California Department of Corrections and Rehabilitation

RESEARCH OVERSIGHT COMMITTEE

RESEARCH APPLICATION GUIDELINES

Division of Correctional Policy Research and Internal Oversight

OFFICE OF RESEARCH
RESEARCH OVERSIGHT COMMITTEE ADMINISTRATION TEAM
SEPTEMBER 2023

Mission

The California Department of Correction and Rehabilitation's (CDCR) mission is to facilitate the successful reintegration of the individuals in our care back to their communities equipped with the tools to be drug-free, healthy, and employable members of society by providing education, treatment, rehabilitative, and restorative justice programs, all in a safe and humane environment.

The CDCR Research Oversight Committee's (ROC) mission is to promote promising and potentially promising ideas and practices to evidence-based education, treatment, rehabilitation, and restorative justice interventions and programs.

Introduction

The CDCR is interested in research that focuses on evaluating and improving education, treatment, rehabilitation and restorative justice programs for individuals in our care. The department promotes evidence-based programs in which their effectiveness can be substantiated by causal evidence obtained through high quality outcome research (e.g., randomized experimental or quasi-experimental designs with control or comparison groups). The department encourages rigorous scientific research with strict application of scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results. The Research Oversight Committee Administration Team (ROCAT) administers the CDCR external research application process.

CDCR assesses, approves, coordinates, and monitors research activities to ensure:

- alignment with CDCR's organizational objectives stated in the January 2016 Blueprint;
- appropriate and lawful access to CDCR resources;
- compliance with all applicable laws, regulations, and policies.

These research guidelines provide:

- key points to consider when requesting to conduct research with CDCR;
- information on how to obtain approval to use CDCR resources for research;
- directions to follow when applying for and conducting research with CDCR.

Contact Information

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Research Oversight Committee Administration Team
Division of Correctional Policy Research and Internal Oversight
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Website: https://www.cdcr.ca.gov/research/research-requests/

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Research Application Guidelines

All research applicants must submit a completed standard CDCR Research Application Form to Data.Requests@cdcr.ca.gov for consideration by the ROC. Research applications are accepted continuously. Applications are processed as they are received and prioritized by level of completeness. Applications that meet the standards presented in these guidelines will be heard by the ROC as expeditiously as possible.

ROC members consider the comprehensiveness of the application in making a decision. Failure to address the following areas in the Research Application Form may result in the administrative rejection of the application:

- alignment with CDCR's research priorities;
- CDCR resources required to implement and complete the research (give a detailed summary of the resources needed, such as access to offenders, facilities, staff, records, etc.);
- intended use of data needed and/or created for the research including an explanation of the impact of not obtaining the data;
- specific data metrics needed to support research goals/objectives;
- research benefits to the CDCR, the CDCR's in-custody and/or parolee populations, and the community;
- the background, scope, proposed methodologies, sampling construct(s) and data analysis for the proposed study;
- basis of research (academic and/or professional);
- identify potential conflicts of interest and steps to mitigate such conflicts;
- intent to submit research to a refereed scientific/criminal for publication (if any);
- proposed start and end date(s) for the research study.

Applicants are required to include the following documents with the research application package. ROC members consider the completeness of the application in making a decision. Failure to include the following documents in the research application package may result in the denial of the application:

- a completed *CDCR Research Application Form* including applicant background information, research rationale, methods and analysis, expected end products, CDCR resources required, and expected research implementation timeline;
- a *Research Staff Contact List* showing all individuals who will be entering institutions or working with CDCR data collected and/or generated as part of the project; list names with respect to project role (e.g., interviewer, data analyst, principal investigator, co-principal investigator, etc.) including their position/title, department/organization affiliation, postal address, telephone number, and email address for each individual. The list must include the project's point-of-contact, data custodian and authorized designee signatory for the research entity;
- current *curriculum vitae/resume* (up to five pages) for all academic/professional staff members involved in the proposed research project;
- Research applications are only accepted from principal investigators who are at or above the academic doctoral level. Co-principal investigators (Co-PIs) below the academic doctoral level are accepted;
- An *Academic Support Letter* is required to be provided by the Principal Academic Advisor of the student Co-PI research applicant(s). Student Co-PI applicant(s) conducting research for a class

project, a thesis/dissertation, or for peer-reviewed publication, etc., must obtain a letter of support from one or more sponsoring academic advisors; support letters must identify the relationship with the student and approve the research scope, methodology (including the plan for data analysis), potential benefits and limitations of the research. The ROC does not recognize research conducted by applicants who are below the academic doctoral level, unless the principal investigator is at or above the academic doctoral level;

- A *Fiduciary Support letter* signed by the fiduciary support entity is required for student Co-PI(s). Applicants conducting academic or professional research as a student Co-PI(s) must specifically identify and acknowledge their fiduciary entity; (the fiduciary entity is ultimately responsible for risks associated with completing the research);
- copies of any research instruments and data collection tools (including survey documents) must be included for review and approval by ROC including any updates or changes;
- a sample *Informed Consent Form* is required to be included with the research application package if human subjects are used in the research.

Research Application Instructions

Project Scope of Work

This section provides a detailed description of the proposed study, including background, significance, and rationale of your research project. Define technical terminology and acronyms.

Background: Summarize the study topic and any relevant published literature or research. The application must include published literature and research findings pertinent to the study, including any relevant CDCR information (policies, publications, etc.). Technical terminology and acronyms must be defined in an annotated list in this section or throughout the research application.

Program evaluations must be conducted by an independent third-party and must include:

- a description of the program/intervention being studied and where the program/intervention is being conducted;
- whether the program/intervention has been implemented previously, and if so where;
- whether the program/intervention has been previously evaluated, and if so the results of the previous evaluation;
- a review of any published best-practices literature about this type of program/intervention;
- a statement identifying any potential conflicts of interest and steps to mitigate such conflicts.

