

Hoffman Clark & Associates
Research. Development. Evaluation
Ethical Principals and Protection of Human Subjects
Polices and Procedures

A. Purpose:

This document was prepared in accordance with the Code of Federal Regulations Title 45 Part 46 Protection of Human Subjects, Sub-part A- Basic Protection of Human Subjects and Sub-part D- Children as subjects guided by the Department of Health and Human Services. This policy establishes responsibilities and procedures for protecting the rights and safeguarding the welfare of human subjects who participate in research conducted or supported by Hoffman Clark & Associates.

B. Background:

In 1979 the National Commission published The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research. The Belmont Report is widely regarded today as a seminal report on the ethical principles for human subjects research. It provides guidance for distinguishing therapeutic medicine from research, identifies three fundamental ethical principles for the protection of human subjects (respect for persons, beneficence, justice), and shows how these ethical principles apply to the conduct of human research. These principles continue to provide the ethical foundation for conducting research with human subjects.

C. Policy:

Hoffman Clark & Associates is a research, development and evaluation agency that specializes in the evaluation of public health and prevention programs. Hoffman Clark & Associates assists organizations that work with youth and their families in improving their health and overall well-being. Studies conducted by Hoffman Clark & Associates are focused through evaluating grant-funded public health and prevention programs. Funding sources, such as government institutions or private foundations, generally seek an evaluative purpose for program implementation. Hoffman Clark & Associates conducts ethical research to protect the rights and safeguard the welfare of human subjects who participate in its research studies by utilizing trained professionals in the areas public health and education research. Hoffman Clark & Associates and adheres to the following:

1. Hoffman Clark & Associates performs research according to the highest scientific and ethical standards and in a manner that promotes and respects the rights and welfare of all human subjects.
2. Hoffman Clark & Associates ensures that the performance of all research involving human subjects conducted complies with applicable Federal laws.
3. Hoffman Clark & Associates complies with the Ethical Principles and Guidelines for the Protection of Human Subjects Research. Under the general principles listed below, HCA conducts research with consideration of the following requirements: informed consent, risk/benefit assessment, and the selection of subjects of research.

3a. **Informed Consent** – Informed consent is required for all participants of research conducted by Hoffman Clark & Associates. Any subjects without written consent of participation are not included in any research. Specific institutions in which the program to be evaluated is being held acquires consent directly from participants (if 18 years and older) or by parental consent for a minor (17 years and younger). All consent forms are reviewed by Hoffman Clark & Associates to ensure the disclosure of accurate and sufficient information regarding the research procedure and purpose, any potential risks and benefits, a statement offering the subject the opportunity to ask questions with sufficient contact information and to withdraw at any time from the research.

3b. **Assessment of Risks and Benefits** -- The term "risk" refers to a possibility that harm may occur. The term "benefit" is used in the research context to refer to something of positive value related to health or welfare. Hoffman Clark & Associates conducts behavioral research with human subjects. Methods of data collection include but are not limited to direct observations, paper and pencil surveys, web-based surveys, face-to-face interviews, group interviews and videotaped interviews. Research protocols are examined to determine the level of risk regarding content sensitivity. Any question, statement or wording deemed inappropriate (with consideration to research purposes) by Hoffman Clark & Associates and participating organizations is not included or re-worded to reduce the potential risk of harm to research participants. Any data collection procedures also reduce the potential risk of harm to subjects by creating ways to increase participant comfort and confidentiality such as providing private and closed environments.

3c. **Selection of Subjects** -- Hoffman Clark & Associates requires fairness so that subjects are selected fairly by investigators and treated fairly in the course of research. Selection of subject must first to accept the risks of research and sign an informed consent (if 18 years and older) or parental consent for a minor (17 years and younger).

4. Hoffman Clark & Associates requires its investigators to understand the regulatory definition of research with human subjects and to know when they are conducting human subjects research.

D. Coverage

Hoffman Clark & Associates is an independent consulting firm that contracts with various institutions such as schools, community based organizations and hospitals. All programs contracted with Hoffman Clark & Associates are covered by this document for the Protection of Human Subjects.

