CALIFORNIA Data System

The Role of Human Subjects Review in External Data Requests

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In 2019, California enacted the Cradle-to-Career Data System Act (Act), which called for the establishment of a state longitudinal data system to link existing education, social service, and workforce information.[1] The Act also articulated the scope of an 18-month planning process to be shaped by a workgroup that consists of the partner entities named in the Act.[2] Suggestions from this workgroup will inform a report to the legislature and the designs for the state data system to be approved by the Governor's Office. The Research Agenda Subcommittee has supported the workgroup by helping to identify parameters for research on the six priority areas spelled out in the legislation (see box on page 2).

This brief supports the ongoing efforts—and final convening—of the Research Agenda Subcommittee by describing how other states have, or have not, incorporated Institutional Review Board (IRB) review into their State Longitudinal Data System (SLDS) data request process. The brief begins by briefly describing the purpose and role of IRB in ensuring the protection of human subjects. The brief then highlights several existing state data systems and their approaches to incorporating IRB review within their data

1 Read the California Cradle-to-Career Data System Act at: https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=EDC&division=1.&title=1.&part=7.&chapter=8.5.&article=

2 The partner entities include the Association of Independent California Colleges and Universities, Bureau for Private Postsecondary Education, California Community Colleges, California Department of Education, California Department of Social Services, California Department of Technology, California Health and Human Services Agency, California School Information Services, California State University, California Student Aid Commission, Commission on Teacher Credentialing, Employment Development Department, Labor and Workforce Development Agency, State Board of Education, and University of California.

request processes. The final section of the brief discusses possible options for a California state data system.

Priority Policy Questions from the California Cradle-to-Career Data System Act

Without a state data system that links information between agencies, it is difficult to answer foundational questions about the impact of state policies and investments. Legislators identified the following topics, which the state data system must be able to address:

- The impact of early education on student success and achievement as a student progresses through education segments and the workforce;
- The long-term effect of state intervention programs and targeted resource allocations in primary education;
- How prepared high school pupils are to succeed in college;
- How long it takes students who transfer from community college to the University of California, the California State University, or another four-year postsecondary education institution to graduate with a baccalaureate degree;
- College access, completion, and long-term effects of access to state financial aid; and
- The workforce effect of graduation from high school, community college, and four-year postsecondary education institutions.

The Purposes and Roles of IRB

Biomedical and behavioral science research builds knowledge, informs practice and guides decision making. Yet, this research is not without risk. History contains many cases of research studies that have, either directly or indirectly, exploited participants and/or placed them at undue risk of psychological, physical, or social harm (Breault, 2006). Institutional Review Boards (IRBs) exist to protect the rights and safety of human subjects involved in research endeavors.

An IRB is a collection of professionals with relevant content area expertise and research experience who can evaluate and mitigate risks to human subjects involved in a

research project. Institutional Review Boards exist within research universities, hospitals, governmental and non-governmental research organizations. Commercial and independently operated IRBs also exist to support privately funded and directed research projects. Institutional Review Board review is a common first step for many research endeavors carried out by government agencies, research and advocacy organizations, and academic researchers.

The Belmont Report, published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), identified and outlined basic ethical principles to underlie the conduct of human subjects research. These principles include (1) respect for persons, (2) beneficence, and (3) justice. The Federal Policy for the Protection of Human Subjects (i.e., "Common Rule") was established in 1991 (and revised in 2017) based—in part—on the principles outlined within the Belmont Report. Today the guidelines articulated by Common Rule provide the regulatory framework for IRBs across the nation, including IRBs within the 19 federal agencies who are Common Rule signatories.

Importantly, Common Rule regulations are different and distinct from other federal protections granted by the Family Educational Rights and Privacy Act (FERPA) and the Health Insurance Portability and Accountability Act (HIPAA). Consequently, an IRB is unable to ensure compliance with FERPA or HIPAA.

