



# **FHIR Consent Management Application Opt-Out**

**Planning and Discussion Document**

**FHIR Consent External API Specification**

**CRISP Shared Services**

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*For Design, Planning and Discussion Purposes Only*



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# 1. Introduction

The purpose of this document is to facilitate design, discussion, planning, and development of an externally facing FHIR Application Program Interface (API) to look up a patient's opt-out status.

## 1.1 Summary of Opt-Out Consent

When patients elect to Opt-Out of sharing their clinical data, they must complete an Opt-Out form. This form is unique to reflect the laws surrounding Protected Health Information (PHI) security. In Maryland, the patient's default status is opt in and the patient must opt out from sharing their clinical data with any of the HIEs in Maryland.

CRISP will not exchange any clinical data we received on patients who opt out. We will exchange the opt-out information with other HIEs per the law and regs.

## 1.2 Data Storage

CSS maintains patient demographics submitted in Optout Form (Name, DOB, Gender, Address, Phone), patient SMRNs (source and medical record numbers) from other sources that match to those on the OPTOUT record.

*CSS keeps all available patient demographics that match those on a patient's OPTOUT record(s) so that CSS can accurately maintain a patient entity of SMRNs from multiple sources. This ensures our processes can remove and/or restrict clinical data relating to optout patients.*

CSS does *not* maintain clinical information associated with the SMRNs in the optout patient's entity.



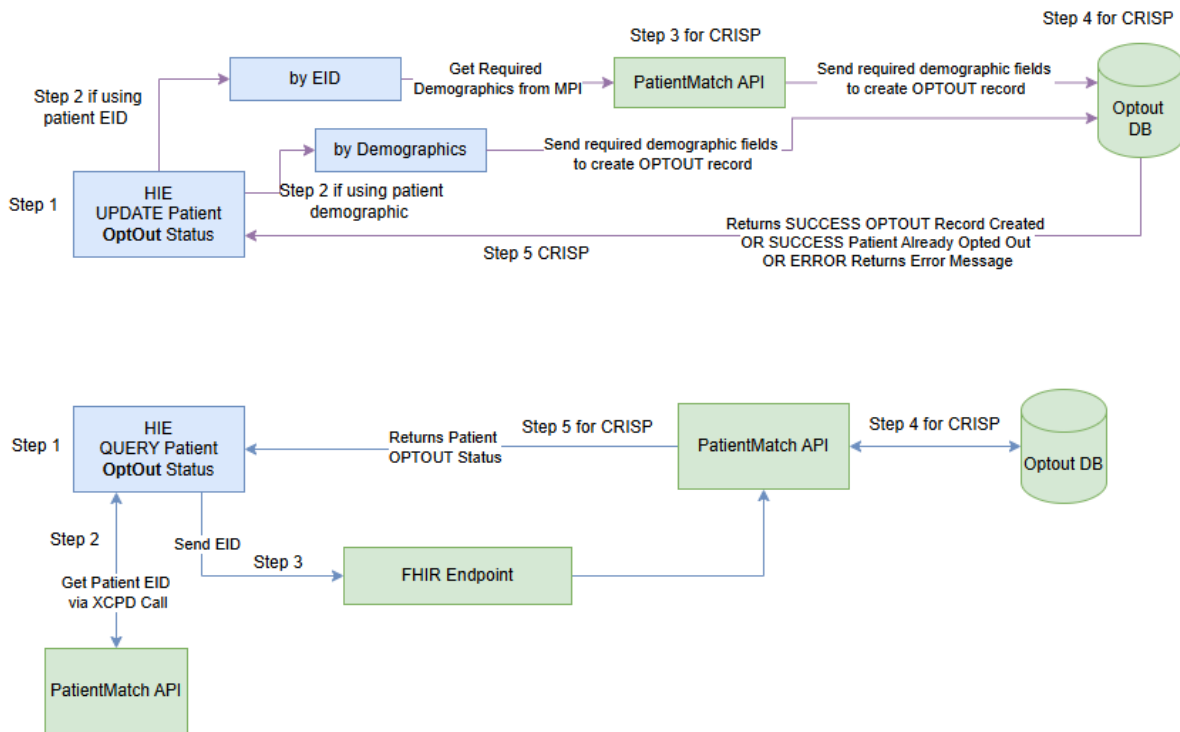
## 2. Opt-Out External Facing API Specifications

### 2.1 Assumption

- XCPD call should happen before any of the calls to get the EID of the patient.
- If the user does not want to call via XCPD, then they can query by demographics to match the patient.

