findings.

Why is it important to share findings?

While class papers might be seen only by the teacher, most research projects include a responsibility to share findings with the people who participated in the study and the scientific community. Social science research is meant to better the lives of people in the communities we study and add to general scientific knowledge about a given topic. Providing a fair and report on a research project is part of the service that social scientists offer to the wider community .

Why must I maintain a working relationship with the community that I study?

One of the hallmarks of ethical research is respecting the people, organizations and communities that you work with. Part of this process involves making sure that you maintain a working relationship with research subjects. This includes not judging them by your standards, maintaining confidentiality , and sharing research findings. Social science research should never aim to produce an expose on a particular subject. Research subjects or the agencies that commission a study may not always like your findings, and you may need to offer some d truths in a report. However, this information can not be presented in a way that harms study participants and should try not to alienate them.

Maintaining a working relationship with a study community is also important so that others can continue to work with that community. Social science research is cumulative: no one study provides all the answers on a given topic. It is important to maintain a good working relationship with study participants so that future researchers can learn more about the topic or double check your findings.

IRB Boards and Qualitative Research:

Bonus Handouts #5
GW Forms and Examples

Presented By: Jo Anne Schneider, PhD

Provided By:

Principal Investigators Association™

Principal Investigators Association

9990 Coconut Road, Ste 316
Bonita Springs, FL 34135
800-303-0129
www.principalinvestigators.org

THE GEORGE WASHINGTON UNIVERSITY
OFFICE OF HUMAN RESEARCH
INSTITUTIONAL REVIEW BOARD

EXEMPT FROM IRB REVIEW REQUEST FORM

***Before completing this form*, complete the *Human Subject Research Determination* worksheet to ensure that you are in fact required to submit your new study to the Office of Human Research. The OHR will only review studies deemed "human subject research."**

Reporting Proposed Changes in Research: This exempt from IRB review determination only applies to this form/protocol, as currently proposed. Therefore, if there are any changes that increase the risks to subjects (e.g., methodology, data gathering instruments, type of information being accessed or disclosed, etc.) the changes must be submitted to the IRB/OHR for approval PRIOR TO implementation.

INVESTIGATOR AND TEAM CONTACT INFORMATION			
IRB# *(ADMIN USE ONLY--WILL BE ASSIGNED UPON SUBMISSION)*		VERSION DATE:	
TYPE OF HIPAA AUTHORIZATION REQUESTED:		- choose one -	
PROTOCOL TITLE AND SPONSOR:			
TITLE :			
SPONSOR :			

PRINCIPAL INVESTIGATOR INFORMATION *(MUST BE GWU FACULTY)*				
LAST NAME:		FIRST NAME:		Degree:
DEPARTMENT		SCHOOL:		
CAMPUS ADDRESS:				
PHONE:		EMAIL:		

PRINCIPAL CONTACT IF OTHER THAN PI: *(THIS MAY BE THE STUDENT/TRAINEE)*			
LAST NAME:		FIRST NAME:	
CAMPUS ADDRESS:			
PHONE:		EMAIL:	

Recommendation:

- ❑ Study Registered as Exempt. Category: _____
- ❑ A HIPAA waiver of research subject authorization is justified for this study under 45 CFR 46 164.512 based on the following criteria:
  1. The proposed uses and disclosures of protected health information (PHI) involve no more than minimal risk to the privacy of individuals.
  2. The research could not practicably be conducted without the waiver.
  3. The research could not practicably be conducted without access to and use of the PHI.

  Please obtain permission from the privacy officer of the health care organization in which you will access protected health information before beginning your research.
- ❑ This research does **NOT** meet the regulatory/institutional requirements for exemption from IRB review. To conduct this research you must complete an IRB submission package for IRB review. For more information on completing a research submission, contact OHR at 202-994-2715.

_____ _____ _____
Authorized Designee Signature Date

This Exempt Registration does not expire nor does it require renewal.

Select the category that describes the proposed research activity:

The exemptions outlined below do not apply to ANY research involving prisoners. Research involving children may be exempt with specific restrictions. See below:

☐	1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies; **or** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
☐	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: *The information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and* *Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.* **This category may not be applied to children, except in the observation of public behavior.**
☐	3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement tests), survey procedures, interview procedures or observation of public behavior: *Of human subjects that are elected or appointed public officials or candidates for public office; or* *Conducted under a Federal statute requiring that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.*
☐ *Date range of pre-existing data:*	4. Research involving the collection or study of pre-existing data sets, documents, records, or specimens, but only if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects [i.e. through use of a key]. If research team does not receive, view or handle identifiable *original source data* at any point, study may be "not human subject research" (see link above to determine). *Research involving one of more of these existing data sets may require you to obtain, prior to using and/or disclosing identifiable health Information from the existing data set, either HIPAA research subject authorization integrated into the consent form (see"HIPAA" section of Medical Consent Guidance) or a waiver of a research subject authorization granted by the GWU IRB.*
☐	5. Research/demonstration projects conducted by other federal departments designed to study or evaluate public programs, procedures for obtaining benefits or services under those programs, possible changes or alternatives to those programs, or possible changes in methods or levels of payment for benefits under those programs.
☐	6. Taste and food quality and evaluation / consumer acceptance studies, as long as safe, normal foods are being consumed, and federal guidelines regarding acceptable levels of agricultural chemical or environmental contaminants are adhered to.

