# POLICY

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| **Series:** | **Board Governance** | **COA: ETH 6.0**<br>**CFOP: 215-8** |
| **Procedure Name:** | Human Subject Research | |
| **Procedure Number:** | GOV-012A | |
| **Reviewed Date:** | 07/18/12, 10/3/16, 4/20/2021 | |
| **Revision #/Date:** | (1)4/22/2021 | |
| **Effective Date:** | 01/18/09 | |
| **Applicable to:** | FOA Board of Directors, Officers, BFP Family of Agencies Staff, Partner Agencies and Clients | |

SUBJECT: Service Recipient Research

PURPOSE: To outline the guidelines for consumer participation in research studies conducted within the Brevard Family Partnership 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.

**References:** GOV012 – Human Subject Research

PROCEDURE:

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

If at any time the Brevard Family Partnership 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 Family Partnership:

- Board approved research projects will be submitted with the plan to the Risk Management Committee which will serve as an internal research review committee.
- The Risk Management 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.

- Brevard Family Partnership will enter into a Business Entity Agreement with external research entities.
- All research participants will sign an informed 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 participation is voluntary, and a 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 Relations Specialist will ensure all necessary consents are distributed to participants and signed consents are returned and maintained on file.
- The Principal 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
  - That the voluntary participant may withdraw from the study at any time, for any reason

Approved by the Brevard Family Partnership Board of Directors on April 22, 2021.

AS APPROVED BY THE BOARD OF DIRECTORS:

BARBARA J. LOFTUS
Board Chair

Signature Date: 4/29/2021

BY DIRECTION OF THE CHIEF EXECUTIVE OFFICER:

PHILIP J. SCARPELLI
Chief Executive Officer

Signature Date: 4/29/2021