### 2.2 API Diagram

The following diagram provides a graphical representation of the API requests.



#### HIE to Obtain OptOut

1. HIE will call via XCPD to get the patient EID
2. HIE obtained EID
3. HIE query a patient using the EID
4. CRISP FHIR endpoint matches the patient from the patient match API and from the optout database
5. CRISP returns patient optout status to the HIE



## 3. Consent Management FHIR API

### 3.1 Overview

The FHIR Consent API supports management of patient privacy consent opt-out using the HL7® FHIR® R4 Consent resource. This API implements a Consent profile aligned with FHIR R4 and is intended to represent a patient's decision to opt out of participation in CRISP's health information exchange.

#### All responses conform to:

- FHIR Version: R4 (4.0.0)
- Primary FHIR Resources:
  - Patient
  - Consent
  - OperationOutcome

#### This API supports:

- Creating an opt-out Consent using patient demographics
- Creating an opt-out Consent using a patient EID identifier
- Returning standardized FHIR error responses

### 3.2 Base URL, Versioning and Capability Statement

- **Base URL:**  
<https://api.crisphealth.org>
- **FHIR Version:**  
R4 (4.0.0)
- **FHIR API Capability Statement:**  
<https://api.crisphealth.org/optout/r4/metadata>

### 3.3 Security

#### 3.3.1 Transport Security

- TLS 1.2+ required
- Mutual TLS (mTLS) using client SSL certificate



### 3.3.2 Authentication

- All endpoints require SSL client certificate for secure access.
- Certificate to be issued by CSS Infrastructure team.
- Certificate validation enforced at API Management layer.

### 3.3.3 Authorization

- Access restricted to approved trading partners
- Access provisioning must follow CRISP onboarding process

## 3.4 Client API Access Flow

1. **Client requests SSL certificate** from CSS point of contact.
2. **Client sends request** with valid certificate to the appropriate endpoint with required parameters and headers.
3. **CSS API validates** input, queries MPI, and processes opt-out logic.
4. **CSS API returns response** as a FHIR resource bundle (Consent or OperationOutcome).
5. **CSS API handles errors** and returns them as FHIR OperationOutcome resource with standardized codes.

## 3.5 CSS Technical Support

- If the user is facing issues they can email or call CCS Support
  - email: [support@crisphealth.org](mailto:support@crisphealth.org)
  - CSS Support number: 1877-952-7477.
- Alternatively, user can provide feedback via InContext app.



## 3.6 Consent Profile Requirements

The API creates a Consent resource representing patient opt-out with the following required constraints:

Element	Requirement
status	SHALL be active
scope	SHALL be patient-privacy
category	SHALL include LOINC 59284-0 (Privacy policy acknowledgment)
patient.identifier	SHALL reference patient opt-out SMRN
policy	SHALL reference MD legal patient consent regulation
provision.type	SHALL be deny

## 3.7 API Operations

### 3.7.1 Create Opt-Out by Demographics

#### 3.7.1.1 Request

*POST /optout*

Creates an opt-out Consent by submitting a FHIR Patient resource containing patient demographics.

Endpoint logic will attempt to find a near-match patient in CRISP's MPI database based on patient demographics passed in the request. If a valid match is not found, a new patient will be created within MPI using demographics provided.

#### 3.7.1.2 Headers

```
Content-Type: application/fhir+json
Accept: application/fhir+json
UserName: <name of the user sending the optout request>
SendingOrganization: <name of the organization from which the opt-out request was sent>
```



### 3.7.1.3 Body Parameters

Endpoint accepts a JSON formatted FHIR Patient resource as defined in [R4 FHIR Patient resource](#)

*Example:*

```
{
  "name": [
    {
      "use": "official",
      "family": "Doe",
      "given": ["John"]
    }
  ],
  "birthDate": "1980-01-01",
  "gender": "male",
  "address": [
    {
      "use": "home",
      "line": ["123 Main St"],
      "city": "Baltimore",
      "state": "MD",
      "postalCode": "21201",
      "country": "USA"
    }
  ],
  "telecom": [
    {
      "value": "555-123-4567",
      "system": "phone",
      "use": "mobile"
    }
  ],
  "identifier": [
    {
      "system": "http://hl7.org/fhir/sid/us-ssn",
      "value": "123456789"
    }
  ]
}
```

### 3.7.1.4 Processing Rules

- If a matching patient is found:
  - A new Consent is created (if not already opted-out).
- If no patient is found:
  - A new Patient is created.
  - A Consent is created.
- If multiple matches are found:
  - No new Consent created.