RESEARCH SUMMARY *(Please see Exempt Instructions to ensure all required information is included in application)*

Research Purpose	
Study Population	
Subject Recruitment Methods	
Methodology *(Step-by-step 1,2,3 description of study design)*	
Research Specific Risks	
Benefits *(to subject and society)*	
Data Analysis and Justification of Sample Size	
Confidentiality and Privacy *(Include plan for data storage, deindentification, and destruction)*	
Use of results/findings *(plan for*	

dissemination of information)	

INVESTIGATIVE TEAM SIGNATURES: My signature indicates that I will respect and protect the rights and welfare of individuals enrolled in this research project. I will also carry out my responsibilities as Principal Investigator as is outlined in Federal-wide Assurance of Protection for Human Subjects, for which GWU is registered with OHRP/DHHS, and as detailed in GWU HRPP policies & procedures. I will be guided by the principles contained in the Belmont Report and The Code of Federal Regulations governing research with human subjects (45 CFR 46). I have queried all members of the research team to determine if they have an economic interest in this study as defined by GWU policies. ***These signatures must be originals and are required for submission.***

Principal Investigator (Print/Type)	Signature	Date
Sub-Investigator (Print/Type)		
Sub-Investigator (Print/Type)		
Student Investigator/Research Coordinator (Print/Type)		

DEPARTMENT CHAIR/DEAN SIGNATURE: My signature indicates that this project has been reviewed by the appropriate departmental parties, who have judged that 1) there is a scholarly and a scientific justification for the protocol, that the study is feasible, and that the proposed methods are scientifically valid, 2) that the department has made the space and time commitment necessary to carry out the project, 3) that the financial implications of the research have been considered and deemed acceptable to the department and 4) that all ethical principles have been appropriately addressed.

Medical, Alan G. Wasserman, MD or Gary Simon, MD, PhD **Non-Medical**, Name of Dept. Chair	Signature
Department Affiliation/Campus Location	

Phone	Fax	Email

Please submit to OHR, 2030 M St. NW Suite 301 with all materials identified in the IRB Submission Checklist

THE GEORGE WASHINGTON UNIVERSITY & MEDICAL CENTER
OFFICE OF HUMAN RESEARCH
INSTITUTIONAL REVIEW BOARD

EXEMPT FROM IRB REVIEW REQUEST FORM

THIS FORM IS FOR INSTRUCTIONAL USE ONLY!

ALL INSTRUCTIONS ARE PROVIDED IN GREEN ITALICS.

Before completing this form, complete the Human Subject Research Determination worksheet to ensure that you are in fact required to submit your new study to the Office of Human Research. The OHR will only review studies deemed "human subject research."

INVESTIGATOR AND TEAM CONTACT INFORMATION			
IRB# *ADMIN USE ONLY—(INCLUDE IF ONE HAS BEEN ASSIGNED TO THIS STUDY)*		**VERSION DATE:** *This must be included on all documents.*	*Date range must be updated if there is a requested change from OHR.*
TYPE OF HIPAA AUTHORIZATION REQUESTED:		- choose one - *Required for the collection of Protected Health Information (PHI) from a covered entity.*	

PROTOCOL TITLE AND SPONSOR:				
TITLE : *Name of study: As listed on the grant or protocol if one. Please be consistent across all documents.*				
SPONSOR :*List any external funding associated with this research*				
PRINCIPAL INVESTIGATOR INFORMATION *PI must be a Full Time GW Faculty Member. Please complete all fields with current information.*				
LAST NAME:	*Smith*	**FIRST NAME:**	*John*	**DEGREE:** *Ph.D.*
DEPARTMENT	*Psychology*	**SCHOOL:**	*CCAS*	
CAMPUS ADDRESS:	*As applicable*			
PHONE:	*Provide PI phone # , not a general #.*	**EMAIL:** *Please use a GWU, GWUMC, GWUH OR MFA address. Other outside servers may not work with GroupWise*		
PRINCIPAL CONTACT IF OTHER THAN PI: *THIS MAY BE THE STUDY COORDINATOR, STUDENT, RESEARCHER, ETC.*				
LAST NAME:	*Researcher*	**FIRST NAME:**	*Sally*	
CAMPUS ADDRESS:	*As applicable*			

Recommendation:

- ❑ Study Registered as Exempt. Category: _____
- ❑ A HIPAA waiver of research subject authorization is justified for this study under 45 CFR 46 164.512 based on the following criteria:
  1. The proposed uses and disclosures of protected health information (PHI) involve no more than minimal risk to the privacy of individuals.
  2. The research could not practicably be conducted without the waiver.
  3. The research could not practicably be conducted without access to and use of the PHI.

  Please obtain permission from the privacy officer of the health care organization in which you will access protected health information before beginning your research.
- ❑ This research does **NOT** meet the regulatory/institutional requirements for exemption from IRB review. To conduct this research you must complete an IRB submission package for IRB review. For more information on completing a research submission, contact OHR at 202-994-2715.

_____ _____ _____
Authorized Designee Signature Date

This Exempt Registration does not expire nor does it require renewal.

Reporting Proposed Changes in Research

This exempt from IRB review determination only applies to this form/protocol, as currently proposed. Therefore, if there are any changes that increase the risk to subjects (e.g., methodology, data gathering instruments, type of information being accessed or disclosed, etc.) the changes must be submitted to the IRB/OHR for approval *PRIOR TO* implementation.

PHONE:		EMAIL:	*Campus email*

Select the category that describes the proposed research activity:

The exemptions outlined below do not apply to ANY research involving prisoners. Research involving children may be exempt with specific restrictions. See below: ***PLEASE CHOOSE ONE OR MORE CATEGORIES OF RESEARCH BELOW***

☐	1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on instructional strategies; **or** research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
☐	2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: *The information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and* *Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.* **This category may not be applied to children, except in the observation of public behavior.**
☐	3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement tests), survey procedures, interview procedures or observation of public behavior: *Of human subjects that are elected or appointed public officials or candidates for public office; or* *Conducted under a Federal statute requiring that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.*
☐ *Date range of data collection:* ***Include specific month/year date range:*** ***04/2006-03/2010***	4. Research involving the collection or study of pre-existing data sets, documents, records, or specimens, but only if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects [i.e. through use of a key]. If research team does not receive, view or handle identifiable *original source data* at any point, study may be "not human subject research" (see link above to determine). *Research involving one of more of these existing data sets may require you to obtain, prior to using and/or disclosing identifiable health Information from the existing data set, either HIPAA research subject authorization integrated into the consent form (see"HIPAA" section of Medical Consent Guidance) or a waiver of a research subject authorization granted by the GWU IRB.* ***Entire date range must be prior to the date of the application submission.*** ***Pre-existing= Retrospective data collection: Information that has already been collected***
☐	5. Research/demonstration projects conducted by other federal departments designed to study or evaluate public programs, procedures for obtaining benefits or services under those programs, possible changes or alternatives to those programs, or possible changes in methods or levels of payment for benefits under those programs.
☐	6. Taste and food quality and evaluation / consumer acceptance studies, as long as safe, normal foods are being consumed, and federal guidelines regarding acceptable levels of agricultural chemical or environmental contaminants are adhered to.

