

First 5 Commission of San Diego

Subject: Guidelines for Human Subjects Protection and Data Security for Research and Evaluation Activities

Policy Number: F5C-020

Effective Date: June 3, 2009

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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)

Purpose

To establish a process for protecting (1) the rights and privacy of persons involved in Commission-related evaluation and research studies and; (2) the ownership, confidentiality and security of data collected on behalf of the First 5 Commission of San Diego.

Background

The First 5 Commission of San Diego (the Commission) is committed to supporting program evaluation and research that helps determine the best outcomes for children and families, the effectiveness of programs and the most efficient use of resources, and that contributes to the knowledge of the field of early childhood.

As an agency that funds, initiates, and monitors program evaluation and research, the Commission is responsible for protecting the rights and welfare of those people who participate in Commission-supported studies. Contractors, subcontractors, grantees, and Commission Partners must understand the ethical standards and regulatory requirements governing the evaluation and research activities they are involved in, either directly or in an oversight role.

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.

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The County Compliance Office and County Counsel are authorized to review the Commission's evaluation and research activities in order to ensure that participants' human subjects rights are upheld in Commission-related research and evaluation studies.

Informed consent is the mechanism by which potential participants in program evaluation and research studies: (1) learn about the study they are invited to participate in and; (2) agree voluntarily to participate. In order for people to truly *volunteer* to participate in evaluation or research studies, they must have information presented to them in 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 evaluation and still receive services.

Participants in Commission-related program evaluation and 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 and evaluation activities and may utilize Commission data. This includes the local, regional and state evaluation teams as well as outside evaluators/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: Applied research that is 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.

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- F. Human Subjects: People who volunteer to participate in a study. A "human subject" is a living individual about whom a researcher, evaluator or investigator obtains either: data through interaction or intervention with the individual or obtains identifiable private information about that individual.
- 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 prenatal to age five, family members, and/or parent/guardians who receive services from a Commission Contractor and/or any Commission contractor, grantee or subcontractor who participates in research and evaluation activities.
- 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, testing, and evaluation, designed to develop or contribute to either general knowledge or to knowledge of the effectiveness of particular programs.
- N. Security: Security is the freedom from risk of unauthorized access, use, or disclosure of confidential information concerning Participants. Security includes a set of technical and administrative procedures to protect data and data systems against unwarranted disclosure, modification, or destruction. Security policy requires that only properly authorized and trained personnel who have a need to know in the course of their duties have access to confidential information.

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All Commission-related data collected from persons receiving Commission-supported services (and/or who participate in Commission-related studies) 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. The

Commission is the information owner of data gathered by or on its behalf. The Commission is therefore responsible for protecting the confidentiality and security of the data.

Procedures

A. Protection of Human Subjects

1. All persons or organization planning to conduct research or evaluation using Commission resources shall obtain written authorization from the Commission prior to the start of the research. Commission staff will track all ongoing research and evaluation activities. All research requests and findings shall be reviewed by the Executive Director of the Commission and/of his/her designee.
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:
 - Systematic data gathering activities or inquiries designed to develop or contribute to generalizable knowledge;
 - Research or evaluation activities involving already existing program data, documents or records, compiled in such a manner that subjects can be individually identified, either directly or through identifiers linked to the subjects;
 - Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior compiled in a manner that allows: (i) subjects to be identified directly or through identifiers linked to the subjects; and (ii) any disclosure of the subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
5. Exempt activities include:
 - Internal quality assurance activities undertaken solely for the purposes of internal program monitoring or improving program performance, and in

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which the information will not be: used outside the agency or program, published or otherwise widely disseminated.

- 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 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 evaluation or research studies sponsored by the Commission 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.

1. The process of presenting participants with written informed consent information will ensure:
 - That all materials be presented in "lay" language that is understandable to the participant.
 - 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.
 - 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.

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- 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 statement that the study involves a research study;
 - An explanation of the purpose of the study;
 - The expected duration of the subject’s participation;
 - A description of the procedures to be followed;
 - Identification of any procedures that are experimental;
 - A description of any reasonably foreseeable risks or discomforts to the subject;
 - A description of any benefits to the subject or to others which may reasonably be expected from the study;
 - A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
 - For studies involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and if so, what they consist of, or where further information may be obtained;
 - 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;
 - 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;
 - 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.

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C. Contractors' Obligation to Obtain Informed Consent

All contractors, subcontractors, and grantees must obtain the informed consent of all participants in Commission-related evaluation or research studies involving human subjects using a consent process that follows the guidelines and procedures in sections A and B.

