

8.25 Resource ResearchSubject - Content

Biomedical Research and Regulation ↗ Work Group	Maturity Level: 0	Trial Use	Security Category: Patient	Compartments: Device, Patient
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A ResearchSubject is a participant or object which is the recipient of investigative activities in a research study.

8.25.1 Scope and Usage

A research subject is typically a human being or an animal, but can also be a device, drug product or biological product, substance, or a tissue or other sort of sample. Research subject can also be a group or part of any of the above.

In contemporary research contexts, where humans are involved, the term "Participant" is preferred over "Research Subject". "Participant" emphasizes the active and voluntary role of the individuals in the research process, reflecting a more ethical and respectful approach. However, some contexts still use "Research Subject" due to its broad use in regulatory documents.

The ResearchSubject resource describes information about the subject in the context of a research study.

Human research subjects are traceable to a particular person but their identifying characteristics are usually hidden to protect study integrity and to protect the subject's privacy.

Note that in a human drug trial the human is the research subject even though the drug is what is being investigated.

The scope of ResearchSubject is intended to support the following use cases:

- Humans and Animals for Clinical and Pre-clinical Trials
- Drug Products for Stability Studies and other Tests
- Devices for non-clinical laboratory studies - in-vivo and in-vitro
- Tissue Sample for bench science studies
- Cases where subjects do not actively participate, but are still represented by their data contributions in retrospective studies

The **Subject State** is the research subject's (participant's) movement through the study protocol from the subject's point of view. In retrospective studies, subjects do not actively participate, but are still in scope of this resource represented by their data contributions. The subjectState codes 'on-study' and

'off-study' track the periods during which their data is included, observed, or considered as part of the study analysis.

The **Subject Milestone** is how the study activities relate to the subject's movement through the study protocol. The two are separate. State is driven by the subject and the Milestone is driven by the study protocol. The values in each element may be the same if necessary for study reasons.

8.25.2 References to this Resource

No references for this Resource.

8.25.3 Resource Content

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Additional definitions: Master Definition [XML + JSON](#), [XML Schema/Schematron + JSON Schema](#), [ShEx](#) (for [Turtle](#)) + [see the extensions](#), the [spreadsheet version](#) & the [dependency analysis](#)

