**Consent Form**

NOTE: PO linkID = element name where text = value. Links Form to Response and both to Resource

Title
PO1 = Research Description & linkID
Title Code: Research Type [e.g., Informed Consent for Clinical Research]
TI1 = Consent Law, Authority, Domain Codes [e.g., 21 CFR 50 FDA, US]
Title linkIDs
Sec 1: Term
PO2 = Research Purpose & Choices & linkID
Sen1.1: Secondary Research Data Use Limitation Code value set [e.g., Any Research]
Sen1.2: Secondary Research Data Use Limitation Modifier Code value set [e.g., Not for Profit]
Sec 2: Term - Consent Decision
PO3 = Consent Decision Description & linkID
Sen2.1: Consent Decision Codes [e.g., Opt-in, Opt-out]
Sec 3: Signers/Signatures
PO4 = Signing Party Instructions & linkID
Sen3.1: Signer Role Code value set [e.g., Consent Grantor/Consent Grantee/Consent Grantor Proxy]
Sen3.2: Signature

**Consent Response**

NOTE: PO linkID = element name where text = value. Links Form to Response and both to Resource

Title
PO1 = Research Description & linkID
Title Code = Informed Consent for Clinical Trial
TI1 = Consent Law, Authority, Domain Codes = 21 CFR 50 FDA, US
Sec 1: Term - Research Purpose
PO2 = Research Purpose & Choices & linkID
Sen1.1: Secondary Research Data Use Limitation Code = Any Research
Sen1.2: Secondary Research Data Use Limitation Modifier Code = Not for Profit
Sec 2: Term - Consent Decision
PO3 = Consent Decision Description & linkID
Sen2.1: Consent Decision Code = Opt-in
Sec 3: Term - Signers/Signatures
PO4 = Signing Party Instructions & linkID
Sen3.1: Signer Role Code = Consent Grantor & Consent Grantee
Sen3.2: Signature = 2 Digital Signatures

**Compound Research Consent Directive**

Populated with Consent Response Content – Mix of coded and PO linkID/text

Title
PO1 Research Description linkID & text
Sec 1: Term - Research Purpose
PO2 Research Purpose & Choices linkID & text
Sen1.1: Secondary Research Data Use Limitation Code = Any Research
Sen1.2: Secondary Research Data Use Limitation Modifier Code = Not for Profit
Sec 2: Term - Consent Decision
PO3 = Consent Decision Description & linkID
Sen2.1: Consent Decision Code = Opt-in
Sec 3: Term - Signers/Signatures
PO4 = Signing Party Instructions linkID & text
Sen3.1: Signer Role Code = Consent Grantor & Consent Grantee
Sen3.2: Signature = 2 Digital Signatures
Sec 4: References & Attachments
Sen4.1: Legally Binding = Signed Consent Response
Sen4.2: Law = 21 CFR 50 FDA, US

**TI** = Title Element
**Sec** = Section
**Sen#** = Term Provision
**PO** = Prose Object
Text from body of the Questionnaire resource. Spicy jalapeno bacon ipsum dolor amet tongue spare ribs chuck in id. Ball tip turducken tail bacon. Ad velit sausage ullamco, bacon spare ribs ut meatloaf. Short loin ipsum fatback, veniam frankfurter proident consectetur ham sunt excepteur exercitation cillum. Nisi culpa ad, duis ball tip voluptate buffalo.

Agree

Signature

Practitioner on FHIR server

ResearchSubject

ResearchSubject references Patient

Subject reference internally to ResearchSubject

Patient

Source reference internally to RelatedPerson

RelatedPerson

valueBoolean: true
FHIM Research Consent Directive with possible Resource References

Can be used for HIPAA Research Authorization and for Compound Research Consent Directive

**Research Consent Directive**

- CD Envelope/Meta & Security Labels protecting a CD instance
- CD Identifier/Version/Status/Content
- CD Time
- CD – Who enforces → FHIM Location → CD Jurisdiction
- CD – What Kind
- CD Subject – Offeree/Grantor
- CD Requestor – Offeror/Grantee
- PO
- CD Term [0..*] – Must be [0..1] at Agreement Level >PO
- Grouped Term 0..*
- CD Term Asset [0..*] >PO
- CD Asset Security Label
- CD Asset Value
- CD Grouped Asset 0..*
- CD Term Agent [0..*] >PO
- CD Term Action [0..*] >PO
- CD Signer [0..*] >PO
- CD Policy Reference/Attachment [0..*]
- CD Form Link Reference/Attachment [0..1]
- CD Legally Binding Reference/Attachment [0..1]
- CD Rule Reference/Attachment [0..1]
- CD Provenance Reference/Attachment [0..1]
An authorization is defective if the expiration date has passed or the expiration event is known by the covered entity to have been revoked. An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.

An authorization is known by the covered entity to have been revoked if the covered entity is informed in writing by the individual, or his or her legal representative, of the individual’s revocation of the authorization. The authorization must contain statements adequate to place the individual on notice of all of the following:

1. The person or entity receiving the notice of revocation.
2. That the authorization is to be revoked.
3. That the individual has a right to revoke the authorization in writing.
4. The individual’s name and address.
5. An effective date for the revocation.