## Family Partnerships of Central Florida

## **POLICY**

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

Procedure Name: Human Subject Research

Procedure Number: GOV012A Reviewed Date: 4/16/2024 Revision #/Date: 3/28/2024 Effective Date: 01/18/09

**Applicable to:** Family Partnerships of Central Florida Family of Agencies (FPoCF FOA)

Board of Directors, Officers, FPoCF FOA Staff, Partner Agencies and

Clients

SUBJECT: Service Recipient Research

<u>PURPOSE</u>: To outline the guidelines for consumer participation in research studies conducted

within the Family Partnerships of Central Florida 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 Family Partnerships of Central Florida Governance Board is responsible for ensuring that the rights and entitlements of all consumers receiving services at Family Partnerships of Central Florida Family of Agencies are approached with the utmost sensitivity and maintained with the highest level of confidentiality. Therefore, Family Partnerships of Central Florida Family of Agencies will refrain from conducting human subject research without advanced FPoCF Governance Board approval.

If at any time the Family Partnerships of Central Florida Governance 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 Family Partnerships of Central Florida:

- Board approved research projects will be submitted with the plan to the FPOCF Risk Management Committee which will serve as an internal research review committee.
- The FPoCF 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 FPoCF FOA President and Chief Executive Officer.
- The entity conducting the research will submit verification of HIPAA compliance accompanied by an outline of their compliance procedure/protocol.
- Family Partnerships of Central Florida will enter into a Business Entity Agreement with external research entities.

## Family Partnerships of Central Florida

- 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 Caregiver Support 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 Governance Board of Directors on Mach 28, 2024.

AS APPROVED BY THE BOARD OF DIRECTORS:

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BY DIRECTION OF THE PRESIDENT AND CHIEF EXECUTIVE OFFICER:

Prix J. Summer

DANIEL P. RODGERS

**Board Chair** 

PHILIP J. SCARPELLI

President and Chief Executive Officer Family Partnerships of Central Florida

Signature Date: <u>4/16/2024</u> Signature Date: <u>4/16/2024</u>