Informed Consent: The Musts, The Shoulds, and The New SOP

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Objectives

1. Attendees will be able to explain the importance of keeping and following SOPs for clinical research
2. Attendees will be able to evaluate whether they are prepared to consent a new research subject
3. Attendees will be able to explain the best practices for verbally consenting a subject
4. Attendees will be able to demonstrate correct documentation for a basic informed consent
Standard Operating Procedures (SOPs)
What is an SOP?
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SOPs are written formal documents that describe how an individual will perform a task, and how to document the performance of that task.
Discuss how SOPs would be useful for the following groups, and what could go wrong if SOPs are not used.
Why don’t more research teams use SOPs?
Why don’t more research teams use SOPs?
Case Studies
Case Study #1

You are a new study team member whose duties include consenting new subjects for the study.

• What do you need to do before you are ready to perform this duty?
Case Study #2

You are a new coordinator who has been asked to consent a potential study subject. You go to the study workroom and find multiple different consent documents.

• What should you look for to decide which one you should use for your new enrollee?
Case Study #3

You are consenting a new study subject in the clinic. The participant had car trouble and was late for his appointment, so by the time you reach the signature stage all of the regular clinic staff has gone home. Aside from you and the subject, there are only three people in the clinic: another member of the study team, the subject’s wife, and a member of the housekeeping staff.

• Which of these people may sign the consent as a witness to the subject’s signature?
• Who would be your first, second, and third choice for a witness? Why?
• Would your answer change if the subject was unable to read?
Case Study #4

You have been asked to consent a new study subject for a randomized controlled trial of a new medicine. You attempt to explain the study to the subject, but the subject interrupts to say that he is in a hurry, but he trusts his doctor and if she thinks that participating in this study is the best way for him to get better, then he is ready to sign up.

• What steps would you take to ensure that the subject understands the study prior to signing the consent document?
• What elements of study participation would you want to be sure to explain to him prior to accepting his signature on the consent form?
Basic elements of informed consent

A statement that the study involves research and an explanation of the purposes of the research
Basic elements of informed consent

How long study participation is expected to take
Basic elements of informed consent

What procedures will be involved?
Basic elements of informed consent

Which procedures are standard care and which are only for research?
Basic elements of informed consent

Describe any risks or discomforts
Basic elements of informed consent

Describe any benefits
Basic elements of informed consent

Any alternative treatments that could be considered
Basic elements of informed consent

Will the subject’s identity be kept confidential in the research records?
Basic elements of informed consent

Are there provisions for research-related injuries?
Basic elements of informed consent

Who can be contacted about questions or a research-related injury?
Basic elements of informed consent

Participation is voluntary, and it’s OK to say no
Case Study #5

Your clinician tells you that he’s found the perfect candidate for that study you’ve been having trouble finding enrollees for. The only hitch is that she recently emigrated from Hungary and knows only a few phrases in English. Her daughter always accompanies her to the clinic and translates between her mother and the clinician.

You don’t speak Hungarian and weren’t anticipating having a Hungarian-speaking enrollee, so you don’t have an IRB-approved Hungarian consent form available, and the study design won’t allow you to obtain one in time to enroll this subject before she becomes ineligible to participate.
Case Study #5, cont.

• What alternate consent document could you use to enroll this subject?

• What approval process would be required to prepare the document for use?

• How would you conduct the consent discussion?

• Would you ask the daughter to translate for you during the consent discussion? Why or why not? Would it make a difference if the daughter was an adult vs. a minor?

• How would you expect to handle this differently for a patient who speaks a language expected to be a common language in your patient population (such as Spanish)?
Consent Documentation
True or False?

A participant is required to write the date he/she is signing on the consent form.
True or False?

A participant is required to write the date he/she is signing on the consent form.

The participant, witness, and person obtaining consent must each personally write the date on the consent.
True or False?

A participant is required to print his or her own name on the consent form.

True  False
True or False?

A participant is required to print his or her own name on the consent form.

False

There is no requirement for the participant, witness, or person obtaining consent to print their own names.
True or False?

