OHSRP Education Series

Informed Consent One Year after the 2018 Common Rule Revisions: Updated Information and Processes

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Office of Human Subjects Research Protection

Learning Objectives

- Identify the ethical and regulatory basis for the requirement for informed consent
- Understand updates related to consent included in the 2018 Common Rule (CR) revisions (referred to here as the 2018 CR)
- Discuss methods to obtain consent from subjects who do not read, speak or understand English
- Review NIH IRB processes related to submission and processing of informed consent documents

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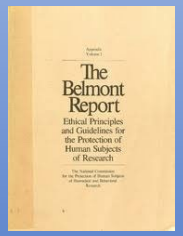
What is the foundation for HHS federal regulations created to protect human research subjects?

The current regulations have their foundation in the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978),* aka **"The Belmont Report"**



Fundamental ethical principles:

Respect for persons

- acknowledge and promote autonomy (self-determination)
- additional protections for individuals with diminished autonomy

Beneficence

Justice

Application of the Principle of Respect for Persons

Three key Elements

1) disclosing **information** to potential research subjects needed to make an informed decision
2) facilitating the **understanding** of what has been disclosed
3) promoting the **voluntariness** of the decision about whether or not to participate in the research under conditions that are free from coercion and undue influence

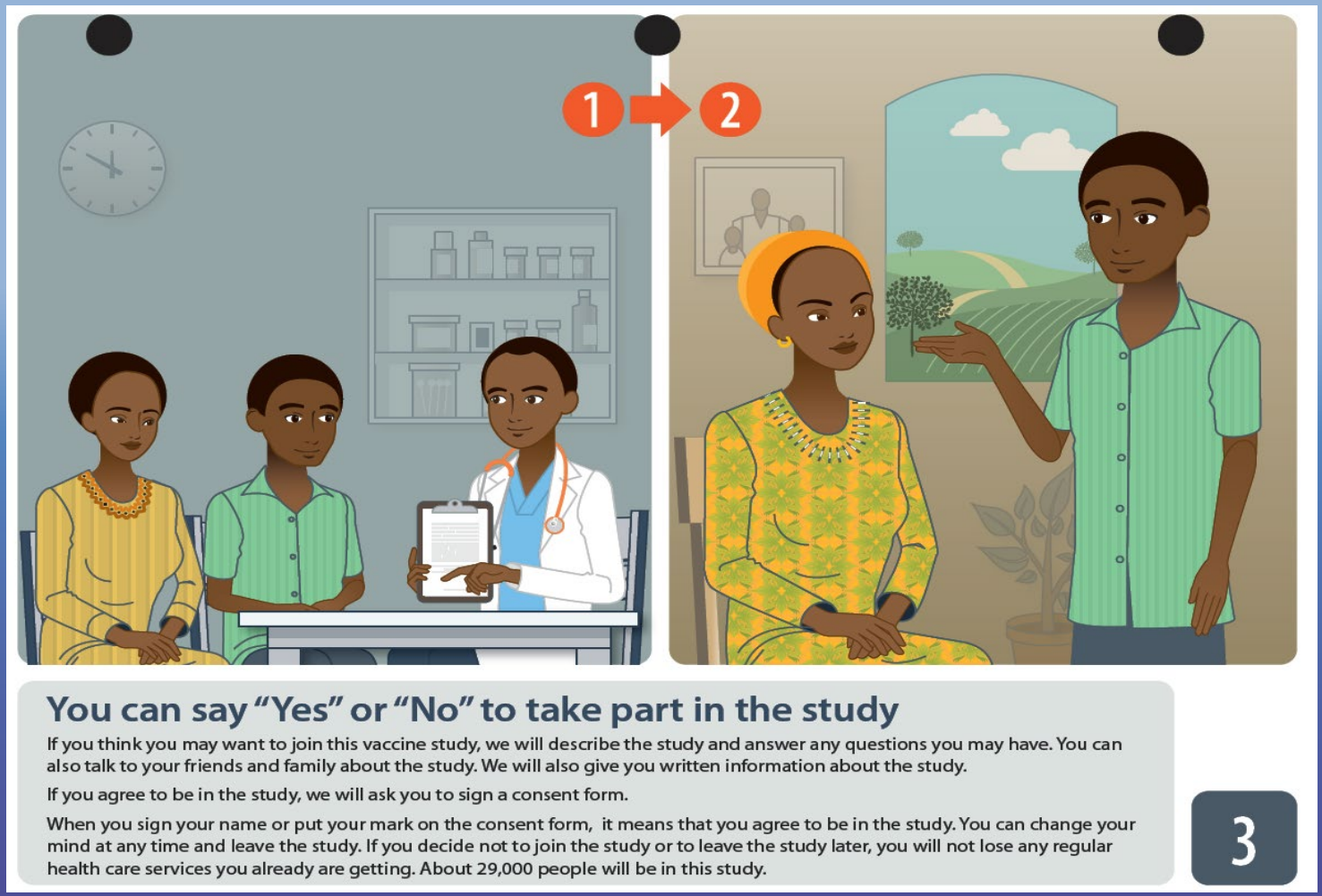
Application of the Principle of Respect for Persons

Three key Elements

#1. Disclosing **information** to potential research subjects needed to make an informed decision

- Identify specific content for disclosure that will assist the subject in making autonomous decisions
- Multi-media options for disclosure
- Not a one size fits all process

Key Concepts
Voluntary Participation



Provided courtesy of Dr. Jerry Pierson, NIAID

Application of the Principle of Respect for Persons

Three Key Elements

#2. Facilitating the **understanding** of what has been disclosed

How can understanding be evaluated?