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

D. Data Ownership and Confidentiality

The County of San Diego has established policies and procedures based on legal requirements and best business practices to protect the integrity, security, and confidentiality of the County's data/information and information systems. These policies outline all users' responsibilities regarding access and use of County data/information. The Commission will maintain strict adherence to these policies and procedures to protect the privacy rights of participants in Commission-sponsored studies.

1. All data/information (data) in the Commission's environment, regardless of its source, will be treated as Commission property for the purpose of monitoring, accessing, retrieving, restoring, deleting, protecting or disclosing such data.
 - The Commission is the owner of all data created by or on behalf of the Commission (regardless of source, i.e., by contractors, subcontractors, and grantees). Data, documents and other materials, whether in hard copy or electronic form, which are prepared by the contractor, subcontractor, or grantees in performance with an agreement with the Commission are and shall remain the property of the Commission.
 - Data gathered which are the result of a Commission funded activity and/or would not exist, save for Commission funding, are and shall remain the property of the Commission.
 - Contractors, subcontractors, and grantees shall maintain data on behalf of the Commission in a form and substance consistent with accepted research practices throughout the course of their contract.
 - Upon termination of a contract with the Commission, contractors, subcontractors, and grantees shall return data (or a full copy of data) in useable electronic format to the Commission within a reasonable time frame as stipulated in the contract.
 - The Commission, as information owner, will retain primary accountability for the data.
 - All data collected by contractors, subcontractors or grantees during the course of a Commission-funded activity, which is already gathered by the entity but utilized as part of the Commission's research and evaluation protocol, shall be the joint property of that entity and the Commission. This shall include activities funded by the Commission and one or more other funding sources. Contractors shall maintain this data and information on behalf of the Commission in form and

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substance consistent with accepted research practices throughout the course of the Commission-funded program. Research findings and results generated from the data may be used by both the Commission and the Contractor for research, evaluation, planning and reporting purposes. The Commission will not disseminate any results from jointly-owned data beyond standard Prop 10 local and state reporting requirements without the consent of the Contractor.

- All data collected by Commission Contractors during the course of a Commission-funded activity, which is already gathered by the entity but NOT utilized as part of the Commission's research and evaluation protocol, shall remain the sole property of the Contractor.
2. The Commission will maintain the confidentiality of all data in accordance with all applicable California and Federal codes and regulations relating to confidentiality, privacy and/or security standards for patient, student and family records. These include, but are not limited to: HIPAA, FERPA and 45 CFR part 46. In order to maintain the data's confidentiality, the Commission will:
- Ensure that, prior to being authorized to access, create, or use data in the performance of their Commission-related duties, all users sign a *Summary of Policies Regarding County Data/information and Information Systems* form, which explains their responsibilities for protecting County data/information and information systems according to the County's policies and departmental procedures.
 - Ensure that all parties accessing/using data will have the required authorization to do so before being given passwords or other access to data.
 - Monitor all users' adherence to the policies for access/use and protection of data.
3. The Commission and its Contractors shall implement and comply with adequate procedures to maintain the security and confidentiality of data collected and stored in connection to projects funded all or in part by the Commission. All parties shall be responsible for complying with all applicable state and federal laws governing the gathering, use, and protection of personal information.

The Commission will keep the data secure by:

- Providing a process by which authorized users can report any suspicious activity regarding data/information misuse to the Commission's Information security manager. Suspicious activity may consist of: signs of unauthorized equipment usage, unidentifiable callers seeking access to sensitive information, unidentifiable files found on file servers, paper containing CONFIDENTIAL, SENSITIVE, or RESTRICTED data/information found in recycle or trash receptacles, unusual activity recorded in log files, or other unusual or unauthorized activities.
- Data will be stored in securely and access will be given only to authorized personnel who have signed the County of San Diego's Summary of Policies Regarding County Data/Information and Information Systems.

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- Following procedures for security of data and data devices as defined by the County of San Diego and the County Health and Human Services Agency.
 - No Commission staff shall have access to or be able to view personally identifiable information of individual participants of projects funded by First 5 San Diego.
4. All intellectual property, such as software, materials, published documents or reports, data and information developed in connection with Commission funded projects shall become the sole property of the Commission upon completion or termination of a contract or grant, unless otherwise determined by the Commission. Contractors, subcontractors and grantees shall have the right to consent to and participate financially in any licensing or sales agreement relating to software or equipment developed at the discretion of the Commission.
- All published documents arising out of the performance of Commission contracts and grants shall attribute in writing that the effort was funded by the First 5 Commission of San Diego County.
 - 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 per Section (D) (1) of this policy.
 - 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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