

A Review of the EMBLEM Consent Process

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THE CONSENT

- An agreement between the study and the subject: Should be given freely by the subject,

But only after all aspects of the study have been explained by the researcher and are well understood by the subject.

- **Definition**

- A process by which a participant voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the participant's decision to participate.

- Informed consent is documented by means of a written, signed and dated informed consent form.

ETHICAL CONSIDERATIONS

Safeguard the dignity, rights, safety, and well-being of all actual or potential research participants.

A cardinal principle of research involving human participants is 'respect for the dignity' of persons

ETHICAL CONSIDERATIONS

- Comply with regulatory requirements, GCP, Declaration of Helsinki. IRB/IEC written approval of materials.
- Written materials up-to-date and approved.
- No coercion
- Not giving up legal rights or release from liability for negligence.

General Requirements for Informed Consent

- No involvement in research without legally effective informed consent.
- Consent under circumstances that allow sufficient opportunity to consider whether or not to participate and avoids coercion.
- Information understandable.

Avoiding Coercion

- Refusing to provide health care
- Excessive financial rewards
- "This is really your only option for your Burkitts Lymphoma Cancer Treatment"
- "I know what's best for you"
- Financial incentives to investigator for enrollment
- Downplaying the risks
- Insufficient time to consider options

CARDINAL RULE

- **KNOW THE CONTENTS OF THE ICF VERY WELL.**
- Know it inside out, back to front to enable you address any questions asked.
- Knowing it well, creates confidence.
- **Consent is a continuous process, not a one-time event.**

Informed Consent (cont.)

- Full information to subject or legally acceptable representative.
- Language as non-technical as is practical.
- Ample time and opportunity for questions.
- **Signed and personally dated by subject and person conducting discussion.**
- Use of impartial witness for illiteracy
- A copy of the signed and dated consent form should be given to the subject.

Informed Consent (cont.)

- Required elements:
 - The trial involves research
 - Treatments and probability of assignment to each arm
 - Procedures
 - Subject responsibilities
 - Aspects of trial that are experimental

Informed Consent (cont.)

- Required elements:
 - Reasonably foreseeable risks or inconvenience
 - Reasonably foreseeable benefits
 - Alternatives to study participation
 - Payments/compensation, if any
 - Expenses, if any

Informed Consent (cont.)

- Required elements:
 - Participation is voluntary. **Withdrawal at any time without penalty.**
 - **Confidentiality.**
 - Records will be monitored.
 - Records confidential to the extent permitted by law. No subject identity in publications.
 - Informed of new information

Informed Consent (cont.)

- Required elements:
 - Who to contact for information about trial, rights of subjects or injury.
 - **Reasons for termination of subject participation.**
 - Expected duration.
 - Expected number of subjects

Consenting of a participant

- **Literate** participant
- **Illiterate** participant

Consent in Non-English Speaking Subjects

- Regulations require language to be understandable
- If subject population includes non-English speakers or investigator or IRB anticipates consent will occur in another language,
 - IRB should require translated document
 - IRB assures document is accurate

Consent in Non-English Speaking Subjects

- Copy of translated consent to subject.
- Ad hoc translation should not be substituted for written translation.
- Oral translation may be used for unexpected situations
 - ethical concerns
 - Short form in language understood by subject used.

Consenting Illiterate Subjects

- Subject may “make their mark”
- If subject can understand and comprehend spoken English but cannot talk or write may be entered into a study if they are competent and able to indicate approval or disapproval.
 - Document method used for communication and indication of approval
 - Impartial third party witnesses, signs and dates

Witnesses

- In literate population, not generally required.
- If required, purpose is to attest to accuracy of presentation and understanding of subject.

ICF case scenarios.

- Qn: Consent was properly obtained but participant declined to take their copy. Is this a protocol violation or deviation? What should you do?
- Ans: This is **NOT** a protocol violation or deviation. Documentation be on file that participant declined to take the consent home. Have both consent forms on file.

Case scenarios (cont.)

Q. Consent obtained however the consentor forgot to date their section. Is this protocol violation or deviation?

A. Protocol violation. Re-consent the subject, report to your IRB stating corrective action taken, both consent forms and documentation to this effect be on file. Refresher training for that staff member.

Case scenarios (cont.)

- Q. Participant signed some sections and forgot to sign a required section, for example, specimen storage? What should be done?
- A. Re-consent the participant, have documentation of what happened on file. Both consent forms be on file. Fill the deviation log to be signed by the monitor.

Case scenarios (cont.)

Q. Participant forgot to append their signature and date at the signature section, but the consentor filled his/her section properly.

A. Protocol violation. Re-consent participant properly and report to your IRB with corrective action taken, both consent forms and documentation be on file. Refresher training for that staff member.

Case scenario (cont.)

- Q. Illiterate participant consented and made their mark, but the witness forgot to address their section.
- A. Protocol violation. Re-consent the participant properly and report this to IRB with corrective action taken. Documentation of what happened be on file. Have both consent forms on file and re-fresher training for that staff member.

Case scenarios (cont.)

Q. Who should write the name/date for the illiterate participant at their section?

A. This should always be written by the consentor.

Case scenario (cont.)

- Q. The consentor forgot to address their signature section?
- A. Protocol violation. Re-consent the participant properly. Report to your IRB with corrective action taken. Have both consent forms on file and document what happened.

Case scenarios (cont.)

Q. Error made by participant at their signature/date section.

A. Have documentation on file indicating that the error correction was made by the participant in your presence.

Case scenarios (cont.)

- Consent missed some information due to errors in photocopying or printing.
- A. Protocol violation. Re-consent the participant properly. Report to your IRB with corrective action taken. Have both consent forms on file and document what happened and provide the full consent to the participant.

Case scenarios (cont.)

- Consent lacks IRB approval stamp
- Currently the recommended practice. Site should have Consent stamped during annual approval

Case scenarios (cont.)

- Child less than 7yrs assents
- Ans: Represents poor understanding of the consent process and necessitates retraining as Corrective Action.

Case scenarios (cont.)

- A thumb mark by witness
- Ans: Represents poor understanding of the consent process and necessitates retraining of staff as Corrective Action.

Case scenarios (cont.)

- Consent administered in the study office, Lab, or Ward.
- Ans: Represents poor understanding of the consent process and necessitates retraining of staff as Corrective Action.
- Its hard to ensure privacy and free atmosphere in such areas.

Case scenarios (cont.)

- A Luo III illiterate patient signs an English consent yet a consent in Luo language exists
- Ans: Represents poor understanding of the consent process and necessitates retraining of staff as Corrective Action.

Confused yet?



- www.fda.gov
- <http://ohrp.osophs.dhhs.gov>