Examples:

- Teach back or test/feedback method
  - *Can you tell me in your own words what we are trying to do through this study?*
  - *What procedures are involved?*
  - *Can you explain the main risks of the study?*
- Do the questions the subject asks reflect understanding of the study?
- Consent quiz
- Pay attention to non-verbal communication and cues

(Continued)

Application of the Principle of Respect for Persons

Facilitating the **understanding** of what has been disclosed

- If there is a question as to whether the subject has the capacity to understand the study, a capacity assessment should be conducted
- At Clinical Center, the Human Subjects Protection Unit* (HSPU):
  - Has Clinical Research Advocates who can administer a capacity assessment for a specific protocol at a specific time
  - Can assist in determining if a subject who does not have the capacity to consent to the study retains the ability to assign a surrogate decision-maker
  - Can provide consent and assent monitoring, as needed
  - Can provide investigator training:
    - *Elements of an Informed Consent*
    - *Objective Structured Clinical Examination (OSCE)* for Obtaining Informed Consent

* https://www.nimh.nih.gov/hspu

(Continued)

Application of the Principle of Respect for Persons

The Objective Structured Clinical Examination (OSCE) for Obtaining Informed Consent

- Used to evaluate an investigator's ("examinee's") ability to obtain informed consent from a potential subject who is eligible to participate in a specific protocol
- The examiner (an HSPU Clinical Research Advocate) observes the consent process between the examinee and a real or mock potential subject
- The examinee is evaluated in three areas:
  - Professionalism
  - Interpersonal and communication skills
  - Required consent elements
- The OSCE results and feedback are shared with the examinee
- Additional OSCEs are scheduled as needed to demonstrate the examinee's improvement

Application of the Principle of Respect for Persons

Three key Elements

#3. Promoting the **voluntariness** of the decision about whether or not to participate in the research under conditions that are free from **coercion** and **undue influence**

Coercion: When overt threat of harm is intentionally presented by one person to another in order to obtain compliance

(Continued)

Application of the Principle of Respect for Persons

Undue influence:

- Occurs when there is an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance
- Inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable

Learning Objectives

- Identify the ethical and regulatory basis for requirement for informed consent
- **Understand updates related to consent included in the 2018 Common Rule revisions (referred to here as the 2018 CR)**

  The pre-2018 Common Rule is still in effect for research approved prior to January 21, 2019 unless/until it is transitioned to the 2018 Requirements
- Discuss methods to obtain consent from subjects who do not read, speak or understand English
- Review NIH IRB processes related to submission and processing of informed consent documents

Review: Updates Regarding Informed Consent in the 2018 Common Rule

- Reasonable Person Standard: what it is and what does it accomplish?
- Requirement for Key Information section
- New required elements related to identifiable biospecimens, identifiable data, and genetic research with biospecimens
- New requirements for posting one IRB-approved informed consent form used to enroll subjects on a publicly available Federal Web site no later than 60 days after the last study visit by any subject
- Additional condition when IRB may waive or alter requirement for consent related to use of identifiable data/biospecimens
- Broad Consent: This will not be addressed in this presentation as this has not yet been implemented at NIH

Reasonable Person Standard

*The prospective subject or the legally authorized representative must be provided with the information that a **reasonable person** would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information*

- The regulations do not define Reasonable Person Standard
- Interpreted in the context of informed consent as relevant information that an ordinary person, with average knowledge, skill and judgement would find to be most important and relevant when making a decision to participate (or not) in the research
- The reasonable person standard shifts the decision about what information should be provided to the potential subject away from what the physician believes should be disclosed, based on professional standard, to information that a reasonable, ordinary person would want in order to decide whether to participate in the research or not. This standard for disclosure is generally considered more ethical than the professional standard.

46.116(a)(4)

Reasonable Person Standard

- In applying this to the consent form, investigators with knowledge of their subject population should include information that they know will likely be important to *this* group of individuals in deciding whether they want to participate in the research or not

- This should also include reasons why the subject might *not* want to participate

- During the consent process, and with knowledge of the potential specific subject's values and goals, the investigator should provide additional information that would be tailored to the individual's decision-making process

(Continued)

Reasonable Person Standard

Examples of using knowledge of the potential subject's values and goals to convey relevant information to assist the individual in deciding to participate in the study under consideration (or not):

- A concert pianist or a surgeon would likely want to know that the study intervention may cause hand tremors
- A ballet dancer would want to know that the study intervention can result in peripheral neuropathy
- A parent with young children would want to know how long they would be hospitalized and away from their children or if side effects of the study treatment would be disabling enough (even temporarily) to make caring for their children alone difficult
- An individual whose occupation or recreational passion (e.g. construction worker or a triathlete, respectively) would want to know the study drug causes marked photosensitivity

Key Information Section

- Except for broad consent which has specific requirements:

  *Informed consent must **begin with a concise and focused presentation of the key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.*

- The 2018 regulations also add that when the short form process is used , the key information as required must be presented first to the subject, before other information, if any, is provided

§46.116(a)(5)(i)
§46.117(b)(2)

Key Information Section

- The regulatory preamble lists 5 items that would **generally** be considered key information (but are not explicitly required as such by the regulations):
  - that consent is being sought for **research** and that participation is **voluntary**
  - the **purposes** of the research, the expected **duration** of the prospective subject's participation, and the **procedures** to be followed in the research
  - the reasonably foreseeable **risks** or discomforts to the prospective subject
  - the **benefits** to the prospective subject or to others that may reasonably be expected from the research
  - appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the prospective subject

Key Information Section

The [HHS] Secretary's Advisory Committee on Human Research Protections (SACHRP) provided examples of additional elements that might be key information in certain studies:

- Study design (E.g. randomization, use of placebo, crossover)
- Difference from clinical care received if not in the trial
- Compensation for injury
- Amount of time/# of study visits required
- Impact on future care (will study treatment make a standard clinical intervention ineffective or unavailable after the study)
- Impact of caregivers or family members
- Post trial access to the experimental intervention

2018 Requirements for Including Information Regarding Future Use of Biospecimens and Data

Consent must now include one of two statements if the research involves collection of identifiable private information or identifiable biospecimens:

- A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, **the information or biospecimens can be used for future research studies** or **distributed to another investigator for future research studies without additional informed consent** from the subject or the legally authorized representative, if this might be a possibility

OR

- A statement that the subject's **information or biospecimens** collected as part of the research, even if identifiers are removed, **will not be used or distributed for future research** studies

§46.116(b)(9)

2018 Requirements for Including Information Regarding Future Use of Biospecimens and Data

Additional elements of consent, when appropriate, should include:

- A statement that the subject's biospecimens (even if identifiers are removed) may be used for **commercial profit** and whether the subject will or will not share in this commercial profit
- A statement regarding whether **clinically relevant research** results, including individual research results, **will be disclosed to subjects**, and if so, under what conditions;
- For research involving biospecimens, whether the research will (if known) or might include **whole genome sequencing** *[Be sure to consider possible future use as well]*

