COMMUNITY CARE ALLIANCE

POLICY & PROCEDURE

TITLE:	Research
AREA:	Ethics
REVIEW FREQUENCY:	Annually
REVIEWED BY:	Human Rights Officer
REFERENCE DOCUMENT(S):	COA – ETH 6 Rules & Regulations for the Licensing of Behavioral Healthcare Organizations; December 2018; Subchapter 10; Section 1.4.6 Research; Subchapter 00; Section 1.26 Individual (Participant) Rights
APPROVED BY BOARD:	June 2015
REVISED:	February 2015; June 2019

POLICY:
Community Care Alliance (CCA) recognizes the value of research to determine best practices to serve our clients. In the event that research, experimentation or clinical trials involving human subjects is to be conducted, CCA must adhere to all relevant licensing and accreditation standards. No client shall be required to participate in any experiment or research project without the full knowledge, understanding and written consent of the client (and/or legal guardian, if appropriate).

When research is conducted, CCA must adhere to established guidelines and to all applicable state and federal laws regulations.

DEFINITIONS:
Research includes all forms of internal or external research involving service recipients, except internal program evaluation and outcomes research, and educational projects carried out by students and interns as part of their internal training

GUIDELINES:
- If a staff member decides to undertake a research project, that staff member or intern, under appropriate supervision, will submit the research proposal to the Research Review Committee for review and approval. The Research Review Committee is comprised of the CEO, the Division Vice President, Human Rights Officer, Director of Program Evaluation, and the Medical Director (when applicable)

- If research is proposed in connection with a university or college, CCA requires documentation verifying that the research has been reviewed and approved by the university's Human Subject Review Committee.

- Each individual asked to participate in a research project will receive an explanation of the research project, and will sign a consent form, giving the organization authorization to include the client in participation. A copy of this consent form will be filed included in the client's health information record.

- Upon completion of the research project, CCA will ensure that actions are taken to alleviate, to the extent possible, any confusion, misinformation, stress, physical discomfort or other harmful consequences that may have arisen with respect to any participant's right to privacy, confidentiality and/or safety.

PROCEDURE:

1. The Research Review Committee designee will review CCA's Research policy expectations and requirements with the potential research organization to ensure their agreement and/or ability to comply with said policy requirements.

2. Proposal elements must be submitted by the potential research organization for review by the appropriate CCA staff and must include the following:

    - The purpose of the study, the treatment proposed and its relation to the organization's mission statement and values;
    - A description of the benefits expected;
    - A description of the potential discomforts and/or risks that could be encountered;
    - A full explanation of the procedures followed;
    - The criteria for inclusion and exclusion;
    - The process to be used to explain the procedures to the subject of the study, experiment or clinical trial;
    - The authorization form to be used is consent to participate in the research, experiment or clinical trial. The authorization form must include:
        - A statement that he or she voluntarily agrees to participate
        - A statement that the organization will continue to provide services whether he or she agrees to participate
        - An explanation of the nature and purpose of the research
        - A clear description of possible risks or discomfort, as applicable
        - A guarantee of confidentiality
        - The name and credentials of the person who supplied the information
        - The process for the subject to withdraw at any point, without comprising his or her access to CCA's services.
    - The method(s) of safeguarding any potential harmful consequences with respect to a client's right to privacy, confidentiality and safety in all phases of research conducted by, or with cooperation of, the organization. Case examples from individual case records must be prepared, prior to dissemination, in a manner that masks the individual's identity in all statistical analyses, reports, and summaries.
    - The inclusion of any vulnerable populations in the study, such as children, pregnant women and prisoners.

3. The Research Review Committee provides written documentation of recommendations regarding the ethics of proposed or existing research, its decision on whether to approve research proposals, and its plan to monitor ongoing research activities.

4. All clients have the right to refuse to participate without penalty.

(D. Stephens & T. O'Brien February 2015; K. Rathbun, June 2019)