

First 5 Commission of San Diego

Subject: Guidelines for Authorizing Research Using Commission Resources

Policy Number: F5C-019

Effective Date: June 29, 2015

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REFERENCE:

Title 45 CFR, Parts 46; 160 and 164; 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), HHS-A-H-4 (Guidelines for Authorizing Research Using HHS-A Resources)

PURPOSE:

To establish a process for authorizing requests to conduct research involving resources, employees, clients or patients, contractors, grantees, records or locations of the First 5 Commission of San Diego (Commission); and to monitor ongoing research activities.

BACKGROUND:

Research of government programs and operations has led to a wide range of improvements in the health and well-being of San Diego County residents. Research is systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge (45 CFR, Part 46, §46.102).

Professional research standards guide the design and conduct of research, setting standards for how researchers gather and analyze information. Research on government operations and programs often involves the analysis of information about the individuals who provide or receive County services. The Commission is responsible for managing, protecting and providing appropriate access to the information it collects, including identification of sensitive and/or confidential information and protection of this information from open exchange. Research that results in the expenditure or use of Commission resources must contribute to either general knowledge regarding the provision of human services or must add value to the organization or to the programs and services it funds. Research should cause no unmitigated risk, financial or otherwise, to the Commission, its partners, its contractors or the people it serves.

DEFINITIONS:

- A. **Commission Resources:** Resources include but are not limited to the Commission's facilities; staff (employees, volunteers or contractors); contractors and grantees; service recipients; records; and data.
- B. **Report:** A written document describing the detailed findings of the research project.

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- C. 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. Research does not include development, testing and evaluation activities that an organization undertakes to carry out treatment, payment and operations as part of the usual business conducted by the organization.

POLICY:

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. The Executive Director shall have the discretion to decline to participate in research activities requiring the resources of Commission staff and/or its contractors. The Commission staff will track all ongoing research activities and provide such information to the Office of Business Intelligence. All research requests and findings will be reviewed and approved by the Executive Director of the Commission and/or his/her designee.

PROCEDURES:

A. Applications from the Community

The Commission's Evaluation Manager/Epidemiologist will serve as the initial point of contact for all external parties wishing to conduct research and as the internal point of coordination for all research involving Commission data and resources.

1. The Evaluation Manager/Epidemiologist of the Commission or other designee shall:
 - Field requests from researchers who want to conduct research involving the Commission and its employees, resources, contractors, grantees or clients.
 - Send application materials to researchers.
 - Review the completed application materials.
 - Assess feasibility, appropriateness and interest in the research if it requires Commission or contractor staff participation, time and/or knowledge.
 - Evaluate each research proposal for overall benefit and risk to the County and the Commission.
 - Provide potential researchers with a billable rate for research participation, (based on fully loaded staff rates) when requested by the Executive Director.
 - Upon the approval of the Executive Director, forward the applications to the Office of Business Intelligence to review for compliance with County policies and state and federal regulations.
 - Communicate the Executive Director's decision to researchers regarding approval of their applications.

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- Develop Memoranda of Agreement (MOAs) to include ownership, acknowledgement and handling of data, timelines, Commission review of materials before publishing, researcher adherence to the agreement, etc.
 - Report the status and risk level of all research projects to the Office of Business Intelligence semi-annually, or upon request.
 - Maintain a record of requested and completed research that involves the Commission and its employees, resources, grantees or clients.
 - Depending on the project, consult with County Counsel regarding intellectual property rights, privacy issues or other potential legal issues.
 - Depending on the project, consult with the County Compliance Office concerning adherence with HIPAA, FERPA and other privacy acts.
 - Report the status of research projects semi-annually and elevate potential risks to the Executive Director of the Commission.
2. The Office of Business Intelligence shall:
- Track the progress of applications, ensuring they are reviewed in a timely manner considering the size and complexity of the requested project.
3. All Researchers shall:
- Comply with all applicable federal, state and local laws and regulations.
 - Sign agreements specifying the terms by which researchers may interview clients/staff or use Commission records or other resources.
 - Sign appropriate MOAs between the Commission and the researcher(s), as warranted by the scope and nature of the research.
 - Obtain authorization to publish from the Commission's Executive Director or his/her designee prior to any publication or presentation that uses Commission data.
 - Identify the First 5 Commission of San Diego as the data source in all publications.
 - Reimburse the Commission for research requiring extensive staff or contractor involvement, data extraction or use of Commission resources, if required by the Executive Director.

B. Applications from County Staff

County employees who initiate research with external parties must follow the guidelines and procedures in Section A, 2-3. Staff will obtain authorization from their Deputy Director and enter into an MOA for use of Commission resources.

Employee research will be included in the semi-annual research report to the Agency Director and Director of Operations.

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C. Reports

1. The Evaluation Manager/Epidemiologist or other designee shall:

- Monitor ongoing research projects to ensure researchers follow the terms and conditions of the approved project.
- Collect and review draft research products from the Principal Investigator.
- Immediately document and convey any disagreements regarding report content to the Executive Director of the Commission.
- Attempt to resolve any disputes concerning the draft report.
- When requested by the Executive Director, coordinate the preparation of a response to any disputed findings in the report content.
- Ensure that First 5 San Diego and the HHS Office of Business Intelligence have copies of all published products, including published interim reports.

2. Researchers shall, for each proposal:

- Submit progress reports to the Commission for review upon request.
- Submit an intermediate progress report to the Commission and the Office of Business Intelligence prior to changes to any of the following:
 - Subject population
 - Hypothesis
 - Title of the project
 - Researchers
 - Method of data collection or analysis, including instruments being used
 - Any other aspect of the research project, if such change(s) could present a risk to the participants of the study and/or to the Commission
- Submit final draft reports for review when the research is completed.
- Submit two final copies (one electronic and one hard copy) of any and all publications/reports developed from their Commission-related work to HHS Office of Business Intelligence, and two final copies (one electronic and one hard copy) to the Commission.

3. Failure to Comply:

A researcher's failure to comply with any of these policies or procedures may result in the immediate cancellation of the research approval by the Commission without advance notice. None of these guidelines takes precedence over any countywide policy or state/federal regulations governing research or the use of data and/or human subjects for research purposes.

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