§46.116(c)(1-7)

Waiver or Alteration of Consent

Under the 2018 Requirements, the IRB can waive or alter consent if it finds and documents all of the following (*yellow font is new to the 2018 Requirements*):

- The research involves no more than minimal risk to the subjects
- The research could not practicably be carried out without the requested waiver or alteration
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in a identifiable format
- The waiver or alteration will not adversely affect the rights and welfare of the subjects **and**
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

§46.116(f)(3)(i-v)

Waiver or Alteration of Consent-FDA

- While FDA permits IRB waiver or alteration of informed consent in some cases, the FDA regulations are not identical to the HHS regulations and, in some cases, FDA does not permit waivers or alterations that are now included in the HHS 2018 Requirements under 45 CFR 46
- For additional information, refer to 21 CFR 50.25 and the July 2017 FDA Guidance Document: *IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More that Minimal Risk to Human Subjects*

Waiver of the Signature Requirement & Alternative Documentation

New:

Requirement to obtain a subject's signature can be waived if:

- Subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm
- Research presents no more than minimal risk of harm
- An alternative mechanism for documenting that consent was obtained

§46.117(c)(1)(iii)

Learning Objectives

- Identify the ethical and regulatory basis for requirement for informed consent
- Understand updates related to consent included in the 2018 Common Rule revisions (referred to here as the 2018 Requirements)
- **Discuss methods to obtain consent from subjects who do not read, speak or understand English**
- Review NIH IRB processes related to submission and processing of informed consent documents

How is informed consent obtained from subjects who do not read, speak or understand English?

- The short form consent process is used when the subject is **unable to read** the long form version of the consent due to a language barrier or illiteracy
- An interpreter is utilized for subjects who are unable to understand the language in which the long form consent is written

Who Can Serve as an Interpreter?

- Whenever possible, a professional interpreter, who is in-person, should be used or, alternatively, professional translation can be via a phone translation service
- Use of a family member for interpretation is not permitted unless a professional medical interpreter cannot be located. The reasons for using a family member and the attempts made to locate a professional translator must be documented in the research record.
- Family members may not have adequate medical knowledge and are not trained as professional medical interpreters. Additionally, family members may not be impartial or may try to speak for the subject which can limit the subject's decision-making process.

How is the consent process conducted when the subject speaks and understands English but is unable to read or write in English?

- There should be a witness to the entire consent process
- Although use of the short form (in English) is not ideal since the subject cannot read the short form, it does provide the opportunity to document that there was a witness to the consent process
- Subjects who are unable to sign their name can make their mark on the signature line. (e.g. They may make an "X," or provide a fingerprint.) The consent note should document the process and include a statement that there was a witness to the entire consent process.

How is the consent process conducted when the subject speaks and understands English but is unable to read or write in English?

How is the consent process conducted for non-English speaking subjects for whom no written language exists?

- An interpreter is required, and the short form process is used with the English short form, with the investigator and interpreter using the English long form as the basis of translation
- A witness must be present for the entire oral presentation and must sign both the short form and the long form used as the basis of translation

At the Clinical Center, is the interpreter required to also serve as the witness?

- NIH federal employees whose job description involves interpretation services should sign the short and long form consent as the witness when facilitating the short form consent process
- Contract staff or volunteers providing interpreter services may sign as witnesses but cannot legally be required to do so
- If the interpreter declines to act as the witness, a separate individual must witness the entire short form consent process and sign as the witness
- Before starting the consent process, confirm with the interpreter if they are willing to witness the consent
- NIH strongly encourages that the witness be fluent in both English and the language of the subject
- The witness must be present for the entire oral presentation

How is the short form consent process conducted when the interpreter is on the phone while the investigator and subject are co-located?

- A phone service interpreter **cannot** act as a witness since they are not physically present to observe the consent process
- Another individual must observe the entire consent process at the site of the investigator and sign as the witness
- Information regarding the interpreter should be included in the administrative section of the long form consent document

Documenting the use of an interpreter on the long and short form consents

- Both the English long form and the translated short form include a section titled **NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER** which must to be completed when the short form consent process is used
- This section:
  - Allows NIH staff to attest that an individual speaking both English and the subject's preferred language facilitated the consent process *and*
  - Indicates whether the individual acting as the interpreter also served as the witness to the short form consent process
- If the individual providing interpretation services did not serve as a witness, the interpreter's name (for on-site interpreters), or ID number (for telephone-based interpreters), should be entered in the designated 2nd field

English Long Form Administrative Block

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

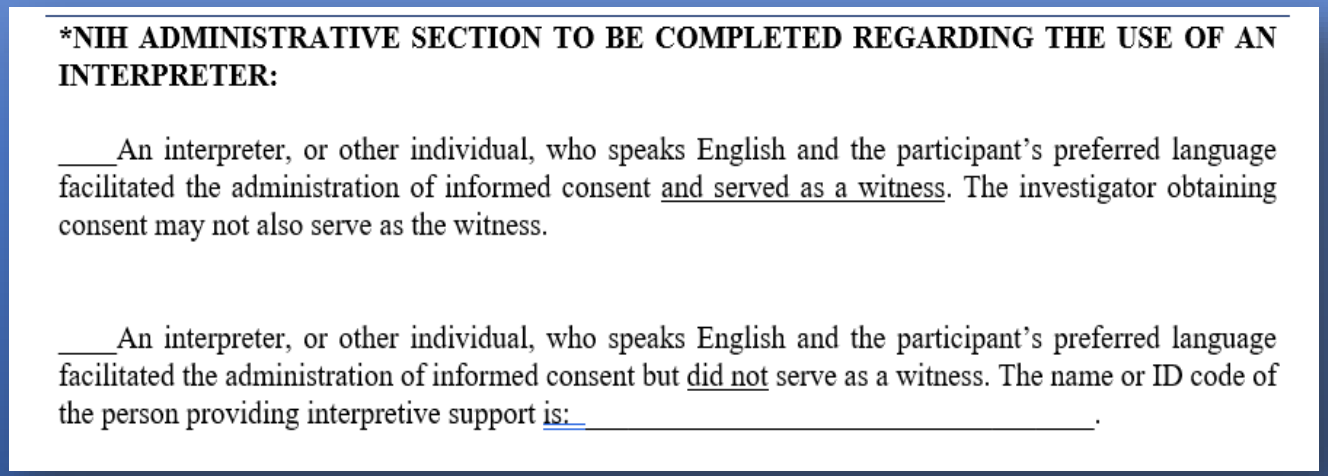
____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

Test Your Knowledge Regarding Signatures in the Administrative Block

Question 1:

An NIH Staff member who is a federal employee and whose job description involves interpretation services acted as interpreter and signed as witness.

