eResearch M REGULATORY MANAGEMENT SAND

Date: Monday, September 21, 2009 9:39:36 AM

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01. General Study Information

All questions marked with a red asterisk (*) require a response. Questions without a red asterisk may or may not require a response, depending on those questions' applicability to this study.

1.1* Study Title:

Sample Application for Research in the Michigan Census Research Data Center Title 13 Projects

1.1.1 Full Study Title:

1.2* Principal Investigator:

Cynthia Shindledecker

Note: If the user is not in the system, you may Create A New User Account...

1.3 Study Team Members:

Study Team Member	Study Team Role	Accepted Role	Conflict of Interest	Edit Rights
Cynthia Shindledecker	PI			yes

1.8* Project Summary:

The project summary should include the individual research question as well as to state that the research will be conducted in the Michigan Census Research Data Center.

1.9* Select the appropriate IRB:

Health Sciences and Behavioral Sciences

1.10* *Estimated* Study Start Date (Not required for IRBMED): *(mm/dd/yyyy)*

1/1/2010

1.11* *Estimated* Duration of Study:

5 years

01-1. Application Type

1-1.1 Some types of projects do not require an eResearch application and others (e.g., secondary data analysis and exempt projects) have shortened, specialized applications available. A Wizard is available to help choose the correct application type, or determine if your project requires an application at all.

1-1.2* Select the appropriate application type.

Exempt Human Subject Research

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator
If other, please specify.

1-2.2* Are any students working on this project being paid from a federally funded training grant?

○ ○ Yes ◉ ○ **No**

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

OVPR-IRB Behavioral/Health Sci

1-2.4 Will the study utilize resources from the following centers?

Select all that apply:

There are no items to display

1-2.6* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)?

◉ ○ **Yes** ○ ○ No

1-2.6.1* List the peer-review organization(s).

US Census Bureau

Study Team Detail

1.4 Team Member:

Cynthia Shindledecker

Department:	OVPR-IRB Behavioral/Health Sci		
Preferred email:	cshindle@umich.edu		
Business phone	734-936-0933		
Business address:	OVPR-Behavioral/Health Sci	540 E Liberty #202	48109-2210

PEERRS Human Subject Modules Completed	Expiration Date
Human Subjects - Social & Behavioral Sciences	01/03/2011
Human Subjects - Biomedical & Health Sciences	07/25/2011

The PI and any Co-Investigators and/or Faculty Advisors involved in this study must complete at least one of the PEERRS Human Research training modules.

1.5 Function with respect to project:

PI

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: *(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions. Co-investigators and faculty advisors are required to receive this information.)*

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
Not my CV	0.02

Conflict of Interest Detail: *Required for PI, Co-Is and Faculty Advisors*

C1* Do you have a potential conflict of interest related to this research? Consider the following statements and check all cases that apply.

Do you, your spouse, domestic partner, or dependents:

Category
There are no items to display

For Health System Employees Only:
There are no items to display

C2 Do you, your spouse, domestic partner, or dependents have any other outside interests or relationships to companies or entities related to this research that the IRB should consider? If so, please provide a short description in the box below.

C2.1 Where have you submitted a disclosure of Conflict of Interest?

C2.2 Has a management plan been formalized?

C2.2.1 If yes, attach the management plan here.

Name	Version

There are no items to display

C2.2.2 If no, describe the financial interest in sufficient detail to permit the IRB to determine if such involvement represents a potential conflict-of-interest and/or should be disclosed to potential research subjects in the informed consent form.

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.

*** Note: At least one of the following sections must be answered. Multiple sponsors or sources of support must be added one at a time.**

2.1 External Sponsor(s)/Support:

Type	Name	Other Direct Sponsor/Support	Support Type	Has PAF?

There are no items to display

2.5 Internal UM Sponsor(s)/Support: [Including department or PI discretionary funding]

Type	Department Sponsor	Support Type

There are no items to display

2.8 Check here if the proposed study does not require external or internal sponsorship or support:

☑ ☑

03. UM Study Functions

3.1* Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:

Primary or secondary analysis (data/specimen)

If other, please specify.