- Suppressed response returned.
- If patient already opted out:
  - No new Consent created.
  - Conflict response returned.

## 3.7.2 Create Opt-Out by EID

### 3.7.2.1 Request

*POST /optout*

Custom FHIR operation for opt-out using Enterprise ID.

Endpoint logic will attempt to find patient by EID in CRISP's MPI database. If an exact EID match is not found, new patient will *not* be created.

### 3.7.2.2 Headers

```
Content-Type: application/fhir+json
Accept: application/fhir+json
UserName: <name of the user sending the optout request>
SendingOrganization: <name of the organization from which the opt-out request was sent>
```

### 3.7.2.3 Body Parameters

Endpoint accepts JSON formatted FHIR Patient Identifier as defined in [R4 FHIR Patient.Identifier](#) with system namespace

`https://api.crisphealth.org/definitions/identifier/eid` and value set to patient's unique Enterprise ID value.

*△ If patient demographics are passed along with an EID identifier, the API will default to using EID when searching for a patient match and ignore any additional demographics passed in the request.*

*Example:*

```
{
  "identifier": [
    {
      "system": "https://api.crisphealth.org/definitions/identifier/eid",
      "value": "123456789"
    }
  ]
}
```

### 3.7.2.4 Processing Rules

- If a matching patient is found:
  - A new Consent is created (if not already opted-out).



- If no patient is found:
  - No new Consent created.
  - Not Found response returned.
- If multiple matches are found:
  - No new Consent created.
  - Suppressed response returned.
- If patient already opted out:
  - No new Consent created.
  - Conflict response returned.

## 3.8 API Responses

### 3.8.1 Consent Created

HTTP/1.1 200 | Created

**Location:** /consent?patient.identifier={system}|{value}

Example:

```
{
  "resourceType": "Bundle",
  "type": "searchset",
  "timestamp": "2026-02-05T21:00:37.3126774+00:00",
  "total": 1,
  "entry": [
    {
      "resource": {
        "resourceType": "Consent",
        "meta": {
          "lastUpdated": "2026-02-05T21:00:37.2882124+00:00"
        },
        "status": "active",
        "scope": {
          "coding": [
            {
              "system": "http://terminology.hl7.org/CodeSystem/consentscope",
              "code": "patient-privacy"
            }
          ]
        },
        "category": [
          {
            "coding": [
              {
                "system": "http://loinc.org",
                "code": "59284-0"
              }
            ]
          }
        ]
      }
    }
  ]
}
```



```
    ],
    "patient": {
      "identifier": {
        "system": "https://api.crisphealth.org/definitions/identifier/smrn",
        "value": "OPTOUT^0S2E4T1Z4E113T1T2YS"
      }
    },
    "policy": [
      {
        "authority": "https://health.maryland.gov",
        "uri": "https://dsd.maryland.gov/regulations/Pages/10.25.18.03.aspx"
      }
    ],
    "provision": {
      "type": "deny"
    }
  }
}
]
```

## 3.8.2 Operation Outcomes

### 3.8.2.1 Patient Already Opted Out

*HTTP/1.1 200 | Request Accepted*

```
{
  "resourceType": "Bundle",
  "type": "searchset",
  "timestamp": "2026-05-14T21:43:32.4310997+00:00",
  "total": 1,
  "entry": [
    {
      "resource": {
        "resourceType": "OperationOutcome",
        "issue": [
          {
            "severity": "information",
            "code": "conflict",
            "details": {
              "text": "The patient has already opted out."
            }
          }
        ]
      }
    }
  ]
}
```

### 3.8.2.2 Patient Not Found

*HTTP/1.1 200 | Request Accepted*

```
{
```



```
"resourceType": "Bundle",
"type": "searchset",
"timestamp": "2026-05-14T21:41:42.9834981+00:00",
"total": 1,
"entry": [
  {
    "resource": {
      "resourceType": "OperationOutcome",
      "issue": [
        {
          "severity": "warning",
          "code": "not-found",
          "details": {
            "text": "The requested patient was not found."
          }
        }
      ]
    }
  }
]
```