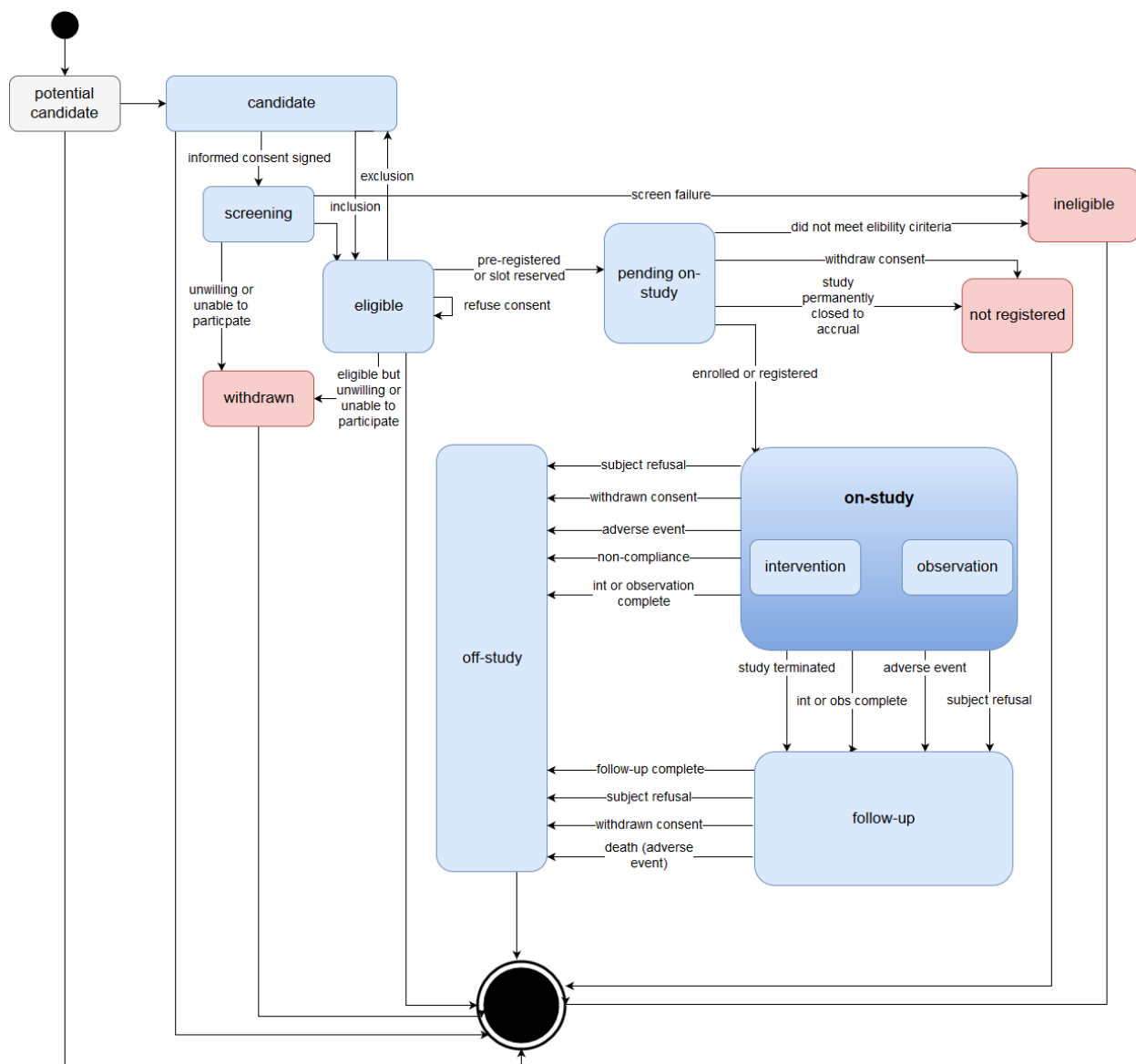
8.25.3.1 Terminology Bindings

Path	ValueSet	Type	Documentation
ResearchSubject.status	PublicationStatus	Required	The lifecycle status of an artifact.
ResearchSubject.subjectState.code	ResearchSubjectState	Extensible	Indicates the progression of a study subject through a study.
ResearchSubject.subjectState.reason	StateChangeReason 	Example	Indicates why the state of the subject changed.

ResearchSubject.subjectMilestone.milestone	ResearchSubjectMilestone	Extensible	Indicates the progression of a study subject through the study milestones.
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8.25.4 ResearchSubject State Machine

The following diagram reflects the "typical" state machine for ResearchSubject.



8.25.5 Search Parameters

Search parameters for this resource. See also the [full list of search parameters for this resource](#), and check the [Extensions registry](#) for search parameters on extensions related to this resource. The [common parameters](#) also apply. See [Searching](#) for more information about searching in REST, messaging, and services.

Name	Type	Description	Expression	In Common
date	date	Start and end of participation	ResearchSubject.period	26 Resources
identifier	token	Business Identifier for research subject in a study	ResearchSubject.identifier	65 Resources
patient	reference	Who or what is part of study	ResearchSubject.subject.where(resolve() is Patient) (Patient)	66 Resources
status	token	draft active retired unknown	ResearchSubject.status	
study	reference	Study subject is part of	ResearchSubject.study (ResearchStudy)	
subject	reference	Who or what is part of study	ResearchSubject.subject (Group , Specimen , BiologicallyDerivedProduct , Device , Medication , Patient , Substance)	

subject_state	token	candidate ResearchSubject.subjectState.code
e		in-prescreening in-screening eligible ineligible on-study on-study-intervention in-follow-up off-study