

## First 5 Commission of San Diego

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### **Subject: Guidelines for Human Subjects Protection for Research Activities Involving Commission Data**

Policy Number: F5C-020

Effective Date: June 4, 2012

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#### ***REFERENCE:***

*Title 45 CFR, Parts 46; 160 and 164; HHS-A-3 (Audits), HHS-A-L-9 (Authorization for Use and Disclosures of Protected Health Information), HHS-A-L-13 (Uses and Disclosures for Which an Authorization or Opportunity to Agree or Object is Not Required), HHS-A-L-21 (Limited Data Sets and De-Identification of Protected Health Information)*

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#### **Purpose**

To establish a process for protecting the rights and privacy of persons involved in Commission-related research studies.

#### **Background**

The First 5 Commission of San Diego (the Commission) regularly engages in program evaluation that helps determine the best outcomes for children and families, the effectiveness of programs and the most efficient use of resources. The Commission or its contractors, subcontractors or grantees may seek to engage in research activities that contribute to the knowledge of the field of early childhood. In such cases, the Commission and its contractors, subcontractors and grantees are responsible for protecting the rights and welfare of those people who participate in research studies involving data gathered from Commission-funded programs.

The Commission's processes for protection of participants' rights are guided by the ethical principles expressed in the Common Rule (45 CFR, Part 46, § 46.102d). The first, respect for persons, recognizes that individuals should be treated as autonomous agents and that those with diminished autonomy should be provided special protections. The second guiding principle, beneficence, recognizes that individuals involved in research should be protected from harm and that efforts should be made to protect their well-being. The third guiding principle, justice, recognizes that participants in research should be selected equitably and that any benefits of research should be equitably distributed.

The County Compliance Office and County Counsel are authorized to review research activities using data from Commission funded programs in order to ensure that participants' human subjects rights are upheld.

Informed consent is the mechanism by which potential participants in research studies: (1) learn about the study they are invited to participate in and; (2) agree voluntarily to participate. In order

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for people to truly *volunteer* to participate in research studies, they must have information presented to them in a language they can fully understand and which makes sense to them culturally. They must also be allowed to make their own decision about whether or not to participate, without being pressured to do so by anyone involved in the study.

The process of obtaining participants' informed consent should follow all ethical standards and regulations while at the same time minimizing the burden of time and redundancy of efforts on study subjects and/or their parents/guardians. In addition, participants must be informed of their right to decline to provide personal data for the purpose of research and still receive services.

Participants in Commission-related research studies also have the right to expect that the data collected about them will be kept confidential, whether through strict data security measures or by ensuring that data that are released are treated in a manner that does not allow the identification of individual participants unless expressly authorized by the Participant and/or Parent/Guardian.

### **Definitions**

- A. **Commission Partner**: An organization or individual that partners with the Commission on research activities and may utilize Commission data. This includes the local, regional and state researchers as well as external researchers and their staff and contractors.
- B. **Confidential Information**: Confidential information is the unique, personal information and services data about a participant that are obtained through written or verbal communication with the participant, through the researcher's or contractor's written observations of the participant, or by reviewing confidential participant records in manual or automated format.
- C. **Confidentiality**: Confidentiality is the protection of personally identifiable information. This information will be disclosed to others only as authorized by the Participant or Parent/Guardian.
- D. **Contractor(s)**: An organization or individual that has a contract, sub-contract or grant with the Commission to develop or provide services or programs.
- E. **Evaluation**: Activities designed to assess the implementation of program goals and objectives by measuring performance outcomes at a variety of levels: individual, family, program, community, and system-wide.
- F. **Human Subjects**: People who volunteer to participate in a study. A "human subject" is a living individual about whom a researcher or investigator obtains either: data through interaction or intervention with the individual or obtains identifiable private information about that individual.

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- G. Human Subjects Protections: A set of ethical principles that guide research involving human beings. These include respect for persons, beneficence, and justice; respect for individuals' autonomy and protection of those with diminished autonomy; a commitment to do no harm or to minimize harm while maximizing possible benefits and; a commitment to justice through equitable selection of participants and equitable distribution of benefits of research.
- H. Information Owner: The specific County office or agency with primary accountability for data/information.
- I. Parent/Guardian: The child's Parent/Guardian or other primary caregivers such as relatives, guardians or other adults who have legal authority to make decisions for the child.
- J. Participant: Any child from prenatal to age five, family members, and/or parent/guardians who receive services from any Commission contractor, grantee or subcontractor.
- K. Personally Identifiable Information: Information that clearly identifies Participants and/or the Participant's family members, including, but not limited to name(s), date and place of birth, gender, current address, ethnicity, and primary language.
- L. Privacy: Privacy is the right of each individual to determine who is entitled to know their personal information. Privacy is the expectation that the entity entrusted with the individual's information will protect it.
- M. Research: A systematic investigation, including research, development, or testing, that is designed to develop or contribute to the general knowledge.

### **Policy**

Data collected for the purpose of research from persons receiving Commission-funded services will be gathered using a process of informed consent designed to fully educate participants regarding the study before consenting to participate, and to protect participants' rights as human subjects of non-medical research.

