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Standard for Trial Use

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1 INTRODUCTION

The templates included in the guide are a direct result of the aligned work on sex and gender representation produced by the HL7 Gender Harmony Project. This project improved upon an initial sex and gender representation logical model and produced aligned approaches to sex and gender representation within each of the HL7 product families with additions and changes to FHIR R5, HL7 V2.9.1, and this set of templates for CDA. The informative HL7 Cross Paradigm Implementation Guide: Gender Harmony - Sex and Gender Representation, Edition 1 brings all of this together and readers of this implementation guide are strongly encouraged to review that guide to better understand the templates in this guide.

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2 ENTRY

2.1 Gender Identity GH

`[observation: identifier urn:hl7ii:2.16.840.1.113883.10.15.1:2022-09-01 (open)]`

An individual's personal sense of being a man, woman, boy, girl, nonbinary, or something else. This represents an individual's identity, ascertained by asking them what that identity is.

This observation is not appropriate for recording administrative gender or birth sex.

This template represents one code value, with associated context and metadata. It is expected to be composed into containing structures with multiple cardinality to support cases that require multiple values.

This template is designed to be aligned with **https://hl7.org/fhir/extensions/StructureDefinition-individual-genderIdentity.html**.

Table 1: Gender Identity GH Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.15.1:2022-09-01)					
@classCode	1..1	SHALL		4536-56	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		4536-57	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		4536-46	
@root	1..1	SHALL		4536-51	2.16.840.1.113883.10.15.1
@extension	1..1	SHALL		4536-52	2022-09-01
code	1..1	SHALL		4536-47	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 76691-5
text	0..1	MAY		4536-140	
statusCode	1..1	SHALL		4536-49	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
effectiveTime	0..1	MAY		4536-50	
value	1..1	SHALL	CD	4536-48	urn:oid:2.16.840.1.113883.4.642.3.3291 (Gender Identity)
@nullFlavor	0..1	MAY		4536-55	

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:4536-56).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:4536-57).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-46) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.1" (CONF:4536-51).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-52).

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4. **SHALL** contain exactly one [1..1] **code**="76691-5" Gender identity (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1 **STATIC**) (CONF:4536-47).
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-140).
6. **SHALL** contain exactly one [1..1] **statusCode**="completed" completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-49).
7. **MAY** contain zero or one [0..1] **effectiveTime** (CONF:4536-50).
8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHOULD** be selected from ValueSet **Gender Identity** urn:oid:2.16.840.1.113883.4.642.3.3291 **DYNAMIC** 2022-07-20 (CONF:4536-48).

To represent additional Gender Identities set nullFlavor="OTH" and use originalText or translation for the gender identity value.

   a. This value **MAY** contain zero or one [0..1] **@nullFlavor** (CONF:4536-55).

Table 2: Gender Identity

Value Set: Gender Identity urn:oid:2.16.840.1.113883.4.642.3.3291 This value set defines a set of codes that can be used to indicate a individual's gender identity. Value Set Source: **http://terminology.hl7.org/ValueSet/gender-identity**			
Code	**Code System**	**Code System OID**	**Print Name**
446141000124107	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Identifies as female gender (finding)
446151000124109	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Identifies as male gender (finding)
33791000087105	SNOMED CT	urn:oid:2.16.840.1.113883.6.96	Identifies as nonbinary gender (finding)
UNK	HL7NullFlavor	urn:oid:2.16.840.1.113883.5.1008	Unknown
asked-declined	DataAbsentReason	urn:oid:2.16.840.1.113883.4.642.4.1048	Asked But Declined

Figure 1: Identifies as male gender since DOB

```
 <!-- Examples - Identifies as male gender since DOB -->
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.15.1" extension="2022-09-01" />
        <code code="76691-5" codeSystem="2.16.840.1.113883.6.1" displayName="Gender
Identity" />
        <statusCode code="completed" />
        <effectiveTime>
            <low value="20140103" />
        </effectiveTime>
        <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
code="446151000124109" displayName="Identifies as male gender">
        </value>
    </observation>
```


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Figure 2: Identifies as male gender since DOB to 15; then as non binary starting in 2014

```
<!-- Examples - Identifies as male gender since DOB to 15; then as non binary starting in
2014 -->
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.15.1" extension="2022-09-01" />
    <code code="76691-5" codeSystem="2.16.840.1.113883.6.1" displayName="Gender Identity"
/>
    <statusCode code="completed" />
    <effectiveTime>
        <low value="19990103" />
        <high value="2014" />
    </effectiveTime>
    <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
code="446151000124109" displayName="Identifies as male gender"></value>
</observation>
...
  <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.15.1" extension="2022-09-01" />
        <code code="76691-5" codeSystem="2.16.840.1.113883.6.1" displayName="Gender
Identity" />
        <statusCode code="completed" />
        <effectiveTime>
            <low value="2014" />
        </effectiveTime>
        <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"
code="33791000087" displayName="Identifies as nonbinary gender">
        </value>
    </observation>
```