Significance: A detailed description including the importance, relevance, and value of the research project in relation to the CDCR mission, especially how your project will move a promising and potentially promising idea or practice to an evidence-based education, treatment, rehabilitation, or restorative justice intervention and program. In addition, state if your research is evaluating a program/intervention funded by a specific CDCR funding stream (e.g., Division of Adult Institutions (DAI) rehabilitative program, Division of Rehabilitative Programs (DRP), Innovative Program Grant). If applicable, applicants must submit grant/contract award documentation relevant to the study, project or program.

Rationale: A detailed description providing a justification for the study design, methods, and participant population. Reference published works or earlier research findings pertinent to the study design and methods.

Description of Research Methodology

This section provides a concise, but comprehensive description of the study's research design and methods, including:

Project Aim(s) and Objective(s): What is hoped to be achieved by conducting this research project; the aims and objectives must be specific and measurable.

Research Question(s) and Hypothesis/Hypotheses: State the research question(s) to be answered by the study. There should be at least one hypothesis for every major study procedure or intervention. If there are no hypotheses, describe your project's goals.

Number of Participants: How many participants will be needed to meet the scientific aims of the research accounting for drop-outs. Show evidence of establishing statistical power. Select the target population from the list provided in the application.

Project Recruitment Procedures: Describe in detail the methods that you will use to identify study participants, including how the opportunity to participate in the study will be announced to potential participants, and how, where, and by whom participants will be contacted. Please include any scripts, ads, and/or letters that will be used for recruitment. List the specific institutions and facilities where recruitment will take place. Attach a copy of your Informed Consent Form.

Recruitment strategies for CDCR personnel must ensure compliance with state bargaining unit agreements and consider the impact imposed on employees' workload and duty schedules. Employees are not permitted to use work hours or state time to participate in voluntary external research studies without the support of the ROC and approval from the impacted hiring authority.

Oral and Signed Written Informed Consent: Oral and signed written informed consent must be obtained from all actual study participants and documented, except in situations where the approved research project only uses large administrative non-identifiable data sets. It is the applicant's responsibility to retain these documents. The CDCR will not collect or have access to these signed informed consent forms. The CDCR will only gain access to these forms through subpoena if necessary for legal purposes. Applicants requiring access to CDCR records relating to specific individuals (e.g., individual patient records or staff records) must obtain departmental approval(s) and explicit informed consent from individual study participants).

Research applicants must ensure that written informed consent of participants is obtained in accordance with California Penal Code § 3521 and the California Civil Code § 1798.24(b). Obtaining oral and signed written informed consent may require researchers to enlist the assistance of interpreters, guardians, and advocates to properly inform potential participants both orally and in writing of key aspects of the study in the language which the potential participant is fluent.

Research applicants must ensure that potential study participants are given an Informed Consent Form that fully explains what information is required from the participant, what consequences will arise out of their cooperation in the study and participant rights in relation to the research project. Specific language is required indicating that participation in the present research is strictly voluntary and participants are entitled to withdraw from this research study at any time.

The CDCR does not permit offering incentives or rewards to any incarcerated individual as an inducement to participate in a research study. It would be acceptable for applicants to reimburse parolees under CDCR jurisdiction for the associated costs incurred during participation in the research study (e.g., travel costs).

Project Inclusion and Exclusion Criteria: A description of the study sample and what criteria, if any, that will be used to include or exclude potential participants. Additionally, if the research methods call for comparing groups of participants, describe the procedures (e.g., random assignment, test scores, naturally occurring groups, etc.) that will be used to place participants in each condition. The use of program waitlists to construct a control or comparison group is discouraged as the use of waitlists may introduce bias in the study's results. Include who will be doing the assignment to conditions, and their level of training on the assignment procedures. Describe how any risks from assigning participants to conditions and how the risk will be mitigated.

Project Procedures: Describe in detail the study's overall timelines, locations, and procedure(s). List all interventions, assessments and interviews, and estimates of duration for each procedure. Provide schedules of events, identify study personnel involved in each procedure, and provide credentials necessary for relevant personnel. For complicated study designs, the applicant is encouraged to attach any applicable tables, flow-charts, and/or study algorithms.

Project Design and Methods: Provide a detailed explanation of how information from study participants will be collected, analyzed, and reported. Include information about recording and transcribing interviews and focus group discussions, if applicable. Data collection tools and instruments must be attached to the application. Provide detailed information about data collection methods such as one-on-one interview (written reply), one-on-one interview audio-recorded, self-administered questionnaire, focus group discussions, data linkage, data extraction, etc.

If applicable, discuss qualitative data validation and normalization strategies.

Applicants who wish to transcribe or record must request permission to allow electronic devices to be brought into CDCR premises and the recording or transcribing of interviews must be obtained from the Warden, and/or Division of Adult Institution Director/Chief, and/or Division of Juvenile Justice Director/Chief. The ROCAT will help applicants coordinate their request and connect them with appropriate CDCR Divisions.

Applicants must ensure that they have an alternative plan for documenting interviews and information if their request to record or transcribe interviews is not approved.

Interviews may only be recorded or transcribed provided that the oral and signed written informed consent of the participant has been obtained.

Data collection efforts should be designed to minimize or exclude the use of state resources such as email, the state computer network, telecommunication devices, and state facilities. Additionally, the use of state resources for external research purposes has potential legal implications. Approval to use state resources for external research purposes is made on a case-by-case basis through the ROC and is dependent on the value of the research to CDCR and the risk to individual safety and security.