RESEARCH SUMMARY *(Indicate in* ***each section below*** *how this research is consistent with the selected category. Please refer to the provided instruction sheet to ensure all required information is submitted to OHR):*

***This application should be in language understandable to OHR reviewers/IRB committee members. Please spell-out any acronyms and abbreviations and use lay-terms, where appropriate.**

Research Purpose	**Give a brief summary of the proposed research:** □ Describe the specific scientific objectives/aims of the study, including hypotheses where applicable. □ Include background information, rationale/significance for the proposed

	research.
Study Population	**Identify the subject population that your research will target for enrollment*:*** □ Give the maximum number of subjects that will be needed to achieve the objectives listed. □ Describe the subject population [females/males, age, children, groups, etc], or type of data/specimen(s) [medical records, deidentified tissue, etc.], that will be studied or reviewed. Provide justification for the exclusion of individuals/groups. (The IRB must follow specific guidance and regulations for certain populations). □ Describe if there are any other specific enrollment criteria that persons may need to have/cannot have in order to participate.[Expertise, occupation, diagnosis, etc]. *NOTE: Research involving prisoners does not qualify for exempt review. Research with children may only be exempted in certain situations (see the review categories above).*
Subject Recruitment Methods	**Describe the plan to recruit participants:** "*Recruitment*" refers to communications and activities with potential participants that support enrollment in the study, prior to consent. □ Describe how you will identify potential participants. Explain where/how information regarding inclusion criteria will be accessed and/or obtained. (i.e., medical/student records review, public/private databases, existing contact list, etc). □ Describe plans and methods for the recruitment of participants; indicate where and how they will be used. □ If advertisements will be used for recruitment purposes, specify method(s) that will be used (flyers, posters, websites, radio, newspaper ads, telephone, television, mass e-mails, subject pool, etc.). *Examples: Email sent by point of contact, calling current patients, posted flyer in store, online ad- website, verbal announcement in a classroom, medical records review from (place) for condition(x).* *NOTE: A copy of all recruitment/advertising materials including ads, emails, letters and telephone scripts, must be submitted with this application.
Methodology (Be specific)	**Provide a step-by-step (1, 2, 3…) description of your research study design, with an emphasis on the collection of human subjects data (see Sample Exempt form for examples):** □ Identify the type of study (i.e. survey, questionnaires, interview, observational, record review, etc.). □ Describe how informed consent will be obtained. (see information sheet) http://www.gwumc.edu/research/human/inside/forms/exempt.html □ If obtaining verbal, scanned or online consent, (i.e., "agree by clicking here"), indicate that an information sheet will be made available to subjects. □ Describe any procedures, surveys, interviews, or questionnaires used in this study. Indicate the following: ▪ All information you will collect for research, pertaining to the subject. Who will conduct each of the research procedures? ▪ How many procedures will there be? How long will each take? ▪ Describe mode of administering all instruments/procedures(e.g., by telephone, in person, one-on-one, group, etc.). Include location of research procedures. (Private, public, etc). □ If data/specimen(s) are <u>not</u> publicly available: ▪ Describe how prior approval will be obtained for accessing information for your research (sites other than GWU, GWUH, or the MFA). ▪ Obtain authorizations site permissions to conduct research, as needed to access files/databases, enter private areas, etc. Include these as attachments. □ Specify actions of and interactions with human subjects. If the research involves the viewing, receiving, collecting or recording of information, list all data points

	you intend to receive/extract from the subject's files (i.e. name, age, email, zip code, etc.). ☐ Indicate if study will involve collection of Protected Health Information (PHI). Please list PHI that will be collected, and submit applicable HIPAA forms. ***Retrospective data collection: Information that has already been collected*** ***Prospective data collection: Information currently being or not yet collected.***
Research Specific Risks	**List all known risks of the procedures to be used, and how you will minimize risks. Include psychological, physical, privacy and/or confidentiality risks:** ☐ When collecting private information from/about individuals there is always a risk of loss of privacy or confidentiality. This applies to internet surveys due to the nature of the internet and email, and privacy cannot be guaranteed. ☐ Describe plans to decrease the likelihood of all risks that are listed. ☐ Identify if data to be collected is of a "sensitive" nature to the participant. ☐ Discuss briefly how the benefits of the results of this research will outweigh the risk to subjects.
Benefits (to subject and society)	**Discuss briefly any potential benefits of this research:** ☐ Describe the individual benefits to the participant, if applicable. (payment is not a benefit). ☐ Explain how will the results of this research contribute to the body of knowledge/ field of study, and to society.
Data Analysis and Justification of Sample Size	**State specific scientific data analysis plan:** ☐ Provide justification to support the planned sample size indicated above. ☐ Explain methods for analyzing data and obtaining statistical conclusions.
Confidentiality and privacy (Include plan for data storage, deindentification, and destruction)	**Outline how you intend to store the data, private information, and/or identifiable information:** ☐ Explain how data will be protected during the research (e.g., locked cabinets, password protection, etc.) by providing a detailed description of data-entry, data transfer, and data storage procedures (How; when, etc.). ☐ Indicate who will have access to the research data/specimens ☐ If study involves the collection of existing records or data, (Exempt Category 4), explain how data will be collected, recorded, and stored without identifiers. Information collected from existing records cannot contain any direct identifiers, codes or links to the subject's identification. ☐ Explain what will be done with the data/specimen(s) once the research is complete ▪ If data will be maintained after the completion of the study, describe data use, protection, and storage plans. ▪ Describe data destruction procedures if applicable.
Use of results/findings (plan for dissemination of information)	**Describe how study results will be made generalizable:** ☐ Explain your intent to publish, present or otherwise share data/results outside of the research entity. (i.e., Journal, book, conference, internet, dissertation, etc). ☐ Describe if data will be aggregated/ summarized such that no individual data will be communicated, or some individual results will be communicated. ☐ Indicate any future research use of data or results.

