GUIDELINE FOR SADCR RVIEW OF RESEARCH INVOLVING CHILDREN

OHSP Policy 601 Research Involving Children indicates that additional review is required if the Reviewing IRB grants waiver of parental permission for human subject research involving children (also referred to as minors). This guideline outlines the procedures for obtaining additional approval by the Senior Associate Dean for Clinical Research (SADCR), or designee.

Procedures for Obtaining SADCR Approval:

1. Confirm that the research involves children and requests waiver of parental permission (see OHSP Policy 601).
    - *Note:* Proposals that only include activities utilizing biospecimens or data with no subject interaction or intervention do not require SADCR review.
2. The research study is reviewed by either the convened board review or expedited review process, waiver of parent permission is granted, and the study is given an "Approvable" determination, contingent upon SADCR (or designee) approval.
    - If the RSRB is **not** the Reviewing IRB, SADCR review and approval will be part of the institutional review process and documented in the institutional review memo. SADCR approval must be obtained prior to completing the institutional review and protocol submission to the Reviewing IRB.
3. RSRB Specialist sends all appropriate study materials to SADCR (i.e., application, protocol, etc.) in preparation for protocol review.
    - In cases where the SADCR has a conflict of interest, the materials will be forwarded to the Senior VP for Research (or designee) for review.
4. A protocol review meeting (or email correspondence as appropriate) is conducted with the study Investigator, study Coordinator, Board Chair, RSRB Specialist, RSRB Director, and SADCR or designee (and other staff or study personnel as appropriate).
5. Once the meeting is completed, the SADCR sends a letter to the Investigator acknowledging the meeting, summarizing the discussion to include any special circumstances that need to be addressed, and providing any other pertinent information relevant to protocol review discussion (see the following pages for example letters).
    a. The letter should indicate the category of study.
    b. The letter should indicate justification of waiver of parental permission.
    c. The letter should indicate justification of waiver of documentation of consent.
    d. The letter should indicate whether an advocate will be utilized as a substitute mechanism for protecting the children.
6. The letter is uploaded into the RSRB application (ROSS) by the study team, along with any changes to the protocol or other study materials that may have resulted from the meeting.
7. RSRB Specialist will review the revised documents (as applicable) and ensure that any changes or issues noted by SADCR review have been addressed. Once this is completed, and no issues remain, the study can then be RSRB approved (or an amendment submitted if RSRB approval previously granted). If the RSRB is not the Reviewing IRB, institutional review will be completed and the study may then be submitted to the Reviewing IRB for review and approval.

EXAMPLE LETTER INVOLVING PREGNANT CHILDREN AGES 15 TO 17

[INSERT INSTITUTIONAL LETTERHEAD]

Date: [INSERT]

TO: Study Investigator

FROM: [INSERT]
Senior Associate Dean for Clinical Research

CC: Board Chair
RSRB Director
RSRB Specialist

RE: **RSRB #XXXXX: STUDY TITLE**

This memo will document the meeting of [INSERT DATE] regarding the risk assessment requested by the RSRB for the study noted above. I am writing to approve your request for a waiver of parental permission for children aged 15 to 17 years who are participating in this study.

The purpose of this study is [INSERT PURPOSE AND SUMMARY OF STUDY ACTIVITIES].

This study presents greater than minimal risk with no prospect of benefit to the individual subjects that participate, but is likely to yield knowledge about the subject's disorder or condition. A consultant to the board, [INSERT], confirmed that the doses of iron given in this study pose no risk to the fetus. The study seeks to enroll 24 subjects.

A waiver of parental permission is sought for the enrollment of children (15 to 17 year old), based on the following rationale:

- New York State Law gives children the right to consent for reproductive health care (e.g., pregnancy).

Your request is consistent with institutional policy permitting a waiver of parental permission under the following condition(s):

- Research with children regarding conditions or procedures for which parental permission is not required under New York State Law.

Per 45 CFR 46.408 (c), an advocate will serve as the substitute mechanism for protecting the children who participate in this research study and the advocate is independent of the study team. A research advocate from the Rochester Adolescent Maternity Program (RAMP) who is familiar with the clinic population has been identified to assist with the consent process and throughout the study. The advocate's contact information will be specifically listed in the consent document and will be separate from the study team's contact information. In addition, a consent quiz has been developed to adequately assess the teen's understanding of the study.

Wards of the state will not be enrolled.

EXAMPLE LETTER INVOLVING REGISTRY STUDY WITH INFANTS

[INSERT INSTITUTIONAL LETTERHEAD]

Date: [INSERT]

TO: Study Investigator

FROM: [INSERT]
Senior Associate Dean for Clinical Research

CC: Board Chair
RSRB Director
RSRB Specialist

RE: **RSRB #XXXXX: STUDY TITLE**

This memo will document our meeting of [INSERT DATE] regarding the risk assessment requested by the RSRB for the study noted above. I am writing to approve your request for a waiver of parental permission for infants participating in this study.

[INSERT SUMMARY TO INCLUDE FUNDING SOURCE, PURPOSE AND STUDY ACTIVITIES]

The study, which poses minimal risk, seeks to enroll…...