Which option should be checked?



***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

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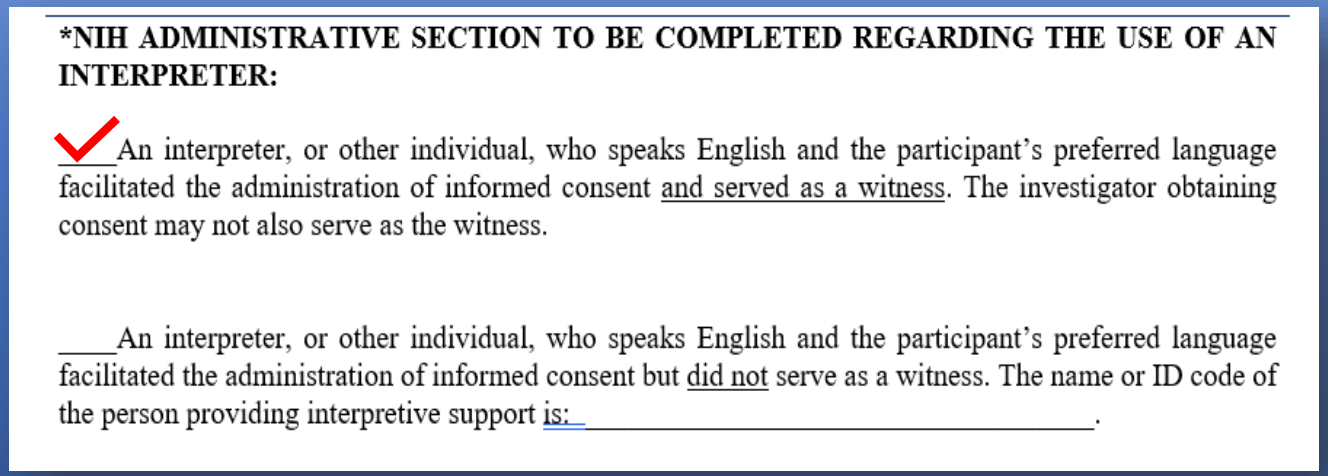
____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

Test Your Knowledge Regarding Signatures in the Administrative Block

Answer 1:

The first option is checked and the interpreter signs as the witness.



***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

✓ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

Test Your Knowledge Regarding Signatures in the Administrative Block

Question 2:

An NIH contract interpreter is used but states they cannot sign as witness.

Which option should be checked?

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

Test Your Knowledge Regarding Signatures in the Administrative Block

Answer 2:

- The second option is checked, and the interpreter's name or ID code is entered on the provided line.
- There must be a separate individual present to observe the entire consent process who signs as the witness.

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

✓ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: *Jane Doe*.

Test Your Knowledge Regarding Signatures in the Administrative Block

Question 3:

A telephone translation service (trans-telephonic interpreter service) is used and the consent is obtained in person (person obtaining consent and the subject are co-located):

Which option should be checked?

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

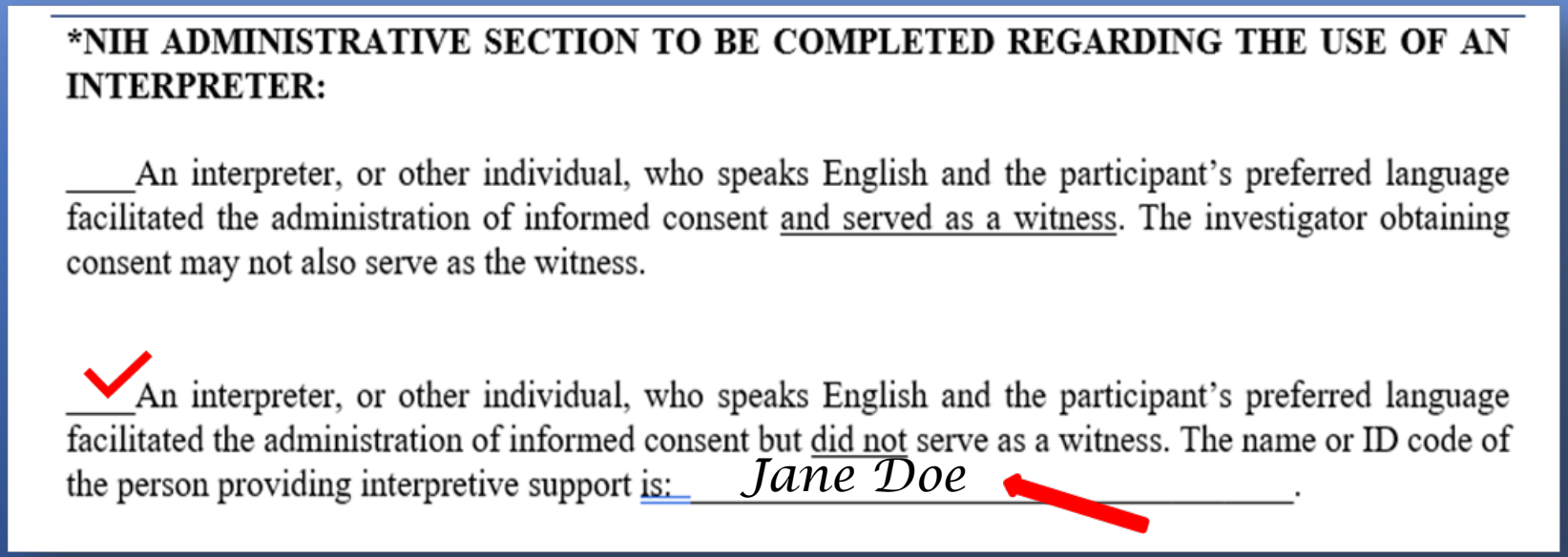
____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.

