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PREVENTION | TREATMENT | RECOVERY

Informed Consent Training

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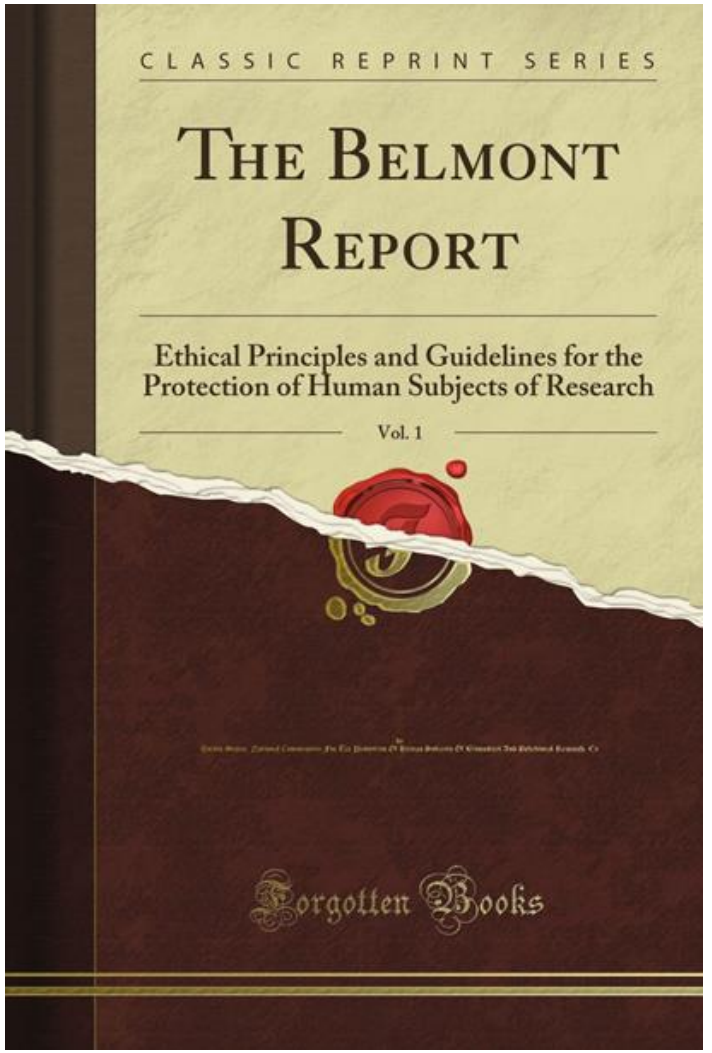
Common consent issues so far in Sleep SMART

- Consent conducted by study personnel not listed to consent on DOA
- Subject consented with the non-IRB-stamped, but current version of the consent
- Witness consent process not used when indicated
- Patient signed a consent form but was found not to be eligible
- Person obtaining consent did not sign the informed consent
- Study coordinator initialed and dated correction for the subject
- LAR used when not appropriate

Informed Consent Process

- Informed Consent = permission prior to intervention
- Valid consent consists of 3 elements:
  - Information
  - Comprehension
  - Voluntariness
- The informed consent process begins prior to any participation and continues throughout the study
- ACRP white paper on Informed Consent process: http://www.acrpnet.org/pdf/ACRPWhitePaperTheProcessofInformedConsent.pdf



The Informed Consent Form

- Used to DOCUMENT the Informed Consent process.
- This documents:
  - What information was provided to the subject
  - Who obtained informed consent
  - Who gave consent
  - When consent was obtained (prior to intervention)

Obtaining Informed Consent

- Use the most current cIRB approved and stamped version of the ICF when obtaining consent.
  - This version (and all approved versions) must be uploaded into the regulatory database in WebDCU
- Consent should be obtained ONLY by staff who have been delegated this responsibility on the DOA.
- Double check consent document to make sure all sections have been correctly signed/dated by subject/LAR and person obtaining consent.
  - Subject/LAR must personally sign AND date consent
- Keep original signed/dated copy of consent and place another signed/dated copy in the medical record (if allowed by institutional standards), and provide a copy to the subject/LAR

Determining Capacity to Consent/Use of LAR

- Subjects who lack cognitive ability to make decisions about study participation cannot give consent.
- If there is any question about a subject's cognitive ability, a trained site investigator must assess the subject for capacity to consent. This assessment must be documented in the subject's medical record.
- When assessing for capacity, the investigator should consider the potential research subject's ability to:
    - Make and express choice
    - Understand relevant information
    - Appreciate the significance of the information relative to the subject's own situation
    - Reason with this relevant information in making decisions
- If a subject lacks capacity to consent, a legally authorized representative *must* consent for the subject to participate.
- If a subject regains the ability to consent during study participation, the consent process should be completed with the subject at that time.
- Details regarding why an LAR was used must be entered on the Informed Consent CRF in WebDCU.