A waiver of parental permission is sought for the enrollment of all subjects, based on the following rationale:

- All data collected for the purposes of this research is information that is recorded as part of clinical care
- Requiring parental permission may result in a biased representation of the population given the known under representation of at-risk minorities in consented research. Biased data would skew the outcomes and compromise the integrity of the results of the research conducted with this data. The validity of the study depends on complete ascertainment of patients in the study population.

The waiver is justified under 45 CFR 46.408 (b), as it qualifies for the waiver referenced at 45 CFR 46.116 (f):

- The research involves no more than minimal risk to the subjects;
- The waiver will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

In addition, the following additional protections are in place to protect the confidentiality of the data collected.

- There is a Data Use Agreement with the Neonatal Research Network Data Coordinating Center documenting that they will not seek to identify any subject.
- A numeric code will be used to transmit data to the Neonatal Research Network Data Coordinating Center. The link to the infant's identifying information (medical record number) will be stored at the local research office, maintained in locked cabinets and will not be available to anyone except the certified research personnel.
- Annually the Neonatal Research Network Data Coordinating Center will "lock" the dataset, which allows for no additional information to be entered on a particular subject. After a subject has been "locked," the link to the medical record number will be destroyed.

EXAMPLE LETTER INVOLVING INTERVIEWS WITH CHILDREN AGE 16 AND 17

[INSERT INSTITUTIONAL LETTERHEAD]

Date: [INSERT]

TO: Study Investigator

FROM: [INSERT]
Senior Associate Dean for Clinical Research

CC: Board Chair
RSRB Director
RSRB Specialist

RE: RSRB #XXXXX: STUDY TITLE

This memo will document our meeting of [INSERT DATE] regarding the risk assessment requested by the RSRB for the study noted above. I am writing to approve your request for a waiver of parental permission for children aged 16 to 17 years who are participating in this study.

The amendment to this study will add children aged 16 to 17 to the currently approved population of 18 to 30 year olds. [SUMMARY OF STUDY PURPOSE AND STUDY ACTIVITIES]

The study, which poses minimal risk, seeks to enroll a maximum of 30 subjects to complete the interviews. The interviews are expected to last 30-90 minutes.

A waiver of parental permission is sought for the enrollment of all children (16 and 17 year olds), based on the following rationale:

- Requiring parental permission would substantially reduce the number of subjects among younger mothers. Many young mothers do not live with their parents or may not have a parent available at the time of the interview. In addition, the younger mothers constitute a substantial portion (1/3) of the NFP and they may have different experiences. Excluding this group may not provide a comprehensive view of the NFP experience.

Your request is consistent with institutional policy permitting a waiver of parental permission under the following condition(s):

- No-risk or minimal-risk research with older adolescents

The waiver is justified under 45 CFR 46.408 (b), as it qualifies for the waiver referenced at 45 CFR 46.116 (f):

- The research involves no more than minimal risk to the subjects;
- The waiver will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The waiver of documentation of consent is consistent with 45 CFR 46.117(c)(2): the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Per 45 CFR 46.408 (c), an advocate will serve as the substitute mechanism for protecting the children who participate in this research study and the advocate is independent of the study team.

Wards of the state will not be enrolled.

EXAMPLE LETTER INVOLVING SURVEYS WITH CHILDREN AGE 16 AND 17

[INSERT INSTITUTIONAL LETTERHEAD]

Date: [INSERT]

TO: Study Investigator

FROM: [INSERT]
Senior Associate Dean for Clinical Research

CC: Board Chair
RSRB Director
RSRB Specialist

RE: **RSRB #XXXXX: STUDY TITLE**

This memo will document our meeting of [INSERT DATE] regarding the risk assessment requested by the RSRB for the study noted above. I am writing to approve your request for a waiver of parental permission for children aged 16 to 17 years who are participating in this study.

The amendment to this study will allow adolescents aged 16 to 17 to enroll in the study in the event their parent/guardian does not accompany them to their regularly scheduled clinic visit. The study will conduct surveys with both parents of adolescents ages 11-17 and adolescents ages 14-17. The surveys will be completed anonymously on a password protected computer laptop suing Survey Monkey®. No PHI or sensitive information will be collected. [INSERT PURPOSE OF STUDY]

The study, which poses minimal risk, seeks to enroll 400 urban and suburban parents of adolescents and 200 adolescents.

A waiver of parental permission is sought for the enrollment of all children (16 and 17 year olds), based on the following rationale:

- Many 16 and 17 year olds attend routine clinic visits without their parent; either driving themselves or taking public transportation. Excluding this cohort of subjects would result in a disproportionate and bias data set.

Your request is consistent with institutional policy permitting a waiver of parental permission under the following condition(s):

- No-risk or minimal-risk research with older adolescents

The waiver is justified under 45 CFR 46.408 (b), as it qualifies for the waiver referenced at 45 CFR 46.116 (f):

- The research involves no more than minimal risk to the subjects;
- The waiver will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The waiver of documentation of consent is consistent with 45 CFR 46.117(c)(2): the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Per 45 CFR 46.408 (c), an advocate will serve as the substitute mechanism for protecting the children who participate in this research study and the advocate is independent of the study team.

Wards of the state will not be enrolled.