5-3. Research Design - Exempt Project

Completion of this section is required based on the response provided to question 1-1.1

5-3.1 Upload scientific protocol if one is available.

Name	Version

There are no items to display

5-3.2* Describe the objective and specific aims of the project. *If included in the attached protocol, please indicate the section.*

Specific to research project

5-3.3* Describe the scientific design of the project. *If included in the attached protocol, please indicate the section.*

Specific to research project

5-3.4* Describe the subject population for the project.

Specific to research project

5-3.5* Will the study involve recruitment and/or participation of subjects in order to produce new data *(e.g., surveys, interaction, intervention)*?

○ ○ Yes ◉ ○ **No**

5-3.10* What is the highest level of risks of harm to the subjects resulting from this research?

No more than minimal risk

5-3.11* Will the research involve the access, collection, use, maintenance, or disclosure of University of Michigan protected health information (PHI)? PHI is:

- **information about a subjects past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; AND**
- **that is maintained by a University of Michigan school, department, division, or other unit that is part of the Universitys HIPAA-covered component (e.g. healthcare provider, helathcare plan, or healthcare clearinghouse).**

○ ○ Yes ◉ ○ **No**

5-3.12* Will subjects receive payment or other incentives for their participation in the study?

○ ○ Yes ◉ ○ **No**

12. Exemption Category

Completion of this section is required based on the response provided to question 1-1.2.

12.1* Which of the following exemption criteria applies to the study?

EXEMPTION #4 of the 45 CFR 46.101.(b):
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.

12-3. Exemption Category 4

Completion of this section is required based on the response provided to question 12.1.

12-3.1* Are all the data, records, and/or specimens already collected and available for research use?

◉ ○ **Yes** ○ ○ No

12-3.2* Are all the data/records/specimens publicly available?

○ ○ Yes ◉ ○ **No**

12-3.3* Will the study team record any information that could be used to identify a subject, either directly or indirectly, during the course of the study?

○ ○ Yes ◉ ◉ **No**

12-3.4* Give the name and source/location of the data/records/specimens.

Name the data sets that will be used and then include the description of the MCRDC: The Michigan Census Research Data Center is a joint project of the University of Michigan and the U.S. Census Bureau. The MCRDC provides a secure facility in the basement of the Institute of Social Research in which researchers with approved projects can access restricted U.S. Census Bureau microdata. These data are all collected by the U.S. Census Bureau's survey and census programs under Title 13. All research proposals are reviewed by the U.S. Census Bureau for both scientific merit and disclosure risk. Researchers undergo security background checks prior to commencing research. Researchers and sponsoring institutions sign contracts, with criminal penalties for violation, commiting them to lifetime confidentiality protection. Researchers must complete annual training programs in confidentiality protection and information technology security. All research is conducted within the secure MCRDC computing facility which is staffed by a U.S. Census Bureau employee. The facility is locked and alarmed, permitting access only to those with approved projects and a U.S. Census Bureau federal ID. The facility has several cameras monitoring the door and the computers 24/7. The camera files are viewable both at ISR and the U.S. Census Bureau. The computing facility allows researchers to log in, via a thin client, to an account at the U.S. Census Bureau in Suitland, Maryland. All processing and analysis of data is done on computers at Suitland. Researchers may not remove any data or research results from the MCRDC. Printing of results is permitted only when a U.S. Census Bureau staff member is present. All printing is on colored paper with a "Title 13 confidential" watermark. No printouts may be removed from the MCRDC. They must be kept in individually locked lockers. All research results (e.g. regression coefficients) are submitted to the U.S. Census Bureau for disclosure review before results are returned to the researcher outside the MCRDC firewall.

45. End of Application

Available Activities

The Submit activity must be executed to send this application to any required committees for review.

Error Check

Submit Application

Move to Ready to Submit Inbox