### 3.8.2.3 Ambiguous Match

HTTP/1.1 200 | Request Accepted

```
{
  "resourceType": "Bundle",
  "type": "searchset",
  "timestamp": "2026-05-14T21:41:42.9834981+00:00",
  "total": 1,
  "entry": [
    {
      "resource": {
        "resourceType": "OperationOutcome",
        "issue": [
          {
            "severity": "warning",
            "code": "suppressed",
            "details": {
              "text": "The requested record is an ambiguous patient."
            }
          }
        ]
      }
    }
  ]
}
```

### 3.8.2.4 Validation Error

HTTP/1.1 400 | Bad Request

```
{
```



```
"resourceType": "OperationOutcome",
"issue": [
  {
    "severity": "error",
    "code": "invalid",
    "details": {
      "text": "Either a valid patient identifier (EID) or complete patient demographics are
required. Demographics must include name (family and given), date of birth, and gender."
    }
  }
]
}
```

### 3.9 Required Request Elements (Demographic Matching)

When submitting a Patient resource for opt-out by demographics, the following elements are required:

Element	Cardinality
Patient.name.family	1..1
Patient.name.given	1..*
Patient.birthDate	1..1
Patient.gender	1..1

All other [FHIR Patient](#) elements are optional.

### 3.10 Conformance Expectation

#### 3.10.1 Clients SHALL:

- Send `application/fhir+json`
- Handle FHIR `OperationOutcome` responses
- Support HTTP status codes 200, 400, 500

#### 3.10.2 Servers SHALL:

- Return valid FHIR R4 JSON



- Preserve idempotency (no duplicate active opt-outs)

### 3.11 Idempotency & Business Rules

- Only one active opt-out Consent per patient.
- Repeated submissions SHALL NOT create duplicate Consents.

## 4. PatientMatch XCPD

### 4.1 XCPD Request

#### 4.1.1 Endpoint

POST <https://patientmatch.crisphealth-build.org/xcpd/FindPatientInfo>

#### 4.1.2 Request body

**Format:** XML

```
<?xml version="1.0" encoding="UTF-8"?>
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing" xmlns:xcpd="urn:ihe:iti:xcpd:2009"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:ihe:iti:xcpd:2009">
<s:Header>
<a:Action s:mustUnderstand="1">urn:h17-
org:v3:PRPA_IN201305UV02:CrossGatewayPatientDiscovery</a:Action>
<a:MessageID>urn:uuid:a02ca8cd-86fa-4afc-a27c-16c183b2055</a:MessageID>
<a:ReplyTo>
<a:Address>http://www.w3.org/2005/08/addressing/anonymous</a:Address>
</a:ReplyTo>
<a:To
s:mustUnderstand="1">https://localhost:5001/api/xcpd/FindPatientInfo</a:To>
<!--Recommend a 7 day cache for correlations resulting from this request. -->
<xcpd:CorrelationTimeToLive>P0Y0M7D</xcpd:CorrelationTimeToLive>
</s:Header>
<s:Body>
<PRPA_IN201305UV02 xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance"
xsi:schemaLocation="urn:h17-org:v3
../../schema/HL7V3/NE2008/multicacheschemas/PRPA_IN201305UV02.xsd"
xmlns="urn:h17-org:v3"
ITSVersion="XML_1.0">
<id root="1.2.840.114350.1.13.0.1.7.1.1" extension="35423"/>
<creationTime value="20090417150301"/>
<interactionId root="2.16.840.1.113883.1.6"
extension="PRPA_IN201305UV02"/>
<processingCode code="P"/>
<processingModeCode code="T"/>
```



```
<acceptAckCode code="AL"/>
<receiver typeCode="RCV">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id root="1.2.840.114350.1.13.999.234"/>
    <telecom value="http://servicelocation/IHXCPCDRespondingGateway"/>
  </device>
</receiver>
<sender typeCode="SND">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id root="1.2.840.114350.1.13.999.567"/>
    <!-- Used to carry the homeCommunityId -->
    <asAgent classCode="AGNT">
      <representedOrganization classCode="ORG"
        determinerCode="INSTANCE">
        <!-- homeCommunityId=urn:oid:1.2.3.928.955 -->
        <id root="1.2.3.928.955"/>
      </representedOrganization>
    </asAgent>
  </device>
</sender>
<controlActProcess classCode="CACT" moodCode="EVN">
  <code code="PRPA_TE201305UV02"
    codeSystem="2.16.840.1.113883.1.6"/>
  <!-- Identifies one of LivingSubjectID for use by responder in XCA Query
  - provisioning the opposite direction -->
  <authorOrPerformer typeCode="AUT">
    <assignedDevice>
      <id root="1.2.840.114350.1.13.99997.2.3412"/>
    </assignedDevice>
  </authorOrPerformer>
  <queryByParameter>
    <queryId root="1.2.840.114350.1.13.28.1.18.5.999" extension="18204"/>
    <!-- <statusCode code="new"/><responsePriorityCode
    code="I"/><responseModalityCode
    code="R"/><matchCriterionList><minimumDegreeMatch><value xsi:type="INT"
    value="75"/><semanticsText>MinimumDegreeMatch</semanticsText></minimumDegreeMatch>
  </matchCriterionList> -->
    <parameterList>
      <livingSubjectAdministrativeGender>
        <value code="F"/>
        <semanticsText>LivingSubject.administrativeGender</semanticsText>
      </livingSubjectAdministrativeGender>
      <livingSubjectBirthTime>
        <value value="19841116"/>
        <semanticsText>LivingSubject.birthTime</semanticsText>
      </livingSubjectBirthTime>
      <livingSubjectName>
        <value>
          <given>Anna</given>
          <family>Cadence</family>
        </value>
        <semanticsText>LivingSubject.name</semanticsText>
      </livingSubjectName>
      <patientAddress>
        <value>
          <city>Columbia</city>
        </value>
      </patientAddress>
    </parameterList>
  </queryByParameter>
</controlActProcess>
```



```
<streetAddressLine>1021 Main St</streetAddressLine>
<state>MD</state>
<postalCode>21046</postalCode>
</value>
</patientAddress>
<livingSubjectId>
<value root="1.2.840.114350.1.13.99997.2.3412" extension="1234"/>
<semanticsText>LivingSubject.id</semanticsText>
</livingSubjectId>
</parameterList>
</queryByParameter>
</controlActProcess>
</PRPA_IN201306UV02>
</s:Body>
</s:Envelope>
```