E. Definitions:

1. **Human Subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information (45 CFR 46.102(f)). Some clinical and basic research activities with human tissues (i.e., blood and tissue samples) may also be considered research involving human subjects.
2. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(e)).
3. **Legally Authorized Representative** means an individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102 (c)).
4. **A Child** is a person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (45 CFR 46.402).
5. **Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102 (i)).

G. Responsibilities:

Hoffman Clark & Associates consists two founders (Joann Hoffman, MPH and Kim Clark, DrPh). Associates of Hoffman Clark & Associates are staff who conduct and support research involving human subjects.

1. Kim Clark is the signatory official for the Federal Wide Assurance and is responsible for oversight of human subjects research.
2. Joann Hoffman is responsible for the overall direction of and allocation of resources for all the research programs carried out at Hoffman Clark & Associates.
3. All Hoffman Clark & Associates' Investigators (including the aforementioned owners) are responsible for designing, conducting and monitoring protocols, ensuring the protection of human subjects, overseeing the informed consent process and the integrity and analysis of research data, including prevention of conflicts of interest by all associate investigators on their protocols. Investigators assure that protocols are followed and that data are collected promptly and accurately. They are responsible for ensuring that necessary approvals are obtained.
4. All sub-contracted associates and employed research staff of Hoffman Clark & Associates must have knowledge of what constitutes research involving human subjects and comply with the terms of the Hoffman Clark & Associates policy and 45 CFR Part 46.

H. Implementation Research Subjects: Rights and Resources

Federal regulatory procedures for the protection of human subjects is implemented at Hoffman Clark & Associates. In addition, Hoffman Clark & Associates has created procedures to ensure that research subjects are treated fairly and are given the opportunity for information regarding research activities.

a. **Information-** a current list of studies can be obtained at Hoffman Clark & Associates 731 South Hwy. 101 #2G Solana Beach, Ca 92075. Protocol information can be obtained either through Hoffman Clark & Associates or participating contracted clients (i.e. school districts, etc.). The participating client conducts the process of obtaining informed consent to help educate research subjects. Copies of the informed consent document provided upon request to prospective subjects before admission, to familiarize them with protocol requirements.

- b. **Complaints and Concerns:** Speaking directly to an Investigator or speaking to the manager of the program being evaluated may address Complaints and concerns. Subjects can withdrawal from participation in research at any time without penalty.
- c. **Costs:** There is no charge for research participation in any study conducted by Hoffman Clark & Associates.
- d. **Compensation:** The Lead Investigator determines whether compensation is appropriate, and if so the amount of compensation.
- e. **Translation and Interpreting Services.** Special efforts are made to ensure that subjects with no or limited proficiency in English receive the same fairness and information as English-speakers. Protocols in need of translation are done so accordingly.
- f. **Privacy and Confidentiality.** Every effort is made to protect the privacy and confidentiality of subjects' research records. Subjects are informed in consent documents of the extent of this protection and their rights under the Federal Privacy Act and any other applicable confidentiality and privacy protections. HCA investigators utilize a system of coding in which personal markers for subject identification are eliminated and replaced with a unique code only for the purposes of linking datasets over time. Master lists of unique identifiers are kept with the participating clients (i.e. Manager of grant-funded program) and these lists are not disclosed to Hoffman Clark investigators. The release of subject names from Hoffman Clark & Associates, prior to coding, to any outside sources always requires written consent from contracted institution. There are no exceptions.

J. Records Retention and Disposal:

All copies of research proposals, scientific evaluations, consent documents, subject data records are kept in either a locked file cabinet or a locked closet in the Hoffman Clark & Associates Offices. 45 CFR 46.115(b) and 21 CFR 56.115(b) state that records required by the regulations should be retained for at least three years after completion of the research. Data expired after the three-year deadline are shredded by a professional Shredding Company. A certificate of data disposal is presented to all clients.