



Enforcing Patient Consent

Report from the ONC LEAP Patient Consent Project

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Patient Consent Challenges

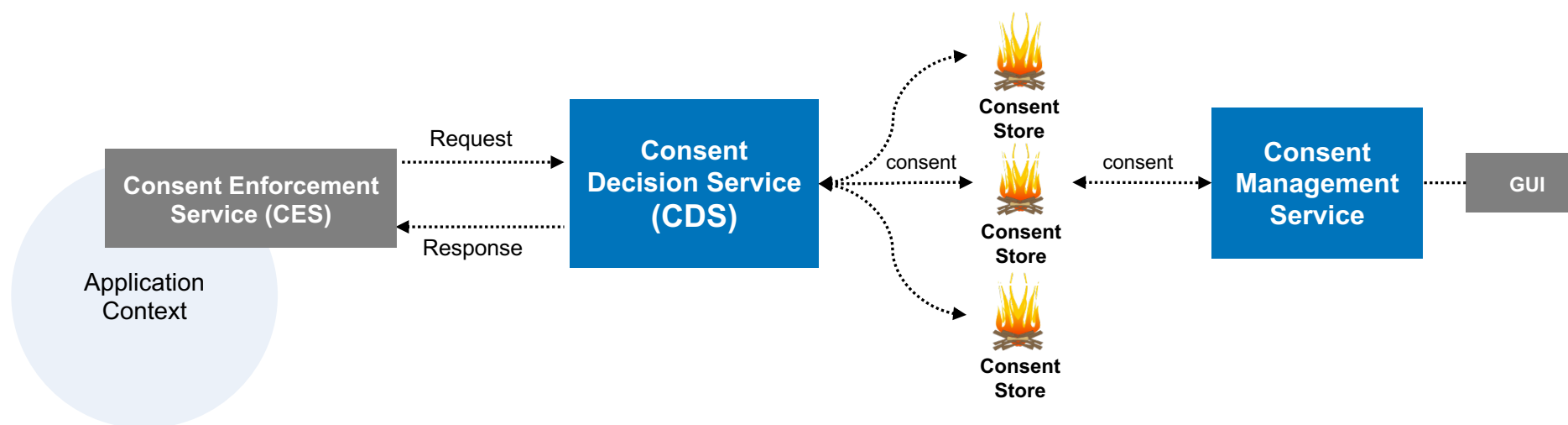
- Patient Consent is often captured in paper form,
 - Challenge: searching and retrieval based on metadata
- when it is captured in electronic form, it is often not in an interoperable form (e.g., a PDF attachment)
 - Challenge: consolidation from multiple sources
- when it is captured in standard electronic form, it is often not computable
 - Challenge: automatic enforcement (without manual steps)
- when it is computable, it often only allows for a binary decision
 - Challenge: consents are often reduced to a binary (“share” or “don’t share”) without allowing more nuanced choices

Goals

Patient Consents that are:

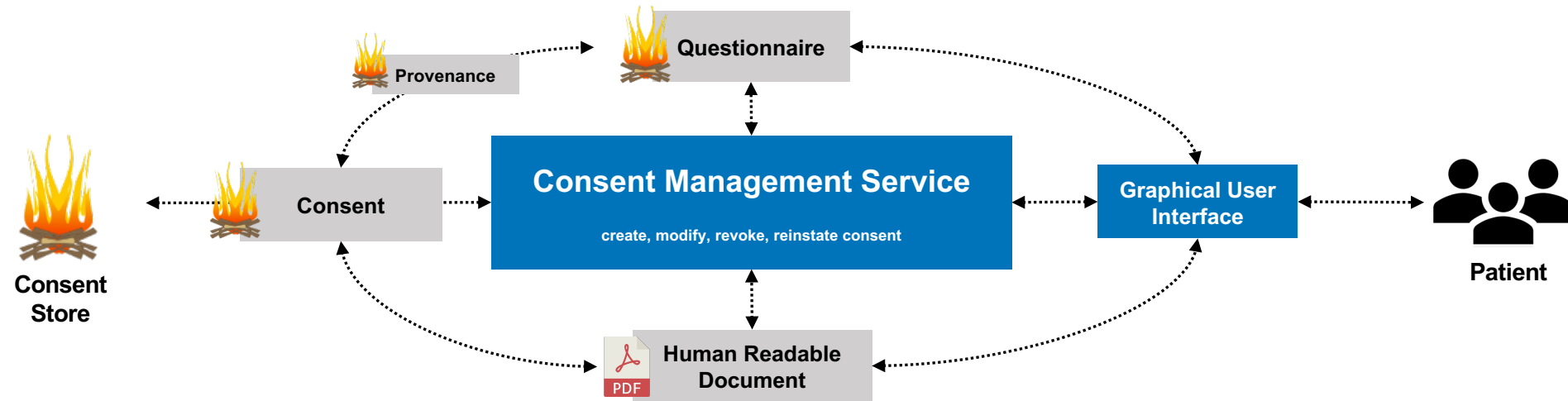
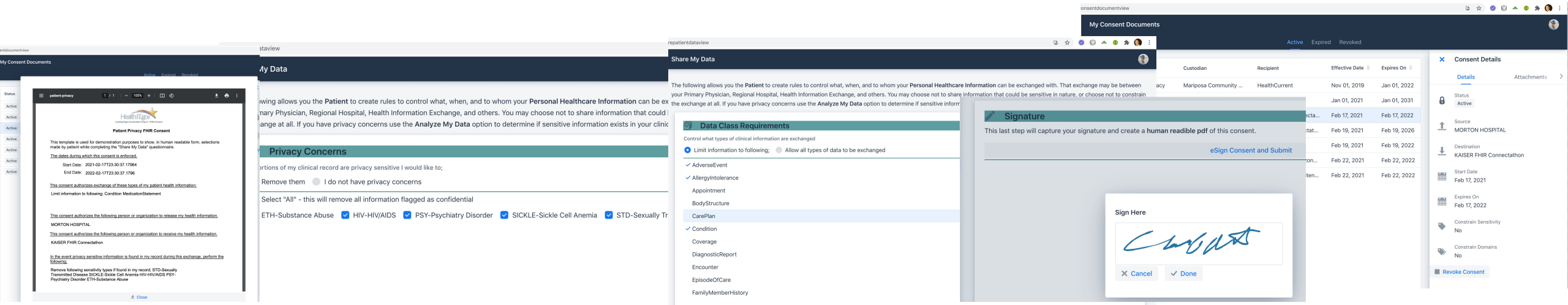
- **Interoperable**
 - FHIR Consent resource and a standard access API
 - An aggregation service to retrieve applicable consent from all sources
- **Computable**
 - A consent decision service to parse and process patient consents
 - An API for query/response about consent decisions
- **Applicable**
 - Different Types of Consent
 - Privacy, Research, Treatment, Advanced Health Directive
 - Proof of concept for various use-cases
 - HL7v2 Exchange, eHealth Exchange, Direct Exchange, FHIR (embedded and proxy)