Test Your Knowledge Regarding Signatures in the Administrative Block

Answer 3:

- The interpreter is not physically present and cannot serve as witness.
- The second option is selected, and the name or ID of the interpreter is entered.
- There must be a separate individual present with the investigator to observe the entire consent process who signs as the witness



***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

✓ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: *Jane Doe*.

How is the short form consent process conducted when obtaining consent by phone from a subject who is not in the same location as the investigator?

- The subject should be provided with both the short form consent and the long-form English consent prior to the phone discussion.
- The investigator who is obtaining consent is in the same place as the witness. (This may/may not be the interpreter.)
- The investigator, interpreter, and witness (if the interpreter will not/cannot serve as the witness) must all be present for the duration of the consent process conducted via phone.

(continued)

How is the short form consent process conducted when obtaining consent by phone from a subject who is not in the same location as the investigator?

- After completion of the consent process, the following should be completed in real time:
  - The subject signs and dates the short form consent and returns it to the investigator (all pages must be returned as is the case if consent is being obtained by phone using the long form)
  - At the time of the consent process, the investigator and the witness sign and date the long form English consent that was used as the basis of translation
  - The administrative section on the last page of the long form English consent is completed
  - The investigator documents the process in a consent note in the subject's medical chart or research record (in real time after the consent discussion)

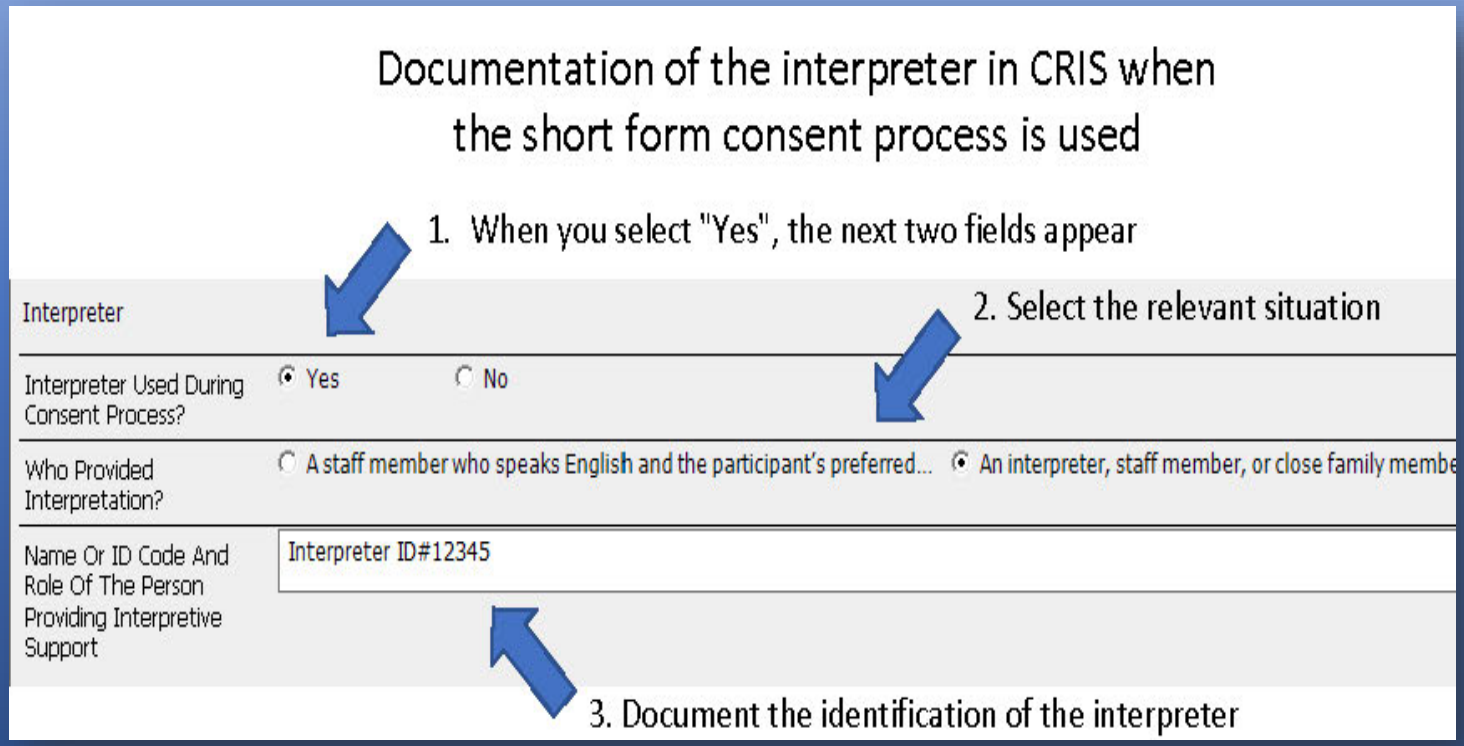
(continued)

How is the short form consent process conducted when obtaining consent by phone from a subject who is not in the same location as the investigator?