ATTESTATIONS AND REQUIRED SIGNATURES		
INVESTIGATIVE TEAM SIGNATURES: My signature indicates that I will respect and protect the rights and welfare of individuals enrolled in this research project. I will also carry out my responsibilities as Principal Investigator as is outlined in Federal-wide Assurance of Protection for Human Subjects, for which GWU is registered with OHRP/DHHS, and as detailed in GWU HRPP policies & procedures. I will be guided by the principles contained in the Belmont Report and The Code of Federal Regulations governing research with human subjects (45 CFR 46). I have queried all members of the research team to determine if they have an economic interest in this study as defined by GWU policies. ***These signatures must be originals and are required for submission.***		
Principal Investigator (Print/Type) ***John Smith***	Signature ***John Smith's original signature (scanned or faxed ok, no electronic signatures)***	Date ***1/11/2011***
Sub-Investigator (Print/Type) ***Sally Researcher (signatures not required)***		
Sub-Investigator (Print/Type) ***James Resident (signatures not required)***		
Student Investigator/Research Coordinator (Print/Type)		
DEPARTMENT CHAIR/DEAN SIGNATURE: My signature indicates that this project has been reviewed by the appropriate departmental parties, who have judged that 1) there is a scholarly and a scientific justification for the protocol, that the study is feasible, and that the proposed methods are scientifically valid, 2) that the department has made the space and time commitment necessary to carry out the project, 3) that the financial implications of the research have been considered and deemed acceptable to the department and 4) that all ethical principles have been appropriately addressed.		
Medical, ***Alan G. Wasserman, MD or Gary Simon, MD, PhD*** **Non-Medical**, ***Name of Dean/Dept. Chair***	Signature: ***Chair or Dean's original signature (scanned or faxed ok, no electronic signatures)***	
Department Affiliation/Campus Location		
Phone	Fax	Email

Please submit to OHR, Ross Hall, Room 613.

GEORGE WASHINGTON UNIVERSITY & MEDICAL CENTER
OFFICE OF HUMAN RESEARCH • INSTITUTIONAL REVIEW BOARD
ohrirb@gwu.edu • **Phone: 202.994.2715 • FAX: 202.994.0247 • WWW.GWUMC.EDU/RESEARCH/HUMAN**

HUMAN RESEARCH STUDY SYNOPSIS (VERSION DATE:)

TITLE:
SPONSOR (FOR EXTERNAL FUNDING ONLY):
IRB # *(if already assigned, otherwise leave blank--will be assigned upon submission)*:

PRINCIPAL INVESTIGATOR (MUST BE GWU FACULTY)
LAST NAME: FIRST NAME: DEGREE:
DEPARTMENT: SCHOOL:
ADDRESS:
PHONE (DAY): EMAIL:

PRINCIPAL CONTACT (IF OTHER THAN P.I.) ☐ STUDENT ☐ COORDINATOR ☐ OTHER:
LAST NAME: FIRST NAME:
PHONE (DAY): EMAIL:

RISK LEVEL

Indicate which of the categories below accurately describe this study, where "minimal risk means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (45 CFR 46.102(h)(i))

☐ Minimal risk
☐ Greater than minimal risk

PRINCIPAL INVESTIGATOR SIGNATURE

My signature indicates that I will respect and protect the rights and welfare of individuals enrolled in this research project. I will also carry out my responsibilities as Principal Investigator as outlined in Federalwide Assurance of Protection for Human Subjects, for which GW is registered with OHRP/DHHS, and as detailed in GW HRPP policies & procedures. I will be guided by the principles contained in the Belmont Report and The Code of Federal Regulations governing research with human subjects (45 CFR 46). I have verified that all members of the research team have agreed to accept the responsibilities required of their roles and I provide my assurance that all will be kept fully briefed on the details of the study. I have queried all members of the research team to determine if they have an economic interest in this study as defined by GW policies.

_____ _____
Signature of Principal Investigator **Date**

DEPARTMENT CHAIR OR MEDICAL CHAIR SIGNATURE

My signature indicates that this project has been reviewed by the appropriate departmental parties, who have judged that 1) there is a scholarly and a scientific justification for the protocol, that the study is feasible, and that the proposed methods are scientifically valid, 2) the PI is sufficiently qualified by training and experience to conduct the research, 3) that the department has made the space and time commitment necessary to carry out the project, 4) that the financial implications of the research have been considered and deemed acceptable to the department and 5) that all ethical principles have been appropriately addressed.

_____ _____
Medical Studies - If the PI is an MFA faculty, signature of Alan G. Wasserman, MD, or Gary Simon, MD, PhD **Date**
-OR-

_____ _____
Non-Medical Studies - Department Chair Signature **Date**

GENERAL INSTRUCTIONS

1. **Grey Fields indicate areas for response.**
2. **Write all responses in layman's terms as reviewers may be from outside your field.**
3. **Do not copy/paste from the protocol-responses should not address issues outside of question domain.**
4. **Call the Office of Human Research for help filling out this form at 202-994-2715**

Section I. Study Characteristics

1. Sites

a. GW's Role in the Project (select one):

- ☐ Sole Site (GW is the only IRB involved in this study)
- ☐ Lead Site (Lead Researcher is GW-based, other IRB's are also evaluating)
  What other institutions are participating?
- ☐ Participating Site (Lead Researcher is not GW-based, other IRB's also evaluating)
  What is the lead institution?
- ☐ Data Collection Site (GW researcher role limited to data analysis, other IRB's also evaluating)
  What is the lead institution?

b. Research Locations *(list locations where subjects participate in GW IRB-supervised activities or from which data is retrieved)*

Organization/Facility/Location (include city, state)	**Research Activity** (including recruitment, consenting, subject/researcher interaction or retrospective data retrieval)
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2. a. Research Team

