

Agenda IV: DRC Board Manual Review

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Development process for HPD DRC Board Manual

- Process began in late June
- Draft content developed and reviewed by:
 - HCAI HPD program staff and leadership
 - DRC members Terry Hill and Miranda Dietz
- Content based on statute, draft regs, similar manuals, HPD specific considerations

DRC Board Manual Components

I. Background, Purpose and Authority

- Background information on HCAI, the HPD and the DRC
- The roles and responsibilities of each entity
- The types of data available for access or release

II. Board Operations

- Board Membership
- Board Leadership
- Travel Reimbursement

III. Application Review Process

- Process for reviewing applications
- Conflict of Interest

Section I: Background

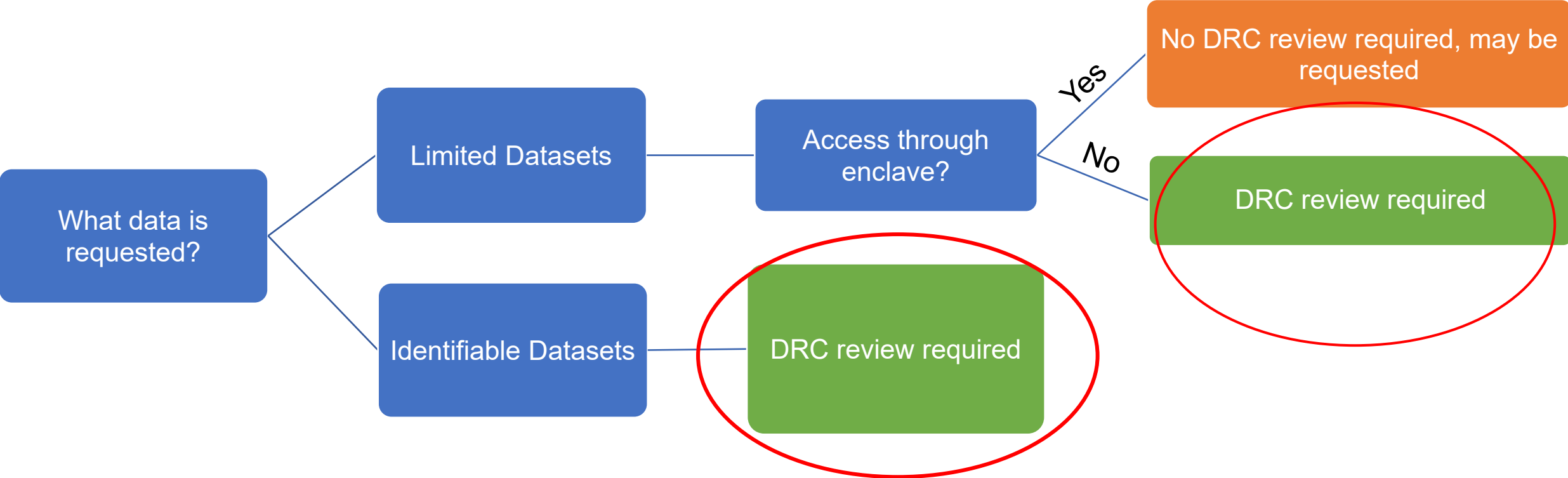
HPD Program Goals

1. Provide **public benefit** for Californians and the state **while protecting individual privacy**.
2. Increase **transparency** about health care costs, utilization, quality, and equity.
3. Inform **policy decisions** on topics including the provision of quality health care, improving public health, reducing disparities, advancing health coverage, reducing health care costs, and oversight of the health care system and health care companies.
4. Support the development of **approaches, services and programs** that deliver health care that is cost effective, responsive to the needs of Californians, and recognizes the diversity of California and the impacts of social determinants of health.
5. Support a **sustainable health care system** and more **equitable access** to affordable and quality health care for all.

