ICF MACRO
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DATE: June 5, 2009

TO: Dan Geller

FROM: Jack Hermann, IRB Chair

SUBJECT: IRB Review Forms

Attached are the following forms for the recent IRB review of your research project:

1. *IRB Review Findings Form,* which documents the review and approval of the project.

2. *IRB Members* list, which identifies the board members who reviewed the project.

3. Instructions on *Reporting Adverse Events and Unanticipated Problems,* which defines unexpected adverse events and unanticipated problems, and details when and how the IRB should be notified of such events and problems. **Note—any problem or incident that could be an adverse event must be reported to the IRB according to the instructions in this form. Failure to comply with the adverse event reporting requirements could result in the suspension of your right to submit studies to the IRB and/or the suspension of IRB approval of this study.**

4. *Agreement to Comply with Human Subject Protection Requirements,* which ***must be signed*** by you and returned to the IRB. By signing this form, you agree to adhere to the human subject protection procedures that were approved by the IRB, and to inform the IRB chair of any changes made to the approved procedures.

The first three forms are for your files; the signed copy of the fourth form must be sent to the IRB Secretary, Rená Agee, and will be kept in the IRB files. Please maintain a copy of the fourth form for your records. If you have any questions about these forms, please contact me at Jack.Hermann@sfr.fr or Rená at (301) 572-0340 (Rena.A.Agee@macrointernational.com).

(Revised 04/08/09)

ICF Macro
Institutional Review Board

IRB Review Findings Form

Name of Project Director(s): Daniel Geller

Title of Project: National Survey of WIC Participants II

ICF Macro Project Number: 35214.00.000.00

Type of Review:

_X_ New

____ Renewal

Findings of the Board:

____ Project is exempt from IRB review

_X_ Project complies with all of the requirements of 45 CFR 46, "Protection of Human Subjects"

____ Project does not comply with all of the requirements of 45 CFR 46

Project Approved Until: September 30, 2011

Next Annual Review Date: May 29, 2010

John A. Hansen

Chair, Institutional Review Board

06/05/09
Date

(Revised 04/08/09)

INSTITUTIONAL REVIEW BOARD MEMBERS

DATE: 06/05/09

ICF Macro
11785 Beltsville Drive, Suite 300
Calverton, MD 20705

NAME (voting members only)[2,3] Last, First	HIGHEST DEGREE EARNED	PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALITY	AFFILIATION WITH INSTITUTION ABOVE (YES/NO)	ATTESTATIONS OF IRB CHAIRPERSON
Hermann, John A.*	PhD	Social Welfare	Yes	FOR ALL RESEARCH CONDUCTED UNDER THIS ASSURANCE, THE IRB CHAIRPERSON HEREBY ATTESTS THAT, EXCEPT WHERE SPECIFICALLY WAIVED OR ALTERED BY THE IRB UNDER 45 CFR 46.116(c), 46.116(d), 46.117(c), THE IRB WILL UPHOLD THE REQUIREMENTS OF 45 CFR 46 FOR WRITTEN INFORMED CONSENT, IN NONEXCULPATORY LANGUAGE UNDERSTANDABLE TO THE SUBJECT (OR THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE), INCLUDING THE FOLLOWING BASIC ELEMENTS PER 45 CFR 46.116(a/b): (1) IDENTIFICATION AS RESEARCH; PURPOSES, DURATION, AND PROCEDURES; PROCEDURES WHICH ARE EXPERIMENTAL; (2) REASONABLY FORESEEABLE RISKS OR DISCOMFORTS; (3) EXPECTED BENEFITS TO THE SUBJECT OR OTHERS; (4) ALTERNATIVE PROCEDURES OR TREATMENTS; (5) EXTENT OF CONFIDENTIALITY TO BE MAINTAINED; (6) WHETHER COMPENSATION OR MEDICAL TREATMENT ARE AVAILABLE IF INJURY OCCURS (IF MORE THAN MINIMAL RISK); (7) WHOM TO CONTACT FOR ANSWERS TO QUESTIONS ABOUT THE RESEARCH, SUBJECT'S RIGHTS, AND RESEARCH-RELATED INJURY; (8) PARTICIPATION IS VOLUNTARY; REFUSAL TO PARTICIPATE WILL INVOLVE NO PENALTY OR LOSS OF BENEFITS TO WHICH SUBJECT IS ENTITLED; SUBJECT MAY DISCONTINUE AT ANY TIME WITHOUT PENALTY OR LOSS OF BENEFITS TO WHICH SUBJECT IS ENTITLED; (9) WHEN APPROPRIATE, ADDITIONAL ELEMENTS PER 45 CFR 46.116(b). AS IRB CHAIRPERSON, I HEREBY SO ATTEST. SIGNATURE: John A. Hermann DATE: 06/05/09 PHONE: (301) 572-0340 E-MAIL: Jack.Hermann@sfr.fr ADDRESS: ICF Macro 11785 Beltsville Drive, Suite 300 Calverton, MD 20705
Arnold, Fred	PhD	Economics/Demography	Yes	
Baum, Herbert M.	PhD	Population Dynamics/Biostatistics	Yes	
Belcher, Frances	PhD	Community Psychology	Yes	
Duffy Jr., Thomas	MA	Political Science	Yes	
Gilford Jr., John	PhD, MSW	Social Work	Yes	
Iachan, Ronaldo	PhD	Statistics	Yes	
Jones, A. Billy S.	MSW	Social Work/Criminal Justice	Yes	
Matsakis, Aphrodite	PhD	Psychology	No	
Morgan, Mark	PhD	Political Science	Yes	
Pacqué, Michel	MD, MPH	Medicine/Public Health	Yes	
Ross, James G**	MS	Psychology	Yes	
Walrath-Greene, Christine	PhD	Community-Social Psychology	Yes	
Yee, Eugene B.	JD	Finance	Yes	

