



**Series:** Board Governance **COA: ETH 6.0**  
**CFOP: 215-8**

**Procedure Name:** Human Subject Research  
**Procedure Number:** GOV-012A  
**Revision #/Date:** N/A  
**Effective Date:** 01/18/09

**Applicable to:** Board of Directors, Officers, Staff, Partner Agencies & Clients

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**SUBJECT:** Service Recipient Research

**PURPOSE:** To outline the guidelines for consumer participation in research studies conducted within the CBC of Brevard system of care. It outlines the safeguards to be taken to ensure the confidentiality of the client, client willingness to participate, continuity of care and communication protocol.

**PROCEDURE:**

## References

CBCB Policies/Procedures: GOV012

The CBC of Brevard Board is responsible for ensuring that the rights and entitlements of all consumers receiving services at CBC of Brevard are approached with the utmost sensitivity and maintained with the highest level of confidentiality. Therefore, CBC of Brevard will refrain from conducting human subject research without advanced Board approval.

If at any time the CBC of Brevard Board of Directors approves an evaluation of service recipients, all research will comply with the standards imposed by the Department of Children and Families Human Subject Research policy 215-8 and State law and Federal regulations found in 45 CFR, 46.4.09 and 21 CFR 50.56.

Further, any statistical analysis, reports, presentations or summaries involving client data will be compiled and presented in a manner that masks the identity and protects the privacy of individual consumers.

The following steps will be taken prior to conducting a research project directly involving consumers at CBC of Brevard:

- Board approved research projects will be submitted with the plan to the Compliance Committee which will serve as an internal research review committee.
- The Compliance Committee will assess the ethics of the proposed project; make recommendations for modification if necessary; and will monitor the ongoing research activities and report any concerns to the CEO.
- The entity conducting the research will submit verification of HIPAA compliance accompanied by an outline of their compliance procedure/protocol.

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- CBC of Brevard will enter into a Business Entity Agreement with external research entities.
- All research participants will sign a consent that includes:
  - A statement that he/she agrees to voluntarily participate
  - A statement that services will continue whether he/she agrees to participate
  - An explanation of the nature and purpose of the study
  - A clear description of risk, if any
  - A guarantee of how confidentiality will be maintained.
  - That a voluntary participant may withdraw from the study at any time, for any reason and in this event, the participant will continue to receive services.
- The Client Relation Specialist will ensure all necessary consents are distributed to participants and signed consents are returned and maintained on file.
- The Principle Investigator or Designee will provide in writing, obtain written verification from participants and verbally review the following:
  - The nature and purpose of the research
  - A clear description of risk
  - A guarantee of continuity of care
  - And a guarantee of individual consumer confidentiality
  - A guarantee that protected health information and other confidential information is maintained in a secure manner and all requirements will be met as required by HIPAA

Approved by the CBC of Brevard Board of Directors January 29, 2009

AS APPROVED BY THE BOARD OF DIRECTORS:



MR. WILLIAM RYDER  
Chair

Signature Date: 1/29/09

BY DIRECTION OF THE CHIEF EXECUTIVE OFFICER:



DR. PATRICIA NELLIUS-GUTHRIE  
Chief Executive Officer

Signature Date: 1/29/09