Last Name, First (External Org if app.)	**GW Faculty, GW Staff, GW Student or External?**	**Research Activities Performed** (indicate subject recruitment, consenting, "prospective" or "retrospective" data collection, data analysis, other)
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b. Effort. What percentage of the PI's total professional effort is devoted to the study and/or paid for by the Sponsor? **Note: This question applies to all research regardless of funding.** For student research, please estimate the amount of time that the PI will supervise the student.

c. Curriculum Vitae (CV). If the Department Chair or Medical Chair has a conflict of interest with certifying the PI's qualification (e.g., the Department Chair is the PI), please include a copy of the PI's CV with the submission. ☐ ATTACHED ☐ NOT APPLICABLE

d. Conflicts of Interest. Do any members of the research team have any economic interest in or consulting relationship with a for-profit company that provides products or services that are a subject of the proposed study?
☐ **No** ☐ **Yes/explanation of how conflict of interest will be managed**

Section II. Narrative

1. Background.

a. What are the principal objectives of the study? (1-2 paragraphs)

b. (1) What is the justification for conducting this study in the context of field advancements and (2) How will the study contribute to generalizable knowledge outside of your research entity (publishing, establishing national standards, etc.)? (2-3 paragraphs)

- *Note: If you have no intent to publish, be sure to complete the Human Subject Research Determination Worksheet to determine if your study requires submission to the Office of Human Research*

2. Subject Identification and Recruitment.

"Identification" refers to determination of potential participants for future recruitment activities.
"Recruitment" refers to communication activities up until consent that support solicitation of participation.

a. Maximum number of subjects to be recruited (or number of retrospective records):
Give rationale for why/how this number was chosen. (1 paragraph)

b. Specify the age range of subjects to be recruited for the research:

c. Indicate any special populations to be involved in the research. ☐N/A

☐Pregnant Women, Fetuses or Neonates	☐Employees
☐Prisoners	☐Students
☐Children	☐Illiterate
☐Educationally Disadvantaged	☐Non-English speaking
☐Economically Disadvantaged	☐Other (specify):
☐Mentally Ill	
☐Decisionally-Impaired	

d. In the space below (2-4 paragraphs):
(1) List the inclusion and exclusion criteria for the identification of potential subjects (condition, ethnicity, employer/position, age, etc.), justifying any exclusion criteria.
(2) Indicate where, how and from whom information regarding these criteria will be accessed, obtained or otherwise determined (i.e. "medical records review from GWU-Hospital for presence of condition xyz")

e. If obtaining, viewing or collecting records or data from medical or clinical settings to support subject selection, are all potential subjects currently under treatment by a member of the research team listed above?
☐N/A ☐No ☐Yes/identify investigator(s) and explain treatment relationship:

f. Explain how and from whom subjects' *contact information* will be obtained for recruitment purposes?

☐N/A or Explain:

g. (1) Check all recruitment methods that apply:
☐Email ☐Phone ☐Flyer ☐Online Ad ☐Verbal Announce ☐Referral/Snowball ☐Other

(2) Describe in detail how each of these methods will be utilized. Include:
- *Who is executing each particular outreach method*
- *Locations (verbal announce in P.I. classroom, already-scheduled patient apt., location of flyers, etc.)*
- *How subjects may privately indicate interest in participating (prior to consent)*
- *Initial as well as follow-up recruitment activities*

3. Informed Consent Process. (See Tips on Informed Consent for more information).

a. Indicate applicable consent procedure (check one):
☐ Standard subject consent (obtaining subject signature)
☐ Waiver of documentation of consent (verbal consent obtained from subject with no signature)
*Justify:
☐ Waiver of consent (subject unable to indicate consent)
*Justify:

*See Charts 10 & 11 at OHR Decision Charts for eligibility requirements

b. Give a detailed description of your informed consent process. Your narrative should include the following elements (3-5 paragraphs):

Required
- *Who will consent/assent the subjects*
- *When consent will occur relative to recruitment and research activities*
- *Where or through what communication channels (telephone, email, etc) it will occur*
- *How privacy will be assured for the subject throughout*
- *How subjects will be given a chance to ask questions and opt out prior to research*
- *How subjects will receive a copy of signed consent form*

If applicable
- *Special considerations for children (assent procedures, etc.), pregnant women, new-borns, fetuses, prisoners, illiterate, non-English-speaking (see Federal Guidelines)*
- *Include an assent process for children aged 7 years or older, and include how parental permission will be obtained*
- *How undue influence will be minimized in authoritative relationships (professor-student, doctor-patient).*
- *Use of Evaluation to Consent or other measures for decisionally-impaired subjects*
- *Methods/amount of compensation*
- *Use of deceptive or withheld information and plan for subject debriefing*
- *Foreign-language translation measures*

4. Research Design.

a. Provide a step-by-step (1, 2, 3…) description of your research study design, with an emphasis on the specific actions of and interactions with human subjects.

Your description should include the following elements as applicable:

- *Describe frequency, duration and location of activities in which subjects participate*
- *Indicate all data sources and identify and attach all data collection instruments (surveys, tests, etc.)*
- *Precisely describe experimental/control design groups*
- *Distinguish between research-specific procedures and standard-of-care or other procedures that would occur even if the research wasn't being conducted*
- *Describe and justify any deceptive measures including use of placebo or withholding/alteration of specific information from subjects*
- *Indicate if/when audio-recording or video-recording are used*

b. How will the collected data be analyzed to answer the research question? (1-2 paragraphs)

- *Describe statistical tests and software, thematic analysis, what factors will be compared*

5. Data Management & Security

a. What personal/demographic data will be collected (check all that apply):

☐ Name	Location of	☐ Employer/School Name
☐ SSN	☐ Residence or	☐ Department/Division
☐ Medical Record #	☐ Employer/School including:	☐ Position/Job
☐ Age or ☐ DOB	☐ State/Other Region	☐ Grade/Year Level
☐ Ethnicity	☐ Zip code/postal code	☐ Course/Class
☐ Gender	☐ City	
☐ Telephone #	☐ Street address	
☐ OTHER (list):		

b. (1) Describe primary research data collected (i.e. "attitudes regarding alcohol use", "biomarkers related to pregnancy", etc.) **and** (2) either list specific data points or reference attached collection instruments (i.e. "see ER Survey and Data Sheet #1"):

(2) When this primary research data is recorded (written-down or entered) by investigator or subject, will it be (check all that apply):

(a) ☐ Identified directly with any personal/demographic data points listed in 5.a.?
Which data points or "all"?
Justification (data and identifiers should be recorded separately per (b) unless impracticable):

(b) ☐ Identified indirectly, through use of a unique alphanumeric code that links to any personal/demographic data points listed in 5.a. using a key stored securely and separately?
Which data points or "all"?