If applicants are requesting administrative data from CDCR, a comprehensive list of data metrics must be provided with the application submission. The comprehensive list of data metrics must include the following information:

- list of specified metrics/variables/data fields
    - Annotate the need for each metric element (e.g., unique identification, demographic, programmatic, etc.);
- time basis of data extraction (e.g., daily, monthly, quarterly, semi-annually);
- over what time period (e.g., March 1, 2022 through March 1, 2023);
- delivery method (e.g., email, cd/dvd, OTECH Secure File Transfer);
- delivery format (e.g., xls, xlsx, csv, html, txt etc.).

If the applicant is requesting Public Records Act (PRA) data, it is recommended that the applicant review the list of data metrics provided through a PRA request as a guide in determining possible data metrics. Please see the following webpage for more information: CDCR Public Records Page

Data Analyses: Include a detailed description of data groupings and statistical tests proposed for use to measure differences between and among groups. Describe the statistical analytic tools and methods to be used in the study.

Risks to Project Participants: Describe any potential harm, burden, and/or inconvenience to research participants and facility operations staff. Please provide a comprehensive description of potential physical, psychological, economic, social, and interpersonal risk(s) to participants. Consider both the probability and magnitude of potential harms. Describe the harms to those who are on waitlists or in control groups. If applicable, include literature, risk rates, and subject experiences with research procedures.

Benefits to Project Participants: Describe benefits to study participants resulting directly from their participation in the study. Incarcerated individuals are not permitted to receive compensation in any form for their participation in the study.

***Detailed Description of Research End Products*:** Select from the list of categories of end products that will be produced from the study provided in the application. If the end product is not listed, select "Other", and described the end product.

Request to Access CDCR Resources: Select from the list of categories of CDCR resources needed to access in order to conduct the study. Data includes, but is not limited to, participants input (through interviews, focus groups, questionnaires, etc.) and any existing information (including clinical, social, observational, etc.) which includes administrative data.

Research Oversight Committee (ROC) Overview

ROC Process

ROC Membership: The ROC membership is comprised of CDCR Directors, General Counsel and Labor Relations Chief. The Division of Correctional Policy Research and Internal Oversight (CPRIO) Director serves as the presiding officer of the ROC. The ROCAT and the CDCR Office of Research provides administrative, technical, and research support for the ROC. The ROC meets monthly on a published schedule.

ROCAT Review: An initial detailed assessment of the research application is conducted by the ROCAT. If the research application is substantively complete, the proposed research appears to be sound, and the intent of the research shows merit, the application will be submitted for hearing by the ROC.

ROC Review and Decision: The ROC process provides a standardized and comprehensive approach for selecting and overseeing CDCR research projects. The ROC process emphasizes a department-wide and open approach in determining which research projects will be approved by the CDCR. The ROC also ensures proper protections for CDCR in-custody and parolee populations as well as staff and CDCR data resources.

Applicants are notified of the ROC's decision by formal letter. The ROC may decide to approve, deny, conditionally approve, or continue an application.

Approved Applications: ROC approvals will expire without cause two years from the date of the approval letter provided to the applicant. Additional time needed and/or resources needed for the research requires a new Research Application.

Denied Applications: If the ROC makes the decision to deny a research application, the ROCAT will communicate this decision by formal letter to the applicant(s) and indicate the reason(s) why the application was denied. The ROC decision to deny an application is final; however, applicants are encouraged to submit new research applications in the future.

Conditionally Approved Applications: The ROC may request minor specific revisions to an application to better meet the department's needs and to comply with CDCR's mission and specific rules and regulations for research activities. Conditionally approved applications must be revised as requested and a complete revised application must be submitted to CDCR within 30 business days of the date of the decision letter for the application to remain under consideration, otherwise the application is subject to administrative denial.

Continued Applications: The ROC may require major significant changes to an application to comply with departmental legal, labor, ethical and procedural concerns, to meet the department's needs, and to comply with CDCR's mission and specific rules and regulations for research activities. If the ROC makes a decision to continue an application, the applicant must provide a complete revised application to CDCR within 90 business days of the date of the formal decision letter for the application to remain under consideration, otherwise the application is subject to an administrative denial.

CDCR Letter of Conceptual Support: A Letter of Conceptual Support (LCS) may be generated by the ROC upon approval of a research application. The LCS shows the department's interest in the research and that the department supports the implementation of the research project. The LCS is provided for approved research applications only if necessary, as preliminary documentation for the Institutional Review Board (IRB) approval process and the Information Practices Act (IPA) approval process through the State of California-funded Committee for the Protection of Human Subjects (CPHS).

Consent Calendar: Following Conditional Approval of a research application and receipt of a complete revised application that fully complies with the ROC's requested changes, the revised application may be placed on the ROC Consent Calendar. This action expedites the final approval of the application.

CDCR Data Request Input Form (DRIF): Upon approval of an application, the ROCAT will provide a DRIF to the applicant for completion and submittal. The DRIF describes the information that will be used to generate the departmental data sharing agreement. The following information is captured on the DRIF:

- research organization – name and contact information;
- custodian of files – name and contact information;
- CDCR point-of-contact – contact information for CDCR staff you are coordinating with other than the office of research, leave blank if this does not apply to you;
- notification contact – name and contact information for individual from requester's organization to notify CDCR in the event of a breach or compromise of security, confidentiality or integrity of computerized data;
- signatory – name and contact information for authorized signatory or approved designee who is authorized to sign on behalf of the organization into a legally binding contract. This person cannot be a student at any level;
- description of intended use of data – detailed description of the need for and intended use of the requested data, including an explanation of the impact of not receiving the data. Include intended product(s) of study (including published literature and research findings, etc.);
- list of project team members and titles – list all individuals that are on the research team. Include their classification/title and their role in the research project;
- data requested including the project length of time, the time basis (how often the data needs to be pulled), time span of the data, delivery format of the requested data and the method data is delivered;
- specific metrics requested, including a detailed description and data source if known. Be sure to be as specific as possible, as a lack of detail will result in data requests not being completed in a timely manner.

