

## Subject: Guidelines for Authorizing Research/Evaluation Using Commission Resources

Policy Number: F5C-019

Effective Date: April 20, 2021

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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)*

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### **PURPOSE:**

To establish a process for authorizing requests to conduct research/evaluation 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 and evaluation of government sponsored 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 and/or evaluation 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 and evaluation 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 and/or evaluation 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.
- D. Evaluation: A process that critically examines a program. It involves collecting and analyzing information about a program's activities, characteristics, and outcomes. Its purpose is to make judgments about a program, to improve its effectiveness, and/or to inform programming decisions

**POLICY:**

All persons or organizations planning to conduct research using Commission resources shall obtain written authorization from the Executive Director prior to the start of the research. The Executive Director shall have the discretion to decline to participate in research/evaluation activities requiring the resources of Commission staff and/or its contractors. The Commission staff will track all ongoing research/evaluation activities and provide such information to HHSA's Office of Strategy and Innovation (OSI). 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 will serve as the initial point of contact for all external parties wishing to conduct research and/or evaluation and as the internal point of contact of coordination for all research involving Commission data and resources.

1. The Evaluation Manager of the Commission or designee shall:
  - Field requests from researchers who want to conduct research/evaluation involving the Commission and its employees, resources, contractors, grantees or clients.
  - Send application materials to researchers/evaluator.
  - Review the completed application materials.
  - Assess feasibility, appropriateness and interest in the research/evaluation project, 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/evaluators with a billable rate for research participation, (based on fully loaded staff rates) when requested by the Executive Director.

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- Upon the approval of the Executive Director, forward the applications to OSI to review for compliance in accordance with County policies and state and federal regulations.
- Communicate the Executive Director's decision to researchers regarding approval of their application.
- Develop a Memorandum of Agreement (MOAs) to include ownership, acknowledgement and handling of data, timelines, Commission review of materials before publishing, researcher/evaluator adherence to the agreement, etc.
- Report the status and risk level of all research/evaluation projects to the OSI semi-annually, or upon request.
- Maintain a record of requested and completed research/evaluation 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/evaluation projects semi-annually and elevate potential risks to the Executive Director of the Commission.

### 2. All Researchers/Evaluators 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)/evaluator(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 and/or evaluation with external parties must follow the guidelines and procedures in Section A, 1-2. Staff will obtain authorization from their Deputy Director and enter into an MOA for use of Commission resources.

Employee research/evaluation 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 or other designee shall:

- Monitor ongoing research/evaluation projects to ensure researchers follow the terms and conditions of the approved project.
- Collect and review draft research/evaluation 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 OSI have copies of all published products, including published interim reports.

2. Researcher/Evaluator shall, for each proposal:

- Submit progress reports to the Commission for review upon request.
- Submit an intermediate progress report to the Commission prior to changes to any of the following:
  - Subject population
  - Hypothesis
  - Title of the project
  - Researcher(s)/Evaluator(s)
  - Method of data collection or analysis, including instruments being used
  - Any other aspect of the research/evaluation 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 project is completed.
- Submit three final copies (one electronic and two hard copy) of any and all publications/reports developed from their Commission-related work to the Commission.

3. Failure to Comply:

A researchers/evaluators 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/evaluation purposes.

Sunset Review: April 2024

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