(c) ☐ Maintain data anonymity by not doing (2.a.) or (2.b.)

c. Is the research team viewing or collecting *Protected Health Information* (i.e., medical records)? ☐ No ☐ Yes

- *See Protected Health Information Determination Worksheet, attach appropriate documents and integrate proper text in Consent Form (see Consent Guidance documents).*

d. Provide a detailed description of data-entry, transfer, storage and destruction procedures.(3-6 paragraphs) Your description should include all of the following elements:

- *Methods to minimize risk of breach of confidentiality including anonymous data collection, use of coding and identity key, sealed envelopes, lock-boxes, digital firewalls b/w data & identity, etc.*
- *Specify digital vs. hard copy and locations for data, key and/or subject roster (data and key should be separate, secured locations; indicate if research data are stored in medical records).*
- *How and when measures will be taken to remove identifying data and codes as soon as possible.*
- *Use of encryption (above minimal risk) and/or password-protection (minimal risk) on computers.*
- *When hard copy or digital versions of data, key, recordings and roster will be destroyed. How long they will otherwise be stored and for what purposes.*

e. Publication and presentation.

(1) Results will be published, presented or otherwise shared outside of my research entity in the following manner (check one):

☐ Data will be aggregated or summarized such that no individual data will be communicated
☐ Some individual results will be communicated.

(a) How will individual results be attributed, specifying use of descriptors from 5.a. (i.e. "one employee of company abc said ____")?

(b) What is the range of the number of subjects in the study who are associated with each of these attributing descriptors (i.e. "5-6 subjects are employees of the company that will be named")?

(2) Will recordings be used in presentations or for any other reasons other than data analysis?
☐ No ☐ Yes
If yes, explain and submit Audio/Video Release Form:

6. Risks & Benefits.

a. Describe all risks to the subject. **Include physical, psychological/emotional, cognitive, privacy, social/cultural stigma, financial, and legal risks**. Confidentiality risks should already be addressed above at Question 5.d.
Common risks that should be acknowledged include:

- *Emotional discomfort, anxiety or other affective risk from survey questions*
- *Breach of privacy from other people observing consenting or research participation*

b. Radiation. Will subjects be exposed to radiation during the research? ☐ No ☐ Yes

- *If yes, please explain use of radiation in detail including maximum number of subject exposures over 12 months, distinguishing between standard of care and research. For research, please specify the type of device and make/model.*

c. What steps will be taken and research procedures implemented to minimize all risks?

- *Describe additional precautions for special populations as defined at 2.b.(2)(see HHS 45 CFR 46 Subparts B-D for considerations specifically regarding children, pregnant women, new-borns, fetuses and prisoners)*

d. Describe the potential benefits of the research.

- *Please specify the direct benefits to subjects (if any) and the benefits to the class of research subjects.*

Section III. Study details for medical or other therapeutic or diagnostic studies ☐ N/A

1. Registered on the www.ClinicalTrials.gov? - choose one -

2. FDA-Regulated Studies:

a. Drug Studies (select one): ☐ N/A

☐ Drug study requiring an IND
(IND Number: , or provide IND Letter from the FDA)

☐ Study not requiring IND, involves off-label use of approved drug
Provide rationale or proof:

b. List of all research agents administered to human subjects in this study.

Agent	FDA Status	Source	Stored Where?	Dispensed By?

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c. Device Studies (select one): ☐ N/A

1. Categorize the device: - choose one -

2. IDE/HDE# IDE/HDE Sponsor:

GEORGE WASHINGTON UNIVERSITY MEDICAL CENTER
OFFICE OF HUMAN RESEARCH • INSTITUTIONAL REVIEW BOARD
ohrirb@gwu.edu • PHONE: 202.994.2715

HUMAN SUBJECTS RESEARCH DETERMINATION WORKSHEET

Complete sections I and II of this worksheet to determine if your research requires submission to the Office of Human Research (OHR). You do not have to submit *this* form to the OHR, but OHR will review completed forms upon request. *If you are not the PI, you should first discuss your research with the PI before submitting this form.*

This is a guide to help investigators determine if their project is considered human subjects research as defined by the Department of Health and Human Services (DHHS).

- Activities that ***do*** meet the definition of "human subject research" will require submission of either an Exempt from IRB Review Request form or Human Research Study Synopsis form (follow steps at Forms Page).
- Activities that ***do not*** meet this definition do not require IRB submission. Please note that you must still conduct all activities in an ethical manner. Please consult with your academic department regarding fulfillment of your ethical obligations.

Section I. DETERMINATION OF RESEARCH

"Research" is defined as a *systematic* investigation designed to develop or contribute to *generalizable* knowledge.

I.A. DOES THE PROPOSED ACTIVITY MEET ALL OF THE FOLLOWING CRITERIA TO BE DEFINED AS RESEARCH?

(1) Y ☐ N ☐ Activities constitute a *systematic investigation*, (at least 4 subjects), that include research development, data collection and analysis, and evaluation.

(2) Y ☐ N ☐ Conclusions will contribute to *generalizable knowledge* (i.e. intent to publish, present, or otherwise apply knowledge gained to a population outside of the local research context/ entity).
*(CE, course/ internal program evaluations, many QA/ QI programs, course requirements, or classroom exercises do not usually qualify as contributing to generalizable knowledge).

☐ IF YOU ANSWERED ***"NO"*** TO (I.A.1) ***OR*** (I.A.2): **STOP HERE-** *DO NOT SUBMIT YOUR PROJECT TO THE OHR.*
☐ IF YOU ANSWERED ***"YES"*** TO (I.A.1) ***AND*** (I.A.2)*:* **CONTINUE TO SECTION II BELOW.**

Section II. DETERMINATION OF THE INVOLVEMENT OF HUMAN SUBJECTS

"Human subject" means a living individual about *whom* an investigator conducting research obtains data through intervention or interaction with the individual, **or** the use of identifiable private information.

- *Data which describe organizational dynamics, external trends, environmental factors or other non-human factors, even if collected from humans, does not itself constitute human subjects research, unless primarily opinion- based.*
- *"About whom"= The information being elicited for the research is about the [living] individual (the "Whom"). The focus on the investigation is the opinions, characteristics, or behavior of the individual(s).*

II.A. DOES THE PROPOSED ACTIVITY INVOLVE HUMAN SUBJECTS?

(1) Y ☐ N ☐ Collect data through *intervention*[1] or *interaction*[2] with an individual, including interviews, surveys, physical procedures manipulations of the subject's environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not).

1. Intervention: Includes both physical procedures by which data are gathered, and manipulations of the subject or subject's environment performed for research purposes.
2. Interaction: Communication or interpersonal contact between investigator and subject.

(2) Y ☐ N ☐ Obtain, view or otherwise handle any *private information*[1] which identifies individual subject(s) through the use of either *direct identifiers*[2] (name, address, etc.), or *indirect identifiers* in the form of a code that links back to the identity of subject through an existing key.

1. Private information includes (but is not limited to)
   - Medical records and charts, specimens, data or tissue repositories
   - Employment or educational records, and observations of behavior which the subject could reasonably expect no observation to be taking place.
   - Personal thoughts, feelings, opinions, attitudes, beliefs, etc.
2. Direct identifiers include (but not limited to) name, street address, audio/ video-recordings, telephone, fax, email, SSN, medical record # (other potential identifiers evaluated on a case by case basis).
   - If codes & key exist: check "N" here, and submit official correspondence from the holder of the key which states that researcher will *not* be given access to the key under any circumstances.

☐ IF YOU ANSWERED ***"NO"*** TO (II.A.1) ***AND*** (II.A.2): **STOP HERE-** *DO NOT SUBMIT YOUR PROJECT TO OHR.*

☐ IF YOU ANSWERED ***"YES"*** TO *EITHER* (II.A.1) ***OR*** (II.A.2.): *YOU **ARE** CONDUCTING HUMAN SUBJECT RESEARCH-* **PLEASE SUBMIT YOUR STUDY TO THE OHR FOR IRB REVIEW.**

IF YOU ARE STILL UNCERTAIN WHETHER OR NOT YOU ARE CONDUCTING HUMAN SUBJECTS RESEARCH AND WOULD LIKE VERIFICATION FROM THE OHR, PLEASE COMPLETE THE FOLLOWING SECTION III.

Section III. RESEARCH DESCRIPTION

III. A. APPLICANT INFORMATION

PROJECT TITLE:					
PRINCIPAL INVESTIGATOR Last Name:		**First Name:**		**Degree:**	
School:		**Department:**			
Phone:		**Email:**			
Grant/Funding Source:		☐ **N/A**			
PRINCIPAL CONTACT Last Name:		**First Name:**			
Phone:		**Email:**			

Please indicate *YOUR* primary research role (check all that apply):

- ☐ Principal Investigator (must be full time GW faculty)
- ☐ Project/study coordinator
- ☐ Research Assistant/ Research team member
- ☐ Other _____
- ☐ GW Co-Investigator or Sub-Investigator
- ☐ Principal contact/administrator only
- ☐ GW Student

Please indicate your type of research:

- ☐ GW Faculty/staff research
- ☐ GW Nursing Practicum/ Clinical Residency requirement
- ☐ GW Dissertation research
- ☐ GW Graduate- Thesis/fieldwork
- ☐ Other _____
- ☐ GW Undergraduate student project
- ☐ GW Culminating Experience (CE) /CE Practicum
- ☐ GW Class/Course/Curriculum requirement only
- ☐ Non-GW research

This research involves: (check all that apply):

- ☐ All or some research activities are taking place at or through GW
- ☐ GW Collaborative research with another institution(s)
- ☐ No research activities will take place at or through GW
- ☐ Study has/will seek IRB approval at a non-GW institution

III. B. PRPOSED STUDY CHARACTERISTICS (PLEASE COMPLETE THE FOLLOWING IN LAYPERSON TERMS).
1. Provide a 3-5 sentence, clear summary of the proposed research activity. Please include the purpose and aims of the research.
2. Briefly describe all research activities that will be performed by or conducted under the supervision of the GW faculty, staff, or students.
3. Briefly describe or list all study procedures to be conducted related to study participants (i.e., screening, recruitment, consenting, enrollment, procedures, etc), types of data being collected, anonymous/identifiable information, and how you will be obtaining data from or about study subjects. *(Please be sure to attach any survey, interview, or focus group questions, if applicable.)*

RESEARCH PROTOCOL
Required Elements

TITLE:

RESEARCH PLAN

A. Specific Aims

List the broad, long-term objectives and describe concisely and realistically what the specific research described in your proposal is intended to accomplish, and the hypothesis to be tested.

Hypothesis:

B. Background and Significance

Briefly give the background to the present proposal, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. Cite literature and include a list of references.

C. Preliminary Studies

Provide an account of the PI/IS's preliminary studies pertinent to the protocol and/or any other information that will help to establish the experience and competence of the PI/IS to pursue the proposed project. The titles and complete references to appropriate publications and manuscripts submitted or accepted for publication may be listed.

D. Research Design and Methods

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include the means by which the data will be collected, analyzed, and interpreted.

1. Describe any new methodology and its advantage over existing methodologies.

2. Discuss potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.

3. Provide a tentative sequence or time table for the study.

4. Specify procedures, situations, or materials that may be hazardous to personnel and the precautions to be taken to ensure safety.