CDCR encourages the applicant to reach out to their research organization before completing their research application in order to verify all the information contained in the DRIF is accurate. Some examples include, assuring the signatory is in fact authorized to sign a legally binding contract, and the correct research organization is entering into a contract with CDCR.

All approved studies require a DRIF. The earlier an applicant completes and returns the DRIF to CDCR the sooner the CDCR can generate a Data Sharing Agreement (DSA) for review and approval by the CDCR Agency Information Security Office.

CDCR DSA: The CDCR DSA is entered into by and between CDCR and the applicant of the applicant's research organization following approval of the research application to establish the content,

appropriate disclosure, use, and protection of the data requested by the applicant to support a contracted service, research study, and/or an operational business need of CDCR or other governmental agency, whether or not such data is provided by CDCR or collected or created by the applicant on behalf of CDCR.

In accordance with the CDCR DSA, applicants requesting access to medical information belonging to CDCR's population must obtain written informed consent from the individual. Some or all of the data specified in the DSA may constitute Protected Health Information (PHI), including PHI in electronic media (ePHI), under federal law, and Personally Identifiable Information (PII) under state law.

The limitations on intended use of data, the constraints on use of the data, requirements for data security, requirements for data metrics, data handling requirements, network security, notification of security breaches, indemnification, requirements to destroy all data upon the termination or natural expiration of the DSA, and the security requirements contained in the associated attachments shall survive this agreement into perpetuity.

Requested Data Metrics: Applicants shall provide a detailed explanation of each data metric requested from CDCR. The comprehensive list of data metrics must include the following information:

- list of specified metrics/variables/data fields
    - Annotate the need for each metric element (e.g., unique identification, demographic, programmatic, etc.);
- time basis of data extraction (e.g., daily, monthly, quarterly, semi-annually);
- over what time period (e.g., March 1, 2022 through March 1, 2023);
- delivery method (e.g., encrypted email, cd/dvd, OTECH Secure File Transfer);
- delivery format (e.g., xls, xlsx, csv, html, txt etc.).

Notification of Breach: Applicants agree to implement reasonable systems for the discovery and prompt reporting of any breach or security incident.

Additional Approvals

It is the responsibility of the researcher with an approved application to independently obtain the following additional approvals before conducting research at the CDCR.

Institutional Review Board

An Institutional Review Board (IRB) is an independent federal administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities.

An IRB is charged with the responsibility of reviewing, prior to its initiation, all research involving human participants. An IRB has the authority to approve, disapprove, monitor and require modifications to all research activities that fall within its jurisdiction, specified by both federal regulations and institutional policy.

Committee for the Protection of Human Subjects

CDCR is guided by the Committee for the Protection of Human Subjects (CPHS) funded through the California Office of Statewide Health Planning and Development (OSHPD). CDCR research applications require a CPHS Information Practices Act approval to provide limits on the collection, management, and dissemination of personal information by state agencies.

Note: As each IRB and the CPHS are independent federal authorities, no reciprocity exists between IRBs. An IRB and/or CPHS approval does not constitute automatic approval of the CDCR research application.

Criminal History Background Check

Before a research workforce member may enter a CDCR facility or access any source data, including, but not limited to, CDCR PHI, personal information (PI), and other confidential data, the workforce member must undergo and pass a state and federal fingerprint-based background check. A criminal history that warrants substantial concerns on the part of CDCR, as a result of either the background check or any subsequent criminal record review, shall exclude that workforce member from access to CDCR facilities and access to any source data, including, but not limited to CDCR PHI, PI, and other confidential data.

Applicants who reside in California may have a background check (Live Scan) performed at a specific CDCR location/facility. Contact the CDCR Research Oversight Committee Administration Team (ROCAT) at Data.Requests@cdcr.ca.gov and provide your business or home address (location). A representative from the CDCR will recommend the CDCR location/facility closest to your location, provide you a form to be completed by the applicant(s) and explain the Live Scan appointment scheduling logistics specific to a certain facility. Once a live scan is completed, processing time is between 30 and 60 business days.

Completing a Live Scan at a local retail outlet is discouraged. The results are often not accepted by CDCR resulting in delays and non-refundable personal fees.

Applicants who reside outside of California will receive a set of fingerprint cards in the mail and a letter of instruction to be presented to a local law enforcement agency where the applicant may receive Live Scan services. It is recommended that applicants contact their selected law enforcement agency to ensure that they offer these services. Please contact the CDCR ROCAT at Data.Requests@cdcr.ca.gov for further detailed instructions.

Additional Items

Program Evaluations

To ensure the quality of CDCR program evaluations, program providers must obtain the services of an independent third-party research entity to ensure the use of an independent rigorous systematic approach to gather, track and report on performance or efficacy measure outcomes for external program evaluation purposes. The approach becomes a program evaluation when the systematic approach is intended to add to "generalizable knowledge" which requires a third-party researcher.

Rigorous Research

The cost and safety considerations for staff, incarcerated individuals, parolees in the community, and researchers associated with permitting research to be conducted within CDCR are measurably significant. Therefore, the ROC directs the department's resources to research that provides high rigor with generalizable and actionable results. The department promotes evidence-based programs in which their effectiveness can be substantiated by causal evidence obtained through high quality outcome research (e.g., randomized experimental or quasi-experimental designs with control or comparison groups). The department encourages rigorous scientific research with strict application of scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results. This includes full transparency in reporting experimental details so that others may replicate and expand on findings. While qualitative research designs may provide useful ancillary information regarding a specific population or sub-population of study participants, sole use of qualitative research designs cannot replace quantitative analyses required for scientific program evaluation. The National Institute of Health (NIH) states that the rules of scientific rigor can differ from study-to-study, depending on methodology, but generally include proper negative and positive controls, randomization, blinding, measures to control bias, controlling for inter-operator variability, robust and accurate statistical methods, appropriate and accurate experimental design. The CDCR considers the following factors in determining the rigor of a study:

- strength of research design;
- breadth of documentation;
- type of analytic procedures used;
- sample size;
- independence of researcher.

