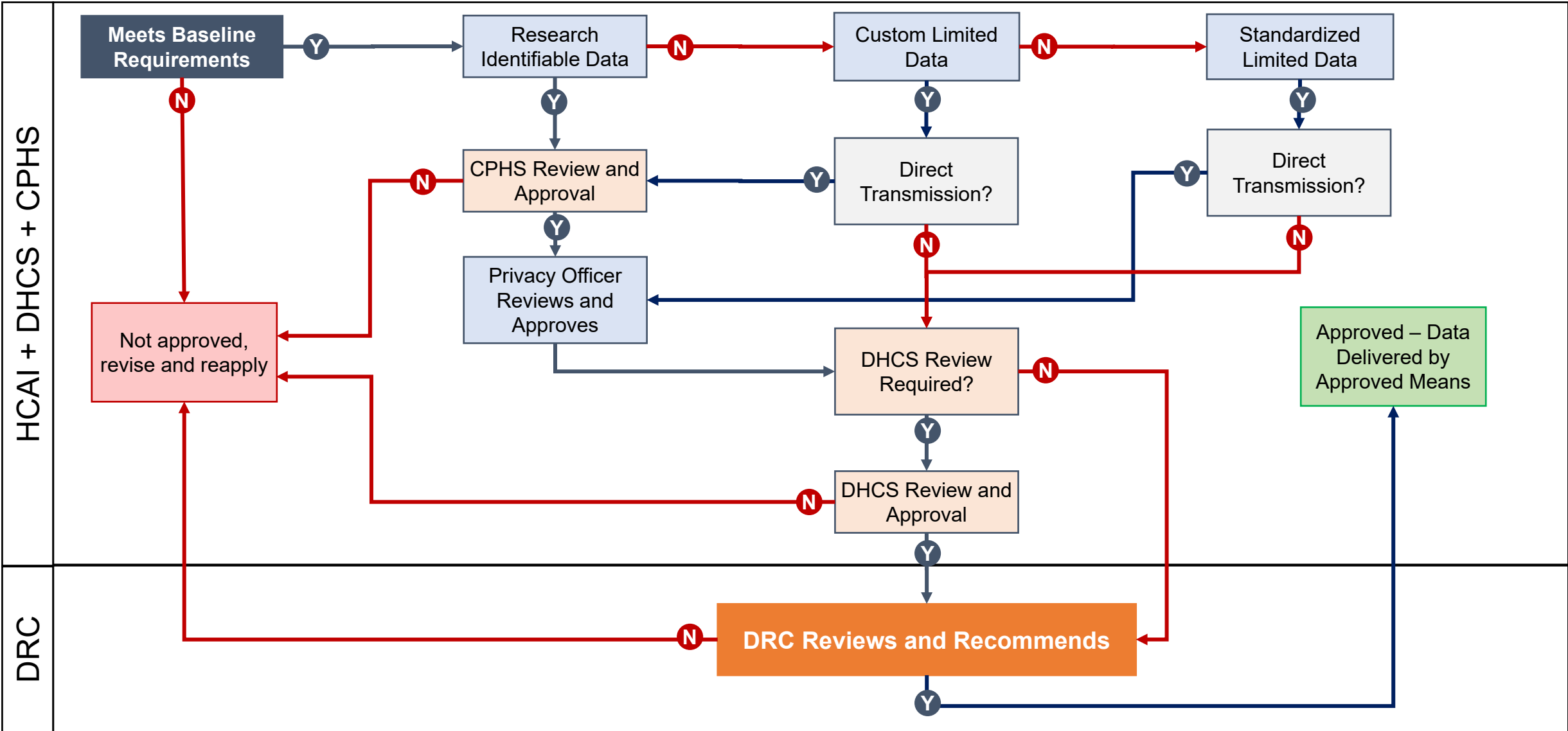


Agenda V: Application Review Process

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Data Request Decision Tree and Flow Diagram



Considerations for Application Review

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, 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

Exception:
data requests
from other state
agencies

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

Considerations for Application Review

- Is a reason/justification required for certain data elements?
 - Direct Identifiers, Indirect Identifiers
 - Entity & Financial Information (EFI)
 - Sensitive diagnoses and procedures
- Further considerations:
 - How does the project meet minimum data necessary standards?
 - Is there a risk for anticompetitive use of the data?
 - Level of aggregation in public outputs/products?
 - Will the research be made available to HCAI?
 - Does the project provide a public benefit for California?
 - Is the request to create a product for commercialization or marketing?

Decisions on Data Applications

- Timeliness: HCAI must notify applicants of decisions within 120 days of submission unless:
 - The applicant agrees to a longer time period
 - The request is subject to DHCS and/or CPHS review
 - HCAI has good cause.
- Options:
 - Denied – The notice must include the reasons for denial
 - Approved – The notice will include data use/access fee information, method of access, and a Data Use Agreement
 - Conditional – HCAI may issue a conditional approval pending DHCS/CPHS approval.

Reasons for Denial

- Mandatory and Discretionary Reasons
- Confidential Data Access (via Enclave):
 - Data is not needed to support the proposed use
 - The request is for more than the minimum necessary data
 - Data access is not limited to members of the project team.
- Obtaining Confidential Data (via direct file transfer):
 - The proposed use can be accommodated through the Enclave
 - Requestor IT systems, policies and procedures do not meet data security standards and requirements
 - Confidential data would be stored outside of the USA.

Proposed DRC Review Operations

- Three major considerations to DRC operations:
 - Materials shared with the majority of the Committee need to be accessible to the public
 - Communication between three or more members of the Committee are subject to Bagley-Keene requirements
 - Committee is to facilitate transparency to the public while ensuring privacy, data security, efficiency, and effectiveness of the review
- Proposed Operations
 - Two primary reviewers will receive whole application w/o detailed security information
 - Remaining committee members receive a summary or excerpt of the application
 - Primary reviewers lead the discussion of the application
 - All present Committee members vote on recommendation
 - If public files a Public Records Act request, they will receive what the reviewers receives and HCAI may withhold information to protect data security information, or privacy