### **Procedures**

- A. Protection of Human Subjects
  - 1) All persons or organizations planning to conduct research using Commission resources shall obtain written authorization from the Commission prior to the start of the research. Commission staff will track all ongoing research activities. All research requests and findings shall be reviewed by the Executive Director of the Commission and/or his/her designee.

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- 2) Commission-related evaluation and research studies and activities shall be reviewed by the County Compliance Office acting as a Privacy Board to ensure that participants' privacy is protected and that appropriate informed consent protocols are in place.
- 3) With the approval of the Executive Director or designee, select research projects, such as partnerships with university or research institutions, may utilize the services of external Institutional Review Boards (IRB's).
- 4) Activities constituting research involving human subjects, which require human subjects protections include:
  - a. Systematic data gathering activities or inquiries designed to develop or contribute to generalized knowledge;
  - b. Research activities involving data that is compiled in such a manner that subjects are or can be individually identified.
- 5) Exempt activities include:
  - a. Internal quality assurance activities undertaken solely for the purposes of internal program monitoring or improving program performance, and in which the information will not be: used outside the agency or program, published, or otherwise widely disseminated.
  - b. Program evaluation activities performed on behalf of the Commission or the Contractor for the purpose of measuring program performance.
  - c. Research or evaluation activities involving the study of already existing, published program data, including documents or records if these sources are already publicly available.

### **B. Informed Consent**

The Commission's informed consent process is designed to ensure that all potential research study participants truly understand what the study is they are asked to participate in before consenting to participate. It is important for agents of the Commission and program staff to understand that informed consent is as much a process of education as a legal process of obtaining signatures.

The informed consent of all participants in research studies sponsored by the Commission or using Commission data will be obtained either by (1) presenting the participant with written materials or (2) by presenting a short form written document and orally explaining the information in the presence of a witness. In either method, the process of obtaining informed consent will take place before the participant's data is gathered. If, however, existing data are to be utilized for expanded or additional studies not covered in the original consent form, participants may be asked to sign consent forms concerning use of data that has already been compiled.

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- 1) The process of presenting participants with written informed consent information will ensure:
  - a. That all materials be presented in “lay” language that is understandable to the participant.
  - b. That all materials be presented in the participant’s native language or in another language understandable to the participant if s/he does not speak English.
  - c. That all participants receive a copy of the signed consent that includes the “California Research Subject’s Bill of Rights.”
  
- 2) The oral process of obtaining informed consent should be used if: 1) it is determined that, due to language or reading level problems, study participants would not be able to fully understand the materials if presented only in the long written form or 2) services are being provided via telephone.
  - a. The process of obtaining oral informed consent for participants with language or reading problems will:
    - Be presented in “lay” language that is understandable to the participant.
    - Be presented in the participant’s native language or in another language understandable to them if the participant does not speak English.
    - Be presented in conjunction with a written short form summary written in a language understandable to the participant.
    - Be presented by the person obtaining the informed consent with a witness present who is fluent in both English and the language being used to explain the informed consent to the participant.
    - Include obtaining the signatures of (1) the participant or his/her authorized representative and (2) the witness on the short form summary and a copy given to the subject.
  
  - b. Participants given consent via telephone will be read a verbal consent form. The individual obtaining the informed consent shall sign the form. All participants giving verbal consent via telephone shall receive a copy of the signed consent that includes the “California Research Subject’s Bill of Rights.”
  
- 3) All informed consent documents shall include the following elements:
  - a. A statement that the study involves a research study;
  - b. An explanation of the purpose of the study;
  - c. The expected duration of the subject’s participation;
  - d. A description of the procedures to be followed;
  - e. Identification of any procedures that are experimental;
  - f. A description of any reasonably foreseeable risks or discomforts to the subject;

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- g. A description of any benefits to the subject or to others which may reasonably be expected from the study;
- h. A disclosure of appropriate alternative procedures or courses of treatment, if, any, that might be advantageous to the subject;
- i. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- j. An explanation of whom to contact for answers to pertinent questions about the study and study subjects' rights, and whom to contact in the event of a research-related injury to the subject;
- k. A statement that participation is completely voluntary, refusal to participate will involve no penalty or loss of benefits or services to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits or services, to which the subject is otherwise entitled;
- l. A statement that data gathered will be publicly reported in aggregate form only, which protects individuals from being personally identified, unless otherwise noted and authorized by the participant.

### C. Contractors' Obligation to Obtain Authorization to Engage in Research Activities

All contractors and subcontractors must obtain the prior written approval from the Executive Director before engaging in any research activity involving data collected from a Commission-sponsored project. A project proposal shall be submitted for review to include any documents or application that will be submitted to an external Institutional Review Board. The project proposal shall be reviewed by Commission staff, the Research Coordinator of the Health and Human Services Agency and the County Privacy Officer to determine if the project requires an informed consent process, as described in sections A and B. First 5 San Diego will ensure that procedures stated here are included (where appropriate) in contract language.

Contractors, subcontractors, and grantees shall use a Commission-approved consent form that includes an explanation of the Commission's access and use of the subjects' data.

- 1) Limitations apply to contractors' future use of data and information collected by Contractors during the course of their work for the Commission, in addition to any other conditions and limitations imposed as part of the contracting process.
- 2) Access to data by outside researchers or use of data for research purposes that are beyond what is described in the original consent by participants is subject to the processes described in Commission Policy F5C-019.

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