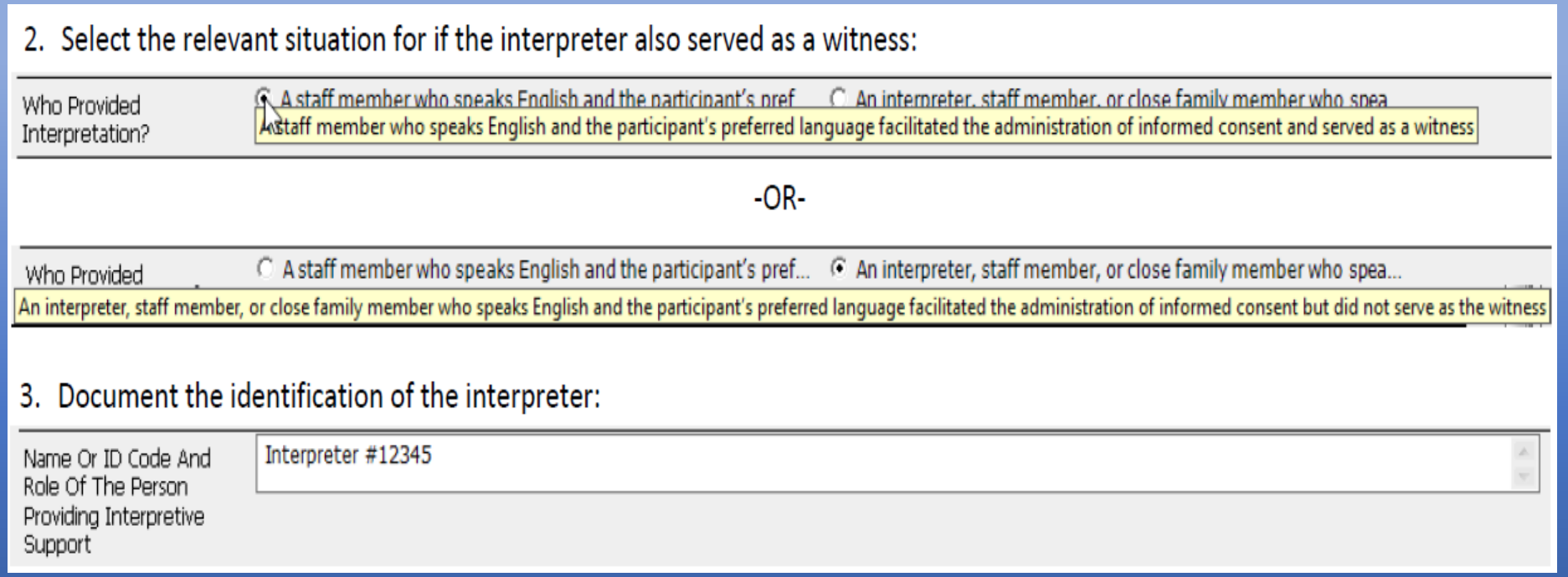
- Upon receipt of the signed and dated short form consent from the subject, the investigator completes the administrative section of the short form, and the same witness signs and dates the short form consent using the current date. (It is not backdated to the date that the consent process was conducted by phone.)
- The subject is provided with copies of the signed short and long form consent documents
- The investigator adds a note to the medical/research record regarding the date the signed short form was received and signed by the witness and indicates when the copies were returned to the subject

What documentation is needed in Clinical Records Information System (CRIS) when an interpreter is used for the short form consent process?

The PI or investigator who is obtaining consent should complete the check box fields in the progress note and include the name or ID number of the interpreter in the designated field.



CRIS documentation when an interpreter is used for the short form consent process

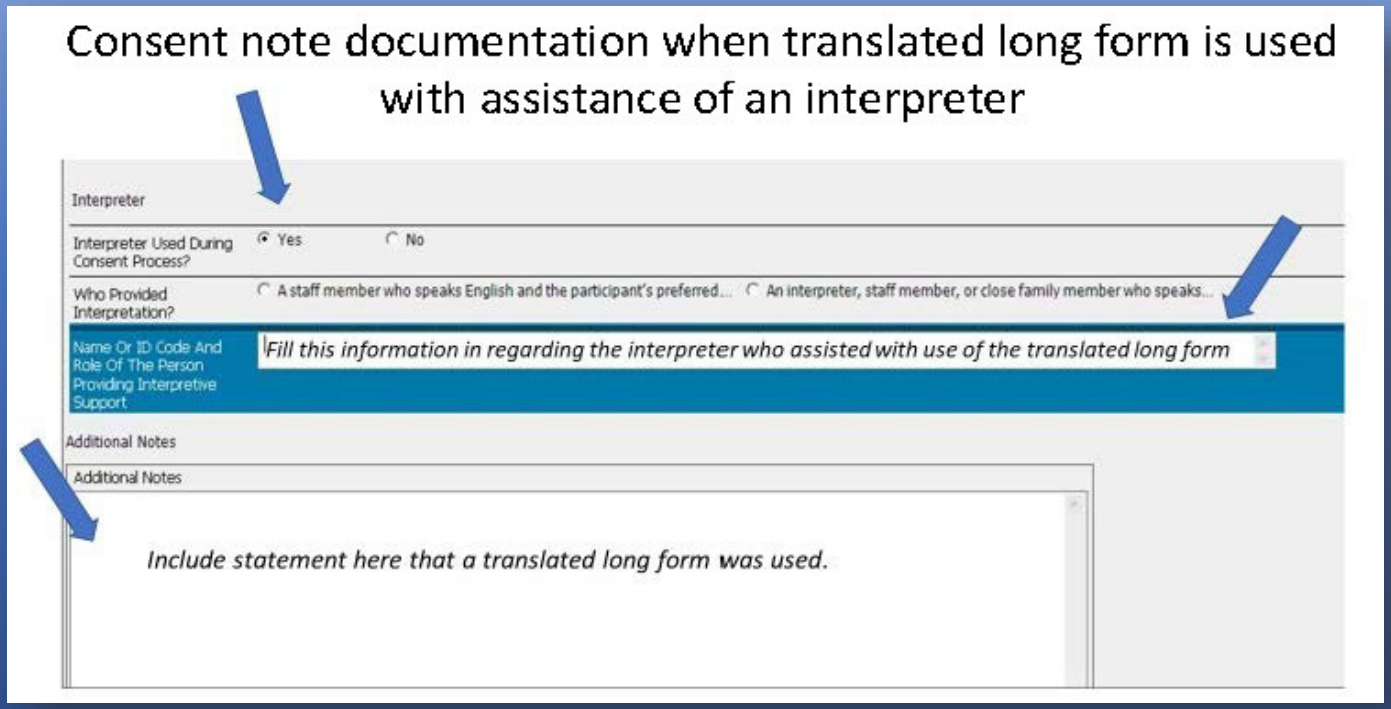


Who signs the IRB-approved fully translated (non-English) long form consent document?

- If investigators anticipate enrolling subjects who speak a specific language other than English, the English long form consent should be fully translated into that language and submitted to the IRB for approval
- In this case, an interpreter is also used to facilitate the discussion and answer the subject's questions, and the investigator obtaining consent and the subject both sign the fully translated long form consent (as they would if the long form was in English)
- In this case, since an interpreter is used but a witness is **not** required on the long form consent, the second box in the administrative section should be checked to indicate that the interpreter facilitated the consent process but did not serve as the witness

How is this documented in CRIS?

