**Instructions**

All UCSF research activity involving resources from the San Francisco Department of Public Health (SFDPH), including those at Zuckerberg San Francisco General Hospital (ZSFG) and additional San Francisco Health Network clinics, requires additional approval through completion of the [**UCSF Research at SFDPH Research Protocol Application**](https://zsfg.ucsf.edu/protocol-applications-and-approvals)**.** Any interaction with SFDPH (ZSFG) patients, their data or use of SFDPH (ZSFG) personnel, resources, funding, facilities, and space, including your own office, requires SFDPH research approval.

We strongly suggest all investigators review the two tables for clinical/operational, dataset and equity approvals in advance of submitting your IRB. The Dean’s Office requires signatures from the medical and nursing leadership, dataset representatives, and/or equity leadership, listed on pages 5-8, before routing this form for final approval.

All research using SFDPH data must complete a [UCSF | SFDPH Research Statement of Work (Appendix A)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) for final approval this protocol application.

**Protocol Application Process, please read and follow the instructions carefully:**

Step 1. Complete all sections relevant to your study on the UCSF Research at San Francisco Department of Public Health: **Research Protocol Application**. Find the most current version of the form and protocol resources at: <https://zsfg.ucsf.edu/protocol-applications-and-approvals>

* + [IRB Information](https://irb.ucsf.edu/). New: All UCSF and SFDPH studies must have an approved IRB number.
  + Subject Category
  + Brief description of protocol highlighting SFDPH resources requested
  + Utilization (Patient Volume and Frequency or Dataset sample size), Human Resources and CTSI / CRC

Step 2. **Pre-Submission Approval Signatures to UCSF Research at SFDPH Protocol Application** (pages 5-8) After receiving IRB approval, collect relevant approval signature(s) for:

* + Space and Clinical Research or Patient Recruitment
  + Dataset Representatives
  + Equity Review (for research involving patients, not applicable for data-only research)

Step 3. Complete the DPH / ZSFG **Resource Checklist** (page 9) to identify any resources pertinent to your study requiring approval.

* + Medical Records / Patient Data (If Yes, PI must initial and date before submission). IT Build Needs and Data Access approvals must be collected prior to submitting the protocol application.
  + Privacy and Compliance (**Automatically** required if Medical Records are needed)
  + Clinical Laboratory Services, Radiology Services, Pharmacy Services

Step 4. Email your **Research Protocol Application** to **UCSF SOM Vice Dean’s Office at ZSFG (**[ZSFGResearch@ucsf.edu](mailto:ZSFGResearch@ucsf.edu))

* Remove the instructions page and convert your application to a **PDF** file.
* Name your file using the following naming convention: **IRB#\_PI’s First Initial (space) Last Name**.
* Attach your study’s IRB Outcome Letter Notification **at the end** of the Research Protocol Application.
* Attach your full UCSF IRB Application
* Attach your unsigned UCSF | SFDPH Research Statement of Work (Appendix A) form

**After submitting the form**

The Dean’s Office will review your **Research Protocol Application** and collect the relevant **Data, Privacy Compliance and ZSFG Service Approval Signatures** and **UCSF – SFDPH Research Statement of Work (Appendix A)** approval signatureson your behalf, based on your research activity location(s), dataset request(s) and DPH / ZSFG Resource Approval checklist selections. Incomplete applications will be returned to you for revision. The Dean's office will email a PDF of the signed application to the PI and any additional contact(s) once the application is approved. Please allow for a typical turnaround time of up to 15 working days.

**Research Protocol Application**

**Research considerations during COVID-19 Pandemic:** I have visited <https://coronavirus.ucsf.edu/research> and reviewed the Guidance and Policies for Researchers set forth by UCSF Office of Research **and** believe I should still receive approval to conduct my research.