Figure 3: Choose not to disclose

```
<!-- Examples - Choose not to disclose using Asked but Unknown (ASKU) -->
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.15.1" extension="2022-09-01" />
    <code code="76691-5" codeSystem="2.16.840.1.113883.6.1" displayName="Gender Identity"
/>
    <statusCode code="completed" />
    <effectiveTime>
        <low value="20140103" />
    </effectiveTime>
    <value xsi:type="CD" code="asked-decline" display="Asked But Declined" codeSystem =
"2.16.840.1.113883.4.642.4.1048" ></value>
</observation>
```


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Figure 4: other (OTH)

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.15.1" extension="2022-09-01" />
    <code code="76691-5" codeSystem="2.16.840.1.113883.6.1" displayName="gender fluid" />
    <statusCode code="completed" />
    <effectiveTime>
        <low value="20140103" />
    </effectiveTime>
    <value xsi:type="CD" nullFlavor="OTH">
        <originalText> Gender nonconforming
            </originalText>
    </value>
</observation>
```

2.2 Individual Pronouns

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.15.2:2022-09-01 (open)]

Pronoun(s) specified by the patient to use when referring to the patient in speech, in clinical notes, and in written instructions to caregivers.

Designed to conform to **https://hl7.org/fhir/extensions/StructureDefinition-individual-pronouns.html**

If information regarding provenance is available, capture using author, informant, and participation appropriately.

Local provenance practices should be adhered to; for example use **US Provenance**.

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Table 3: Individual Pronouns Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.15.2:2022-09-01)					
@classCode	1..1	SHALL		4536-70	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		4536-71	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		4536-59	
@root	1..1	SHALL		4536-63	2.16.840.1.113883.10.15.2
@extension	1..1	SHALL		4536-64	2022-09-01
code	1..1	SHALL		4536-60	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 90778-2
text	0..1	MAY		4536-72	
statusCode	1..1	SHALL		4536-62	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
effectiveTime	0..1	MAY		4536-69	
value	1..1	SHALL	CD	4536-61	urn:oid:2.16.840.1.113883.11.19755 (Pronouns)
@nullFlavor	0..1	MAY		4536-67	
performer	0..*	SHOULD		4536-180	
author	0..*	SHOULD		4536-181	
informant	0..*	SHOULD		4536-182	

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6 **STATIC**) (CONF:4536-70).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001 **STATIC**) (CONF:4536-71).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-59) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.2" (CONF:4536-63).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-64).
4. **SHALL** contain exactly one [1..1] **code**="90778-2" Personal pronouns – Reported (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4536-60).
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-72).
6. **SHALL** contain exactly one [1..1] **statusCode**="completed" completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-62).
7. **MAY** contain zero or one [0..1] **effectiveTime** (CONF:4536-69).
8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **MAY** be selected from ValueSet **Pronouns** urn:oid:2.16.840.1.113883.11.19755 **DYNAMIC** 2022-07-20 (CONF:4536-61).

To represent additional individual pronouns set nullFlavor="OTH" and use originalText or translation for the individual pronouns value.

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a. This value **MAY** contain zero or one [0..1] **@nullFlavor** (CONF:4536-67).

Used to capture performer provenance when available

9. **SHOULD** contain zero or more [0..*] **performer** (CONF:4536-180).

Used to capture author provenance when available

10. **SHOULD** contain zero or more [0..*] **author** (CONF:4536-181).

Used to capture informant provenance when available

11. **SHOULD** contain zero or more [0..*] **informant** (CONF:4536-182).

Table 4: Pronouns

Value Set: Pronouns urn:oid:2.16.840.1.113883.11.19755 This value set defines a set of codes that can be used to indicate the pronouns used to communicate about an individual. Value Set Source: https://terminology.hl7.org/ValueSet-pronouns.html			
Code	**Code System**	**Code System OID**	**Print Name**
LA29518-0	LOINC	urn:oid:2.16.840.1.113883.6.1	He, Him, His, Himself
LA29519-8	LOINC	urn:oid:2.16.840.1.113883.6.1	She, Her, Hers, Herself
LA29520-6	LOINC	urn:oid:2.16.840.1.113883.6.1	They, Them, Their, Theirs, Themself

Figure 5: Individual Pronouns Observation Example