The IRB submission and approval process depends on the IRB board. Generally speaking, however, once a researcher has identified a suitable IRB, the researcher then submits the study proposal for IRB review. Many IRBs carry out an initial screening of the submission to ensure completeness and appropriateness. Incomplete or noncompliant submissions may be returned to the researcher. After the initial screening, members of the IRB committee will review the submission and arrive at one of three possible review decisions. Exempt studies require no further IRB review because they pose little risk to human subjects and/or they do not meet the federal definition of human subjects research. Expedited studies pose low risk to human subjects but require the additional review of one or more IRB board members before they are approved. Full-board review studies pose elevated risks to human subjects and require a thorough review of a majority of IRB board members prior to approval. Studies within the full-board review category often pose high risk to participants' physical, emotional, or economic well-being. Research studies involving the use of vulnerable populations also may require a full-board review.

Key Terms and Definitions

Common Rule – The Common Rule (45 CFR Part 46 of the Code of Federal Regulations), regulates ethics for research projects involving human subjects that are funded by the United States Department of Health and Human Services and many other federal departments. It also provides specific requirements for the form and function of Institutional Review Boards (IRBs).

Identifiable information (i.e., data) – "private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information" [45 CFR 46.102(e)(5).

Human subject – The Code of Federal Regulations (45 CFR Part 46) defines a human subject as a "living individual about whom an investigator (whether professional or student) conducting research: (i)obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

Research – "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes" (45 CFR 46.102(l)).

Existing Approaches to the Protection of Human Subjects within P20W Data Systems

Because a California state data system will be of high value to researchers both in and out of the state, it is very likely the system will receive a high number of data requests from partnering entities and external researchers. Given their topical content expertise and extensive research experience, members of the Research Agenda Subcommittee are uniquely positioned to consider whether, and how, to incorporate IRB review within the California state data system data request process.

A scan of existing state longitudinal data systems reveals different approaches to this issue. Some states provide clear guidance and information for external researchers seeking access to data. The Washington Education Data Research Center (ERDC) requires the Washington State Institutional Review Board to review requests for student-level data.[3] Similarly, the Pennsylvania Information Management System (PIMS) requires external researchers to receive study approval from the Pennsylvania Department of Education's IRB before PIMS will enter into a data access agreement.[4] The Utah Data Research Center (UDRC) states on its website that external researchers (i.e., researchers not affiliated with partnering entities) must demonstrate successful IRB review as part of its data request process.[5] Yet, while the UDRC General Governance document states that research conducted by external researchers shall be reviewed by the Utah State Board of Education Institutional Review Board (Utah Data Research Center, n.d.), UDRC does allow researchers to upload an IRB determination from another IRB (J. Solari, personal communication, August 8, 2020).

The Georgia Academic and Workforce Analysis and Research Data System (GA AWARDS) is also quite clear that external researchers must demonstrate IRB approval as part of its data request process, and like UDRC, it appears that researchers can receive approval or exemption from their institution's in-house IRB (Georgia Academic and Workforce Analysis and Research Data System, n.d.). The Maryland Longitudinal Data System (MLDS) states within its Policies and Procedures for External Data and Grant Funded Projects manual that every research project approved by the MLDS must obtain IRB approval and that proof of the approval must be submitted to the Executive Director before access is given (Maryland Longitudinal Data System Center, n.d.). Like GA AWARDS, it appears that external researchers can receive IRB approval from their institution's in-house IRB. This also appears to be the case with the Hawaii Data Exchange Partnership (Hawaii Data Exchange Partnership, n.d.) and the Kentucky Center for Statistics (KYSTATS) which asks external researchers if their study has been reviewed by "an IRB" (Kentucky Center for Statistics, 2017).

3 See the ERDC data request process here: https://erdc.wa.gov/sites/default/files/ERDC-Data-Request-Approval-Chart.pdf

4 See the PIMS data request process here: https://www.education.pa.gov/DataAndReporting/ResearchEvaluation/Pages/Apply-for-a-Data-Research-Project.aspx

5 See a description of UDRC's data request process here: https://udrc.utah.gov/data-request.html

It is important to note that some states do not appear to require external researchers to engage with an IRB as part of its data request process. Florida does not require IRB review, for example.[6] Similarly, Connecticut's P20 WIN does not require external researchers to demonstrate IRB approval in order to secure a data sharing agreement. This said, Jan Kiehne, the P20 WIN Program Manager, shared that while requests for administrative data do not require IRB approval, P20 WIN is "expanding significantly" and she anticipates P20 WIN "will need to build a formal step into our processes for and require proof of IRB approval if necessary" (J. Kiehne, personal communication, August 7, 2020). Like P20 WIN, the Minnesota Statewide Longitudinal Education Data System (SLEDS) has not historically required external researchers to receive IRB approval but SLEDS intends to change this in the coming year (M. Fergus, personal communication, July 20, 2020).

