TITLE: Sixty & Better (S&B) Research Policy

Purpose: To ensure that all public and non-profit entities, scientific institutions, and individuals engaged in conducting research within the S&B center network adhere to standardized procedure and review process, and conduct research that is appropriate and reasonable.

Definition

Research - Any study, investigation, experiment or survey aimed at the discovery of information or facts, the testing of a hypothesis or theory by external researchers, academic institutions, etc.

Policy

1. ***Responsibilities:***
    a. Any research conducted by S&B staff, external researchers, academic institutions, graduate students, etc. intending to use S&B participants, volunteers or staff as subjects in research projects shall obtain prior approval from the S&B CEO.
    b. S&B Centers, partner sites and central office will obtain the approval of S&B CEO prior to any research being conducted with S&B participants.
    c. S&B Centers or partner sites have the right to refuse any research request if the site believes it would not be in the best interest of the participants or would be a burden to the site staff.
    d. S&B participants, volunteers and staff have the right to refuse participation in any approved research study.
    e. S&B CEO and authorized representatives and designees appointed by the CEO will assure approved research involving S&B participants, volunteers and staff is handled in accordance to this policy and as directed by law.

2. ***Approval Process:***
    a. The principal investigator of a research study will submit a copy of the study protocol to the S&B CEO or Program Director prior to initiate the study. The study protocol will consist of the following items:
        i. Principal investigator, credentials and affiliated Institution / Organization
        ii. Designated liaison for the agency who is a member of the research team to direct S&B questions or concerns
        iii. Background / Study Significance
        iv. Methods & HIPPA Compliance
        v. Data collection analysis
        vi. Consent process and informed consent document
        vii. Protection of confidential information, including HIPAA compliance as required
        viii. Risks and benefits to research participants
        ix. Mechanism to maintain confidentiality of research subjects
        x. Funding source(s)
        xi. Schedule for submission of progress and final reports to S&B

xii. Allocated funding as a negotiated rate or fee for S&B review of proposal and S&B's consultation and technical assistance as applies
xiii. Institutional approval or copy of the Institutional Review Board (IRB) Approval or exemption, and the IRB approved study protocol, which will comply with all federal requirements for the protection of human subjects in research (45 CFR 46 and 21 CFR 56), and procedures for application to and review by the sponsoring institution's IRB.

3. ***Review process -*** Submitted items are reviewed by an authorized representative(s) or designee(s) of the agency with final approval, approval with conditions, or disapproval provided by the agency CEO.

4. ***Study Implementation -*** Principal investigator will provide the agency CEO or authorized designee with a regular review of study progress as scheduled in the study protocol, as well as direct feedback or meetings.

5. ***Revocation of approval -*** The S&B CEO may revoke approval of any research study for violations of participant rights or for deviation or noncompliance to the written and approved proposal.

6. ***Study Results***
   a. Written reports will be presented to the S&B CEO or authorized designee as scheduled in the research protocol.
   b. The principal investigator will submit a final written report to the S&B CEO at the conclusion of the study. A copy of the manuscript for publication may be submitted in lieu of a final report.

Approved by the Board of Directors on 9/17/15

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