```
<observation classCode="OBS" moodCode="EVN">
     <templateId root="2.16.840.1.113883.10.15.2" extension="2022-09-01"/>
     <code code="90778-2" codeSystem="2.16.840.1.113883.6.1"
          displayName="Personal pronouns"/>
          <statusCode code="completed"/>
     <value xsi:type="CD" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" code="LA29518-0"
          displayName="He, Him, His, Himself"/>
</observation>
```

2.3 Jurisdiction Observation

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.15.4.1:2022-09-01 (open)]

Table 5: Jurisdiction Observation Contexts

Contained By:	**Contains:**
Recorded Sex or Gender (optional)	

Jurisdiction Observation

Jurisdiction is the entity that issued the document and therefore defines the concept. Typically a state or nation, but possibly a firm or professional society.

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Table 6: Jurisdiction Observation Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.15.4.1:2022-09-01)					
@classCode	1..1	SHALL		4536-160	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		4536-161	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		4536-198	
@root	1..1	SHALL		4536-199	2.16.840.1.113883.10.15.4.1
@extension	1..1	SHALL		4536-200	2022-09-01
code	1..1	SHALL		4536-162	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 77969-4
statusCode	1..1	SHALL		4536-163	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
value	1..1	SHALL	CD	4536-164	urn:oid:2.16.840.1.113883.4.642.3.48 (JurisdictionValueSet)

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:4536-160).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-161).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-198) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.4.1" (CONF:4536-199).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-200).
4. **SHALL** contain exactly one [1..1] **code**="77969-4" Jurisdiction code (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4536-162).
5. **SHALL** contain exactly one [1..1] **statusCode**="completed" completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-163).
6. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet **JurisdictionValueSet** urn:oid:2.16.840.1.113883.4.642.3.48 (CONF:4536-164).

Table 7: JurisdictionValueSet

Value Set: JurisdictionValueSet urn:oid:2.16.840.1.113883.4.642.3.48 Value Set Source: **http://hl7.org/fhir/ValueSet/jurisdiction**			
Code	**Code System**	**Code System OID**	**Print Name**
AU	ISO 3166 Part 1 Country Codes, 2nd Edition, Alpha-2	urn:oid:1.0.3166.1.2.2	Australia
…			

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Figure 6: Jurisdiction Observation

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.15.4.1" extension="2022-09-01"/>
    <code code="77969-4" codeSystem="2.16.840.1.113883.6.1"
          displayName="Jurisdiction code"/>
    <statusCode code="completed"/>
    <value xsi:type="CD" codeSystem="urn:iso:std:iso:3166"
          codeSystemName="LOINC" code="AU"
          displayName="Australia"/>
</observation>
```

2.4 Recorded Sex or Gender

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.15.4:2022-09-01 (open)]

Table 8: Recorded Sex or Gender Contexts

Contained By:	Contains:
	Jurisdiction Observation (optional) Source Record Field (optional)

Recorded sex or gender (RSG) information includes the various sex and gender concepts that are often used in existing systems but are known to NOT represent a gender identity, sex parameter for clinical use, or attributes related to sexuality, such as sexual orientation, sexual activity, or sexual attraction. If a medical system needs to exchange a single internal field labeled “sex” which, over time, has been used to capture both sex and gender, recorded sex or gender may be an appropriate way to exchange such data. Administrative gender, administrative sex, and sex assigned at birth are not to be considered a gender identity (GI) or sex parameter for clinical use (SPCU). Because of this each of these can be considered examples of recorded sex or gender (RSG), yet these represent constructs where established specific exchange structures already exist. If exchange is already established for one of these data items with known models, the existing exchange model may be used while their use lessen during transition to the use of gender identity or SPCU. Any other representation of sex (or gender) that is not gender identity or SPCU may be exchanged using the RSG template.

This template is designed to support correspondence with **https://hl7.org/fhir/extensions/StructureDefinition-individual-recordedSexOrGender.html**.

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Table 9: Recorded Sex or Gender Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.15.4:2022-09-01)					
@classCode	1..1	SHALL		4536-84	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		4536-85	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		4536-86	
@root	1..1	SHALL		4536-87	2.16.840.1.113883.10.15.4
@extension	1..1	SHALL		4536-88	2022-09-01
code	1..1	SHALL		4536-89	urn:oid:2.16.840.1.113883.11.19757 (Recorded Sex Or Gender Type)
text	0..1	MAY		4536-91	
statusCode	1..1	SHALL		4536-92	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
effectiveTime	0..1	MAY		4536-94	
value	1..1	SHALL	CD	4536-93	urn:oid:2.16.840.1.113883.4.642.3.1 (Administrative-Gender)
author	0..1	MAY		4536-186	
time	0..1	MAY		4536-187	
assignedAuthor	0..1	MAY		4536-188	
assignedPerson	0..1	MAY		4536-189	
entryRelationship	0..1	MAY		4536-107	
@typeCode	1..1	SHALL		4536-146	QUALF
observation	0..1	MAY		4536-108	Jurisdiction Observation (identifier: urn:hl7ii:2.16.840.1.113883.10.15.4.1:2022-09-01
entryRelationship	0..1	MAY		4536-130	
@typeCode	1..1	SHALL		4536-149	REFR
observation	1..1	SHALL		4536-131	Source Record Field (identifier: urn:hl7ii:2.16.840.1.113883.10.15.4.7:2022-09-01
reference	0..1	MAY		4536-129	
externalDocument	1..1	SHALL		4536-190	
code	0..1	MAY		4536-191	
text	0..1	MAY		4536-192	

