



Series: Board Governance COA: ETH 6.0

Procedure Name: Human Subject Research
Procedure Number: GOV BC 1006
Revision #/Date: (1) 04/19/2013, (2) 05/08/2017
Reviewed Date: 10/14/2020
Effective Date: 02/13/2012

Applicable to: Brevard C.A.R.E.S. Board of Directors, Officers, Partner Agencies, Staff and Clients

SUBJECT: Service Recipient Research

PURPOSE: To outline the guidelines for consumer participation in research studies conducted within Brevard C.A.R.E.S. 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:

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

If at any time the Brevard C.A.R.E.S. 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 Brevard C.A.R.E.S.:

- The entity conducting the research will submit verification of HIPAA compliance accompanied by an outline of their compliance procedure/protocol.
- Brevard C.A.R.E.S. will enter into an Agreement with external research entities.
- All research participants will sign a consent that includes:
 - A statement that he or she agrees to voluntarily participate;
 - A statement that services will continue regardless of whether he or 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 and

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- 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 Principle Investigator or Designee 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;
 - A guarantee of individual consumer confidentiality, and
 - 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.
- That the voluntary participant may withdraw from the study at any time, and for any reason.

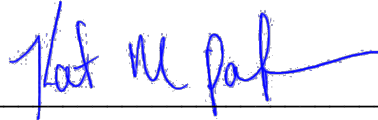
Approved by the Brevard C.A.R.E.S. Board of Directors October 14, 2020

AS APPROVED BY THE BOARD OF DIRECTORS:



Dan Rodgers, Board Chair

BY DIRECTION OF THE EXECUTIVE DIRECTOR:



Kathryn Parker, Executive Director

Signature Date: 10/14/2020

Signature Date: 10/14/2020