Inappropriate Use of LAR/Surrogate Consent

LAR signature on an ICF = LAR made decision because subject was not capable.

LAR signature is **NEVER** an appropriate way to document consent provided by the subject.

Examples of when LAR signature is used **incorrectly** to document a subject's consent:

- Subject has trouble physically signing and dating the ICF
- Subject is illiterate
- Subject is blind
- Subject does not speak English
- Subject prefers to have friend/family member sign documents

When to use the Witnessed Consent Process

When subject is cognitively capable of providing consent, BUT:

- Is illiterate
- Is visually impaired
- Is consenting using a short form
- Is unable to physically sign AND date the consent
  - The subject should make their *mark* if able.
  - If the site cannot find an impartial witness for this 4th scenario, then they can create a note-to-file (NTF) to detail the process followed, and the reason an impartial witness was unable to be used. The site can then add the NTF to the ICF they upload for the subject.

Change in consent capacity

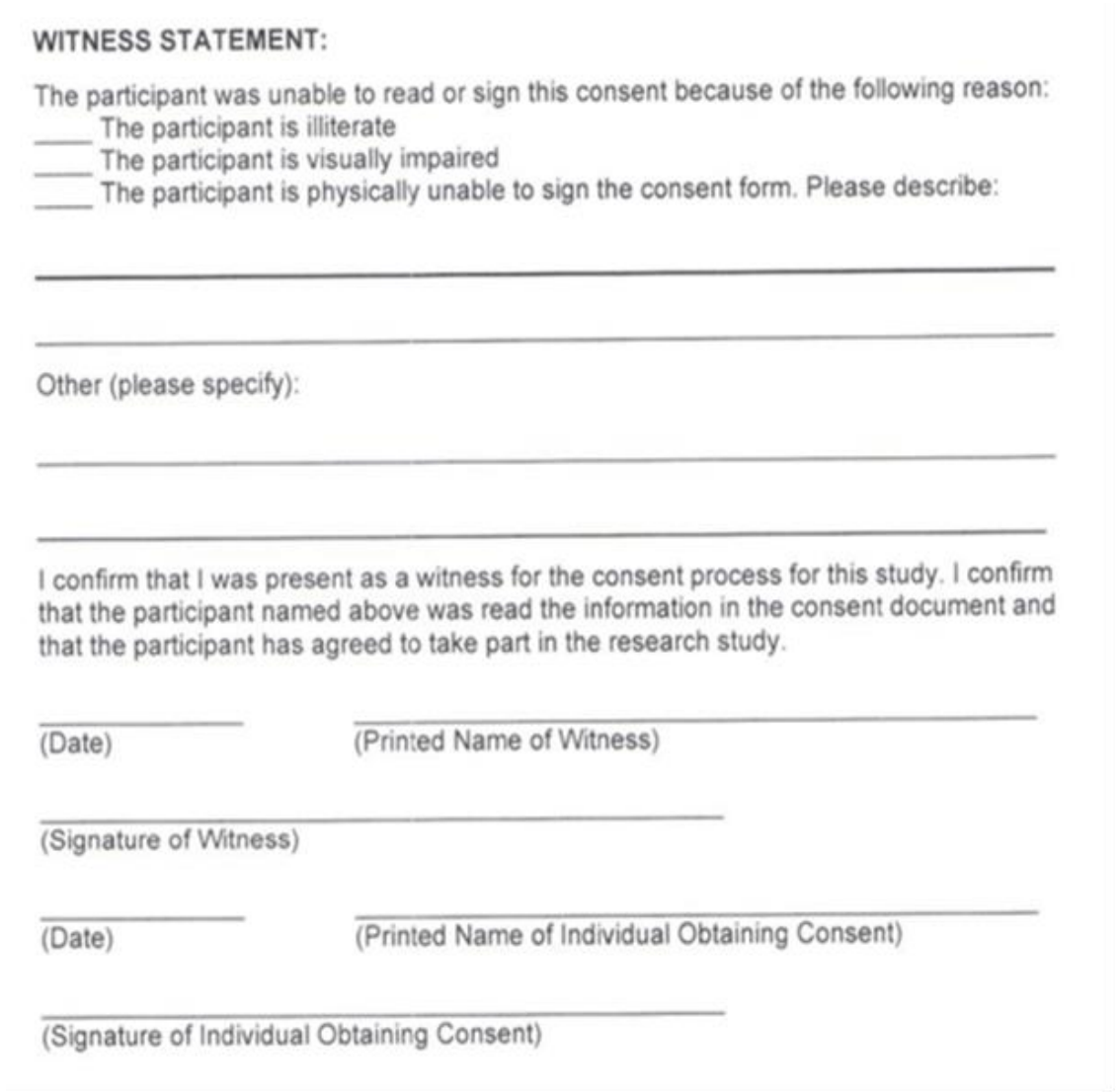
- If subject has a change in capacity, he/she will need to be re-consented
  - If subject initially provided consent, but now lacks capacity: re-consent using LAR +/- assent participant
  - If LAR initially provided consent, but subject's capacity regained: re-consent subject