High Level Architecture



Consent Management Service

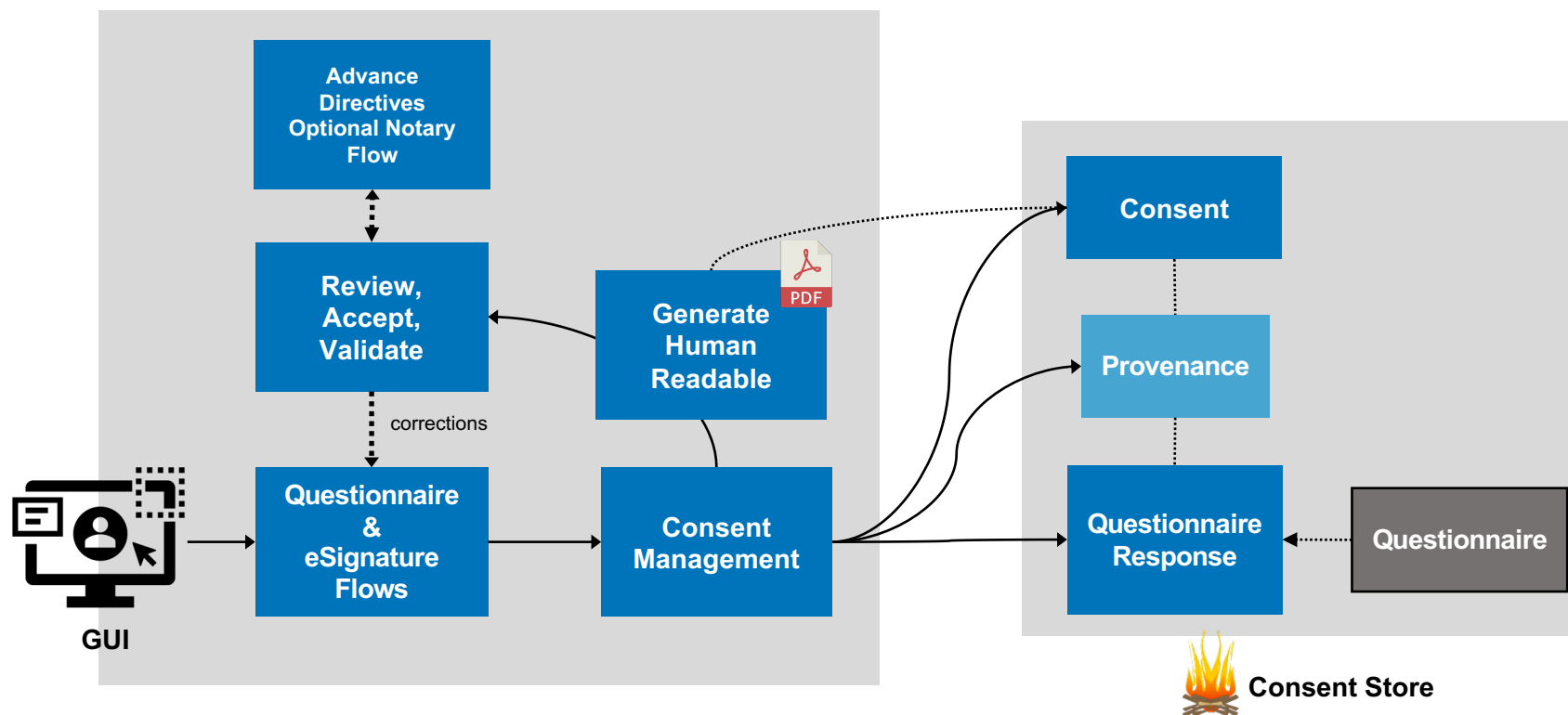
A service for patients to create, modify, revoke, and reinstate consents.

The bottom section shows three overlapping screenshots of the web application interface:

- Left Screenshot:** Displays a "Patient Privacy PHIR Consent" form. It includes sections for "Privacy Concerns" (with radio buttons for "I do not have privacy concerns" and "I have privacy concerns") and "Data Class Requirements" (a list of clinical information types with checkboxes for selection).
- Middle Screenshot:** Shows a "Share My Data" section with a table of data exchange rules. The table has columns for "Custodian", "Recipient", "Effective Date", and "Expires On".
- Right Screenshot:** Displays a "Signature" step where the user is prompted to "Sign Here" and create a human readable PDF. It includes a "Sign Here" button and a "Cancel" button.