5. Provide justification of the sampling procedure and sample size. Gender and Minority Inclusion, it is required that all research involving human subjects and human materials include minorities and women, as well as males and females of all ages. If one gender and/or minorities are excluded or are inadequately represented in a protocol, particularly in proposed population-based studies, a clear compelling rationale for exclusion or inadequate representation should be provided.

   The composition of the study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice (by age distribution, risk factors, incidence/prevalence, etc.)

6. Identify all drugs and devices to be used, if applicable,. If the drug or device is investigational under FDA policy, list the actual IND/IDE number and respective source, supplier, and/or sponsor. If an IND/IDE has been assigned provide the FDA stage status. Note the proposed dosage related information including instructions for administering, adverse effects, compatibility in infusions, and stability.

7. Identify all procedures that will be used for the purpose of this research. If blood is to be drawn, indicate amount to be withdrawn per single withdrawal, and the total amount of blood to be drawn. If transfusions are anticipated, include assurance that the volume of blood removed for research purposes will not necessitate a transfusion. [*Refer to Section 1.5.5*]

E. Study Population –(Gender and Minority Inclusions):

1. Describe the ***characteristics of the subject population***, include the anticipated number of normal volunteers, age ranges, sex, ethnic background, and health status. Identify the criteria for inclusion or exclusion (especially women and/or minorities). Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, or others who are likely to be vulnerable, especially those whose ability to give voluntary informed consent may be questionable.

F. Human Subjects (Risks & Benefits)

1. Identify ***sources of research material*** obtained from individually identifiable living human subjects in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data. Subjects with specific diseases or conditions are often identified as potential subjects through some type of record (e.g., medical records, patient charts, registries for cancer cases, surgical or X-ray log books, school records). Controls may come from the same population as the subjects (which is always the case in a randomized clinical trial), be persons with unrelated conditions or be volunteers from the general population.

2. Describe ***plans for recruitment of subjects and the consent procedures*** to be followed; including the circumstances under which consent will be sought and obtained, who will seek it, who will give consent, the age range of the individual who will give consent, the nature of the information to be provided to prospective subjects, payment for participation (if applicable), the prospective subjects, and the method of documenting consent. (State if you are requesting a 'waiver of consent' from the IRB and why.) [*Refer to Section 3.0*]

G. Risks and Side Effects:

1. Describe any ***potential risks--physical, psychological, social, legal, or other*** and assess their likelihood and seriousness. Describe the alternative treatments and procedures that might be advantageous to the subjects.

2. Describe the ***procedures for protecting against or minimizing any potential risks***, including risks to confidentiality, and assess their likely effectiveness. Discuss provisions for insuring necessary medical or professional intervention in the event of adverse effects to the subjects. Describe the provisions for monitoring the data to insure the safety of subjects.

3. Discuss ***why the risks to subjects are reasonable in relation to the anticipated benefits*** to subjects and in relation to the importance of the knowledge that may be reasonably expected to result.

4. List all risks that are more than minimal (no greater probability or magnitude than those ordinarily encountered in daily life or during routine medical tests). Include physical, psychological, social, economic, legal or other risks, where present.

5. Describe the severity and probability of all material risks, and the implications, in understandable terms. Use a table for Common (21-100/100), Occasional (5-20/100) and Rare (<5/100) risks sorted by Immediate (1-2 days of treatment), Prompt (within 2-3 weeks before next course), Delayed (any later time during treatment) and Late (after completion of treatment) onset wherever possible.

H. Benefits:

1. The risks must be reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge reasonably expected to result.

2. The use of modest compensation for the burdens imposed by the research may be permitted, especially if benefits are minimal, but should be incremental and not conditioned on completion of the entire study.

3. Explain the expected benefits, if any, and their likelihood. If none, say so.

4. You may mention general benefits for science, or for other persons, if any.

I. Outside Consultants/Collaborators

Attach a letter from the consultant(s) and/or their signature(s) on the Application (Sign-Off) Form confirming their role in the project.

J. Contractual Agreements

Describe the nature of these collaborations. Attach an appropriate letter from each individual/institution involved confirming the agreement. If the protocol originates at another institution, explain how that institution will be involved and provide the name and department of the Institutional Sponsor. The assigned PI/IS must be a faculty/staff member of that institution.

K. Costs To Subjects:

1. The Research Plan and the consent documents must describe the costs to such compensation plans in detail, including the provision of free care or medicines related to the study.

   Example: Children's Hospital will give you the medicine used in this study for free. You will not be charged for anything else we do that is part of the study. You will still have to pay for any medical care that is not part of the study.

L. Conflicts Of Interest:

1. Describe any financial or other conflicts of interest as indicated. Any interests of the investigators or provider institutions in the outcome of the research, the study product, or the sponsoring entities, any support received by the researchers or provider institutions from same in excess of $10,000 per year, and any other relationship to the sponsor or the research that could be material to any subject.
2. Where such interests exist, describe the disclosures that will be made to subjects in the consent process and consent documents and discuss the factors considered in selecting the appropriate disclosures. Consult §2.3 of the Manual for a discussion of materiality and appropriate disclosure to subjects, including disclosure of sponsor identity and source of funding where potentially material to subjects.
3. Review the *Financial Interest Disclosure* form submitted to the Office of Sponsored Programs to ensure that it is current and consistent with the *Application* disclosure.

M. Confidentiality:

Include appropriate provisions to protect the privacy of subjects and maintain the confidentiality of data, and include safeguards to protect the rights and welfare of vulnerable subjects.

N. Subject Compensation:

The Research Plan must describe such compensation plans in detail, including the provision of free care or medicines related to the study.

O. Facilities and Equipment

Describe the facilities and equipment to be used. Indicate the extent to which these facilities and equipment are available or will be obtained for the project.

P. References & Literature Cited

Compile a judicious list of relevant literature citations. Each literature citation must include the title, names of authors, book or journal, volume number, page numbers, and year of publication.

Q. Appendix

Attach the letters of confirmation from collaborating institutions, consultants, research documents (e.g., questionnaires, scales, tables, charts, diagrams, manufacturers brochures, etc.) in this section.

PLEASE REMEMBER TO PAGE NUMBER THE ENTIRE DOCUMENT