Assent

- When LAR is used, obtain verbal assent from subject when appropriate
  - Subject understands purpose, benefits, risks, alternatives, procedures at basic level, but does not have capacity to consent for self
- If patient has capacity to assent but does not want to participate in Sleep SMART, the patient should not be enrolled

Documenting consent for subjects with non-cognitive impairments

- When subject is capable of giving consent, but is unable physically to sign and date the consent:
  - Impartial witness must be present during the consent process and sign consent document.
    - *An impartial witness is someone who is not a family member/friend of the subject or a study team member*
  - If possible, subject should make his/her mark on signature lines.
- When a subject is illiterate or visually impaired:
  - The entire consent must be read aloud to the subject.
  - Impartial witness must be present during the consent process and sign consent document.
  - If possible, subject should make his/her mark on signature lines.



WITNESS STATEMENT:

The participant was unable to read or sign this consent because of the following reason:

____ The participant is illiterate
____ The participant is visually impaired
____ The participant is physically unable to sign the consent form. Please describe:

_____

_____

Other (please specify):

_____

_____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____ _____
(Date) (Printed Name of Witness)

_____
(Signature of Witness)

_____ _____
(Date) (Printed Name of Individual Obtaining Consent)

_____
(Signature of Individual Obtaining Consent)

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Obtaining Consent from non-English Speaking Subjects

- To obtain consent from non-English speaking subjects, you must have either a cIRB approved **Full Translated ICF** or a translated **Short Form consent** in the subject's language.
- The presentation of the consent must be done in the subject's language. Either the person obtaining consent must be fluent in the subject's language or an interpreter must be used. **The subject's friends or family members MAY NOT be used as interpreters.**
- Language of choice
  - language ≥10% of the patient population at the site, a full-translated version of the consent will be provided to site by CIRB
  - language <10%, a CIRB approved short form will be provided to the site

Short Form Consent

The short form is used when the consent is presented orally (because there is no translated full consent document).

Consent to Participate in Research

We would like you to join a research study: _____

Before you agree, the investigator must tell you about 12 topics:

1. Why the study is being done
2. What will happen during the study
3. Risks and benefits of joining the study
4. Other treatments or studies
5. Your privacy

Where applicable:

6. Who pays for treatment if you are injured in the study
7. The chance of risks we do not yet know about
8. Why you may be removed from the study
9. If you have to pay
10. What happens if you decide to leave the study
11. When you will learn about new findings related to the study
12. How many people will be in the study

If you agree to join, you will get a signed copy of this form and a written summary of the research.

You may contact _____ (PI Name) at _____ (PI phone #) any time you have questions about the research.

You may contact University of Cincinnati IRB at (513) 558-5259 if you have questions about your rights as a research subject or what to do if you are injured.

You do not have to join the study. If you do join, you can leave later without losing any benefits.

If you sign this form, it means we have described the study to you, and you agree to join it.