- Check “yes” to the question, “*Interpreter used during the consent process?*”
- Fill in the name or ID code of the person providing interpretive support
- Under additional notes, include a statement that a translated consent long form was used



What is the process when a bilingual investigator approved by the IRB to obtain consent uses the translated long consent form or the short form?

- If the investigator is truly fluent in English and the language of the subject, consent may be obtained using the IRB approved **translated long form** if it exists, and no witness is needed
- When the **short form** process is used because the long form has not been translated into the subject's language, the bilingual investigator conducts the consent process in the language of the subject and explains all applicable elements of consent using the English long form as the summary of what is said to the subject
- The investigator obtaining consent using the **short form** cannot act as the witness, so there must be a separate individual present to observe the entire consent process who signs as the witness

How is assent of a minor subject who does not read/speak English obtained?

When the IRB has approved use of a study-specific English assent form for minor subjects:

- NIH does not have translated short form assent documents
- Verbal assent should be obtained from the minor, and the process should be documented in the consent note
- When obtaining assent from a non-English speaking older minor, if there is a translated long form and the IRB has approved a process that allows older minors to provide their assent on the long form, then the older minor can read and indicate their assent on the translated long form

When does the NIH IRB require that an English long form consent be translated into another language?

- At the time of Continuing Review, the IRB will review how many times the short form process was used for specific non-English languages and will inform the PI if the long form must be translated into a specific language

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- **Review NIH IRB processes related to submission and processing of informed consent documents**

Use of the NIH Consent Template—Revised Common Rule

- Key information section

KEY INFORMATION ABOUT THIS RESEARCH

[Required NIH language. This language should remain at the top of this section]:

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you make a decision can be found in other sections of the document. Taking part in research at the NIH is your choice.

This Key Information section is meant to provide prospective participants with information that will help them decide whether or not they want to participate in this study. It is not meant to cover the entire contents of the consent in a shorter format or contain all the standard elements of consent. The organization of the information should be designed to facilitate understanding and decision-making by the participant. You should consider the particular participant

Use of the NIH Consent Template—Revised Common Rule

- Research collecting identifiable private information and/or identifiable biospecimens must state that either:
  - Collected samples/data may be de-identified and used for future research or be given to another investigator for future research without consent *OR*
  - Collected samples/data will not be used or distributed for future research even if de-identified.

*In addition to the above sections, **one of the two following paragraphs must be included** to satisfy a required regulatory element of consent.*

If you might anonymize the specimens and data and use or share them, include the following language:

OR

*If you will **never** use or share any anonymized specimens or data include the following language:*

*(NOTE: If you include this language, you are prohibited from ever using or sharing the specimens or data except as explicitly described in this consent document. If your subjects' data will be available in CRIS and therefore will go into BTRIS or if your protocol involves generating large-scale genomic data which must be shared in a repository, you **must** NOT include this paragraph below.)*

Use of the NIH Consent Template—Revised Common Rule

- New additional elements of consent that should also be included when applicable:
  - Statement that biospecimens, even if de-identified, may be used for commercial profit, and whether/if that profit will be shared.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

*If you might use specimens/data for future research, you **must** include the following language:*

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding [*disease/condition*], or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

Use of the NIH Consent Template—Revised Common Rule

- New additional elements of consent that should also be included when applicable:
  - For research involving biospecimens, whether the research will or might include whole genome or exome sequencing.

WHAT WILL HAPPEN DURING THE STUDY?

Inform subjects about research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Use of the NIH Consent Template—Revised Common Rule

- New additional elements of consent that should also be included when applicable:
  - Statement regarding whether clinically relevant research results will be given to the participant and under what conditions.

Return of research results

Your plan for returning clinically relevant research results, including individual results if applicable, to participants should be described in this section. This includes primary research results as well as secondary or incidental findings. You should also include the plan for returning the outcome of the study analysis to participants, if applicable.

If you do not plan to return any results, that should be stated.

If you are planning on returning results, you must have a return of results plan incorporated into your study protocol and it must be reviewed by the IRB.

Use of the NIH Consent Template—General Tips

- Conflict of Interest
  - If your protocol is “covered” under SOP 21, you must insert the first paragraph of this section.
  - If your protocol involves any technology licenses, including patents, or has a CRADA or CTA associated with it, you must insert the appropriate language from the template
- If your protocol is an Interventional Clinical Trial, you must include the clinicaltrials.gov language

Use of the NIH Consent Template—General Tips

- Headers and Footers—what does the content mean?

PRINCIPAL INVESTIGATOR:

STUDY TITLE:

STUDY SITE:

Cohort: *Identify the cohort or sub-study (e.g. healthy volunteer, normal control, affected patient etc.)*

Consent Version: *Consents should be versioned using the date of the last revision. Each time the consent is revised, you must update the version date. Use this space to specify the version date.*

PATIENT IDENTIFICATION	**Consent to Participate in a Clinical Research Study** NIH-2977 (4-17) File in Section 4: Protocol Consent (#) Version Date: [XX/XX/XXXX] Page 2 of 15

Use of the NIH Consent Template—General Tips

- How do I move my consent in the old format to the new format?
  - Select the correct site consent. Copy the current content of your consent (minus the first and last pages) into the new template in the appropriate sections. Complete the new sections (compensation, reimbursement).
  - Do not "track" this change. DO "track" any additional changes you want to make beyond that.