If a participant cannot sign his/her own name, but can “make their mark,” a witness must be present for the entire consent process.

True

False
True or False?

If a participant cannot sign his/her own name, but can “make their mark,” a witness must be present for the entire consent process.

False

A witness must be present for the entire consent process if the subject cannot either sign or “make their mark.”
True or False?

A family member of the participant cannot sign as a consent witness.
True or False?

A family member of the participant cannot sign as a consent witness.

False

It is preferable to use an impartial witness if one is available, but it is better to let a family member sign as a witness to the signature than to have no witness.
True or False?

A witness to the participant’s signature is not required to sign the consent for UT Health studies.

True

False
True or False?

A witness to the participant’s signature is not required to sign the consent for UT Health studies.

False

While the federal regulations do not require a witness, our local institutional policies do.
True or False?

A copy of the signed consent form must be provided to the subject.

True  False
True or False?

A copy of the signed consent form must be provided to the subject.

False

A copy of the consent form must be provided to the subject, but it does not have to be a signed copy.
True or False?

A participant may sign a consent and return it to the study team by postal mail if the study team has explained the study and answered the participant’s questions by telephone.

True  False
True or False?

A participant may sign a consent and return it to the study team by postal mail if the study team has explained the study and answered the participant’s questions by telephone.

True

A subject can return a consent form by mail or fax after a telephone consent; the person obtaining consent should sign it upon receipt.
True or False?

A participant may return a signed consent to the study team via email.

True

False
True or False?

A participant may return a signed consent to the study team via email.

False

Unless an IRB-approved method such as encrypted email or a secure portal is provided, electronic transmission of consents presents an increased risk of accidental disclosure of identifiable protected health information.
True or False?

If a minor participant becomes of legal age during study participation, there is no need for him/her to sign a new consent.

True  False
True or False?

If a minor participant becomes of legal age during study participation, there is no need for him/her to sign a new consent.

False

Children reaching the age of majority during a study should be re-consented as adults prior to any further interactions or interventions.
All of this information and more can be found in our new SOP!

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- This SOP can be implemented as written without additional IRB approval OR edited for your local needs.
- If you edit, we ask that you let us review it for consistency with local and federal requirements before you start using it.

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Research Concierge Service

Offering Regulatory Guidance and Assistance for Research Staff at no charge!

Representatives from IRB, IACP, OCR and CTO are eager to assist you.

Wednesday, March 28, 2018 – 9:00 a.m. to 12:00 p.m.
Tuesday, April 3, 2018 - 1:00 p.m. to 4:00 p.m.
Wednesday, April 11, 2018 – 9:00 a.m. to 12:00 p.m.
Wednesday, April 25, 2018 – 9:00 a.m. to 12:00 p.m.

Location: Library - 2nd Floor Computer Classroom  Room 2.011

Starting February 15, 2018, clinical trials will be reviewed and cleared by the Clinical Trials Office (CTO) before the research application is submitted to the IRB or the OCR. Learn more about this new clinical trial submission process!
http://research.uthscsa.edu/cto/index.shtml
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Time by Carin Araujo
https://www.freeimages.com/photo/time-1494392

Old Stamp by Marcelo Gerpe
https://www.freeimages.com/photo/old-stamp-1223603

Calendar series 4 by Maxime Perron Caissy
https://www.freeimages.com/photo/calendar-series-4-1192550

3. Objects - Telephone by Michal Bahn
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Ouch by Julia Freeman-Woolpert
https://www.freeimages.com/photo/ouch-1434056

Drugs by Marcin Jochimczyk
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Slip Hazard by fcl1971
https://www.freeimages.com/photo/slip-hazard-1244060

Top secret by B S K
https://www.freeimages.com/photo/top-secret-1239728

physical therapy by Luis solis
https://www.freeimages.com/photo/physical-therapy-1431535

question con 1 by Svilen Milev (www.effective.com)
https://www.freeimages.com/photo/question-con-1-1444528

Stop sign by Johnny Magnusson
https://www.freeimages.com/photo/stop-sign-1496105

3D Business Graph by env1ro
https://www.freeimages.com/photo/3d-business-graph-1629660