INSTITUTIONAL DATA

1. Purpose

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 must be reviewed and approved by the IRB prior to engaging participants in any way.

2. General Information

A. The policy governing the use of Institutional Data is found in the IRB Policy, “Research Involving the Use of Institutional Data.”

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

C. Institute policy¹ 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 staff² data) and
   (4) the Provost and Associate Vice President for Human Resources (for postdoc data).

D. 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.

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.”

IRB SOP 7
Revised 3/02/23
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3. PI Training Requirements

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.

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
RESEARCH INVOLVING THE USE OF INSTITUTIONAL DATA

Institutional Data includes data generated by Caltech through the course of its business or teaching, including de-identified data. Institute policy, based upon a memo issued by Caltech leadership in 2020, requires that PIs wishing to use Institutional Data in their research obtain approval for the use of such data from an Institutional Approver. The Institutional Approver is the Provost (for faculty data), the Vice President for Student Affairs (for student data) and the Associate Vice President for Human Resources (for staff data). Use of postdoc data requires the approval of both the Provost and the Associate Vice President for Human Resources.

To facilitate the approval process and to ensure the proper consideration of human subjects protection, PI’s wishing to use Institutional Data must submit a Query describing the data requested, indicating the campus population (student, staff, postdoc, faculty or a combination), explaining how the data will be obtained, stored, used in analysis and reported, and describing how the PI will employ best efforts to provide notice to or obtain consent from the subjects whose data is being used. A subcommittee of the IRB will meet with the appropriate Institutional Approver and a decision will be made as to whether or not the Institutional Data may be used for this purpose. 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. An informed consent or notice to subjects will be required, as determined by the IRB. Please see Caltech IRB SOP 7: Institutional Data for the detailed process.