

First 5 Commission of San Diego

Subject: Guidelines for Authorizing Research Using Commission Resources

Policy Number: F5C-019

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 authorizing requests to conduct research involving resources, employees, clients or patients, contractors, grantees, records, or locations of the First 5 Commission of San Diego (the 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 Strategy Management. All research requests and findings will be reviewed by the Executive Director of the Commission and/or his/her designee. The additional approval of the Office of Strategy and Planning and/or the County Compliance Office may be required for sensitive projects.

PROCEDURES:

A. Applications from the Community

The Commission's Program and Evaluation Manager will serve as 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 Program and Evaluation Manager of the First 5 Commission will:
 - Field requests from investigators who want to conduct research involving the Commission and its employees, resources, contractors, grantees, clients, or patients.
 - Send application materials to investigators.
 - Provide the completed application materials to the Evaluation Leadership Team for review.
 - Assess feasibility, appropriateness, and interest in the research if it requires Commission or contractor staff participation, time and/or knowledge.
 - Provide potential researchers with a billable rate for research participation, (based on fully loaded staff rates) when requested by the Executive Director.
 - Provide the recommendations of the Evaluation Leadership Team to the Executive Director of the First 5 Commission of San Diego for s/he to determine whether to forward for County review.
 - Upon the approval of the Executive Director, forward the applications to the Office of Strategy Management to review for compliance with County policies and state and federal regulations

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- Communicate the Executive Director's decision to researchers regarding approval of their applications.
 - 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.
 - All draft MOA's will be approved through County Counsel.
 - Report the status and risk level of all research projects to the Office of Strategy Management semi-annually, or upon request.
 - Maintain a record of requested and completed research that involves the Commission and its employees, resources, grantees, clients, or patients.
 - Report the status of research projects semi-annually and elevate potential risks to the Executive Director of the First 5 Commission.
2. The Evaluation Leadership Team will:
- Review the proposed research design to determine: whether the methodology is sound, whether the proposed research supports the Commission's Strategic Plan and if and how the proposed research fits within the Evaluation Framework of the Commission.
 - Make recommendations to the Executive Director as to whether or not to support the research effort.
3. The Office of Strategy Management will:
- Track the progress of applications, ensuring they are reviewed in a timely manner, considering the size and complexity of the requested project.
 - Evaluate each research proposal for overall benefit and risk to the County and the Commission.
 - Depending on the project, consult with the County Compliance Office concerning adherence with HIPAA, FERPA and other privacy acts.
 - Depending on the project, consult with County Counsel regarding intellectual property rights, privacy issues or other potential legal issues.
 - Recommend to the Executive Director of the First 5 Commission whether or not to approve such research, based on compliance with County, State and federal regulations; and the risk to human subjects, to the First 5 Commission and to the County.
4. 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.

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- Obtain authorization to publish by the Commission's Executive Director or his/her designee prior to any publication that uses Commission data.
- Identify the First 5 Commission of San Diego County 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.

C. Reports

1. The Program and Evaluation Manager will:

- 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 First 5 Commission of San Diego.
- 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 the Commission has 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 Strategy Management 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

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- 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 HHSa, Office of Strategy Management, 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.

Sunset Review: June 2012

Approved:

June 18, 2007
Date

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Commission Item No.

Approved:

June 3, 2009
Date

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Commission Item No.