Consent Management Flow

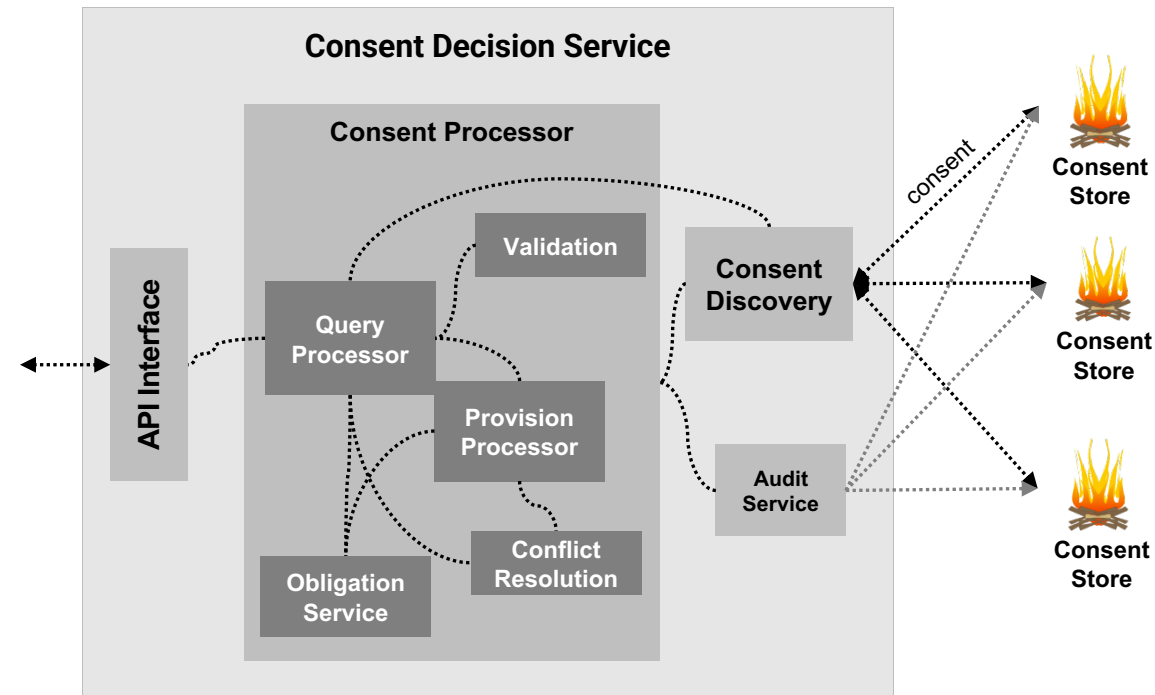


- Attached digitally signed pdf(custodian)
- Reference to QuestionnaireResponse (R4 Extension)
- Provisions for Consent Enforcement

Consent Decision Service

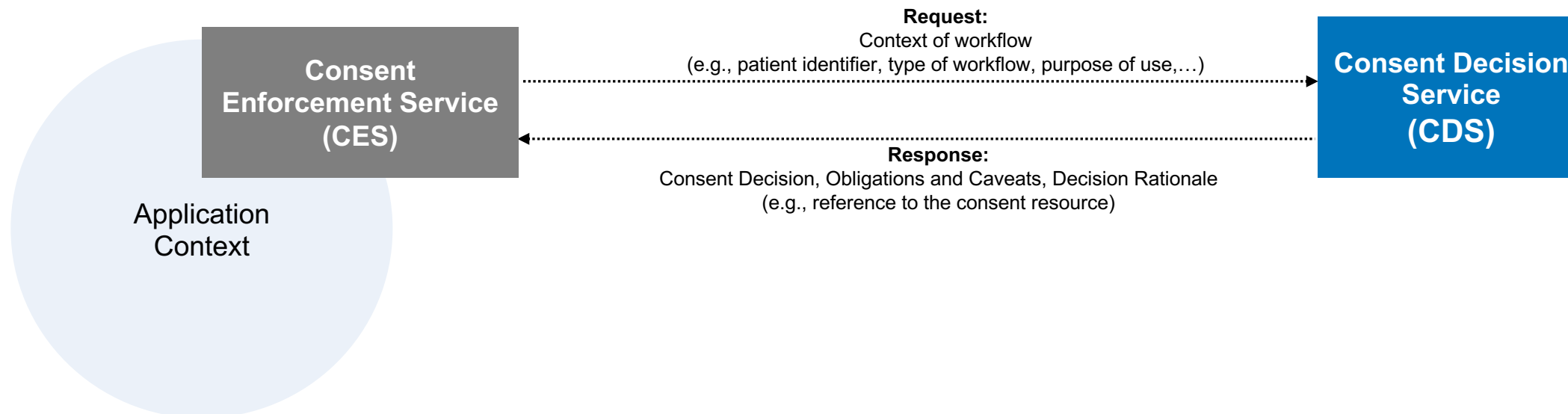
A service to determine whether, in a given context, requested access is permitted or denied and whether any obligations apply

