IRB Number: _008_____

The American College of Obstetricians & Gynecologists
Institutional Review Board
Request for Exemption (AB-4)

Investigator: Jay Schulkin	Date: 7/14/16
Title of Protocol: Perinatal Substance Use, Screening and Practices	

The human subjects regulations (45 CFR Part 46) define **research** as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)]. A **human subject** is "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" [45 CFR 46.102(f)].

However, some research involving human subjects may be exempt from the regulations. The categories below describe these exemptions. Please note that an exemption can be invoked only if **all** components of the research fit the category as described. You might find the following decision charts helpful:

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm

If you believe that your research may fall into one of the exempt categories, please indicate the relevant category in the space next to the category number below, and one of the IRB Chairpersons will review your research to determine if an exemption can be granted. If granted, your exemption request will be returned to you with an approval in Section Three along with the signature of an IRB Chairperson, and you may begin your research. You must notify the IRB if your research changes in any way, because the exemption may no longer apply. The IRB may request periodic follow-up. If an exemption cannot be granted, your exemption request will be returned to you with the reason listed in Section Three, and your research will be reviewed by the IRB. Please direct questions to the IRB Office at (202) 863-2556.

Section One: Categories Eligible for Exemption (Please indicate the relevant category in the space next to the category number. Categories continue on the next page.):

NOTE: These exemptions do not apply to research involving prisoners, pregnant women, human fetuses, or human in vitro fertilization.

1. ___ Research conducted in established or commonly accepted educational settings, involving normal educational practices. Examples include:
   a) Research on regular and special education instructional strategies, **OR**
   b) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. _X_ Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior. *NOTE: Except as noted above, this exemption applies to all such research involving ADULT subjects unless BOTH of the following conditions apply:*
   a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects (NOTE: Codes constitute identifiers.); **AND**
   b) Any disclosure of the subjects' responses 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.

   NOTE: This exemption applies to research involving CHILDREN EXCEPT that (i) research involving survey or interview procedures with children is NOT EXEMPT, and (ii) research involving observation of the public behavior of children is NOT EXEMPT if the investigator(s) participate(s) in the actions being observed.

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 category 2 above, 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.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (**existing** means research materials are already on the shelf or archived when the research is proposed; e.g., blood samples already taken from patients or subjects for other clinical or research purposes). This exemption applies if:
   ___ a) These sources are publicly available, **OR**
   ___ b) The information is recorded by the investigator in such a manner that individual subjects cannot be identified, directly or through identifiers linked to the subjects.

5. ___ Research and demonstration projects that are designed to study, evaluate, or otherwise examine:
   a) Public benefit or service programs;
   b) The procedures for obtaining benefits or services under such programs;
   c) Possible changes in or alternatives to such programs or procedures; or
   d) Possible changes in methods or levels of payment for benefits or services under such programs.

   NOTE: This exemption applies ONLY to research and demonstration projects

studying FEDERAL programs, and its use must be authorized by the Federal Agency supporting the research. As with all exemptions, IRBs and institutions retain the authority not to invoke the exemption, even if so authorized by the relevant Federal Agency. Studies of state and local public service programs require IRB review. Waiver of informed consent is possible for such programs under 45 CFR 46.116(c).

6. Taste and food quality evaluation and consumer acceptance studies, which meet any of the following conditions:

___ a) If wholesome foods without additives are consumed; **OR**

___ b) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection of the US Department of Agriculture.

J Schulkin 7/15/16

Signature of Investigator Date

Section Two: Additional Materials

Please attach the following materials to this application:

1. IRB Protocol Application
2. Informed consent document (if applicable)
3. Any survey tools or questionnaires

Section Three: FOR IRB USE ONLY

☒ Exemption Allowed (Category _2_) ☐ Exemption Not Allowed (Please see Comments) Sandra Quinlan 8/23/16 Signature of IRB Chair Date	Comments: The IRB recommends adding choices to the questionairre that would allow the respondent to indicate whether they have a program for opioid-addicted pregnant women at their institution or a nearby institution to which they can refer, as well as whether these patients are co-managed with social work, psychiatry, and/or specialists. Possibly allowing respondents to comment on the legal/ political climate that may impair their ability to provide services. Possibly include a question regarding the suboxone versus subutex use in pregnancy.