1. **SHALL** contain exactly one [1..1] **`@classCode`**="`OBS`" Observation (CodeSystem: `HL7ActClass urn:oid:2.16.840.1.113883.5.6`) (CONF:4536-84).
2. **SHALL** contain exactly one [1..1] **`@moodCode`**="`EVN`" Event (CodeSystem: `HL7ActMood urn:oid:2.16.840.1.113883.5.1001`) (CONF:4536-85).

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3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-86) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.4" (CONF:4536-87).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-88).

The type or category of sex or gender that is recorded.

4. **SHALL** contain exactly one [1..1] **code**, which **MAY** be selected from ValueSet **Recorded Sex Or Gender Type** urn:oid:2.16.840.1.113883.11.19757 **STATIC** (CONF:4536-89).
   Note: Corresponds to http://hl7.org/fhir/StructureDefinition/individual-recordedSexOrGender/type
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-91).
6. **SHALL** contain exactly one [1..1] **statusCode**="completed" completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-92).

The time period during which the recorded sex or gender value applies to the individual. To represent the clinical relevant time period of the recorded sex or recorded gender item, use effectiveTime low and high

7. **MAY** contain zero or one [0..1] **effectiveTime** (CONF:4536-94).
   Note: Corresponds to http://hl7.org/fhir/StructureDefinition/individual-recordedSexOrGender/effectivePeriod

A sex or gender property for the individual from a document or other record. If it is encoded, the code and system should be captured; if it is from a document, it's likely it will consist of originalText only.

8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **MAY** be selected from ValueSet **Administrative-Gender** urn:oid:2.16.840.1.113883.4.642.3.1 (CONF:4536-93).
   Note: Corresponds to http://hl7.org/fhir/StructureDefinition/individual-recordedSexOrGender/value
9. **MAY** contain zero or one [0..1] **author** (CONF:4536-186).

The date/time when the sex or gender value was first recorded in the system.

    a. The author, if present, **MAY** contain zero or one [0..1] **time** (CONF:4536-187).
       Note: Corresponds to http://hl7.org/fhir/StructureDefinition/individual-recordedSexOrGender/acquisitionDate
    b. The author, if present, **MAY** contain zero or one [0..1] **assignedAuthor** (CONF:4536-188).
        i. The assignedAuthor, if present, **MAY** contain zero or one [0..1] **assignedPerson** (CONF:4536-189).

10. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:4536-107) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="QUALF" (CONF:4536-146).
    b. **MAY** contain zero or one [0..1] **Jurisdiction Observation** (identifier: urn:hl7ii:2.16.840.1.113883.10.15.4.1:2022-09-01) (CONF:4536-108).
11. **MAY** contain zero or one [0..1] **entryRelationship** (CONF:4536-130) such that it
    a. **SHALL** contain exactly one [1..1] **@typeCode**="REFR" (CONF:4536-149).
    b. **SHALL** contain exactly one [1..1] **Source Record Field** (identifier: urn:hl7ii:2.16.840.1.113883.10.15.4.7:2022-09-01) (CONF:4536-131).

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If the source document can be represented and linked electronically, it can be supported via ExternalDocument/text/@data or ExternalDocument/text/@reference.

12. **MAY** contain zero or one [0..1] **reference** (CONF:4536-129).

The reference to the source document (text) or the code representing the type of document where this sex or gender property is initially recorded.

a. The reference, if present, **SHALL** contain exactly one [1..1] **externalDocument** (CONF:4536-190).
Note: Corresponds to http://hl7.org/fhir/StructureDefinition/individual-recordedSexOrGender/sourceDocument

The code representing the type of document where this sex or gender property is initially recorded.

i. This externalDocument **MAY** contain zero or one [0..1] **code** (CONF:4536-191).

The reference to the source document.

ii. This externalDocument **MAY** contain zero or one [0..1] **text** (CONF:4536-192).