HPD Data Access & Release Objectives

1. Protect Patient Privacy
2. Support Program Goals
3. Ensure appropriate data users, uses, methodologies, and compliance with all requirements
4. Provide timely data access to qualified applicants and make decisions in a consistent manner
5. Enable & support diverse users, representing multiple audiences & levels of expertise
6. Complement the HPD public reporting program
7. Support sustainability through user fees that balance program support and affordability

Non-State Agency Data Requests: Review Process Flow



Section II: Board Operations

Statutory Authority

- In December 2022, HCAI established the Data Release Committee, pursuant to California Health & Safety Code Section 127673.84.
- The statute establishes:
 - Number of members
 - Composition of the Committee,
 - Term lengths,
 - Appointment authority,
 - Creation of the Chair position,
 - Allowable compensation, and
 - Role of the DRC.

Purpose

- DRC will meet monthly in 2024 to advise HCAI on requests for access to non-public data.
- The DRC is an integral part of the HPD Program and will be supporting HCAI to:
 - Lay the foundation for HPD data access and release and contribute to the launch of an effective and credible Data Release Program
 - Advise HCAI on relevant policies and processes
 - Participate in thoughtful deliberation to weigh broad use of HPD data and public benefit to Californians with protection of patient privacy
 - Review and make recommendations to HCAI on access to and release of non-public HPD data

DRC Membership

- The DRC is comprised of 11 health care data, privacy, and security subject matter experts representing key stakeholder groups including: consumers, labor, providers (both at clinician and hospital levels), payers, purchasers, suppliers, and researchers.
- Members are appointed by the HCAI Director.
 - A member may be removed by the HCAI Director for cause.
- Members serve staggered one- or two-year terms; following the initial term, the standard term is for two years.
- Members are expected to regularly attend meetings and review materials in advance to contribute to discussions.
- Members may not appoint designees, substitutes, or proxies.

Bagley-Keene Open Meeting Act

- DRC meetings are subject to the Bagley-Keene Open Meeting and must be **open and public**. Act (Gov. Code Section 111.21(a))
- The Act also applies to any advisory subcommittee created if the subcommittee consists of 3 or more persons. (Gov. Code section 111.21(c))
- The Act requires the physical presence of Committee members at meetings and a physical meeting location where the public may go.
- Meeting notices are required and must be posted at least 10 days before the meeting.
 - If a topic doesn't appear on the agenda, members may request an update for the next meeting during the "Next Meeting Topics" section.

Member Vacancies

- Members are appointed by the HCAI Director.
- Members must sign an Oath of Office at their first meeting.
- At the end of a member's two-year term, they are eligible to be re-appointed to continue serving in their role:
 - If a member cannot complete their term, HCAI solicits nominations for candidates when a position becomes vacant
 - Each candidate is required to submit a resume and statement of interest for consideration

Reimbursements

- DRC members outside of state government serve without compensation but receive a \$100 per diem for each meeting attended.
- Members receive travel reimbursements for any actual and necessary expenses related to the meetings attended.

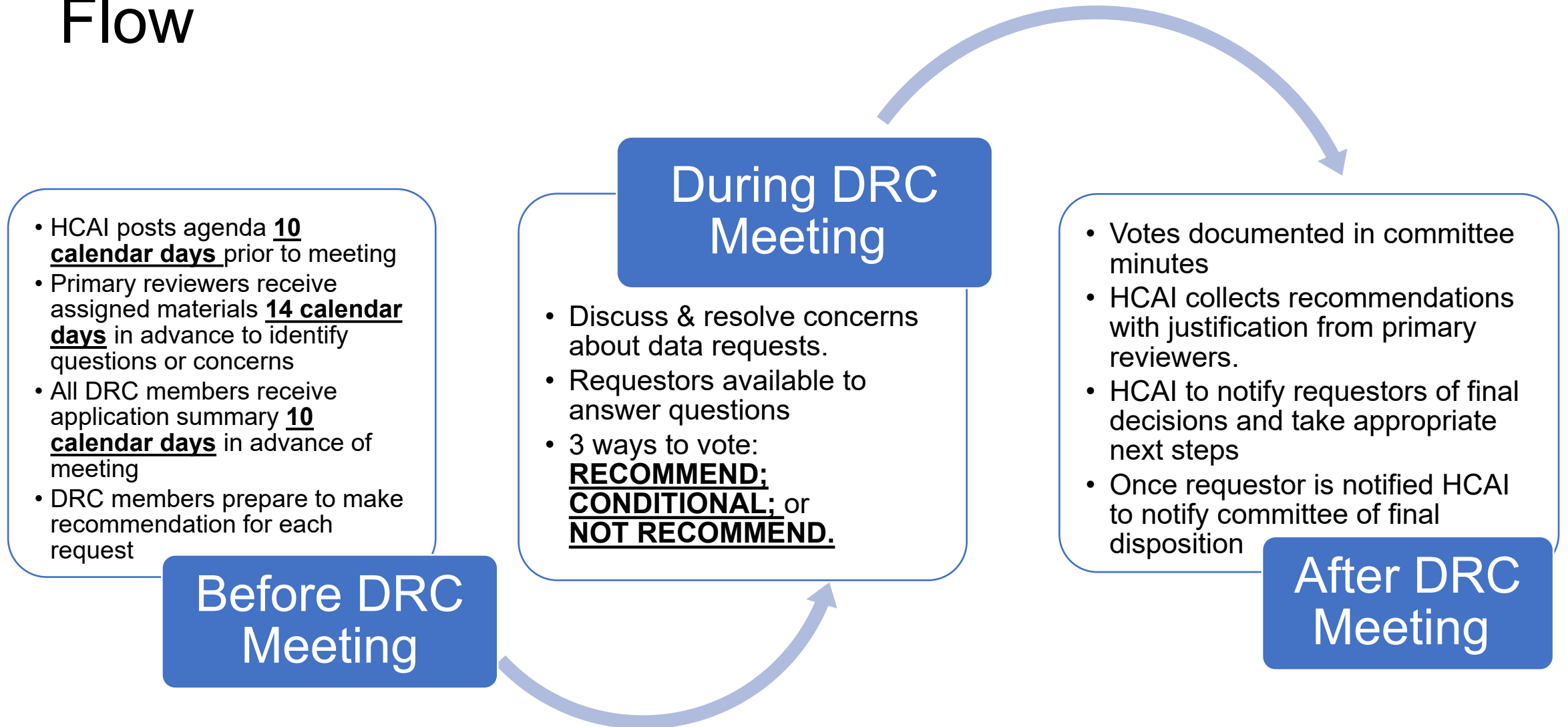
Section III: Application Review Process

Initial HCAI Application Review



HCAI analysts will perform a thorough evaluation of applications for completeness and alignment with statutory, regulatory, and other requirements before referring any request to the DRC.

Proposed Data Release Committee - Process Flow



Bagley Keene Implications

- **Serial Communications are Prohibited**: A quorum of (five DRC) members cannot, outside of a properly noticed meeting, engage in a series of communications of any kind either directly or through intermediaries regarding items within the subject matter of the committee. This includes email communication between primary reviewers that may be inadvertently sent to all DRC members.
- **Meeting Documents**: Generally, materials distributed to the Committee prior to or during a meeting are disclosable public records. Some materials can be held confidential pursuant to certain sections of the California Public Records Act. Materials prepared by Committee members or committee staff are required to be available to the public at the meeting
- **Public Participation**: The Committee must give the public an opportunity to directly address the Committee on each agenda item before or during the Committee's discussion or consideration of the item. Public criticism of the Committee cannot be prohibited.

Bagley Keene Implications (cont.)

- **Voting:** The vote or abstention of each Committee member must be publicly reported; If teleconferencing, votes must be taken by roll call. Vote by proxy or secret ballot at a meeting is not allowed. A quorum (at least 5 members) must be in attendance at the agendaized physical location to vote on an action.
- **Abstentions:** In general, a state body cannot act without the support of at least a majority of its quorum. For the full DRC, a quorum consists of at least 5 members. Members who voluntarily abstain are counted toward a quorum, but decisions only require the majority of those members who actually vote as long as there is support from a majority of the quorum. Members who are disqualified from voting by law are not counted toward a quorum.

Proposed DRC Review Process

- Two primary reviewers will receive the complete application and perform a full review:
 - This will not include confidential information about the requestor's data security policies and procedures
 - HCAI staff will perform a compliance review of this information
- Remaining DRC members will receive an application summary including key findings and questions for further discussion at the meeting
- HCAI will work with the DRC Chair to determine assignment of applications
- DRC members should be prepared to discuss and make a recommendation on each application considered at a meeting
- Primary reviewers are responsible for “closing out” their review process by documenting final DRC recommendations in writing, which will be collected by HCAI

Proposed DRC Recommendation Options

- Recommended :
 - The committee recommends the approval of the application
 - HCAI to make final determination and provide information on user fees and method of data access and the appropriate DUA with the written notification
 - HCAI to report back to DRC on determination
- Conditional:
 - The committee recommends conditional approval for applications that require additional information to address minor issues or deficiencies
 - HCAI will work with the requestor to modify the application or obtain additional information to address DRC concerns
 - HCAI may bring back information to DRC if it is a substantive adjustment to the application
 - HCAI makes the final determination on approval and reports back to DRC on determination
- Not Recommended:
 - The committee does not recommend the approval of the application
 - HCAI makes the final determination on denial and reports back to DRC on determination

Proposed Conflict of Interest Provisions

- Upon reviewing application summary or application (if primary reviewer) DRC members notify HCAI and the DRC Chair of any self-disclosed or discovered conflict of interest and will be excused from discussion of the application.
- If a primary reviewer has a conflict, the application gets re-assigned.
- Some examples of conflict of interest for consideration:
 - **Financial Conflicts:** A DRC member “shall not make, participate in making, or in any way attempt to use the [their] official position to influence a governmental decision in which the [member] knows or has reason to know the [member] has a financial interest.”
 - **Common Law Doctrine:** A DRC member is “prohibit[ed] from placing themselves in a position where their private, personal interests may conflict with their official duties.”
 - **Incompatible Activities:** A DRC member “shall not engage in any employment, activity, or enterprise which is clearly inconsistent, incompatible, in conflict with, or inimical to his or her duties as a state officer or employee.”
- The State of California is concerned with not just actual conflicts of interest, but also the appearance of impropriety. This is to instill confidence and build public trust in government and that its decisions are legitimate
- **What are other conflicts of interest that the committee may want to consider?**

How HCAI Supports the DRC in the Review Process

During the Review Process

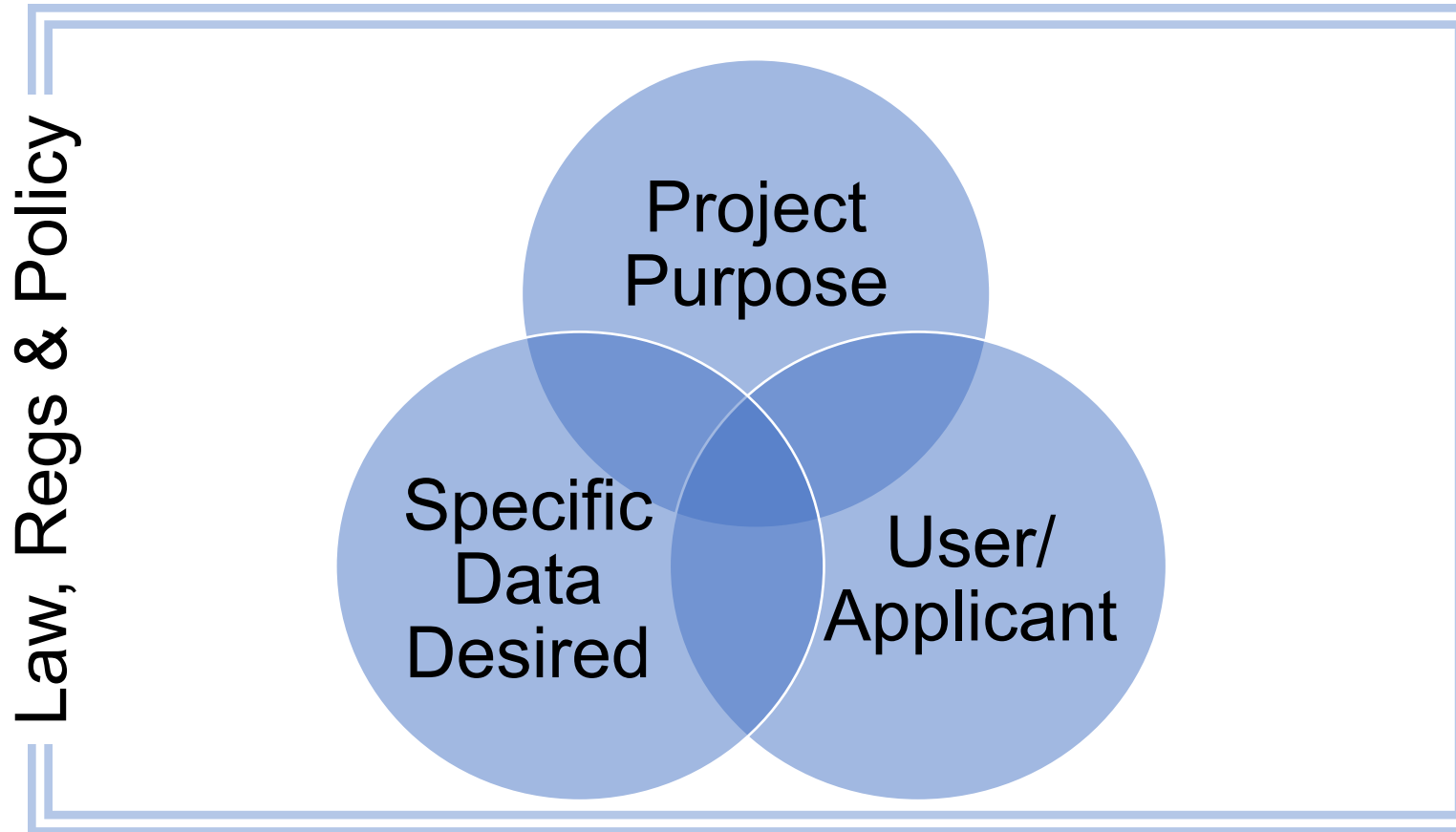
- Coordinate all communication with the applicant
- Distribute documents for DRC review
- Prepare & distribute agendas and meeting materials
- Facilitate DRC meetings, take minutes, collect final decisions from primary reviewers.

After Application Approval

- Generate decision letters, collect fees, execute a DUA
- Coordinate with the applicant to fulfill the request
- Review project outputs for compliance with deidentification and other requirements
- Close-out completed projects
- Report back to DRC on final disposition once requestor is notified

Criteria for Board Decision Making

Intersecting Factors in Data Access Approvals



DRC Application Review Statutory Considerations

- In reviewing applications and making recommendations, Health and Safety Code (HSC) Section 127673.84(d)(2) requires the DRC to consider:
 - Whether and to what extent the data use is consistent with to program goals.
 - Whether the use of the data provides greater transparency.
 - How the information may be used to inform policy decisions.

Proposed Considerations That Could Be Applied

Category	Consideration
Privacy	Is reason or justification provided for all confidential or sensitive data elements requested? These include direct identifiers, indirect identifiers (dates, 5-digit ZIP), and sensitive diagnoses and procedures.
	Does the request satisfy minimum data necessary standards?
Results and Information Products	What are the expected findings/outputs and what level of aggregation will be applied to reports, presentations, and other information products intended for public dissemination?
	Will the research and results be made available to HCAI?
	Does the project generate a public benefit for California?
Anticompetitive Use & Commercialization of HPD Data	Is the request to create a product for commercialization or marketing? If so, is the project being conducted on behalf of or in collaboration with the state?
	Is there a risk for anticompetitive use of the data?