Agenda VI: Data Release Process - DRC's Role

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For Today

- Overview of DRC Role in reviewing applications for HPD data
- Administrative processes of other public data review committees
  - Committee for the Protection of Human Subjects (CPHS)
  - Vital Statistics Advisory Committee (VSAC)
- Discuss proposed approach for Data Release Committee Process

Statutory Provisions for Data Release Committee

- Advise on criteria, policies, and procedures for access to and release of HPD data.

- **Make recommendations about applications for HPD data.**

- **Consider whether the use of the data is consistent with the goals of the system, whether it provides greater transparency regarding health care costs, utilization, quality, or equity, or how the information may be used to inform policy decisions regarding the provision of quality health care, improving public health, reducing health disparities, advancing health coverage, or reducing health care costs.**

- Advise the HCAI director about privacy and security matters related to the program.

- Provide feedback on the program's data application review processes and other matters.

HSC Section 127671-127674

Other Committees that Review Data Requests

Other Committees that Review Data Requests

- Review the administrative process two (2) Bagley Keene public committees that review data requests.
- Opportunity to understand similarities and differences across the programs as the DRC considers feedback on what should be developed for this committee.

- **Committee for the Protection of Human Subjects** – CalHHS Institutional Review Board

- **Vital Statistics Advisory Committee** – provides recommendations on the release of vital statistics and confidentiality of personal health and medical information

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CPHS– Process Flows

Before the Meeting

- Application requests submitted **30-days in advance** of CPHS Committee Meeting
- The committee members review the applications to make determinations on approval
- CPHS agenda released and includes a listing of all the projects submitted during a cycle

During the Meeting

- Review of Adverse Events/Unanticipated Problems reports and Full Committee Projects
- Vote on each Full Committee Project
- A representative for each project attends the meeting to provide an overview of the project, answer questions and provide clarifications
- Live minutes are taken to capture any application revisions, which are later incorporated into the letters sent to the researchers after the meeting.

After the Meeting

- Letters sent out to researchers documenting the formal approval
- Meeting minutes published on the website

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Vital Statistics Advisory Committee – Process Flow

Before Meeting

- Applications **submitted 2 weeks** prior to meeting
- Applications are screened by CDPH staff (including scientific advisors)

During the Meeting

- **2 sets of review**: Consent Calendar and New Projects
- **Consent Calendar:**
  - Projects already been approved but there is a change to the principal investigator or a request for an additional year of data; VSAC votes on these as a full calendar
- **New projects:**
  - Each application is reviewed one by one at the committee and there is an individual motion for each individual project
  - Scientific advisor from CDPH outlines if there are any concerns
- Researchers not required to be at the meeting to answer questions

After the Meeting

- Within 10 days applicants receive notification of meeting results

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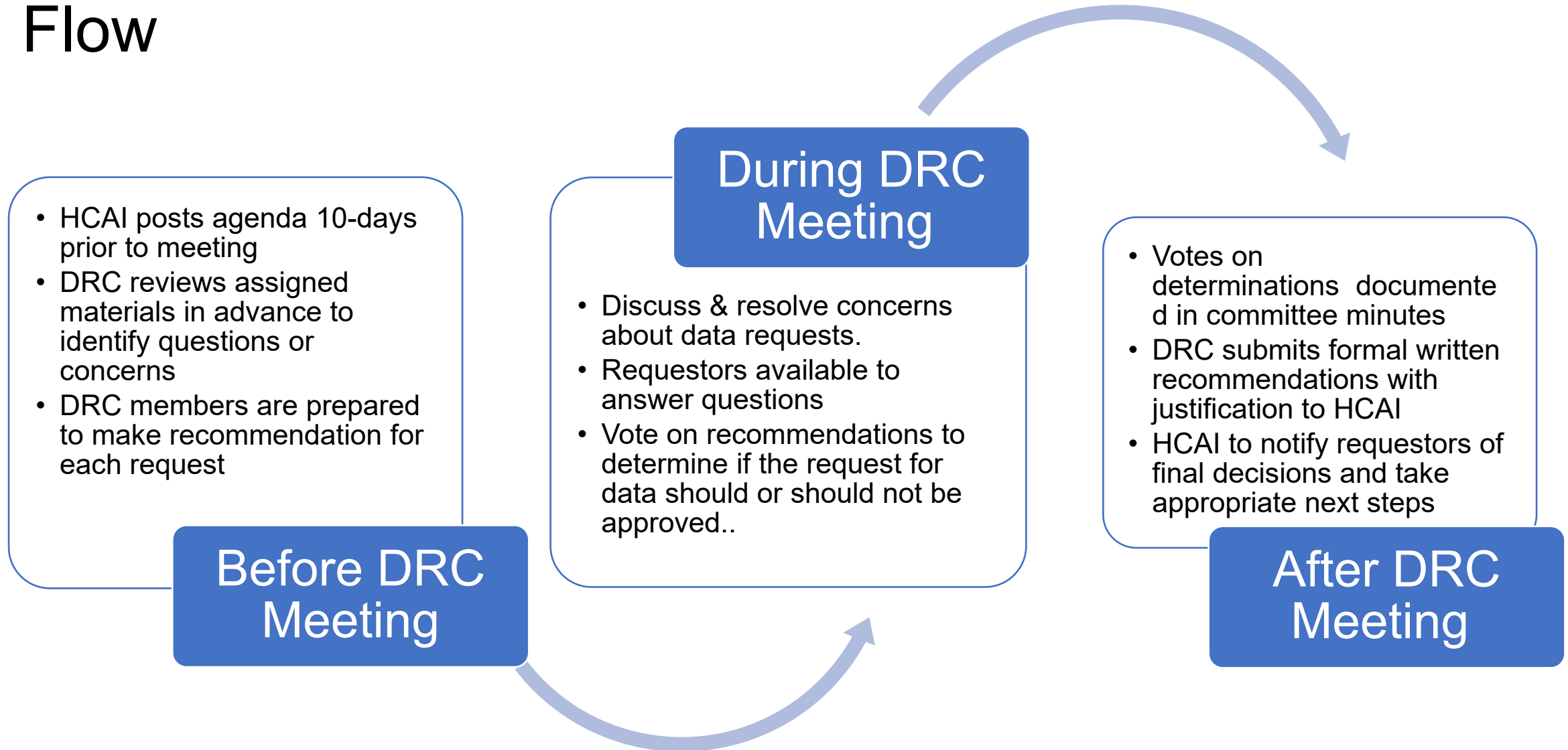Access and Information