Conflicts of Interest

A complete CDCR research application must disclose and discuss any potential conflicts of interests, specifically if any personal interests may be in conflict with the applicant's professional obligations. The application must state all efforts to mitigate any potential conflicts of interest. If participant-based research is conducted, the application must disclose and discuss the extent and duration of participation regarding the research rationale, the study design/methodology, data collection, analysis, and report writing.

Access to Department Premises

Visitations cannot be used to conduct research in CDCR headquarter locations, parole offices, or institutions/correctional facilities. All research within CDCR location/facilities must be approved by the ROC and specific warden(s) prior to initiation of the research. Additionally, ROC approved research applicants visiting and/or providing research materials to any CDCR location must adhere to all departmental rules, regulations, protocols, procedures and directions indicated on CDCR's visitation information website.

Termination of Approved Research Projects

Approved research projects are subject to termination if the methodology or project scope is changed at any time during the course of the approved project without CDCR approval.

CDCR reserves the right to suspend or terminate an approved research project when:

- continuation of the approved research project may prove detrimental to participant(s) or the safe and orderly operation of Departmental premises;
- CDCR determines, at its sole discretion, that a researcher is not abiding by the Research Guidelines, Department's Code of Conduct, rules, regulations, protocols, procedures or directions, or;
- a researcher is arrested for a criminal offense or is engaged in misconduct contrary to CDCR's Code of Conduct.

In the event that CDCR terminates an approved research project, approval to access CDCR's premises is terminated and researchers must leave CDCR premises immediately.

Frequently Asked Questions

1. **Must a potential study participant (incarcerated or paroled individual or CDCR employee) be informed orally and in writing about the study to obtain informed consent?**

   Yes. Per CDCR policy, the researcher must obtain oral and written informed consent from all potential research study participants prior to participation in the study with the understanding that this consent may be withdrawn at any time by the participant after consent has been provided. The Department reserves the right to request documentation of written informed consent from the researcher at any time.

2. **Must an entity operating under contract with CDCR to provide a service or program submit a research application for ROC approval if the entity intends to publish their research findings to the public?**

   Yes. All research/program evaluations within CDCR locations/facilities and/or using CDCR data and/or data generated by the researcher (e.g., interviews, surveys, focus groups) that is intended for public release must be approved by the ROC prior to initiation of the research.

3. **Must a CDCR research application disclose all potential conflicts of interest?**

   Yes. A complete CDCR research application does disclose and discuss any potential conflicts of interests, specifically if any personal interests that may be in conflict with the applicant's professional obligations. The research application must clearly delineate the relationship between the research organization and the organization responsible for providing the program. If evaluating a program, the application should clearly distinguish the role of the research staff and program staff with regard to conducting the study. The application must disclose and discuss the extent and duration of any potential conflicts of interest regarding the research rationale, the study design/methodology, data collection, analysis, and report writing. The research application must clearly delineate all efforts to mitigate any potential conflicts of interest.

4. **Must an entity under contract with CDCR (contractee) to provide a rehabilitative program for CDCR secure the services of an independent third-party research entity to evaluate their program if the contractee also intends to externally publish their program research findings to add to generalizable knowledge?**

   Yes. If a CDCR contractee is responsible for providing a rehabilitative program for CDCR and this contractee also desires to evaluate the efficacy of their program for external publication, the contractee must obtain the services of an independent third-party research entity to ensure the use of an independent rigorous systematic research effort to gather, track, and report on performance/efficacy outcomes.

5. **Is there any CDCR administrative data that is not permitted for release to external entities for research purposes?**

   Yes. There are administrative data that CDCR will not share with external entities. These data include, but are not limited to, any data not owned by CDCR (e.g., DOJ owned data such as CII#), gender identity, Social Security Numbers, complete date of birth (or day and month of birth year), and HIPAA-covered health care data.

6. **Can an individual below the doctoral level be the Principal Investigator for a study?**

   No. Academic students below the doctoral level are not permitted to apply independently and/or serve as the sole Principal Investigator (PI) to conduct research with CDCR. An academic student below the doctoral level may apply as a Co-PI with their university academic advisor serving as the PI for the study. Multiple Co-PIs are permissible on a specific application. High school students may not apply as PI or co-PI. Students who do not meet the above criteria are encouraged to explore data available publicly or accessible through the CDCR Public Records Act Process.

7. **What technical guidance can the CDCR provide to a research applicant to increase the thoroughness of their research application to limit any alternative explanations for the observed changes?**

   Consider the impact(s) on their proposed study participants who are simultaneously participating in or have previously completed other rehabilitative programs. The CDCR is interested in studies that can single out the cause/association of the observed behavioral change that their study participant may demonstrate.

   The below considerations may add thoroughness to the study and help provide CDCR with valuable results.

   - Consider including proper negative and positive controls, randomization, blinding, measures to control bias, controlling for inter-operator variability, robust and accurate statistical methods, and appropriate experimental design;
   - Consider using a comparison or control group with comparable characteristics to the experimental group for comparative purposes;
   - Consider adding intermediate outcome measures to the study design;
   - Consider requesting administrative data that is collected by CDCR and other governmental agencies;
   - Consider the limitation of solely relying on pre- and post- self-assessed surveys;
   - Consider identifying and providing steps to mitigate all potential biases and weaknesses in the study design;
   - Consider including a limitations discussion with the study design.

