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ACOG IRB Number:
Institutional Review Board

The American College of Obstetricians & Gynecologists Institutional Review Board

Request for Expedited Review/or Chart Review (AB-3)

Investi ator: Amanda Guiliano	Date: 12/18/17
Title of Project: Local Health Department Field Assianee Survey on Zika	

The ACOG IRB may determine that research activities that (l) present no more than minimal risk to human subjects and (2) involve only procedures listed in one or more of the categories below in Section One may be reviewed by the IRB through the expedited review procedure. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If you believe that your research falls into one of the following categories, please indicate which category or categories you believe is or are appropriate. One of the IRB Chairpersons or his or her designee will review your research to determine if expedited review is warranted. If warranted, your research will be reviewed to determine if approval can be granted. If granted, the form will be returned to you with an approval stamp in Section Three along with the signature of an IRB Chairperson, and you may begin your research. You must notify the IRB if your proposed research changes in any way. The IRB will request periodic updates, no less frequently than annually. If expedited procedures cannot be used, the reason will be explained in Section Three, and your research must be reviewed during a convened IRB meeting. Please direct questions to the IRB Office at (202) 863-2556.

Section One: Categories Eligible for Expedited Review (Please indicate one or more category, as appropriate, in the space next to the category numbers below.)

l . Clinical studies of drugs and medical devices only when condition (a) or (b) is met: ___

(a) Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) OR

___ (b) Research on medical devices for which (i) an investigational device exemption application is not required or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from:

___ (a) Healthy, nonpregnant adults who weigh at least 1 10 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; OR

___ (b) Other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn

may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

Note: 'Children ' in (b) above are defined in the HHS regulations as "persons who have not attained the legal agefor consentfor treatments or procedures involved in the research, under the applicable law ofthe jurisdiction in which the research will be conducted" [45 CFR 46.402(a)].

3, Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(a) Hair and nail clippings in a nondisfiguring manner

(b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction

(c) Permanent teeth if routine patient care indicates a need for extraction

(d) Excreta and external secretions (including sweat)

(e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue

(f) Placenta removed at delivery

(g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

(h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques

(i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

(j) Sputum collected after saline mist nebulization

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

(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy

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(b) Weighing or testing sensory acuity
(c) Magnetic resonance imaging
(d) Electrocardiography, elecroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

5.* Research involving materials (data, documents, records, or specimens) that :
___ (a) have already been collected for some other purpose, OR
___ (b) will be collected for non-research purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7.* Research on:
___ (a) individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, x cultural beliefs or practices, and social behavior), OR
(b) research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened IRB as follows:
(a) Where:
(i) The research is permanently closed to the enrollment of new subjects, and
(ii) All subjects have completed all research-related interventions, and
(iii)The research remains active only for long-term follow-up of subjects, OR
(b) Where no subjects have been enrolled and no additional risks have been identified; OR
___ (c) Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories 2 through 8 do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

* Note regarding categories 5 and 7: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.

Section Two: Additional Materials
Please attach the following materials to this application:

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l . IRB Application

2. Informed consent form (if applicable)

3. Any survey tools or questionnaires

Digitally signed by Amanda Guiliano
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email=aguillano@acog.org, c=US
Date: 2017.12.18 11:44:20 -05'00'

12/18/17

Signature of Investigator Date

Section Three: FOR IRB USE ONLY

R Research Approved by Expedited Review (Category a Expedited Review Not Allowed Si nature of IRB Chair or Desi nee | ate	Comments: