
VIT
VICTORY

Obtaining Consent

What is Informed Consent?

ICH Definition of Consent

"A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form."

Types of Consent for VICToRY

There are three possible consent types for VICToRY:

Standard: Consent is obtained from the patient or SDM prior to study enrollment and can be done in person, by phone, or electronically.

Deferred: If the SI/Sub-I deems the patient appropriate for the study the patient will be enrolled. Consent will be obtained from the patient or SDM following enrollment.

Professional: Consent will be obtained from an impartial third party (i.e. a physician not involved in VICToRY).

The type of consent allowed will be determined by local ethics.

Standard Consent Procedures

- Treating physician/delegate **provide update on patient's condition** to patient/SDM (Substitute Decision Maker)
- If **Physician** is not obtaining consent, **introduce study team member** who will be discussing consent to **patient/SDM**
- Physician/study team member **find a quiet, private location to review study details** with patient/SDM
- **Fully inform** patient/SDM of **all aspects of the study**
- Assess **if language barriers – enlist a translator** if necessary
- **Do Not coerce** patient/SDM **to provide consent to participate**

Standard Consent Procedures

- Provide a copy of the ICF to patient/SDM and **allow time to read**
- **Ask questions to ensure** patient/SDM **understands**
- **Obtain** patient/SDM **signature** on ICF and record the date and time of the signature on the ICF
- **Sign, date and time** the ICF
- **Provide** patient/SDM with a **copy of the signed ICF**
- **Document** consent **& file copy** of signed ICF **in** patient's **medical chart**
- **File original signed ICF in the patient study folder** with the study-related documentation

Medical Chart Documentation

Document patient participation in the medical chart, including the following:

+ Study Name
+ Eligibility was confirmed
+ Physician who confirmed eligibility (must be on the Delegation Log)
+ Date and Time consent was obtained
+ Who provided consent (patient, spouse, child, etc.)
+ Who obtained consent (SI, sub-I, RC, nurse, etc.), signed & dated

Consent Date & Time

- When standard or professional consent are used, document the date and time consent was obtained.
- When deferred consent is used document the date and time the final decision was made by the SI/Sub-I to move forward. This may or may not be the same as when eligibility was confirmed.

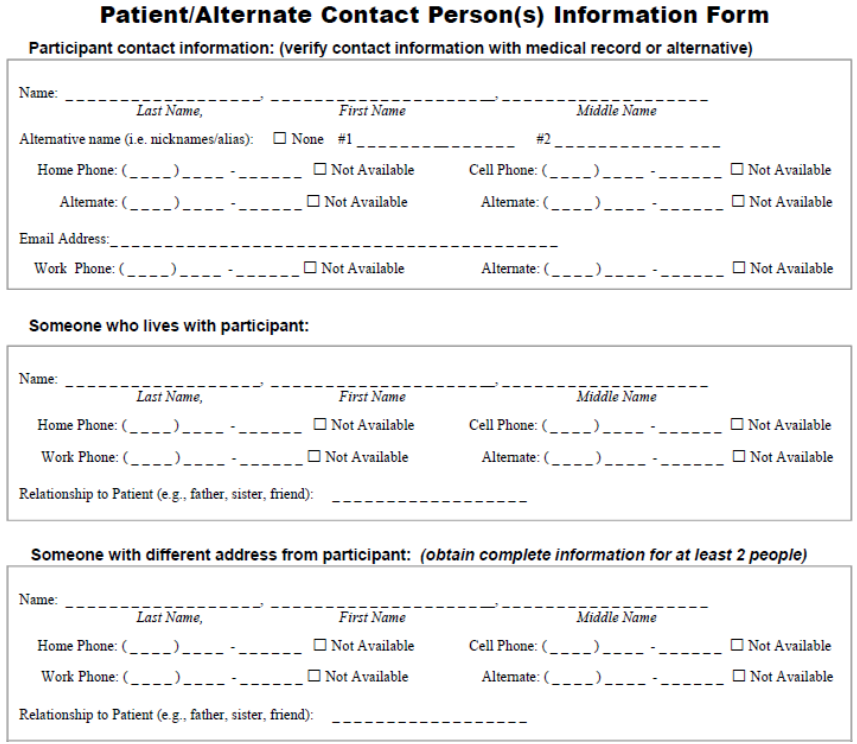
  For example, you confirmed eligibility, but are waiting for a family member you've been told should arrive shortly. After waiting a reasonable amount of time there's no sign of the family member, so you decide to proceed with deferred consent.

Contact Information

After obtaining consent, ensure the Contact Information Form is completed.

This will aid in obtaining 6 month follow-up data.

<5% Lost-to-Follow-up is a primary outcome and mortality is a secondary outcome.



Patient/Alternate Contact Person(s) Information Form

Participant contact information: (verify contact information with medical record or alternative)

Name: _____, _____, _____
Last Name, First Name Middle Name

Alternative name (i.e. nicknames/alias): ☐ None #1 _____ #2 _____

Home Phone: (____) ____ - _____ ☐ Not Available Cell Phone: (____) ____ - _____ ☐ Not Available

Alternate: (____) ____ - _____ ☐ Not Available Alternate: (____) ____ - _____ ☐ Not Available

Email Address: _____

Work Phone: (____) ____ - _____ ☐ Not Available Alternate: (____) ____ - _____ ☐ Not Available

Someone who lives with participant:

Name: _____, _____, _____
Last Name, First Name Middle Name

Home Phone: (____) ____ - _____ ☐ Not Available Cell Phone: (____) ____ - _____ ☐ Not Available

Work Phone: (____) ____ - _____ ☐ Not Available Alternate: (____) ____ - _____ ☐ Not Available

Relationship to Patient (e.g., father, sister, friend): _____

Someone with different address from participant: ***(obtain complete information for at least 2 people)***

Name: _____, _____, _____
Last Name, First Name Middle Name

Home Phone: (____) ____ - _____ ☐ Not Available Cell Phone: (____) ____ - _____ ☐ Not Available

Work Phone: (____) ____ - _____ ☐ Not Available Alternate: (____) ____ - _____ ☐ Not Available

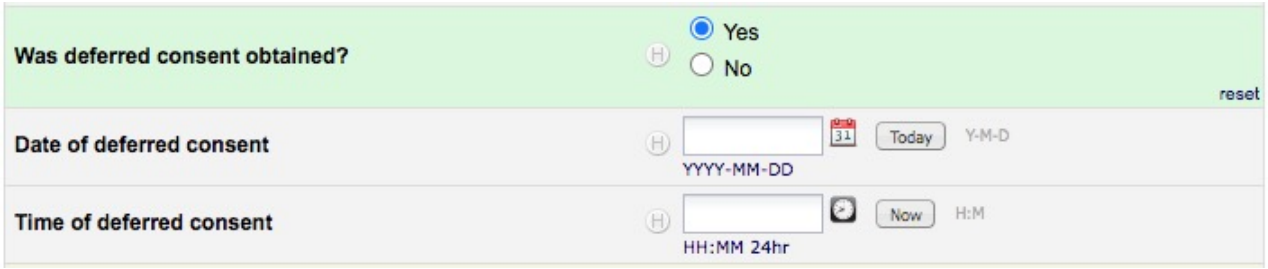
Relationship to Patient (e.g., father, sister, friend): _____

Re-Consenting Patients

- When consent is obtained from a SDM (Personal Consultee) or Professional (impartial third party), you may need to obtain consent from the patient once they are competent to provide consent.
- Approach for prospective consent.
- If consent is denied:
  - Explore reason for denial
  - Request consent to collect data
  - If consent to collect data is denied, request consent to obtain 6 month outcome data
  - Record on the Hospital Overview form in REDCap as a withdrawal of consent

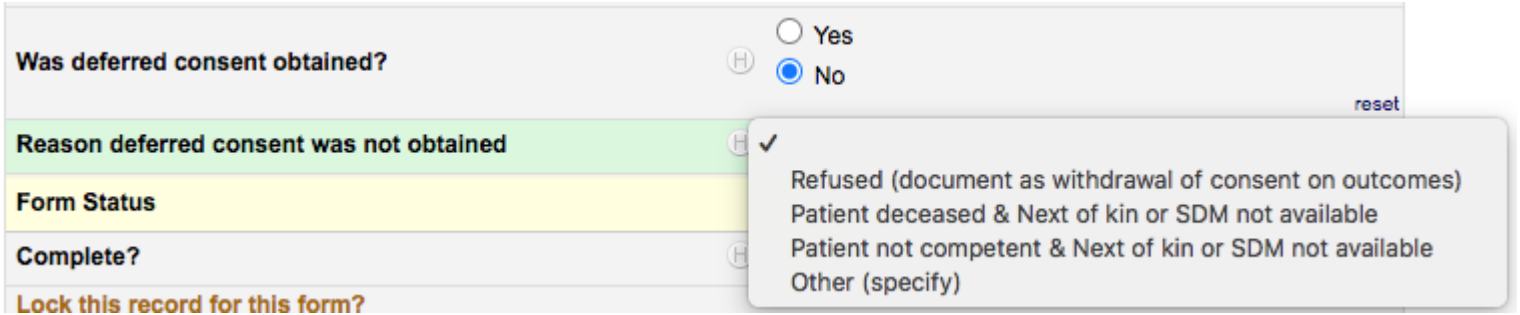
Deferred Consent

- If using deferred consent you will need to obtain consent from the patient once they are competent to provide consent or the SDM (Personal Consultee) when they become available.
- Approach for consent.
- If consent is obtained record the date obtained on the Deferred Consent form in REDCap.



Deferred Consent

- If consent is denied follow the same process outline for ‘Re-Consenting Patients’. You’ll need to select ‘Refused’ on the Deferred Consent form and record as a withdrawal of consent on the Hospital Overview form.
- If it is not possible to obtain deferred consent, please record the reason on the Deferred Consent form.



Questions

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