8. **Are CDCR staff email addresses obtainable through the CDCR ROC process?**

   No. CDCR staff employee email addresses are public information. As such, CDCR staff email addresses may be obtained through the CDCR PRA request process. However, if an individual wants to contact CDCR staff for the purpose of conducting a research study, it is required that the study receive ROC approval before any CDCR employee is contacted.

9. **Can the CDCR provide an incarcerated or paroled individual's arrest record to a researcher?**

   No. The CDCR cannot provide an incarcerated or paroled individual's arrest record to a researcher. The US or the California Department of Justice may be able to assist a researcher to obtain this information independent from CDCR.

10. What administrative data is available to a researcher to add thoroughness to the study?

The CDCR collects administrative data as part of ongoing operations; this information is available in various forms to assist the researcher. It is the responsibility of the researcher in preparing their application to describe the categories of data relevant to the aims/objectives of the study. Below is a simple non-extensive and incomplete list of CDCR in-custody population metrics available:

- Rules Violations Reports (RVRs): RVRs are categorized as "counseling", "administrative", or "serious." Serious RVRs are for the most egregious level of misconduct, which could be prosecuted as a criminal offense (misdemeanor or felony). Administrative RVRs are misconduct at a lower level, but which could not be prosecuted as a criminal offense;
- Reports of facility incidents;
- Visitation information;
- Participation in and/or completion of rehabilitative programs.

11. Must data custodians identified in the CDCR Data Sharing Agreement be cleared through CDCR's criminal background check process?

Yes. Data custodians identified in the Data Sharing Agreement must clear CDCR's criminal background check process.

12. How often does the ROC review research applications?

The ROCAT receives research applications on a continuous basis. The ROC reviews research applications on a monthly basis based on the completeness of an application. The CDCR only accepts research applications submitted to Data.Requests@cdcr.ca.gov.

13. What does the ROC review process consist of?

When a CDCR research application is received by the ROCAT, the following process occurs:

1. ROCAT methodological and administrative review;
2. If warranted, administrative rejection due to failure to submit a fully completed application, otherwise;
3. Application hearing by the ROC resulting in decisions of "approve", "deny", "conditional approve", or "continue";
4. Letter sent to applicant indicating ROC decision;
5. A revised application may be prepared by the applicant for subsequent consideration by the ROC if the decision is "conditional approve", or "continue";
6. ROC review of revised applications for conditionally approved and continued projects;
7. Final decisions of "approve" or "deny" for a project.

14. What obligations are placed on Principal Investigators (PI) when conducting research with CDCR?

The PI is responsible for obtaining Institutional Review Board and California Committee for the Protection of Human Subjects approvals as necessary and criminal history background check clearances for the PI and PI's research team. Additionally, the CDCR requires a fully executed CDCR Data Sharing Agreement or Business Use Case Proposal between the PI/PI's agency and the department before the study can be started. Given the subject matter of this research, strict,

comprehensive, and detailed written protocols and procedures must be developed and implemented in accordance with all applicable CDCR regulations, State of California laws, federal regulations such as 45 CFR 46 Subpart C (§46.306), and CDCR's requirement to obtain verbal and signed written informed consent from all study participants prior to data collection. Researchers must observe and comply with all Departmental rules, regulations, protocols, procedures and directions. Progress reports must be provided to the ROCAT every three to six months or as advised by the ROCAT.

15. What are applicable laws governing the CDCR ROC Process?

Applications should comply with the following rules and regulations:

- 45 CFR Part 46 (Protection of Human Subjects)
- California Penal Code § 3500-3524 (Biomedical and Behavioral Research)
- California Civil Code § 1798-1798.78 (Information Practice Act)
- California Government Code § 13989.6 (California Taxpayer Access to Publicly Funded Research)

16. What is the difference between a "Public Records Act (PRA)" request and a request for data for research purposes?

A "Public Records Act" request must conform to the requirements and limitations of the California Public Records Act. External requests for data for research purposes must be approved through the ROC process.

17. How does CDCR assess research applications?

CDCR assesses research applications based on the following criteria:

- alignment to CDCR's research priorities;
- value of the research to CDCR and the corrections research community;
- scientific rigor of the proposed study and potential conflicts of interest;
- human subject impacts on offenders under CDCR care, and CDCR staff and resources;
- CDCR capacity to support and facilitate the proposed research;
- availability of needed data/information for research purposes;
- advice from relevant subject matter experts.

18. When does fiduciary responsibility become important to student researchers?

Research applications are only accepted from principal investigators who are at or above the academic doctoral level. Co-principal investigators or students below the academic doctoral level are accepted but are required to identify and acknowledge a fiduciary entity responsible for funding the proposed research project. These students may not be the data custodian, the primary contact for the proposed study, or the signatory for the academic institution where the student is enrolled. Students are required to provide an academic support letter and a fiduciary letter from the academic institution stating the institution will be responsible for conducting the research study if approved.

19. Can changes be made to the research application after submission?

Applicants have the opportunity for substantive application revisions only following a ROC decision of "conditional approval" or "continue." The applicant is not permitted to make any substantive changes to their application after receiving approval from the ROC, IRB, CPHS and execution of the CDCR data sharing agreement.

20. Can a research application be re-submitted if it is denied by the ROC?

No. The applicant may submit a new application taking into account reasons for the denial of the original application and the entire review process restarts.

21. When can a research application be submitted?

A research application can be submitted at any time. The ROCAT receives research applications on a continuous basis. The CDCR only accepts research applications submitted to Data.Requests@cdcr.ca.gov.

22. Can different titles be used for my CDCR, IRB and CPHS applications?

No. Project titles must be the same across all applications. Failure to do so will result in additional processing time and may result in application denial/rejection.