_____ Signature of Participant _____ Date

_____ Signature of Witness (Interpreter) _____ Date

(To be signed if the subject is unable to read the English version of the consent document and it has been read to the subject instead)

Non-English Speaking Short Form English Version CIRB Approved for use 3/8/2017

Short Form Consent

- ❑The subject should read and sign the short form in their language.
- ❑A study team member who has been delegated responsibility to obtain consent should perform the consent process orally. If the person obtaining consent is not fluent in the subject's native language, an interpreter should be used.
- ❑ A witness, who is fluent in both English and the subject's native language must witness the entire consent process. If an interpreter is used, the interpreter may serve as the witness. The witness/translator will sign the English consent as well as the short form as the "witness."
- ❑ The study team member who obtains consent must sign the English ICF. A copy of the short form and English ICF must be provided to the participant.
- ❑Notify the project manager who will request a fully translated consent in that language to be signed by the subject within 30 days.

Document of Short Form Consent

On Short Form:

If you agree to join, you will get a signed copy of this form and a written summary of the research.

You may contact _____ at _____
(PI Name) (PI phone #)
any time you have questions about the research.

You may contact University of Cincinnati IRB at (513) 558-5259 if you have questions about your rights as a research subject or what to do if you are injured.

You do not have to join the study. If you do join, you can leave later without losing any benefits.

If you sign this form, it means we have described the study to you, and you agree to join it.

Subject

_____ _____
Signature of Participant Date

Interpreter OR witness fluent in both languages

_____ _____
Signature of Witness (Interpreter) Date
(To be signed if the subject is unable to read the English version of the consent document and it has been read to the subject instead)

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Non-English Speaking Short Form English Version CIRB Approved for use 3/8/2017

On Consent:

Interpreter OR witness fluent in both languages

WITNESS STATEMENT (if required):

The participant or LAR is unable to read or sign this consent form because of the following reason(s):
___ The participant or LAR is non-English speaking.
___ The participant or LAR is illiterate.
___ The participant or LAR is visually impaired.
___ The participant or LAR is physically unable to sign the consent form. Please describe:
_____
___ Other (please specify): _____

I confirm that I was present as a witness for the consent process for this study. I confirm that the participant named above was read the information in the consent document and that the participant has agreed to take part in the research study.

_____
Name of Impartial Witness (PRINT)

(may be interpreter if participant/LAR is non-English speaking)

_____ _____
Signature of Impartial Witness Date

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Faxed consent procedure

- Faxed consent is approved by the CIRB for Sleep SMART. A site may use this procedure if allowed by its local IRB
  - Telephone consent conversation
  - ICF sent to LAR by fax or email – opportunity for questions
  - Signed ICF returned by fax
  - Participation may start only after signed consent has been returned to study team

Informed Consent Checklist

- ☐ Person who obtained consent has been assigned this responsibility on the DOA
- ☐ Most recently CIRB-approved and stamped consent document used
- ☐ Patient or LAR personally signed and dated document, in all the correct spots
- ☐ If the patient lacked cognitive capacity to consent for him or herself, the appropriate LAR was used
- ☐ If an LAR was used, the reason for using an LAR was documented in the subject's medical or research record (as per local procedures) and on the informed consent CRF in WebDCU
- ☐ An impartial witness (of consent process and signature) was used, and documented appropriately, if any of the following situations apply:
    - ☐ Short form consent used
    - ☐ Patient physically incapable of signature
    - ☐ Patient is illiterate
    - ☐ Patient is visually impaired

Informed Consent Checklist Continued

☐ Assent obtained if appropriate

☐ If patient/LAR is not English-speaking, then the following were performed:

- ☐ the consent conversation was conducted in the patient/LAR's primary language (either the person obtaining consent was fluent or a formal interpreter was used), **AND**
- ☐ a fully translated ICF (CIRB-approved) was used, **OR**
- ☐ a translated CIRB-approved short form was used, the process was witnessed (translator may perform), and a fully translated consent was provided within 30 days

☐ If faxed consent procedure was available locally and used, a signed and dated ICF was returned to the site prior to performing any study procedure

☐ Copy of signed/dated consent given to patient/LAR for his/her records

☐ Consent process documented per institutional process

☐ Re-consent performed if a change in consent capacity occurred during the study