## 4.2 XCPD Response

### Format: XML

```
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing">
  <s:Header>
    <a:Action s:mustUnderstand="1">urn:h17
org:v3:PRPA_IN201306UV02:CrossGatewayPatientDiscovery</a:Action>
    <a:RelatesTo>urn:uuid:a02ca8cd-86fa-4afc-a27c-16c183b2055</a:RelatesTo>
  </s:Header>
  <s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
    <PRPA_IN201306UV02 ITSVersion="XML_1.0" xmlns="urn:h17-org:v3">
      <id root="2.16.840.1.113883.3.651" extension="175632"/>
      <creationTime value="202508110135"/>
      <interactionId root="2.16.840.1.113883.1.6" extension="PRPA_IN201306UV02"/>
      <processingCode code="P"/>
      <processingModeCode code="T"/>
      <acceptAckCode code="NE"/>
      <receiver typeCode="RCV">
        <device classCode="DEV" determinerCode="INSTANCE">
          <id root="1.2.840.114350.1.13.999.567"/>
          <asAgent classCode="AGNT">
            <representedOrganization classCode="ORG"
determinerCode="INSTANCE">
              <id root="1.2.3.928.955"/>
              <notificationParty xsi:nil="true"/>
            </representedOrganization>
          </asAgent>
        </device>
      </receiver>
      <sender typeCode="SND">
        <device classCode="DEV"
determinerCode="INSTANCE">
          <id root="2.16.840.1.113883.3.651"/>
          <telecom value="https://tinithub1.test.local/xcpd-responding-gateway-service-
0.1.0/ws"/>
          <asAgent classCode="AUT">
            <representedOrganization classCode="ORG"
```



```
determinerCode="INSTANCE">
  <id root="2.16.840.1.113883.3.651"/>
  <notificationParty xsi:nil="true"/>
</representedOrganization>
</asAgent>
</device>
</sender>
<acknowledgement>
  <typeCode code="AA"/>
  <targetMessage>
    <id root="1.2.840.114350.1.13.0.1.7.1.1" extension="35423"/>
  </targetMessage>
</acknowledgement>
<controlActProcess classCode="CACT" moodCode="EVN">
  <code code="PRPA_TE201306UV02"
codeSystem="2.16.840.1.113883.1.6"/>
  <authorOrPerformer typeCode="AUT">
    <assignedDevice>
      <id root="2.16.840.1.113883.3.651"/>
      <assignedDevice xsi:nil="true"/>
      <representedOrganization xsi:nil="true"/>
    </assignedDevice>
  </authorOrPerformer>
  <subject typeCode="SUBJ">
    <registrationEvent classCode="REG" moodCode="EVN">
      <statusCode code="active"/>
      <subject1 typeCode="SBJ">
        <patient classCode="PAT">
          <id root="2.16.840.1.113883.3.651" extension="82175974"
assigningAuthorityName="SMPI"/>
          <statusCode code="active"/>
          <patientPerson classCode="PSN" determinerCode="INSTANCE">
            <name>
              <given>Anna</given>
              <family>Cadence</family>
            </name>
            <administrativeGenderCode code="F"/>
            <birthTime value="1984-11-16"/>
            <addr>
              <streetAddressLine>1021 Main St</streetAddressLine>
              <city>Columbia</city>
