INSTITUTIONAL DATA	**SOP 4.4.03**

1. Purpose & Policy

The purpose of this SOP is to provide guidance to researchers wishing to use Caltech data regarding students, faculty or staff that has been generated solely for Caltech business or academic purposes (Institutional Data), that were originally "Not Human Subjects Research" (NHSR) data. All human subjects research <u>must be reviewed and approved by the IRB prior to engaging participants in any way.</u> IRB Policy *Section 4.4*.

2. General Information

A. Institutional Data includes data generated by Caltech through the course of its business or teaching, including de-identified data.

B. Institute policy[1] requires that PIs wishing to use Institutional Data in their research obtain approval for the use of such data from the appropriate Institutional Approver(s). The Institutional Approver is

    (1) the Provost (for faculty data),

    (2) the Vice President for Student Affairs (for student data),

    (3) the Associate Vice President for Human Resources (for staff[2] data) and

    (4) the Provost and Associate Vice President for Human Resources (for postdoc data).

C. To facilitate the approval process and to ensure the proper consideration and protection of students, faculty, or staff, PI's wishing to use Institutional Data must submit a Query, as described, below.

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[1] Per a memo from the Vice Provost, AVP Human Resources, and the VP for Student Affairs dated July 1, 2020 to the Division Chairs, IRB Chair and IO:

"Moving forward, we believe that [institutional] data should not be made available unless [the researcher] specifically obtain consent from (or at least notify) all Caltech users. Further, any request for such data will require the consent of the Provost for faculty data, Vice President for Students for student data and Associate Vice President for Human Resources for staff data. Please direct all request for data accordingly."

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3. **PI Training Requirements**

Other than the normally required and study specific training for all human subjects research, there are no specific training requirements associated with use of Institutional Data; however, PIs should follow this guidance, IRB *SOP 12: Students and Lab Members as Research Study Participants* and should consider training regarding use of data of vulnerable subjects (e.g. students, postdocs, and staff).

4. **Procedure**

A. Determine whether you wish to use Institutional Data regarding students, staff, faculty or multiple groups of these individuals.

B. Initiate a Query in the IRB system and answer Yes to the question, "Does your study intend to use Caltech student, faculty or staff data that has been acquired by Caltech for business or academic purposes?" You will then be prompted to choose which groups' data will be used in your research, how you will receive, store, and report the data, what will be done with the data when your research project is complete, and how you will obtain consent or request for a waiver of consent.

Request to Use Caltech Community Member Data (Institutional Data):

Save Caltech Data

Institutional data includes data generated by Caltech through the course of its business or teaching, including de-identified data. See SOP 7: Institutional Data.

* I would like to use Institutional Data from Caltech regarding (Check all that apply):

☐ Students (e.g. Data from Registrar, Housing, Institutional Surveys, Activity related to UID etc.) Approver: Vice President for Student Affairs (Kevin Gilmartin)

☐ Staff (e.g. Data including Employee Records, Activity related to UID, Training, etc.) Approver: Associate VP for Human Resources (Julia McCallin)

☐ Faculty/Postdoc (e.g. Data including Faculty or Employee Records, Activity related to UID, Training, etc.) Approver: Provost (David Tirrell)

* List, name or describe the Institutional data you are requesting:

* The data received from Caltech will be:

☐ Anonymous   ☐ Deidentified   ☐ Coded/Traceable

* Describe how the data will be stored and secured after receiving it from Caltech:

See SOP 13 need URL for guidance on how to properly classify the identifiability of your research data.

* The data will be reported in research papers as:

☐ Anonymous   ☐ Deidentified   ☐ Coded/Traceable   ☐ Aggregated (Not Identifiable to an Individual)

* After use, the data will be:

○ Destroyed Upon Completion of the Project ○ Stored for Future Use

* If possible, you should obtain informed consent from every Caltech community member. If you would like to request a waiver to obtain informed consent, please provide your request and rationale here.

○ Obtain Informed Consent from Each Caltech Community Member ○ Notify the Caltech Community Members ○ Request a Waiver

Your description of the research (Project Summary/Background, Specific Aims, and Scientific Purpose), along with the information regarding storage and use of Institutional Data will be provided to the Institutional Approver(s). Per Caltech Policy, a subcommittee of the IRB will consult with the Institutional Approver(s). The IRB will record the Institutional Approver's decision as a response to this Query and provide you with IRB requirements for proceeding to obtain IRB exemption or approval of the proposed work.

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C. Importantly, Institutional Policy requires that, to the extent practicable, the participants consent or receive notice that their data will be used in this way. The Institutional Approver and the IRB would like to know how you anticipate this will be done; however, the IRB will ultimately make the decision as to which process will be followed.

D. After submission of the Query, a subcommittee of the IRB will meet with the appropriate Institutional Approver(s) and a decision will be made as to whether or not the Institutional Data may be used for the proposed research.

E. If approved, the IRB will determine whether the Query qualifies for an exemption and, if not, request that the PI submit a full Caltech IRB application.

5. **Informed Consent (IC) Language or Notice**

A. There is no specific IC language prescribed; however, the use of Institutional Data requires that the PI, to the extent practicable, either obtain Informed Consent or provide notice to the individuals whose data will be used.

B. The IRB will decide whether IC or notice is appropriate in review of the Query or Full Application.

C. Notice Language TBD

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