Table 10: Recorded Sex Or Gender Type

Value Set: Recorded Sex Or Gender Type urn:oid:2.16.840.1.113883.11.19757 Codes that represent the type of the recorded sex and gender. Value Set Source: http://terminology.hl7.org/ValueSet/recorded-sex-or-gender-type			
Code	**Code System**	**Code System OID**	**Print Name**
46098-0	LOINC	urn:oid:2.16.840.1.113883.6.1	Sex
76689-9	LOINC	urn:oid:2.16.840.1.113883.6.1	Sex assigned at birth
76691-5	LOINC	urn:oid:2.16.840.1.113883.6.1	Gender identity

Table 11: Administrative-Gender

Value Set: Administrative-Gender urn:oid:2.16.840.1.113883.4.642.3.1 Value Set Source: https://www.hl7.org/fhir/valueset-administrative-gender.html			
Code	**Code System**	**Code System OID**	**Print Name**
male	AdministrativeGender	urn:oid:2.16.840.1.113883.4.642.4.2	Male
female	AdministrativeGender	urn:oid:2.16.840.1.113883.4.642.4.2	Female
other	AdministrativeGender	urn:oid:2.16.840.1.113883.4.642.4.2	Other
unknown	AdministrativeGender	urn:oid:2.16.840.1.113883.4.642.4.2	Unknown
…			

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Figure 7: Recorded Sex or Gender