** Alternate Chair

*DENOTES CHAIRPERSON
**DENOTES ALTERNATES (IF ANY, DENOTE MEMBER FOR WHOM ALTERNATE WILL SERVE)

(1) WHERE REVIEW IS CONDUCTED BY ANOTHER INSTITUTION'S IRB, THE IRB MUST ENSURE ADEQUATE KNOWLEDGE OF LOCAL CONDITIONS, INCLUDING COMMUNITY ATTITUDES, RELEVANT CULTURAL SENSITIVITIES, INSTITUTIONAL POLICIES/ COMMITMENTS, APPLICABLE LAW, AND STANDARDS OF PROFESSIONAL CONDUCT/PRACTICE.
(2) NO IRB MEMBER MAY PARTICIPATE IN THE REVIEW OF ANY PROJECT IN WHICH THE MEMBER HAS A CONFLICTING INTEREST.
(3) IRBs MUST BE CONSTITUTED SO AS TO ENSURE APPROPRIATE REVIEW AND ADDITIONAL SAFEGUARDS FOR RESEARCH INVOLVING VULNERABLE CATEGORIES OF SUBJECTS.
(4) AFFILIATION MAY TAKE THE FORM OF EMPLOYMENT, MEMBER OF GOVERNING BOARD, STOCKHOLDER, OR PAID/UNPAID CONSULTANT (FOR PURPOSES OTHER THAN IRB FUNCTIONS).

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Institutional Review Board
Reporting Adverse Events and Unanticipated Problems

Federal human subject protection regulations require the principal investigator (PI) or project director (PD) of an IRB approved research study to report to the IRB any *unexpected adverse events* and *unanticipated problems* that occur during the conduct of the research.

What Is an Unexpected Adverse Event?

Some adverse events are expected to occur during research, while others are unexpected. An *adverse event* is considered to be an undesirable and unintended effect of the research occurring in study subjects or others as a result of (a) the interventions and/or interactions used in the research; or (b) the collection of identifiable private information under the research. Such events are included among the risks of participating in the research. Even though an event is unintended, we often expect that a certain number of adverse events will happen during the course of the research. For example, when conducting telephone surveys, we expect some complaints from individuals who are called. Each complaint is an adverse event and should be documented, but it is not unexpected. Research protocols should include procedures for dealing with expected adverse events (risks). An *unexpected adverse event* is one that was not anticipated in the research protocol. During the IRB review of a research study, the IRB tries to make sure that all anticipated risks have been identified and included in the informed consent form, and that there are procedures in place to minimize and address those risks.

What Is an Unanticipated Problem?

An *unanticipated problem* is considered to be any event that (a) was not expected given the nature of the research procedures and the subject population being studied; and (b) suggests that the research places subjects or others at a greater risk of harm or discomfort than was previously known or recognized. Note that it is only when both conditions (a and b) are present, that a problem is defined as *unanticipated*. Unexpected adverse events are also unanticipated problems, but there can be unanticipated problems that do not meet the definition of an unexpected adverse event.

What Must Be Reported to the IRB?