23. How do researchers obtain approval to publish CDCR research findings?

Researchers must obtain approval from CDCR before any research findings that use CDCR data (including but not limited to survey data obtained from individuals under CDCR custody) are published or are otherwise made available to the public. This approval may be stipulated to in the researcher's approved CDCR research application; otherwise, approval of a new CDCR research application is required. Any research findings made available to the public must meet the publication conditions set out in the California Government Code § 13989.6 in order to be approved for publication.

24. Should researcher(s) notify the CDCR about their publications based on CDCR data?

Yes. Researcher(s) must notify the CDCR about their publications and research findings that use CDCR data (including but not limited to survey data obtained from individuals under CDCR custody). Researcher(s) should also know that the final copy of the research findings should be posted on the CDCR's website. California Government Code § 13989.6 specifies that anyone receiving funding, whole or in part, shall provide for free, public access to any publication of peer reviewed manuscript describing state-agency-funded knowledge, a state-agency-funded invention, or state-agency-funded technology.

25. Is a CDCR DSA needed for all proposed studies involving offenders under the CDCR jurisdiction?

Yes. An executed DSA is required for all research studies involving offenders under the CDCR jurisdiction independent of the type of data collection. The CDCR either solely owns or co-owns with the researcher/research entity all data used and/or generated as part of a ROC-approved research

study. The applicant must have a completed and signed DSA between the researcher's organization and CDCR before the applicant can begin a research study (or any aspects of the study).

26. Do researchers need to go through the criminal background process?

Any research staff person who is not an employee of the CDCR and is requesting access to the CDCR facilities, and/or processing/analyzing individual-level data owned by CDCR must clear a criminal background check prior to initiating work. The CDCR is required to hold current criminal background check results, even if the applicant recently cleared a previous criminal background check for another study (or purpose).

27. How long does it take to begin a study after receiving a ROC approval letter?

Once an approval letter is received by the applicant, it may take three to six months to begin a study. The estimated timeframe includes completing the criminal background check, the CDCR Data Request Input Form (DRIF), and DSA processes. Process time can fluctuate based on the number of research staff requiring a criminal background check, the completeness and timeliness of the DRIF, the data requested (e.g., types [administrative and/or survey] of data or timeframe), and the level of detail and clarity of the request.

28. What is the difference between program performance measures (internal) versus program evaluation?

Program providers are encouraged to use a systematic approach to gather, track and report on performance measure outcomes for internal management purposes. If this approach is intended to add to "generalizable knowledge," the approach becomes defined as research and an independent third-party evaluation of the program/activity is required for approval of the effort by the ROC.

29. Can applicants evaluate a program they are also providing?

No. Applicants are not permitted to evaluate their own program(s) for research purposes. The entity responsible for implementing and conducting the program must obtain the services of an independent third-party research entity to ensure the use of independent rigorous systematic approach to gather, track, and report on performance/efficacy-measure outcomes for external program evaluation purposes.

Definitions

Approved Research Project/Study

A research application approved by the ROC, together with a fully executed CDCR DSA.

Authorized Designee Signatory

Person who is the designated signatory, authorized to sign on behalf of the organization and enter the organization into a legally binding contract. Authorized designated signatory is needed to sign the Data Sharing Agreement which is entered into between the Principal Investigator's research organization and CDCR.

Data

Information, written or digital (including image and voice recordings), the disclosure of which is restricted or prohibited by any provision of law. Some examples of confidential information include, but are not limited to, personal information about individuals as defined in California Civil Code § 1798.3 of the Information Practices Act (IPA) if the disclosure of the personal information is not otherwise allowed by the IPA.

Data include but are not limited to:

- What people say in interviews, focus groups, questionnaires, personal histories and biographies;
- Analysis of existing information or administrative data (clinical, social, observational or other).

Data Custodian

Member of Principal Investigator's organization with permanent status who is responsible for the observance of all conditions of data use and for establishment and maintenance of security arrangement to prevent unauthorized use or disclosure of the data. The Data Custodian must go through the CDCR's criminal background process.

Fiduciary Entity

The fiduciary entity (i.e., the Principal Investigator's research organization) is ultimately responsible for risks associated with completing the research with CDCR.

Notification Contact Person

Member of data requestor's organization designated to notify CDCR in the event of any breach or compromise of the security, confidentiality or integrity of computerized data).

Point of Contact

Member of data requestor's organization designated to notify CDCR in the event of any breach or compromise of the security, confidentiality or integrity of computerized data.

Principal Academic Advisor

Person at or above the doctoral level who provides academic support to a student researcher.

Principal Investigator (PI)

Person responsible for the research study with CDCR. Research applications are only accepted from principal investigators who are at or above the academic doctoral level. Co-principal investigators (Co-PIs) below the academic doctoral level are accepted.

Publication

Any public dissemination, presentation, performance, or exhibition of research findings. Outputs of research include research reports, journal articles, theses, dissertations, manuscripts, conference presentations, posters, discussion papers, press releases, internet postings and chapters in edited books.

Research

According the U.S. Department of Justice the following provision regarding the protection of human subjects [28 CFR 46.102(d)] defines research as: "… a systematic investigation, including research, development, testing and evaluation, designed to contribute to generalizable knowledge." The California Penal Code § 3500 expands this definition to include data upon which such knowledge may be based, and requires that such knowledge can be corroborated by accepted scientific observation and inferences.

This definition encompasses research and evaluation conducted by the CDCR employees, contractors, faculty at institutions of higher education, researchers with private research firms, governmental agencies, and students. Studies that involve personal interaction with adult offenders committed to and paroled from the CDCR, program evaluation, clinical trials of interventions, and any requests by outside researchers for access to adult offenders, staff, or data are subject to this review and approval process.

Activities that would not contribute to generalizable knowledge are not considered research if a program evaluation, program assessment, or other activity is used only for internal operational improvements to a program or if for internal service or quality assurance monitoring purposes, or upon request from a CDCR control agency.