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.15.4" extension="2022-09-01" />
    <!--  http://hl7.org/fhir/StructureDefinition/individual-recordedSexOrGender/type  -->
    <code code="76689-9" codeSystem="2.16.840.1.113883.6.1" displayName="Sex assigned at
birth" />
    <statusCode code="completed" />
    <!--  http://hl7.org/fhir/StructureDefinition/individual-
recordedSexOrGender/effectivePeriod -->
    <effectiveTime>
        <low value="202103" />
    </effectiveTime>
    <!--  http://hl7.org/fhir/StructureDefinition/individual-recordedSexOrGender/value -->
    <value xsi:type="CD" code="M" codeSystem="2.16.840.1.113883.5.1" displayName="Male"
codeSystemName="AdministrativeGender" />
    <author>
        <!--  http://hl7.org/fhir/StructureDefinition/individual-
recordedSexOrGender/acquisitionDate -->
        <time value="20230115" />
    </author>
    <entryRelationship typeCode="QUALF">
        <!-- Jurisdiction -->
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="22.16.840.1.113883.10.15.4.1" extension="2022-09-01" />
            <code code="77969-4" codeSystem="2.16.840.1.113883.6.1"
displayName="Jurisdiction code" />
            <statusCode code="completed" />
            <value xsi:type="CD" nullFlavor="OTH" codeSystem="NP">
                <!-- This may be coded but does not have to be -->
                <originalText>California</originalText>
            </value>
        </observation>
    </entryRelationship>
    <entryRelationship typeCode="REFR">
        <!-- Source Record Field Type -->
        <observation classCode="OBS" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.15.4.74" extension="2022-09-01" />
            <code code="48766-0" codeSystem="2.16.840.1.113883.6.1"
displayName="Information Source" />
            <statusCode code="completed" />
            <value xsi:type="ED">BIRTH SEX</value>
        </observation>
    </entryRelationship>
    <reference typeCode="REFR">
        <!--  http://hl7.org/fhir/StructureDefinition/individual-
recordedSexOrGender/sourceDocument -->
        <externalDocument classCode="DOCCLIN" moodCode="EVN">
            <code codeSystem="" codeSystemName="" code="" displayName="" />
            <text>California Drivers License</text>
        </externalDocument>
    </reference>
</observation>
```


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2.5 Sex Parameter for Clinical Use

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.15.3:2022-09-01 (open)]

Sex Parameter for Clinical Use (SPCU) is a categorization of sex derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc., or from interventions with relevant effects such as hormone therapy. This property is intended for use in clinical decision making and indicates that treatment or diagnostic tests should consider best practices associated with the relevant reference population.

While clinical decision-making processes could support inference of specific physiological or anatomical attributes of the patient, there are several practical considerations, such as patient privacy and limited capabilities of existing systems which create the need for a categorization that is easy to exchange. The SPCU categorization is intended to bridge the gap between the hypothetical ideal and the practical needs of operational systems. "Prescription for testosterone" is not an SPCU value, though it may be a supporting observation for one.

This template is designed to support correspondence with **https://hl7.org/fhir/extensions/StructureDefinition-patient-sexParameterForClinicalUse.html**

SPCU is a contextual concept. For example, a patient may generally be categorized as male, but for a specific lab test, the resulting lab should use the reference ranges associated with a female reference population. In this case, systems may annotate the lab order with a context-specific SPCU. Systems may determine what enclosing contexts are useful, but Patient, entry, and encounter are three contexts that may often apply.

Clinical scenarios include setting up procedures and interpreting results. For the procedure case, SPCU will be needed on the order, and it may be carried on subsequent descriptions of the procedure. An "Order" is represented in the body of CDA documents using most any of the Clinical Statement classes (Act, Procedure, Observation) and applying a moodCode of INT (Intent) or RQO (Request) and therefore can be used in the workflow of Sex Parameter for Clinical Use construct. The Order Structure in the document header, is to identify the order(s) (aka RQO or INT) for which the document itself provides information. For example , a Radiology report that is written in response to an Xray order. The Order Structure in the document header does not support entry relationships so the SPCU can not be documented for the whole document but must be documented individually in the document body.

For the results scenario, relevant SPCU observations should be carried on result Observations just as a reference range would be.

Evidence

SPCU observations may be based on clinical evidence documented elsewhere in the document. These relationships are supported by Entry Relationships.

Establishing context

Context is established for an **entry**-specific SPCU observation by nesting it under its target entry using entryRelationship. This approach uses CDA Context Conduction to manage scope appropriately: the observation is a component of the enclosing entry with no implication of relevance outside of that entry.

This means that, in cases where one SPCU observation pertains to multiple entries, an implementer should use an Entry Reference to assert other instances of the relationship. In these cases, the Entry Reference should be a sub-entry of the target, not the SPCU, with entryRelationship.typeCode "COMP" to indicate subordination to the entry of interest.

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In cases where the SPCU Observation pertains to an entire **encounter**, an encounter entry can be used to contain the SPCU observation. Note that the entry is required: the header EncompassingEncounter cannot contain entries.

In cases where the SPCU Observation pertains to the **patient** categorically, in all contexts, it can be included as an independent entry (placed in, e.g., a Social History section), where its independence from a containing entry implies general applicability to the patient. In this scenario, entries do not need to identify the observation explicitly.

In no case should SPCU pertain to a **document**, unless incidentally by one of the tactics described above. A document has a clinical context, but it does not establish a clinical context. In a procedure note, for instance, the SPCU may pertain to the procedure itself, not the document.

Values

The “male” and “female” values indicate that the patient is meets the criteria for that value in the context of the identified entry; e.g., “use the male reference range.”

The “unknown” value means that a determination cannot be made.

The “specified” value indicates that such an assignment cannot be made but that relevant data is specified elsewhere, e.g., in a medication order for hormone therapy that is not sufficient to change the value to from one binary value to the other, but that does indicate caution in using either assumption. In such a case the relevant specification SHOULD be associated with the SPCU as “has support” (“SPRT”).

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Table 12: Sex Parameter for Clinical Use Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.15.3:2022-09-01)					
@classCode	1..1	SHALL		4536-74	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		4536-75	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		4536-76	
@root	1..1	SHALL		4536-77	2.16.840.1.113883.10.15.3
@extension	1..1	SHALL		4536-78	2022-09-01
code	1..1	SHALL		4536-79	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 99501-9
text	0..1	MAY		4536-80	
statusCode	1..1	SHALL		4536-81	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
effectiveTime	0..1	SHOULD		4536-82	
value	1..1	SHALL	CD	4536-83	urn:oid:2.16.840.1.113883.4.642.3.3181 (Sex Parameter for-Clinical Use)
entryRelationship	0..*	MAY		4536-101	
@typeCode	1..1	SHALL		4536-104	SPRT
act	1..1	SHALL		4536-102	Entry Reference (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.122

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:4536-74).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-75).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-76) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.3" (CONF:4536-77).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-78).
4. **SHALL** contain exactly one [1..1] **code**="99501-9" Sex parameter for clinical use (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4536-79).
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-80).
6. **SHALL** contain exactly one [1..1] **statusCode**="completed" completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-81).
7. **SHOULD** contain zero or one [0..1] **effectiveTime** (CONF:4536-82).
8. **SHALL** contain exactly one [1..1] **value** with @xsi:type="CD", where the code **SHALL** be selected from ValueSet **Sex Parameter for-Clinical Use** http://terminology.hl7.org/ValueSet/sex-parameter-for-clinical-use (CONF:4536-83).

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9. **MAY** contain zero or more [0..*] **entryRelationship** (CONF:4536-101) such that it

This Entry Reference associates the assertion of Sex Parameter for Clinical Use with supporting clinical data - Observations, Procedures, SubstanceAdministrations, or other entries that support or explain the assignment.

   a. **SHALL** contain exactly one [1..1] **@typeCode**="SPRT" has support (CONF:4536-104).
   b. **SHALL** contain exactly one [1..1] Entry Reference (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.122) (CONF:4536-102).

Table 13: Sex Parameter for-Clinical Use

Value Set: Sex Parameter for-Clinical Use urn:oid:2.16.840.1.113883.4.642.3.3181
A summary parameter that provides guidance on how a receiver should apply settings or reference ranges that are derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc..
Value Set Source: **http://terminology.hl7.org/ValueSet/sex-parameter-for-clinical-use**

Code	Code System	Code System OID	Print Name
female-typical	Sex Parameter for Clinical Use	urn:oid:2.16.840.1.113883.4.642.4.2038	Apply female-typical setting or reference range
male-typical	Sex Parameter for Clinical Use	urn:oid:2.16.840.1.113883.4.642.4.2038	Apply male-typical setting or reference range
specified	Sex Parameter for Clinical Use	urn:oid:2.16.840.1.113883.4.642.4.2038	Apply specified setting or reference range
unknown	Sex Parameter for Clinical Use	urn:oid:2.16.840.1.113883.4.642.4.2038	Unknown

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Figure 8: Sex Parameter for Clinical Use