**IRB Information**

(All studies must have an IRB Number unless indicated otherwise by the [IRB](https://irb.ucsf.edu/). Please attach IRB outcome letter.)

|  |  |
| --- | --- |
| **Protocol Title:**­­­­­ Click or tap here to enter text. | **Grant Title (if different)** Click or tap here to enter text. |
| **Grant No. if available:** Click or tap here to enter text. | **Beginning Date of Grant:** Click or tap here to enter text.  **End Date of Grant:** Click or tap here to enter text. |
| **Principal Investigator:** Click or tap here to enter text.  **Phone:** Click or tap here to enter text.  **Email:** Click or tap here to enter text. | **Additional Contact (if any):** Click or tap here to enter text.  **Phone:** Click or tap here to enter text.  **Email:** Click or tap here to enter text. |
| **Approved IRB #­:** Click or tap here to enter text. | **Expiration date:**  Click or tap here to enter text.  NA |
| **Study Status** (e.g., Active, Active-Expedited, Exempt, Closed, etc.): Click or tap here to enter text. | **Research:**  New  Continuing |

**Subject Category**

Please select the appropriate classification(s) below:

Subjects seen for research purposes only. Source of funding (e.g., NIH, industry, other): Click or tap here to enter text.

Subjects seen for research and for established medical care. Source of funding (e.g., NIH, industry, other): Click or tap here to enter text.

Please answer the following questions: (REQUIRED)

* Who are the anticipated study participants? Click or tap here to enter text.
* How will you obtain their information? Click or tap here to enter text.
* How will your study recruit the participants? Please list approvable recruitment methods:

A member of the patient's clinical team gives approval for the research team to approach the patient.

Flyers (please develop with input and approval of the clinic director)

UCSF researchers use an electronic health record (e.g., Epic) research module to screen for potentially eligible patients, DPH clinician approves list of patients to contact and approves contact email or phone script

Other (please specify) Click or tap here to enter text.

**Brief Description of the Research**

Please check relevant items and provide a brief description of your research below.

I have provided a brief description of the nature, goals, and process of the study, including any hypotheses and study goals; recruitment procedures; and dataset specifications if data access or sharing is requested. Click or tap here to enter text.

I have attached the complete UCSF IRB Application for the research study.

Please check research activity location(s) for all clinical recruitment and/or data.

ZSFG Hospital

Ambulatory Care, such as community-based San Francisco Health Network clinics

Laguna Honda Hospital

Behavioral Health Services

Population Health Division Clinics (TB Clinic, City Clinic, AITC) or Datasets

Study will access/request de-identified data only

Data will be sent outside of UCSF Research study team to (enter each organization)

|  |  |
| --- | --- |
| **Organization** | **Data Received** |
| Click or tap here to enter text. | Identified  De-Identified |
| Click or tap here to enter text. | Identified  De-Identified |
| Click or tap here to enter text. | Identified  De-Identified |
| Click or tap here to enter text. | Identified  De-Identified |
| Click or tap here to enter text. | Identified  De-Identified |

There is a [**SFDPH Business Associates Agreement (BAA) Contract Exhibit E**](https://www.sfdph.org/dph/files/HIPAAdocs/SFDPH-Business-Associate-Agreement.pdf) for any organization receiving identified data.

Has your project undergone a [UCSF IT Security Risk Assessment](https://it.ucsf.edu/service/it-security-risk-assessment)? If so, please attach approval letter and all documents and forms completed as part of this process.

**Estimated Sample Size**

State ‘0’ if not applicable

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Estimate the study subject sample size from SFDPH per year: Year | 1: | 2: | 3: | 4: | 5: |

Check here if sample size is more than 5 years. Explain (see IRB section 9.0): Click or tap here to enter text.

**Key Personnel**

Please indicate UCSF staff involved in this study (e.g., 1 CRC, 2 ACRCs, UCSF graduate student). State ‘0’ or “None’ if not applicable.