The following would contribute to generalized knowledge, if the program evaluation, program assessment, demonstration study, or other activity is:

- conducted to determine whether or not the program/program change had the desired effect on program participants, and that evaluation can inform other programs;
- conducted with the intent to replicate the program;
- designed to draw general conclusions;
- designed to inform policymakers.

Research Application

A research application form completed by research applicants requires a comprehensive explanation of the proposed research to be undertaken. The applicant may provide additional relevant information about the proposed research study in the text field sections that may not have been requested in the application.

Study Participant/Subject

Any person who or group of persons that are the participants in the research. Participating in research includes:

- taking part in surveys or interviews;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- personal documents or other materials being accessed by researchers;
- information/numerical data that is part of an existing database being accessed by researchers.

Reporting Expectations

The CDCR reserves the right to require the inclusion of a research limitation section in any research report that contains information or data obtained from the CDCR for research purposes and published to a public audience.

Progress Reports/Completion Reports

For all approved research projects, applicants must provide progress reports to the ROCAT as specified in the ROC approval letter and in the CDCR DSA. A final completion report is also required by the ROC at the conclusion/termination of the research.

Since the ROC approval expires two years from the date of the approval letter, applicants are encouraged to submit updated IRB and CPHS approval notices to the ROC during the second year of the approved research agreement to ensure that the approved application remains in compliance. Projects exempted from California Committee for the Protection of Human Subjects (CPHS) review are excluded. Projects not exempted from CPHS review must be re-submitted annually providing revised action dates.

Applicants may submit a progress or completion report via email to Data.Requests@cdcr.ca.gov. Failure to provide progress reports and IRB/CPHS renewal approvals may result in CDCR terminating the approved research project.

Publication of Research Findings

Applicants must notify CDCR of the publication efforts to disclose research findings when known. Researchers should note that the final copy of the research findings submitted to CDCR may be made available on CDCR's website. The CDCR reserves the right to require the inclusion of a research limitation section in the publication of approved project's final report.

Email research findings of approved research projects to Data.Requests@cdcr.ca.gov prior to publication. Submission of research reports, thesis, dissertations, manuscripts, conference presentations, journal publications, press releases, internet postings, discussion papers, posters, chapters in edited books are considered publications.

A ROC approval is granted to an applicant for a specific research project/purpose. Subsequent use of the data obtained for or generated by this research project is not permitted. A separate ROC approval is required if the data obtained for or generated by this research project is planned for use in a subsequent research project, thereby necessitating another CDCR DSA.

Approval to publish research findings will be granted only if the following publication conditions are met:

- the research findings are based on research that is factually correct;
- the research findings do not identify any individuals;
- the research findings do not reveal confidential CDCR information;
- the research findings do not pose a security risk, including risk to the operations of CDCR or the safety of the community.

In accordance with California Government Code § 13989.6(a)(1), any researcher who has received research funding from the CDCR or any California state agency, in whole or in part, shall provide for free public access to any publication of a peer-reviewed manuscript describing state agency-funded knowledge, a state agency-funded invention, or state agency-funded technology. Failure to comply with the provisions delineated in California Government Code § 13989.6(a)(1) may result in termination of any existing CDCR DSA executed between the research entity and the Agency, as well as forfeiture of the party to establish any future agreements.

Additionally, applicants must:

- acknowledge, in a form approved by the CDCR, the participation and/or assistance of the CDCR and relevant service providers in the conduct of the research;
- publicly state that any material published or made publicly available by a researcher cannot be considered as either endorsed by the CDCR or an expression of the policies or view of the CDCR;
- publicly state that any errors of omission or commission are the responsibility of the researchers.

Recordkeeping, Communication and Official Information

To ensure compliance with the State Records Management Act 2000 (Government Code § 12270-12279), applicants (including Departmental staff) must comply with the CDCR's Recordkeeping Policy and Confidentiality and Information Privacy Policy which are incorporated in the CDCR's Code of Regulations.

When interviews with research participants are to be audio recorded or transcribed, research personnel must:

- obtain written informed consent to record or transcribe participant interviews from the prison warden, Manager or Director of a facility;
- obtain participant's informed consent;
- protect the privacy and confidentiality of participants;
- ensure that audio files and transcripts are kept confidential, only used for authorized purposes, and maintained in accordance with CDCR's Recordkeeping Policy and Confidentiality and Information Privacy Policy.

Applicant Checklist

Submitting the application

☐ Read Research Guidelines and Research Application Form

☐ Complete all sections of the application

☐ Create and include the following supporting documentation with your application:

- ☐ Research Staff/Affiliate(s) List
- ☐ Resume(s)/CV(s) of each research member
- ☐ Letter of Support from Fiduciary Entity (*only required for students*)
- ☐ Letter of Support from Principal Academic Advisor (*only required for students*)
- ☐ Copies of research instruments and data collection tools
- ☐ Copies of written Informed Consent Forms if interacting with subjects
- ☐ Copies of grant/contract award documentation relevant to the study, project or program if applicable

☐ Submit Research Application Form including all required supporting documentation

Processing and review of the application

☐ The applicant will receive a reply email stating the ROCAT received the application

☐ The ROC will review qualifying applications during monthly ROC meetings (see ROC Calendar for time constraints)

☐ The applicant will receive a letter indicating the ROC decision: approve, deny, conditionally approve or continue the application

Complete the following after receiving a ROC approval letter

☐ CDCR Data Request Input Form (DRIF)

☐ CDCR Data Sharing Agreement (DSA) signatures

☐ Institutional Review Board Approval (IRB)

☐ California Committee for the Protection of Human Subjects (CPHS) Information Practices Act (IPA) approval request

☐ Criminal Background Check

☐ Other required documents

Research may be started when all the above requirements are completed.