Pre 2018 CR Consent Templates

- NIH Pre 2018 CR Consent Template for use at NIDA, Baltimore Campus - 09/27/2019 (Word)
- NIH Pre 2018 CR Consent Template for use at the NIH Clinical Center - 09/27/2019 (Word)
- NIH Pre 2018 CR Consent Template for use at NIA - 09/27/2019 (Word)
- NIH Pre 2018 CR Consent Template for use at NIDDK, Phoenix Campus - 09/27/2019 (Word)
- NIH Pre 2018 CR Consent Template for use at NIEHS CRU - 09/27/19 (Word)

Use of Consent Templates for Studies Not Being Conducted at the Clinical Center (CC)

- Templates
- Forms
- Guidance

Templates

Protocol Templates

- Interventional Drug/Device Clinical Trials Only - 12/11/19 (Word) UPDATED
- Prospective Data (Request for Exemption): Prospective Data Collection - 11/03/19 (Word)

- Secondary Research (Request for Exemption): Secondary Research - 08/27/19 (Word)
- Repositories - 10/11/19 (Word)

Standard Consent

- NIH Consent Template for use at the NIH Clinical Center - 09/30/2019 (Word)
  - Common Rule Bulletin #1: Key Information

- NIH Consent Template for use at NIDA - 09/27/2019 (Word)
- NIH Consent Template for use at NIDDK - 09/27/2019 (Word)
- NIH Consent Template for use at NIA - 09/27/2019 (Word)
- NIH Consent Template for use at NIEHS CRU - 9/27/2019 (Word)

Use of Consent Templates for Studies Not Being Conducted at the Clinical Center (CC)

- Follow the model consent template and fill in the applicable information for the site where the research is being conducted.
- Should not include language that is specific to the Clinical Center, for example:
  - In the section about who to call if the subject has a research-related complaint or concern, do not include the NIH Clinical Center Patient Representative
  - If research is being conducted at a non-CC site, identify the location of the research activities
  - Do not use the Clinical Center medical record ICF headers/footers

Use of Consent Templates for Studies Not Being Conducted at the Clinical Center (CC)

- HHS regulations state that the following basic element of consent be included: "For research involving more than minimal risk, *[highlight added]* an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained."
- When NIH is the Reviewing IRB, studies that are minimal risk are not required to include the compensation for research-related injury language in the ICF for research that is not being conducted at NIH sites

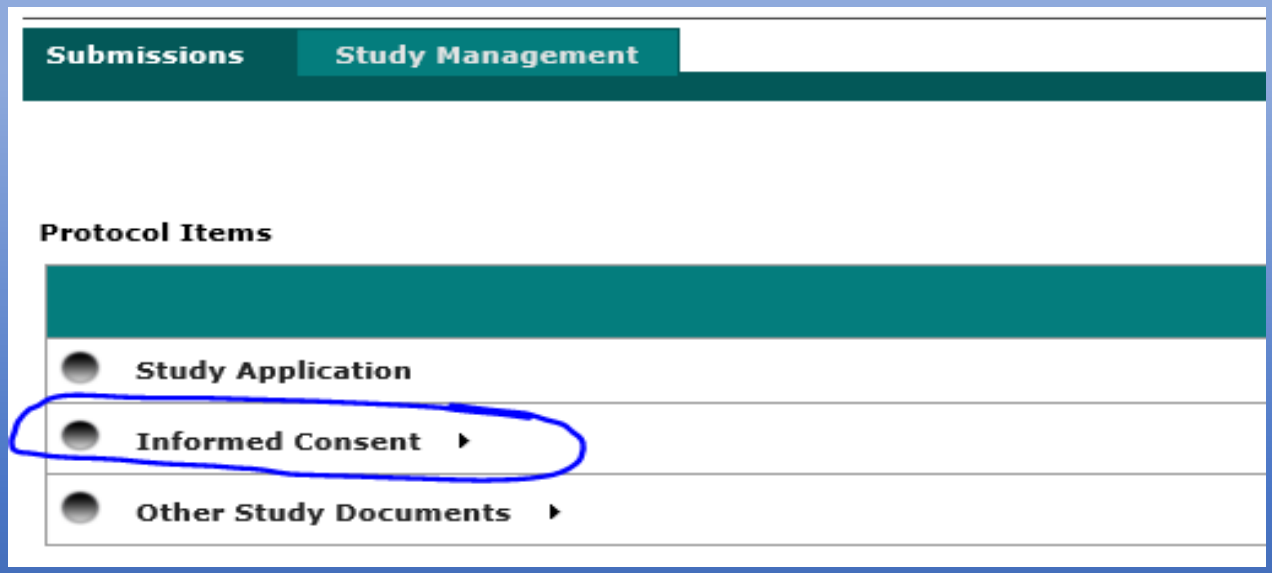
45 CFR 46.116(b)(6)

Submitting the ICF to the NIH IRB

- Use the currently approved ICF to “create a revision” to the consent.
  - There are iRIS training sessions available to all users
- Attach the revised ICF to the Amendment Submission Form.
- The version dates of the consent and protocol do not have to match. You only need to revise and attach your consent if you actually need to modify your consent document.
- The IRB will put an approval stamp with the date of approval on any modified, approved ICF.

Submitting the ICF to the NIH IRB

- How do I find my approved ICF in iRIS?



View History	Edit/ View	Title/Category	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checked Out By	Create a Revised Document
		04-C-0165.7.Consult OPS Final WM *Added by the IRB									
		Clean Consent	1.1 03/13/2019	English			Approved	10/02/2019	10/15/2020		Add Revision
		04-C-0165.4.Donor OPS Final WM *Added by the IRB									
		Clean Consent	1.1 03/13/2019	English			Approved	10/02/2019	10/15/2020		Add Revision

Submitting a Translated Long Form ICF to the NIH IRB

- Once the IRB has approved your revised consent, send that version to the NIH library (or other service) for translation.
  - https://www.nihlibrary.nih.gov/services/translations
- Submit the translated consent document and the certification of translation to the IRB via the miscellaneous document submission form.
- The IRB will approve and “stamp” the new translated consent for your use.

Links to References and Additional Information

- The Belmont Report
- 2018 Revised Common Rule Requirements (45 CFR 46-Protection of Human Subjects)
- OHRP, *Informed Consent FAQs*
- OHRP: *General Informed Consent Requirements (video)*
- OHSRP, *Informed Consent of Subjects Who Do Not Speak English (1995)*
- SACHRP *Commentary on the New "Key Information" Informed Consent Requirements* (October 17, 2018)
- SACHRP, *Addressing Ethical Concerns Regarding Offers of Payment to Research Participants* (September 30, 2019)
- NIH Human Subjects Protection Unit (HSPU)
- IRBO Consent Templates

Questions?

Thank you!

IRBO: IRB@od.nih.gov

Phone: 301-402-3713