Agenda V: Data Release Process - Other Reviewer's Role

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DHCS Role

- What types of requests will need DHCS approval?
  - All that request Medi-Cal data
- DHCS Review is required before DRC review
- DHCS will provide their approval before DRC reviews requests
- Request will not proceed to DRC if DHCS does not approve

DHCS Data Access Rules

- Research or Public Health purposes only
- Data and Research Committee (DRC) assesses the appropriateness of requests for protected data, assigns a priority status to each request, and recommends approval/denial to DHCS Executive Management
- Will not support research that leads to creation of a product or tool that the researcher or funder intends to market
- DHCS Decisions are Guided by
  - Social Security Act – A state plan for medical assistance must provide safeguards which restrict the use or disclosure of information
  - HIPAA – Data Privacy and Security requirements
  - California Welfare Institutions Code
  - California Civil Code (Information Practices Act)

DHCS DRC Review Criteria

- **Program Relevance:** Includes the value to DHCS of expected findings, potential impacts on DHCS' beneficiaries and the general public, and whether the project focuses on a topic that will provide new and useful information for DHCS programs.

- **Methodology:** DHCS' assessment of the reliability, accuracy, and practicality of the proposed methodology in answering identified research or public health question(s).

- **Risk Assessment:** Of the potential data security and patient confidentiality risks of releasing the requested data.

- **Department Impact:** On DHCS resources needed to fulfill the data request and assist requesters.

- **Investigator Qualifications:** DRC's assessment of the investigator's experience and qualifications.

CPHS Process Questions

- Policy and Process for CPHS review
- Vice Chair to provide an overview of current CPHS process and types of requests that require review
- Where does CPHS review come into play in the process?
- Will the DRC see requests that require CPHS approval if they have not yet been approved by CPHS?
- How can CPHS and HCAI work together to coordinate and expedite the review process?

CPHS Research Request Considerations & Guidelines

CPHS reviews all research involving human participants conducted or supported by the CalHHS and all research using private information held by any State agency.

- CPHS Decisions are Guided by
  - Common Rule (45 CFR Part 46 of the Code of Federal Regulations) for human subjects contact.
  - California Information Practices Act (Civil Code, Section 1798.2 section t) for private information.
- Other Important Laws
  - Food and Drug Administration regulations (21 CFR, Part 50; 21 CFR, Part 56)
  - Privacy Rule of the Health Insurance Portability and Accountability Act (45 CFR, Part 160)

CPHS Review Criteria

- CPHS serves as the institutional review board (IRB) for the CalHHS. The role of the CPHS and other IRBs is to assure that research involving human subjects is conducted ethically and with acceptable risk to participants.
- CPHS may carry out an expedited review (by subcommittee) for research requests that present no more than minimal risk for human subjects or use data or materials that have already been collected for other purposes and which will not involve any contact with human subjects.
- CPHS conducts a full committee review for all new research requests involving direct or indirect contact with human subjects. Full committee meetings occur every two months. (First Fridays of February, April, June, August, October, and December)

CPHS Review Types for New Projects

Expedited Review

- Intended for data-only projects and some minimal risk human subject research
- ~3-week approval process
- Can be approved by subcommittee of two reviewers through online submission system, IRBManager

Full Committee Review

- Intended for projects involving human subject contact
- ~1-2 Month approval process
- Must be approved by the full committee at public meeting