Many adverse events are anticipated possible risks of participating in the research and do not need to be reported to the IRB. For example, emotional discomfort may be a risk of participating in an interview and is identified as a risk in the informed consent form. An interview that is terminated by a subject because of emotional discomfort is an adverse event, but it is expected that some interviews will be terminated for such reasons and it should not be reported to the IRB. Only adverse events that are *unexpected* need to be reported to the IRB. If the study subject threatened suicide during the interview and suicidal ideation is not identified in the study protocol and in the informed consent as a risk of participating in the interview, the suicide threat would be an unexpected adverse event and must be reported to the IRB. Also, if the researcher anticipated that very few interviews would be terminated because of emotional discomfort, but finds that a higher number of interviews than expected are being terminated for discomfort, the risk of emotional discomfort is greater than expected and must be reported to the IRB.

Many unanticipated problems are also adverse events in that the problems are unexpected consequences of exposure to the research design and/or methods. However, there are some unanticipated problems that are not related to the research but must be reported to the IRB. For example, a field interviewer has her laptop computer stolen and the interview data are not encrypted. The study subjects have been placed at greater risk of harm from breach in confidentiality of the study.

Another example of an unanticipated problem is unethical behavior on the part of a study team member when interacting with study participants or using study data. Even if an unexpected problem is not likely to happen again, it must be reported to the IRB.

Problems that do not place study subjects at increased risk of harm or discomfort do not need to be reported to the IRB. For example, the termination of employment for a field data collector because he reported administering surveys that were never administered. This problem does not have to be reported to the IRB because it did not place the study subject(s) at greater risk.

What If I'm Unsure If an Event or Problem Needs to Be Reported to the IRB?

If it is unclear to you that an event or problem should be reported to the IRB, contact the IRB chair at Jack.Hermann@sfr.fr or the IRB Secretary, Rena Agee at Rena.A.Agee@macrointernational.com or (301) 572-0340.

When Should the IRB Be Notified?

The IRB should be notified as soon a possible from the time a determination is made that an event represents an unanticipated problem or unexpected adverse event. The notification must be made within 2 weeks of the event or problem.

How Should the IRB Be Notified?

If an adverse event occurs during an IRB approved study, the principal investigator (PI) or project director (PD) must report the event to the IRB using the online IRB Adverse Event Report. The online IRB Adverse Event Report is located on ICF MacroNet (https://intranet.macrointernational.com/) [under the main page, Project Resources, Institutional Review Board]. Once you press submit, the report and any accompanying documentation will be automatically sent to the IRB Secretary. A copy of the submission can be accessed by selecting the output/view link.

Can I Suggest Changes In the Research Protocol When I Report the Adverse Event?

Yes. You may suggest changes, and the IRB chair will consider your suggestions. Also, the Adverse Event Report requires that you document any changes that were made as a result of the event or problem. The IRB chair will determine if such changes are adequate or if other changes are needed to protect the study subjects.

What Does the IRB Do When an Adverse Event or Unexpected Problem Is Reported?

The IRB reviews the research protocol to determine if changes are needed in the study procedures to protect subjects from the identified risk or increase in risk. The IRB has the authority to require changes in the study procedures to minimize the risk of harm to subjects. The IRB will send the PI or PD an Adverse Event Findings Form that will document any required changes to the study procedures. The IRB also submits a report to the Office of Human Research Protections (within DHHS) that documents the event or problem and any actions taken by the IRB.

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Agreement to Comply with Human Subject Protection Requirements

The following project has been found by the Institutional Review Board (IRB) to be in compliance with the human subject protection requirements as specified in 45 CFR 46.

Project Title: National Survey of WIC Participants II

Project Director(s): Daniel Geller

ICF Macro Project Number: 35214.00.000.00

Approval Date: May 29, 2009

Next Annual Review Date: May 29, 2010

As the responsible principal investigator for this project, I agree to adhere to the human subject protection procedures that were approved by the IRB, and to inform the chair of the IRB when any changes are made in the approved procedures. The approved procedures include all of the following:

- Subject selection and recruitment procedures
- Data collection procedures
- Informed consent procedures
- Protection of privacy and confidentiality procedures
- Data security procedures
- Additional safeguards specified by the IRB.

If you have any questions regarding changes in procedures that are subject to IRB review, please contact Jack Hermann (Jack.Hermann@sfr.fr) to discuss your concerns.

Also, as the responsible principal investigator, I agree to cooperate with the IRB annual review(s) of this project. Several weeks prior to the next annual review date listed above, the IRB secretary will send you an IRB Project Annual Review Form to complete and submit to the IRB before the annual review date. The purposes of the IRB Project Annual Review Form are 1) to provide the IRB with updated information on the procedures used to protect the human subjects who are involved in this project, and 2) to help the IRB determine if the project is in compliance with the requirements in 45 CFR 46.

_____ _____

(signature) (date)

Make a copy of the signed form for your files, and return the original copy to Renáa Agee, IRB secretary.

(Revised 04/08/09)