Proposed DRC Process

Considerations for DRC in Making Recommendations

Statute requires consideration of:

- Whether and to what extent the data use will contribute to program goals:
  - For all requests, whether the use of the data is "**consistent with the goals"**
  - For requests that include direct personal identifiers or are transmitted outside of the enclave, the bar is higher: access may only be provided for research projects that offer "**significant opportunities to achieve program goals**"

- Whether the use of the data provides **greater transparency** regarding health care costs, utilization, quality, or equity, or

- How the information may be used to **inform policy decisions** regarding the provision of quality health care, improving public health, reducing health disparities, advancing health coverage, or reducing health care costs

HSC Section 127673.83(b)(2), 127673.84(d)(2)

Proposed Data Release Committee - Process Flow

Before DRC Meeting

- HCAI posts agenda 10-days prior to meeting
- DRC reviews assigned materials in advance to identify questions or concerns
- DRC members are prepared to make recommendation for each request

During DRC Meeting

- Discuss & resolve concerns about data requests.
- Requestors available to answer questions
- Vote on recommendations to determine if the request for data should or should not be approved..

After DRC Meeting

- Votes on determinations documented in committee minutes
- DRC submits formal written recommendations with justification to HCAI
- HCAI to notify requestors of final decisions and take appropriate next steps

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Data Release Committee Review - Considerations

- When Reviewing Applications Consider:
  - Is the use case aligned with program goals?
  - Qualifications of requestor/Principal Investigator
  - Appropriateness of use case, research questions, hypothesis, proposed methods
  - Adequacy of data privacy and security protections

How can HCAI support the DRC in applying these considerations?

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Public Engagement

- All DRC Meetings are subject to the Bagley-Keene Open Meeting Act
  - Agendas including information that will be discussed at the meeting posted 10-days prior to the meeting
  - Meeting minutes including votes and discussions posted on the DRC website
  - Members of the public have an opportunity to provide public comment on each application that is discussed, prior to the committee members taking a vote on the application

Are there other forms of Public Engagement HCAI should consider ?

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APCD Public Review Processes

APCD	Publicly Release Application	Public Comments	Publicly Release Data Fees	Publicly Release Decision
Maryland APCD	Yes (redacted)	Yes (via website, 10-day comment period)	Yes	Yes
Delaware HCCD	Yes (redacted)	Yes (during meeting)	No	Yes
RI APCD	Yes (redacted)	Yes	No (general fee structure only)	Only in meeting minutes
CO APCD	No	No	Yes (base fee and additional costs)	Summarized in Annual Reports
Oregon APAC	Yes	Yes	No (general fee structure only)	Only in meeting minutes
Washington APCD	Yes (request name, summary, data type)	Yes	Yes	Yes (status and reason for decision)

Data Release Committee Board Manual

- Document that is developed in partnership with the DRC to outline rules and processes
  - Creates a public and transparent document that outlines the committee processes
  - Clearly outlines roles and responsibilities to support HCAI and committee accountability
- Many Boards have Board Manuals:
  - CPHS Manual
  - Office of Health Care Affordability Board Manual

Should the DRC develop a Board Manual ?

Engagement of Outside Experts

- Seeking input from external subject matter experts on applications that involve complex analysis methods or that raise novel research issues

- Present at the public board meeting, or provide 1:1 input to committee members during the application review

- Opportunity for creation of subcommittees with 2 members + external subject matter expert to review applications

- Consideration needed for alignment with Bagley-Keene Open Meeting Act

Should HCAI develop a process that allows for engagement of outside subject matter experts to support application review?