```
<observation classCode="OBS" moodCode="EVN">
    <templateId root="2.16.840.1.113883.10.15.3"
         extension="2022-09-01"/>
    <code code="99501-9" codeSystem="2.16.840.1.113883.6.1"
         displayName="Sex Parameter for clinical use"/>
    <statusCode code="completed"/>
    <value xsi:type="CD" code="female-typical"
         codeSystem="2.16.840.1.113883.4.642.4.2038"
         codeSystemName="Sex Parameter For Clinical Use"
         displayName="Apply female-typical setting or reference range"></value>
    <!-- Supporting Reference for Sex Parameter for Clinical Use -->
    <entryRelationship typeCode="SPRT">
        <act classCode="ACT" moodCode="EVN">
            <templateId root="2.16.840.1.113883.10.20.22.4.122"/>
            <id root="6C844C75-AA34-411C-B7BD-5E4A9F206E29"/>
            <code nullFlavor="OTH" />
            <statusCode code="completed"/>
        </act>
    </entryRelationship>
</observation>
```

2.6 Source Record Field

[observation: identifier urn:hl7ii:2.16.840.1.113883.10.15.4.7:2022-09-01 (open)]

Table 14: Source Record Field Contexts

Contained By:	Contains:
Recorded Sex or Gender (optional)	

The name of the field within the source document where this sex or gender property is initially recorded.

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Table 15: Source Record Field Constraints Overview

XPath	Card.	Verb	Data Type	CONF#	Value
observation (identifier: urn:hl7ii:2.16.840.1.113883.10.15.4.7:2022-09-01)					
@classCode	1..1	SHALL		4536-175	urn:oid:2.16.840.1.113883.5.6 (HL7ActClass) = OBS
@moodCode	1..1	SHALL		4536-176	urn:oid:2.16.840.1.113883.5.1001 (HL7ActMood) = EVN
templateId	1..1	SHALL		4536-195	
@root	1..1	SHALL		4536-196	2.16.840.1.113883.10.15.4.7
@extension	1..1	SHALL		4536-197	2022-09-01
code	1..1	SHALL		4536-177	urn:oid:2.16.840.1.113883.6.1 (LOINC) = 48766-0
text	0..1	MAY		4536-184	
statusCode	1..1	SHALL		4536-178	urn:oid:2.16.840.1.113883.5.14 (HL7ActStatus) = completed
value	1..1	SHALL	ED	4536-179	

1. **SHALL** contain exactly one [1..1] **@classCode**="OBS" Observation (CodeSystem: HL7ActClass urn:oid:2.16.840.1.113883.5.6) (CONF:4536-175).
2. **SHALL** contain exactly one [1..1] **@moodCode**="EVN" Event (CodeSystem: HL7ActMood urn:oid:2.16.840.1.113883.5.1001) (CONF:4536-176).
3. **SHALL** contain exactly one [1..1] **templateId** (CONF:4536-195) such that it
    a. **SHALL** contain exactly one [1..1] **@root**="2.16.840.1.113883.10.15.4.7" (CONF:4536-196).
    b. **SHALL** contain exactly one [1..1] **@extension**="2022-09-01" (CONF:4536-197).
4. **SHALL** contain exactly one [1..1] **code**="48766-0" Information Source (CodeSystem: LOINC urn:oid:2.16.840.1.113883.6.1) (CONF:4536-177).
5. **MAY** contain zero or one [0..1] **text** (CONF:4536-184).
6. **SHALL** contain exactly one [1..1] **statusCode**="completed" completed (CodeSystem: HL7ActStatus urn:oid:2.16.840.1.113883.5.14) (CONF:4536-178).
7. **SHALL** contain exactly one [1..1] **value** with @xsi:type="ED" (CONF:4536-179).

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Figure 9: Source Record Field Observation Example