The Protection of Human Subjects within a California State Data System

Members of the Research Agenda Subcommittee will convene for a final time in August to discuss how an IRB review of research studies proposed by external researchers might mitigate any potential risks to Californians for whom data has been collected within one or all of the partnering California state longitudinal data system entities. More specifically, members of the subcommittee may want to deliberate on the following questions. First, the subcommittee may want to discuss whether a formal IRB review is required for an external researcher seeking access to data within the state data system. As we have seen, states like Utah, Maryland, and Georgia have this requirement in place. By contrast, states like Florida, Connecticut, and Minnesota do not currently.

Once members of the subcommittee address the issue of whether IRB review should be a necessary condition for data access, members may want to consider when in the data request process researchers might be required to show proof of IRB review. For example, should external researchers be required to demonstrate IRB approval prior to beginning the data request process, or should they be required to demonstrate IRB approval before any data are shared. Also, members of the subcommittee may want

6 See the Florida data request process here: http://www.fldoe.org/accountability/accountability-reporting/external-research-requests/

to discuss the distinction between the demonstration of ongoing IRB review (IRB reviews that are currently in progress) and confirmed IRB approval.

In the event that members of the subcommittee suggest IRB approval be required, the subcommittee may then also wish to consider which IRB is best positioned to evaluate research proposals seeking access to the California state data system. Options include having external researchers receive IRB approval from their affiliated universities or organizations. For example, a researcher from the University of California at Merced could seek IRB approval from the Office of Research Compliance and Integrity within UC Merced.[7] The UC Merced's IRB approval could be submitted along with the researcher's data request. Independent researchers could seek IRB review from commercial or private IRB boards.

An alternative approach is to establish a new IRB whose primary focus is the research requests related to the state longitudinal data system. Benefits of this approach include a specialized staff who, after time and with sufficient personnel and resources, could expertly and efficiently process the many research requests that are likely to come into the system. A drawback of this approach is the inefficiencies that might stem from the creation of a new and, potentially, redundant organization. A more efficient option were the subcommittee to prefer a centralized and specialized IRB to review all California state data system external data requests is to direct all data requests to an existing IRB within the state.

One example is the Committee for the Protection of Human Subjects (CPHS)[8] within the Office of Statewide Health Planning and Development (OSHPD). The CPHS would bring substantial existing resources, including processes and personnel, to the table. And given the CPHS currently evaluates all research proposals involving California Department of Education student data, it is likely that many researchers throughout the state are familiar with CPHS policy and procedures.

Preparing for the Subcommittee Meeting

The Research Agenda Subcommittee will be making a recommendation about the need for an IRB to the workgroup for its September 2020 meeting.

7 Visit the Office of Research Compliance and Integrity at UC Merced here: https://rci.ucmerced.edu/

8 Visit the CPHS website here: https://oshpd.ca.gov/data-and-reports/data-resources/cphs/

References

Breault, J. L. (2006). Protecting human research subjects: The past defines the future. *The Ochsner Journal, 6*(1), 15–20.

Georgia Academic and Workforce Analysis and Research Data System. (n.d.) *Researcher's guide to Georgia Academic and Workforce Analysis and Research Data System (GA AWARDS)*. Retrieved from https://gosa.georgia.gov/document/document/researchers-guide/download

Hawaii Data Exchange Partnership. (n.d.). *Hawaii Data Exchange Partnership Data Request Form*. Retrieved from http://hawaiidxp.org/files/HawaiiDXP_Data_Request_Form.pdf

Kentucky Center for Statistics. (2017). *Data access and use policy*. Retrieved from https://kystats.ky.gov/Content/DataAccessAndUsePolicy.pdf?v=20200804071518

Maryland Longitudinal Data System Center. (n.d.). *Policies and procedures for external data and grant funded projects*. Retrieved from https://mldscenter.maryland.gov/Externalresearchprojects.html

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. Retrieved from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Utah Data Research Center. (n.d.). *General governance*. Retrieved from https://udrc.utah.gov/governance_May2020.pdf