**Total # of Staff:** Click or tap here to enter text.

|  |  |
| --- | --- |
| **Names of Staff** | **Job Titles** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

Please indicate the classification(s) of SFDPH/ZSFG staff who may be involved in this study.

|  |  |
| --- | --- |
| **Names of Staff** | **Job Titles** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |

**Total # of Staff:** Click or tap here to enter text.

**CTSI / CRS**

Will all or part of the study be conducted in the ZSFG Clinical Translational Science Institute (CTSI) Clinical Research Services ([CRS](https://crs.ucsf.edu/clinical-research-services-crs))? Yes  No  NA

**If yes, please complete the following:**

1. Contact the CRS budget team at [crsbudgetrequest@ucsf.edu](mailto:crsbudgetrequest@ucsf.edu) to set up the budget for the study.
2. Once the budget portion is set up, contact [crsprotocolservices@ucsf.edu](mailto:crsprotocolservices@ucsf.edu) to schedule a start-up meeting.

**Pre-Submission Approval Signatures**

Please obtain all approvals from the Unit where research will occur, data set representative, and equity review representative **before submitting the Protocol Application for remaining approval routing**. A signature is always required by authorized approvers (below).

**Space Utilization** (if applicable)

Where will this study be conducted? (Select **all** that apply). SFDPH includes space at ZSFG.

|  |  |  |  |
| --- | --- | --- | --- |
| Clinical Space at SFDPH (including ZSFG) | Lab Space at SFDPH | Office Space at SFDPH | Other, please specify: Click or tap here to enter text. |

ZSFG Service/Department: Click or tap here to enter text. ZSFG Building/Room: Click or tap here to enter text.

Non ZSFG space, indicate locations (community-based clinics or non-ZSFG campus clinics or programs) Click or tap here to enter text.

**Clinical Research and/or Patient Recruitment Pre-** **Submission Approval** (if applicable)

Operational stakeholders listed below must approve protocols if study procedures or patient recruitment will occur in any of the following inpatient or outpatient clinical service areas. Please add information for other clinical areas. Medical and nursing leadership may require advance discussion and approval from local clinic/unit leader for an area ***before*** signing the form. Approval requires either a wet signature or via DocuSign

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study procedures in area** | **Recruiting patients receiving care from this area** | **ZSFG / SFDPH Clinical Area\*** | **Nursing Director Approval**  **Back up: (Medical Director)** | **Nursing Director**  **Signature** |
|  |  | ZSFG Emergency Services | David Staconis  (Chris Colwell, MD) |  |
|  |  | ZSFG Intensive Care | Christina Bloom  (Antonio Gomez, MD) |  |
|  |  | ZSFG Maternal & Child Inpatient | Gillian Otway  (Biftu Mengesha, MD) |  |
|  |  | ZSFG Medical-Surgical Inpatient | Leslie Holpit  (Gabriel Ortiz, MD) |  |
|  |  | ZSFG Perioperative Care | Patty Coggan  (Laura Lang, MD) |  |
|  |  | ZSFG Occupational Health | Zaw Maung  Allyson Villanueva |  |
|  |  | SFDPH Primary Care at ZSFG | Carol Taniguchi  (Joseph Pace, MD) |  |
|  |  | ZSFG Psychiatry | Kathy Ballou  (Mark Leary, MD) |  |
|  |  | ZSFG Specialty Ambulatory Care | Rosaly Ferrer  (Delphine Tuot, MD) |  |
|  |  | Other: |  |  |