```
<entryRelationship typeCode="REFR">
    <!-- Source Record Field Type -->
    <observation classCode="OBS" moodCode="EVN">
        <templateId root="2.16.840.1.113883.10.15.4.7"
            extension="2022-09-01" />
        <code code="48766-0" codeSystem="2.16.840.1.113883.6.1"
            displayName="Information Source" />
        <statusCode code="completed" />
        <value xsi:type="ED">BIRTH SEX</value>
    </observation>
</entryRelationship>
<reference typeCode="REFR">
    <!-- http://hl7.org/fhir/StructureDefinition/individual-
recordedSexOrGender/sourceDocument -->
    <externalDocument classCode="DOCCLIN"
          moodCode="EVN">
        <code nullFlavor="UNK" />
        <text>California Drivers License</text>
    </externalDocument>
</reference>
```


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3 TEMPLATE IDS IN THIS GUIDE

Table 16: Template List

Template Title	Template Type	templateId
Gender Identity GH	entry	urn:hl7ii:2.16.840.1.113883.10.15.1:2022-09-01
Individual Pronouns	entry	urn:hl7ii:2.16.840.1.113883.10.15.2:2022-09-01
Jurisdiction Observation	entry	urn:hl7ii:2.16.840.1.113883.10.15.4.1:2022-09-01
Recorded Sex or Gender	entry	urn:hl7ii:2.16.840.1.113883.10.15.4:2022-09-01
Sex Parameter for Clinical Use	entry	urn:hl7ii:2.16.840.1.113883.10.15.3:2022-09-01
Source Record Field	entry	urn:hl7ii:2.16.840.1.113883.10.15.4.7:2022-09-01

Table 17: Template Containments

Template Title	Template Type	templateId
Gender Identity GH	entry	urn:hl7ii:2.16.840.1.113883.10.15.1:2022-09-01
Individual Pronouns	entry	urn:hl7ii:2.16.840.1.113883.10.15.2:2022-09-01
Recorded Sex or Gender	entry	urn:hl7ii:2.16.840.1.113883.10.15.4:2022-09-01
Jurisdiction Observation	entry	urn:hl7ii:2.16.840.1.113883.10.15.4.1:2022-09-01
Source Record Field	entry	urn:hl7ii:2.16.840.1.113883.10.15.4.7:2022-09-01
Sex Parameter for Clinical Use	entry	urn:hl7ii:2.16.840.1.113883.10.15.3:2022-09-01

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4 VALUE SETS IN THIS GUIDE

Table 18: Value Sets

Name	OID	URL
Administrative-Gender	urn:oid:2.16.840.1.113883.4.642.3.1	https://www.hl7.org/fhir/valueset-administrative-gender.html
Gender Identity	urn:oid:2.16.840.1.113883.4.642.3.3291	http://terminology.hl7.org/ValueSet/gender-identity
JurisdictionValueSet	urn:oid:2.16.840.1.113883.4.642.3.48	http://hl7.org/fhir/ValueSet/jurisdiction
Pronouns	urn:oid:2.16.840.1.113883.11.19755	https://terminology.hl7.org/ValueSet-pronouns.html
Recorded Sex Or Gender Type	urn:oid:2.16.840.1.113883.11.19757	http://terminology.hl7.org/ValueSet/recorded-sex-or-gender-type
Sex Parameter for-Clinical Use	urn:oid:2.16.840.1.113883.4.642.3.3181	http://terminology.hl7.org/ValueSet/sex-parameter-for-clinical-use

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5 CODE SYSTEMS IN THIS GUIDE

Table 19: Code Systems

Name	OID
AdministrativeGender	urn:oid:2.16.840.1.113883.4.642.4.2
DataAbsentReason	urn:oid:2.16.840.1.113883.4.642.4.1048
HL7ActClass	urn:oid:2.16.840.1.113883.5.6
HL7ActMood	urn:oid:2.16.840.1.113883.5.1001
HL7ActStatus	urn:oid:2.16.840.1.113883.5.14
HL7NullFlavor	urn:oid:2.16.840.1.113883.5.1008
ISO 3166 Part 1 Country Codes, 2nd Edition, Alpha-2	urn:oid:1.0.3166.1.2.2
LOINC	urn:oid:2.16.840.1.113883.6.1
Sex Parameter for Clinical Use	urn:oid:2.16.840.1.113883.4.642.4.2038
SNOMED CT	urn:oid:2.16.840.1.113883.6.96

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