4.5 Local 407 Panel Review of Pediatric Research

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for convening a local 407 Panel to consider pediatric research which is not federally funded or FDA regulated.

2.0 Policy

It is the policy of the Organization that research involving minors which is neither funded by HHS nor regulated by FDA, and which presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children but does not meet the requirements of HHS regulations at 45 CFR 46.404, 46.405, or 46.406 may be reviewed by a local 407 panel.

3.0 Definitions

- **3.1.** ***Children*** are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. See HRPP policy 4.4 (Research Involving Children), section 3.1] for additional details.

4.0 Eligibility for Local 407 Panel Review

- **4.1.** The Executive Chair or the Chair IRB-04 (Joint Pediatric IRB) may convene a local 407 Panel if all of the following conditions are met:
  - **4.1.1.** The research neither funded by HHS nor regulated by FDA; and
  - **4.1.2.** The IRB determines, by two-thirds majority vote, that:
    - **4.1.2.1.** A research protocol presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, and
    - **4.1.2.2.** The IRB does not believe the research meets the requirements of HHS regulations at 45 CFR 46.404, 46.405, or 46.406.

5.0 Local 407 Panel Membership

- **5.1.** The local 407 Panel will include at least 5 voting members and 1 non-voting member:
  - **5.1.1.** Two or more members in a discipline relevant to the research being reviewed. At least one must be unaffiliated with the institution.
  - **5.1.2.** Two or more members with general pediatrics experience. If possible, these members will have been present at the IRB-04 meeting during which the protocol was previously reviewed.
  - **5.1.3.** One non-scientist
  - **5.1.4.** The IRB Executive Chair or the Chair of IRB-04 will serve as the Chair of the local 407 panel, and will be non-voting
- **5.2.** If a member with the expertise in a discipline relevant to the research being reviewed is not available locally, then the IRB Executive Chair will enlist the services of a non-local consultant. The consultant will receive the materials described below and will provide a written response to the general and specific questions noted below for consideration by the Panel.
- **5.3.** The role of the Local 407 Panel Chair will be to:
  - **5.3.1.** Chair the meeting and focus relevant discussion.
  - **5.3.2.** Provide relevant regulatory information and guidance to the 407 Panel to assist their analysis.
  - **5.3.3.** Present a summary of the research.
  - **5.3.4.** Present the analysis of the IRB with respect to classification under 45 CFR 46.404, 405, and 406.
  - **5.3.5.** Answer questions from the panel relevant to the deliberations of the IRB.

6.0 407 Panel Review

- **6.1.** Prior to the Local 407 Panel Review, the investigator will be informed the panel will be

convened and will be given the opportunity to present written comments to the Panel in support of the criteria described in section 6.4B and 6.4C below (that is, the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and the research will be conducted in accordance with sound ethical principles).

- **6.2.** The following materials will be distributed to the 407 Panel members, at least one week prior to the meeting:
  - **6.2.1.** A copy of the IRB application, full protocol, ICF and information sheet, and all other relevant protocol related documents.
  - **6.2.2.** Any relevant questions for consideration.
  - **6.2.3.** Any additional written materials provided by the investigator
- **6.3.** At the scheduled Local 407 Panel meeting, the Chair will present a summary of the research, followed by the analysis of the IRB with respect to the classification under 45 CFR 46.404, 405, and 406.
- **6.4.** The Local 407 Panel will determine whether the research satisfies the following criteria:
  - **6.4.1.** The research does not meet the requirements of 46.404, 405 or 406; and
  - **6.4.2.** The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
  - **6.4.3.** The research will be conducted in accordance with sound ethical principles
- **6.5.** Recommendations from the Panel whether the research satisfies the criteria in section 6.4 above will be made based on a simple majority vote. The Panel may also comment, as a group or individually, on the specific criteria in section 6.4.
- **6.6.** The recommendations of the Local 407 Panel, including individual comments and findings, will be transmitted to the full IRB.

7.0 Full IRB Review

- **7.1.** At its subsequent convened meeting, the IRB will re-review the research, utilizing the findings of the Local 407 Panel in its deliberations, and make one of the following determinations:
  - **7.1.1.** The research, in fact, satisfies the regulatory criteria for approval under HHS regulations at 45 CFR 46.404, 405, or 406.
  - **7.1.2.** The research satisfies the criteria for approval under 45 CFR 46.407; specifically:
    - **7.1.2.1.** The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
    - **7.1.2.2.** The research will be conducted in accordance with sound ethical principles; and
    - **7.1.2.3.** Adequate provisions have been made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45 CFR 46.408.
  - **7.1.3.** The research is not approved.
- **7.2.** A two-thirds majority vote will be required to approve the research under section 7.1.1 or 7.1.2 above. If a two-thirds majority vote is not obtained then the research is not approved.
- **7.3.** The investigator will be informed, in writing, of the decision of the IRB promptly after the meeting of the convened IRB.

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