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

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 discomfort 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of organization events and meetings, interviews with key leaders regarding organization activity, analysis of historical documents, and focus groups regarding the same issues.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.
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 __________________________ Date 1/18/2008

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

Chair, IRB Committee __________________________ Date 1/22/09

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
Jo Anne Schneider

Name of Co-Investigator (Co-PI)

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

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

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

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)
☐ Non-Exempt

If exempt, briefly describe the reason(s) for exemption.
This is a study of organizations, not individuals

6/22/09

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.)
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-1.11 and 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](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.
## 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.

<table>
<thead>
<tr>
<th>Project Title</th>
<th>[This title should be the same as the project title used in the IRB application.]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Why is this research being done?</strong></td>
<td>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]</td>
</tr>
<tr>
<td><strong>What will I be asked to do?</strong></td>
<td>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.]</td>
</tr>
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<td>Project Title</td>
<td>[This title should be the same as the project title used in the IRB application.]</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>What about confidentiality?</td>
<td>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.</td>
</tr>
</tbody>
</table>

[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 unforeseeable. 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. ****
**CONSENT FORM**

<table>
<thead>
<tr>
<th>Project Title</th>
<th>Prolonged Sleep Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Why is this research being done?</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>What will I be asked to do?</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>What about confidentiality?</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>What are the risks of this research?</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
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.
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<td>Signature and Date</td>
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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. ****
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 in the research, 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 _______________________. 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.]
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  ☐ 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  ☐ Yes  ☐ Not Applicable, research does not involve future data collection

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

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

10. **Signatures**

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Principal Investigator  _______________  6/22/09  
__________________________  Date

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.
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 website at: [http://www.umresearch.umd.edu/IRB/irb_Addendum%20Protocol.htm](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.
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

Principal Investigator

Date

IRB APPROVED
EXPIRES ON

JUL 06 2010

UNIVERSITY OF MARYLAND
COLLEGE PARK