**Clinical Research and/or Patient Recruitment Pre-** **Submission Approval (continued)**

**SFDPH Clinical Areas**

(San Francisco Health Network, community-based clinics or non-ZSFG campus clinics or programs)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study procedures in area** | **Recruiting patients receiving care from this area** | **ZSFG / SFDPH Clinical Area\*** | **Nursing Director Approval**  **Back up: (Medical Director)** | **Nursing Director**  **Signature** |
|  |  | PHD Tuberculosis Clinic | Rocio Agraz-Lara  (Susannah Graves, MD, MPH) |  |
|  |  | PHD City Clinic | Stephanie Cohen, MD |  |
|  |  | PHD Adult Immunization & Travel Clinic | David Stier, MD |  |
|  |  | Laguna Honda Hospital | Crystal Figlietti, RN  Lisa Pascual, MD |  |
|  |  | SFDPH Primary Care  [List of Clinics](https://www.sfdph.org/dph/comupg/oservices/medSvs/hlthCtrs/default.asp) | Carol Taniguchi  (Joseph Pace, MD) |  |
|  |  | SFDPH Maternal Child and Adolescent Health | Aline Armstrong, MSN, RN  Jennifer Lopez |  |
|  |  | SFDPH Jail Health Services, Ambulatory | Lisa Pratt, MD, MPH |  |
|  |  | SFDPH Behavioral Health Services | Diane Prentiss |  |
|  |  | SFDPH Whole Person Integrated Care (Ambulatory) | Dara Papo, MSW |  |
|  |  | Pharmacy- ZSFG/Primary Care | Swati Patel, PharmD |  |
|  |  | Pharmacy-BHS | David Smith, PharmD Michelle Geier, PharmD |  |
|  |  | Pharmacy- Laguna Honda Hospital | Michelle Fouts, PharmD Jeanette Cavano, PharmD |  |
|  |  | Other: |  |  |

**Dataset Representative Pre-****Submission Approval** (if applicable)

The dataset stakeholders listed below must approve protocols if data access or sharing is required from the systems below. If data sources other than those listed below are required for the research, please add the data source name and dataset representative name and signature.

All SFDPH data will require completion and approval of the [UCSF | SFDPH Research Statement of Work (Appendix A)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) form

All SFDPH datasets will need to be accessed through [UCSF Academic Research Systems](https://ars.ucsf.edu/academic-research-systems) (ARS). ARS requires a signed UCSF Research at SFDPH Protocol Application before providing data.

|  |  |  |  |
| --- | --- | --- | --- |
| **Data access or sharing needed** | **SFDPH Electronic Health Record or Data Source** | **Dataset representative** | **Signature** |
| ☐ | Epic |  | *Approved during DocuSign process.* |
|  | LCR or ECW (pre-Epic EHRs, data prior to Epic launch in August 2019) |  | *Approved during DocuSign process.* |
|  | Avatar, Behavioral Health Services | Diane Prentiss, MPH |  |
|  | CCMS/WPIC Data | Spencer Williams, JD |  |
|  | DPH COVID Task Force Database | Trang Nguyen- Epi, PhD Surveillance Lead |  |
|  | HIV Surveillance, PHD | Ling Hsu, MPH |  |
|  | JIM (Jail Health) Ambulatory | Lisa Pratt, MD |  |
|  | Material, Child, and Adolescent Health  Ambulatory | Aline Armstrong, MSN, RN |  |
|  | MAVEN (viral hepatology & general ELR, non-TB) PHD | Wayne Enanoria, PhD |  |
|  | OSHPD ER and Hospitalization Data | Jodi Stookey, PhD |  |
|  | Pharmacy - QSI | Michelle Fouts, PharmD |  |
|  | Vital statistics data (VRBIS birth, death data) | Susan Philip, MD MPH  Michelle Kirian, MPH |  |
|  | Other | Dataset Approver Name:  Click or tap here to enter text. |  |

**Equity Review Checklist**

Research projects involving direct contact with people at a ZSFG or SFDPH clinic must complete the Equity Review Checklist below. **If no is checked on questions 3-7**, please email your IRB application and protocol form to [equity@sfdph.org](mailto:equity@sfdph.org). Equity review is not required for projects with data analysis only.