- Consent discovery
- Query processor
 - Query processor,
 - Validation service
 - Provision processor
 - Obligation service
 - Conflict resolution service
- Audit Service
- API interface
 - *Clinical Decision Support Hooks & eXtensible Access Control Markup Language (XACML)*



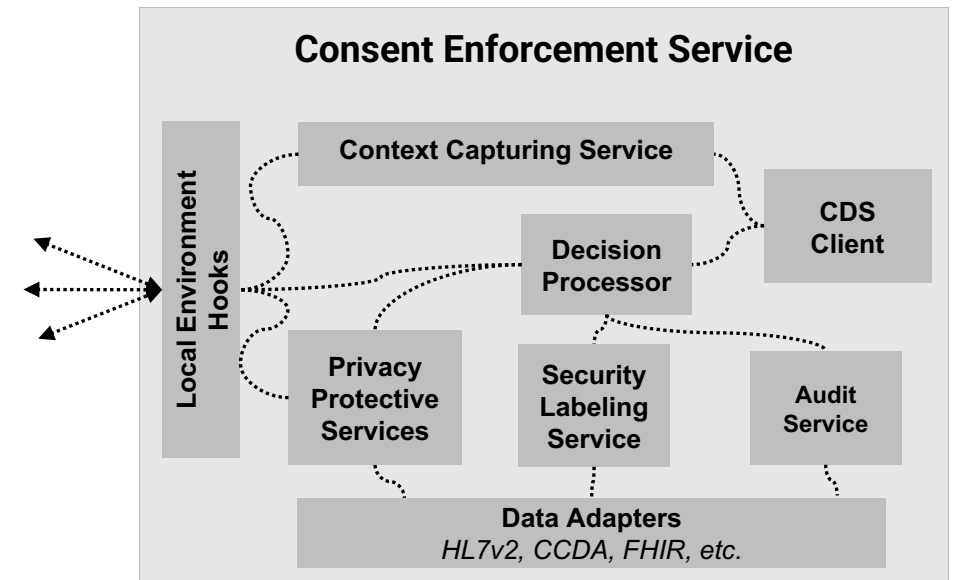
Consent Enforcement Service

Individual modules integrating with different application contexts to enforce consent decisions



Consent Enforcement Service

- Capture and report the context of the workflow (a LEAP-CDS query)
- Send the query to the Consent Decision Service
- Receive and process the response
- Apply and enforce the decision in the local environment
 - Block access,
 - Modify the data based on obligations



Resources

- **Code and Documentations Artifacts:**

- Documentation: <https://sdhealthconnect.github.io/leap/>
- LEAP Consent Decision Service: <https://github.com/sdhealthconnect/leap-cds>
- LEAP Consent Management User Interface: <https://github.com/sdhealthconnect/leap-consent-ui>
- LEAP Consent Enforcement Service (CES) for FHIR (Proxy-Based): <https://github.com/sdhealthconnect/leap-fhir-ces>
- LEAP Consent Enforcement Service (CES) for FHIR (Embedded): <https://github.com/sdhealthconnect/leap-hapi-fhir-ces-embedded>
- LEAP Consent Enforcement Service (CES) Demo Use-Cases, including HL7 v2.0 Messaging, eHealth Exchange, and Direct Exchange: <https://github.com/sdhealthconnect/leap-demos>
- LEAP Security Labeling Services (SLS): <https://github.com/sdhealthconnect/leap-sls>
- LEAP Consent Enforcement Service (CES) Java Client Library: <https://github.com/sdhealthconnect/leap-ces-java-clients>

- **Continuous Delivery Deployments**

- LEAP Consent UI: <https://leap-gui-yop7t2tkfq-uc.a.run.app/>
- LEAP Consent Decision Service: <https://sdhc-leap.appspot.com/cds-services/patient-consent-consult>
- LEAP Consent Store (HAPI-FHIR): <https://sdhc-hapi-fhir-leap-wafxyq4bza-uc.a.run.app/>
- LEAP FHIR Proxy Consent Enforcement Service: <https://leap-fhir-ces.uc.r.appspot.com/>
- LEAP Security Labeling Service (SLS): <http://sdhc-sls-leap.uc.r.appspot.com>