New Policy Summary

Policy Number and Topic: 09.17.00 Human Subjects Review Plan

Submitted by: Kim Sperber

This is a: New _____ Revised ___X___ policy.

The major changes or additions covered in this policy are as follows:

Changed language to be congruent with agency’s new Human Research Protection Plan and to be in compliance with the agency’s newly acquired Federal Wide Assurance (FWA)

III. DEFINITIONS – changed the definition of “human Subject” to the definition used by the U.S. Department of Health and Human Services to be consistent with the agency’s FWA, the definition in the CFR, and the definition in the agency’s Human Research Protection Plan.

Added language to the definition of “IRB” to clarify the difference between a federally-registered IRB and the agency’s Human Subjects Committee.

Slight changes to the definition of “Human Subjects Review Committee” simply to increase accuracy of the description.

IV B and IV C - Updated staff titles

IV D – deleted language requiring PI’s to provide ongoing reports to Executive CQI Committee; this has never been done in practice and is not practical/feasible.

IV F – Clarified role of external researchers now that agency has internal research center.

IV G – added reference to affiliation human research protection plan.
SUBJECT:

Human Subjects Review Plan

I. PURPOSE:

To evaluate research proposals involving human subjects and monitor these research projects to ensure that subjects’ rights are protected.

II. APPLICATION:

All Agency staff performing or participating in research and all external researchers

III. DEFINITIONS:

Human Subject: 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.

IRB: Institutional Review Board. Board of a University, Hospital, etc. that reviews and approves research proposals and is registered with the U.S. Department of Health and Human Services Office for Human Research Protections.

Human Subjects Review Committee: an internal Agency committee consisting of the Research Director, Clinical Director, Medical Director, QI Administrator and a "non-scientific representative" (typically an administrative specialist) who will review, approve, and monitor research involving Agency clients, family members of clients, and/or staff. Client representation may be obtained also at the committee's discretion.

PHI: Protected Health Information; any health information protected under HIPAA.

Primary Investigator (PI): The individual, whether internal or external, generally viewed as conducting the research. This individual usually will be the first author, will have written the proposal and will be responsible to see that the research is conducted as approved. In cases of grant applications, the PI is defined as the primary writer/requestor of grant dollars.

IV. SUBJECT CONTENT:

A. Evaluate proposed research projects based on the following criteria:

1. The biological, psychological, social, legal, and ethical issues involved in the proposed study.
2. The scientific merit and methodology of the proposed study.
3. The possible risks to the subjects.
4. The adequacy and legality of the proposed informed consent procedures by the subjects or legally responsible others. The consent should not waive any legal rights of the subjects including release of liability for negligence.
5. The Agency’s and Researcher’s grievance procedures.
6. Appropriateness of written and oral material to be given to subjects in the course of the research.
7. Signed consent forms of subjects.
8. Assurance that subjects will be informed orally and in writing of the possible risks and benefits of the study. Clients shall have the freedom to ask questions and to withdraw consent at any time.

Children and those adults who have a guardian serving as human subjects will have a signed consent by the legal guardian. The consent shall be attested to by the signature of a witness.

B. During application of grants that require outcome measurement or external reporting of data containing PHI of persons served, the PI (grant applicant) shall review proposed procedures and measurement instruments with the Quality Improvement (QI) administrator and/or Research Director prior to submission of the application. It is the discretion of the QI administrator or Research Director to request a Human Subjects Committee or IRB review.

C. The Research Director will assist the primary investigator with logistics issues within the Agency, including understanding and abiding by all legal, confidentiality, client rights, and HIPAA regulations.

D. The Primary Investigator, the primary person conducting the research, will monitor the ongoing research study to assure that:

1. A Human Subjects Review committee member is available and made known to subjects to discuss any concerns subjects might have in the course of the study.
2. Unanticipated risks or problems are reported to the committee within twenty-four (24) hours.
3. The study is being implemented as proposed.
4. Subjects are informed orally and in writing of the nature and the purpose of the study and the procedures to be used.

E. The Human Subjects Committee is a sub-committee of the Executive CQI Committee. Other members of the Executive CQI Committee may be asked to review and approve the proposal. Approvals or denials of research proposals will be documented in the Executive CQI minutes. The Primary Investigator shall submit a full copy of the research proposal to the Chair of the Human Subjects Committee for review and approval.

F. External researchers applying to use the Agency’s staff or clients as research subjects must submit a copy of their institution’s IRB approval letter, or independent reviewer, when applicable. If a research proposal has not been approved by an outside Institutional Review Board, the Human Subjects Committee may provide approval. All research proposals, regardless of IRB approval, must be approved by the Human Subjects Committee before any data collection can begin.
G. Grievance procedures for research subjects must include the right to grieve through the Agency’s Grievance process. Procedures for reporting allegations of noncompliance with human subjects protections are outlined in the Affiliation Human Research Protection Plan.

V. RESPONSIBILITIES:

Human Subjects Review Committee
Executive CQI Committee
Clinical Director
Agency Research Coordinators
Medical Director
Client Rights Officer

VI. REFERENCES:

Policy Client/Clinical 09.18.00 Client Rights and Grievances
CQI Plan
Human Research Protection Plan

VII. APPROVAL(S):

Prepared by: Approved by:

[Signature]
Assistant Clinical Director, President/CEO
Quality and Clinical Services Talbert House

[Signature]
Director, Quality and Clinical Services Executive Director

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Gateways

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