1. Does your research include direct contact with ZSFG or SFDPH patients?

|  |  |
| --- | --- |
| YES | NO. You may skip the Equity Review Checklist |

1. What is the research study population? Is the study addressing a health disparity for this group?

|  |  |  |
| --- | --- | --- |
| **Demographic variables** | **Groups to be included in this research project:** | **Is this group disproportionately affected by the health problem to be studied?** |
| Age | Click or tap here to enter text. | Click or tap here to enter text. |
| Sex & Gender Identity | Click or tap here to enter text. | Click or tap here to enter text. |
| Race-ethnicity | Click or tap here to enter text. | Click or tap here to enter text. |
| Income | Click or tap here to enter text. | Click or tap here to enter text. |
| Other key variables: | Click or tap here to enter text. | Click or tap here to enter text. |

1. Does the research question and procedure integrate input on the topic from members of the target population?

YES. The research team directly solicited input from people with lived experience of the study issue.

YES. The research team is relying on past studies or other sources that document this input.

NO. The study plan includes engagement with people with lived experience or is intended to document such input.

NO, unsure, not possible

1. Have the study materials been reviewed with members of the study population?

YES. The research team directly co-designed or reviewed the materials with people with lived experience of the study issue.

☐ YES. The research team is utilizing materials from past studies relying on input from the study population.

NO. The study does not utilize materials

NO, unsure, not possible

1. Materials for this project are written at an 8th grade literacy level and in the most common languages spoken at home by the study participants?

|  |  |
| --- | --- |
| YES | No, unsure, not possible |

1. Is there a plan to report findings to the community?

|  |  |
| --- | --- |
| YES, Directly to study participants  YES. Through internal media (e.g., newsletters from DPH or UCSF) | YES. Through public media.  NO. The results are inappropriate for sharing.  NO, unsure, not possible |

1. Is any equity training (cultural humility, racial disparities, historical trauma, etc.) being offered to or been completed by research staff interacting with participants?

|  |  |
| --- | --- |
| YES. Required internal training from DPH or UCSF  ☐ YES. Training specific to this study. | No, unsure, not possible |

**Resource Approval Checklist**

Please indicate if your research will use **any** of the following SFDPH / ZSFG resources by selecting Yes, No, or NA for all. After selecting your responses, some approval signatures will be collected by the Dean’s Office. Please do not request approvals directly from approvers below (unless otherwise indicated) as this may slow down the process.

|  |  |
| --- | --- |
| **MEDICAL RECORDS | PATIENT DATA**  This section must be marked Yes if your study will access (read or write) any DPH / ZSFG paper or electronic patient data or interacting with patients via phone/letter/in-person.  Per HIPAA regulations, all patient health information (PHI) must be encrypted/password protected. If stored on computers and/or portable electronic devices, PI must initial/date here:  Medical Records (628-206-6210) or [Diane.Lovko-Premeau@sfdph.org](mailto:Diane.Lovko-Premeau@sfdph.org)  **PRIVACY AND COMPLIANCE** (automatically **required** if study will access any DPH/ ZSFG data)  Privacy & Compliance (628-206-4104) or [Catherine.Argumedo@sfdph.org](mailto:Catherine.Argumedo@sfdph.org) | Yes  No  NA  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *PI initial and date* |
| **DATA ACCESS, DATA SHARING, or EPIC RESEARCH MODULE | IT BUILD (**Must be signed if you use any SFDPH patient data). See Approvals Dataset Representative Pre-Approval section (page 7). (also **required** if study will access any DPH/ ZSFG data)    Liz Goldman [Lauren.Goldman@ucsf.edu](mailto:Lauren.Goldman@ucsf.edu) | Yes  No  NA |
| **CLINICAL LABORATORY SERVICES**  If yes, approval for the [Request to Set Up Research Study](http://labmed.ucsf.edu/sfghlab/test/research_testing.html) must be obtained **before** submitting the ZSFG Research Protocol Application Form. *Indicate Clinical Labs Request to Set Up Research Study Form* approval account number: Click or tap here to enter text.  Clinical Laboratory (628-206-6786) or [Andy.Yeh@ucsf.edu](mailto:Andy.Yeh@ucsf.edu) | Yes  No  NA |
| **RADIOLOGY SERVICES**  If yes, approval for the [Imaging Research Application](https://radiology.ucsf.edu/research/core-services/img-srvs-piple/zsfg-imaging-app) (UCSF / ZSFG Radiology Research Proposal Request) must be obtained **before** submitting the ZSFG Research Protocol Application form. Indicate *Imaging Research Application* approval date: Click or tap here to enter text.  Radiology email [Lorel.Hiramoto@ucsf.edu](mailto:Lorel.Hiramoto@ucsf.edu) | Yes  No  NA |
| **PHARMACY SERVICES**  If the study involves the administration of **any medications**, approval for ZSFG [Pharmacy Investigational Drug Service (IDS)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) Service Request Form and Agreement must be obtained **before** submitting the ZSFG Research Protocol Application form. Indicate *Pharmacy Investigational Drug Service (IDS) Service Request Form* approval date: Click or tap here to enter text. For more information on Pharmacy IDS Services Fees, send an email to the email address below.  Pharmacy (628-206-8460) or email [DPH-ZSFG-Pharmacy-IDS@sfdph.org](mailto:DPH-ZSFG-Pharmacy-IDS@sfdph.org) | Yes  No  NA |