              <state>MD</state>
              <postalCode>21046</postalCode>
            </addr>
            <birthPlace xsi:nil="true"/>
          </patientPerson>
          <providerOrganization classCode="ORG"
determinerCode="INSTANCE">
            <id root="2.16.840.1.113883.3.651"/>
            <contactParty classCode="CON">
              <contactPerson xsi:nil="true"/>
            </contactParty>
          </providerOrganization>
          <subjectOf1>
            <queryMatchObservation classCode="OBS" moodCode="EVN">
              <code code="IHE_PDQ"
```



```
codeSystem="2.16.840.1.113883.1.11.19914"/>
  <value xsi:type="INT" value="100"/>
</queryMatchObservation>
</subjectOf1>
</patient>
</subject1>
<author xsi:nil="true"/>
<custodian typeCode="CST">
  <assignedEntity classCode="ASSIGNED">
    <id root="2.16.840.1.113883.3.651"/>
    <code code="NotHealthDataLocator"
codeSystem="1.3.6.1.4.1.19376.1.2.27.2"/>
  <representedOrganization classCode="ORG"
determinerCode="INSTANCE">
    <id root="2.16.840.1.113883.3.651.2.1"/>
    <name>SMPI</name>
    <contactParty classCode="CON">
      <contactPerson xsi:nil="true"/>
    </contactParty>
    </representedOrganization>
  </assignedEntity>
</custodian>
</registrationEvent>
</subject>
<queryAck>
  <queryId root="null" extension="null"/>
  <statusCode code="OK"/>
  <queryResponseCode code="OK"/>
</queryAck>
<queryByParameter>
  <queryId root="1.2.840.114350.1.13.28.1.18.5.999" extension="18204"/>
  <matchCriterionList xsi:nil="true"/>
  <parameterList>
    <livingSubjectAdministrativeGender>
      <value code="F"/>
      <semanticsText>LivingSubject.administrativeGender</semanticsText>
    </livingSubjectAdministrativeGender>
    <livingSubjectBirthTime>
      <value value="19841116"/>
      <semanticsText>LivingSubject.birthTime</semanticsText>
    </livingSubjectBirthTime>
    <livingSubjectId>
      <value root="1.2.840.114350.1.13.99997.2.3412" extension="1234"/>
      <semanticsText>LivingSubject.id</semanticsText>
    </livingSubjectId>
    <livingSubjectName>
      <value>
        <given>Anna</given>
        <family>Cadence</family>
      </value>
      <semanticsText>LivingSubject.name</semanticsText>
    </livingSubjectName>
    <patientAddress>
      <value>
        <city>Columbia</city>
        <streetAddressLine>1021 Main St</streetAddressLine>
```



```

    <state>MD</state>
    <postalCode>21046</postalCode>
  </value>
</patientAddress>
</parameterList>
</queryByParameter>
</controlActProcess>
</PRPA_IN201306UV02>
</s:Body>
</s:Envelope>
  
```

## 5. Terminology

Term	Definition
EID	Enterprise Identifier
SMRN	Source Medical Record Number
Consent	<a href="#">FHIR R4 Consent resource</a>
OperationOutcome	<a href="#">Standard FHIR error resource</a>
Patient	<a href="#">FHIR R4 Patient resource</a>
Opt-Out	Consent with <code>provision.type = deny</code>