

HHSA-H-4.2 Appendix B

INSTRUCTIONS FOR HHSA DEPARTMENT/OFFICE(S)

Directors of the Department/Office(s) shall adhere to the following procedures for research applications associated with their Department/Office(s).

I. Research Application Requests

The Director of the Department/Office(s) or their designee(s) will:

- A. Serve as the initial point of contact for all parties wishing to conduct research using their applicable resources
- B. Respond to requests from Applicant (Principal Investigators (PI) or Co-Principal Investigator (Co-PI)) by directing interested parties to the [HHSA Research website](#), and request all documents be submitted to them or their designee(s) for further review.
- C. Receive and review all documentation from interested parties including the HHSA Research Application AND any departmental requirements, where applicable.

II. Research Application Administration

A. For submitted research applications, the Director of the Department/Office(s) or their designee involved in the research will:

1. Serve as the primary point of contact with the PI regarding all correspondence related to the approval of the research application.
2. Provide List of Data Fields and Database Names determined to be appropriate for research.
3. If a researcher seeks to conduct research with Contractor sites or access Contractor-owned data at a County funded facility, the HHSA Application Review process is still required and the Researcher may **also** need to go through the Contractor's review process.

B. Application Review and Recommendations for Approval

1. The Director of the Department/Office(s) involved in the research or their designee will:

- a) Evaluate the research application considering pertinence to their program, feasibility, appropriateness, value added, financial, operational, and other risks to the County in coordination with all related HHSA departments involved in research activities.
- b) Complete a risk/value assessment, as specified by the Department/Office(s).
- c) Once the Department/Office(s) reviews and approves the research request, submit Appendix A, supporting materials, and completed risk/value assessment to Office of Strategy and Innovation (OSI) by visiting and completing the [HHSA Submission Form](#). Research applications that impact multiple Department/Office(s) shall require recommended approval by each affected Executive.

(1) Department/Office(s) must ensure that source system(s) and data fields to be used are provided to OSI for review.

- d) OSI will complete a preliminary review of the research applications received from Department/Office(s) and then route to Compliance for review and approval.

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- e) During the HHSA Compliance review and approval process, note:
 - (1) HHSA Compliance will review research application within 30-days of submission from OSI.
 - (2) If a previously approved research project has not begun by IRB expiration date, the approval will become void and HHSA Compliance must perform an additional review with the new IRB.
 - Continuous IRB's without expiration date may still be subject for additional review at the discretion of HHSA Compliance.
 - (3) HHSA Compliance requires the entire IRB application packet, including consent and assent to participate, recruitment fliers, etc.
 - (4) HHSA Compliance review of the research application precedes, and is separate from, HHSA Compliance review of the HHSA Agreements.
 - (5) For Department/Office(s) that have an internal research committee or team, HHSA Compliance may be invited to the internal review for faster approval.
 - (6) HHSA Compliance does not need to be involved with any routine research amendment approvals.
 - f) Department/Office(s) will receive and review Amendment Forms for Research and will:
 - (1) Evaluate the modification requests and impact to potential risks and mitigation.
 - (2) Recommend to OSI, whether HHSA should approve modifications to research project based on risk/value assessment and submit documentation to OSI.
 - (3) For approved Amendment Form Requests, OSI will send to HHSA Compliance (if needed) for their review and approval.
- C. For All Research Applications accepted by the Department/Office(s) and HHSA Compliance, the Director of the OSI or their designee will:
- 1. Review the research applications for risk to the HHSA or County, in coordination with the HHSA Research Committee, within 30-days of submission from Department/Office(s) for an initial review, and within 30-days of each subsequent submission until a formal approval of the research application is approved.
 - 2. Communicate the review findings with the Department/Office(s).
 - 3. If a consensus cannot be reached the research application will be elevated to the HHSA Director's Office for final resolution.
- D. For Approved Research Applications, the Director of the Department/Office(s) or their designee will:
- 1. Proceed with establishing associated HHSA Agreements (e.g. MOA, MOU, DUA) (if applicable), and
 - a) Ensure the PI adheres to the terms and conditions specified in the

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research application and approved HHSA Agreement(s). Note standard HHSA Agreement template and routing process prior to obtaining signatures (See [HHSA L-03 -Accounting of Disclosures of Protected Health Information](#) and [HHSA-G-1.9 HHSA Agreements](#)).

- b) Ensure OSI has copies of all associated HHSA Agreements, as applicable, once executed.
2. Serve as the primary point of contact for approved research projects until completed.
3. Collect completed research products from the PI.
4. Be entitled to 60 days to review and suggest edits to any and all reports, articles, white papers, or other media based on the project. In the case of substantive disagreements, HHSA may provide written rebuttals that will be included with all publications and other presentations of materials.
5. Ensure that OSI has copies of all published products, including published interim, final and/or progress reports.
6. Ensure that OSI receives research progress and reports according to project timeline and schedule.
7. Immediately document and convey any disagreements or risks and mitigation regarding report content to the Director of OSI.
8. Report the status and risk level of all research projects to OSI annually, or upon request.
9. Ensure that HHSA Compliance has evaluated and provided recommendation of whether to proceed with research activities.
10. Maintain a record of IRB approval letter according to the procedures included in [HHSA-H-4](#) and the subjects' authorizations for release of Protected Health Information (PHI), or Privacy Board approval, as provided under the Health Insurance Portability and Accountability Act (HIPAA). The following link provides information about the US

Department of Health and Human Services HIPAA Privacy Rule and IRB approval:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/>.

- E. OSI, for all research applications, will:
 1. Maintain a record of ongoing and completed research that involves HHSA resources for three years from the end date of the research agreement.
 2. Work with Department/Office(s) and HHSA Compliance to assess approved research applications for risk/value to the HHSA or County on a semi- annual or as-needed basis.
 3. Communicate review findings and recommendations of semi-annual research inventory to HHSA Director's Office.
 4. Maintain and update HHSA Research policy and procedures, as needed.
 5. Serve as the HHSA liaison to the County's Office of Evaluation, Performance, and Analytics.

III. Research Applications from HHSA Staff

HHSA employees who initiate research with external parties must follow the policy and procedures set forth in this document; including obtaining authorization from Director of

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the Department/Office(s) involved in the research and submitting the application for review to the Director of OSI or designate, HHSA Compliance and enter into associated HHSA Agreements (e.g. MOA, MOU, DUA) for use of HHSA resources. Employee research will be included in any research updates to the HHSA Director's Office.

III. QUESTIONS / INFORMATION

HHSA Department/Office(s) with questions regarding the research application or review process, may contact the Office of Strategy and Innovation at OSI.Research.HHSA@sdcounty.ca.gov. In the email Subject Line: Include the Words "HHSA RESEARCH APPLICATION." Please do not direct researchers with questions to OSI. Department/Office(s) should elevate these to OSI appropriately.