Dean's Office obtains approvals

**Data, Privacy Compliance and ZSFG Service Approval Signatures**

The following approval signatures are collected by the Dean’s Office. Please do not request approvals directly from approvers below as this may slow down the process)

**MEDICAL RECORDS / PATIENT DATA** (Must be signed **if** you are using any SFDPH patient data)

Use of SFDPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: Director, Medical Records***

***Additional Notes/Comments:***

**DATA ACCESS, DATA SHARING, or IT BUILD** (Must be signed **if** you are using any SFDPH patient data)

Use of SFDPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: Professor of Medicine, OHI Director of Research***

**PRIVACY AND COMPLIANCE** (Must be signed **if** you are using any DPH/ ZSFG patient data)

Use of SFDPH patient information is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: SFDPH Privacy and Compliance Officer***

***Additional Notes/Comments:***

**CLINICAL LABORATORY SERVICES**

Use of Clinical Laboratory is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: ZSFG Clinical Lab Administration***

***Additional Notes/Comments:***

**RADIOLOGY SERVICES**

Use of Radiology is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: ZSFG Radiology Administration***

***Additional Notes/Comments:***

**PHARMACY SERVICES**

Use of Pharmacy is approved: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Signature/Date: ZSFG Pharmacy Administration***

***Additional Notes/Comments:***

**Executive Approval Signatures**

Elena Fuentes-Afflick, MD MPH (Date)

Susan P. Ehrlich, MD, MPP (Date)

UCSF SOM Vice Dean at ZSFG Chief Executive Officer, ZSFG

Hali Hammer, MD (Date)

Michael Phillips, MHA, FACHE (Date)

Director of Ambulatory Care, SFDPH Chief Executive Officer, Laguna Honda Hospital

(Primary Care in Community or ZSFG, Maternal Child

Adolescent Health, Jail Health Services, Whole Person

Integrated Care)

Hillary Kunins, MD, MPH, MS (Date)

Susan Phillip, MD, MPH (Date)

Director of Behavioral Health Services & MHSF Population Health Division Clinics

TB Clinic, City Clinic, AITC or Datasets

**UCSF | SFDPH Research Data Sharing Statement of Work (Appendix A) Approval Signatures**

Please include unsigned [UCSF | SFDPH Research Statement of Work (Appendix A)](https://zsfg.ucsf.edu/protocol-applications-and-approvals) with this Protocol and the approved IRB. The Dean’s Office at ZSFG will route all documents to the UCSF Office of Sponsored Research and DPH Office of Contract Management and Compliance. We will notify you once this final approval is complete.

***\*\*\* FOR DEAN’S OFFICE USE ONLY \*\*\****

*Submission process finalized.*

*Copy of final document forwarded to the study’s Principal Investigator and additional contact(s)*