Consent Forms and Processes: What Investigators Need to Know

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Objectives

- Understand the purpose of consent as well as the ethical underpinning and regulatory requirements
- Recognize what consent related processes must be described in the protocol
- Identify where to find techniques/tools to simplify the consent form and improve readability
- Appreciate how various consent processes should be conducted and documented when conducting non-exempt human subjects research (HSR)
- Be aware of issues related to the consent process that most commonly result in noncompliance

Purpose of Informed Consent

- Purpose is to provide the information that people need to make an informed decision about whether or not to participate in the research
  - This information helps the individual determine if the research is consistent with their own goals and values
- Ethical imperative based on Belmont principle of respect for persons
  - *Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied*. (National Commission 1979)
- The document is a basis for a meaningful exchange between the investigator and the subject
- Strengthens trust with the researcher
- Thorough understanding may also enhance participant safety during the research

Informed Consent-What do the HHS Regulations* Require?

Unless the IRB waives the requirement to obtain consent or waives the need to document consent, HHS regulations state, in part, the following (bold font added):

- **Before** involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR).
- Seek informed consent only under circumstances that provide the prospective subject or LAR sufficient opportunity to discuss and consider whether or not to participate and that **minimize the possibility of coercion or undue influence.**
- Information given to the subject or the legally authorized representative (LAR) shall be in **language understandable to the subject** or the LAR. (*More about that later!)*
- Must present information in sufficient detail relating to the research and be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.
- No consent may include any exculpatory language.

*45 CFR 46.116 (a) (2018 Common Rule)

Visit our NIH PROTECT Help Center page for more information

IRB Templates

Protocol Templates and Forms

Consent Templates and Guidance

Assent Templates and Assent Information

Short Form Consents

Alternate Consent Processes

Consent FAQs

How to Name Your Documents

Three Key Elements in the Informed Consent Process

Disclose information	disclose information to potential research subjects needed to make an informed decision
Facilitate understanding	facilitate the understanding of what has been disclosed
Promote voluntariness	promote voluntariness of the decision about whether to participate in the research under conditions free of coercion and undue influence

Readability of Consent Forms

- 137 consent forms from 88 protocols at Johns Hopkins Oncology Center
- Used grade level readability as determined by two different readability formulas (the Flesch-Kincaid Formula and the Gunning Fog Index)
- The mean grade level was 11.1 using the Flesch-Kincaid Formula and 14.1 using the Gunning Fog Index
- Readability at or below an eighth-grade level was found in 6% of the consent forms using the Flesch-Kincaid Formula and in 1% using the Gunning Fog Index
- Readability was similar for consent forms that described institutional, cooperative group, and phase I, II, and III protocols

Grossman et al. *J Clin Oncol 12:2211-2215*

Consent Documents in Phase 1 Cancer Trials

Malik and Cooper analyzed 310 ICFs from Phase 1 trials for metastatic cancer conducted between 1986 and 1999 and 2000–2015 periods at Cancer Therapy and Research Center, University of Texas Health Science Center

	1986-1999	2000-2015
Median page length	12	23
Included statement that the participant might not benefit from the investigational therapy	42%	57%
Written at $\leq 8^{th}$ grade level	21%	12%
Flesch–Kincaid Grade Level	8.8	10.7
Gunning Fog Index	9.5	12.4

Malik L, Cooper J. *Cancer Chemotherapy and Pharmacology* 82:907–910

Facilitate Understanding

Consent Templates and Guidance

The templates on this page are intended to help investigators construct documents that are as short as possible and written in plain language. The informed consent form (ICF) templates provided by the IRB comply with federal regulations.

What if I only need to provide new study information to a limited number of previously enrolled subjects or inform enrolled subjects of a minor change?

Consent Templates for use at NIH sites →

Creating an Informed Consent for Verbal Consent →

Single Patient IND/Expanded Access →

Considerations Before Writing the Consent Document

Tips for Developing a New Consent Form

Writing a consent form that uses plain language, and that is brief and clear, requires substantial effort. This effort can be lessened by using the consent template and adding the required information from the consent library (see more information below). However, making the effort to develop consents with these attributes, at the time of the initial submission, will greatly speed up the approval of the study. To get your consent form (s) approved quickly, it is incumbent upon the study team to create clear, simple consent documents.

Getting your Consent Form (ICF) Approved Quickly

To create clear, simple consent documents:

Additional Resources for Consent Forms

- Resources and Tools to Improve Consent Form Readability
- PRISM Readability Toolkit
- Side Effect Tables for Common Oncology Drugs

Resource Information and Tools to Improve Consent Form Readability

NIH Office of Intramural Research
Office of Human Subjects Research Protections

Resources for Simplifying Terms-PRISM Readability Toolkit*

Excerpt from the PRISM Readability Toolkit, Third Edition

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
activate	begin, start
acute	sudden, new, recent; intense flare-up, serious pain; short-term
addictive	habit-forming
additional	added, extra, more, other
address	talk about, discuss
adequate	enough
adjacent	next to, by
administer	give
advantageous	helpful, useful
adverse	harmful, bad
adversely impact	hurt, set back
affirmative	yes, positive
aggravate	make worse

* See list of resources at the end of this slide set

NATIONAL COMPREHENSIVE CANCER NETWORK
NCCN ONCOLOGY RESEARCH PROGRAM

NCCN Informed Consent Language (ICL) Database *

TERM	LAY TERM 1	LAY TERM 2
DVT	Blood clot formed in the veins of the leg which may manifest as a dull ache or heaviness in the limb. If the clot moves to other organs, it can be serious or life threatening.	blood clots in a vein (possible pain, swelling, and/or redness)
dysarthria	difficulty forming or speaking words	
dysautonomia	decreased function of the part of the nervous system that controls automatic functions (possible fatigue and/or low blood pressure)	
dysesthesia	painful or abnormal skin sensations	
dysgeusia	Taste changes which may affect the way foods normally taste	abnormal taste
dyskinesia	uncontrolled movements	
dyslipidemia	abnormal blood levels of fat	
dysmenorrhea	painful menstruation	

* See list of resources at the end of this slide set

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Lay Terms For Use With Pediatric Participants Can Be Found In The Page Listing Glossaries at the End of This Slide Set

Nemours KidsHealth

for Parents | for Kids

Word! C

- Word! Cancer
- Word! Canine Teeth
- Word! Canker Sore
- Word! Carbohydrate
- Word! Carbohydrate Counting
- Word! Cardiologist
- Word! Caries
- Word! Cartilage
- Word! Cast
- Word! Cells
- Word! Cellulitis
- Word! Cerebellum
- Word! Cerebral Cortex

Word! Cystic Fibrosis

Listen | AAA

Cystic Fibrosis

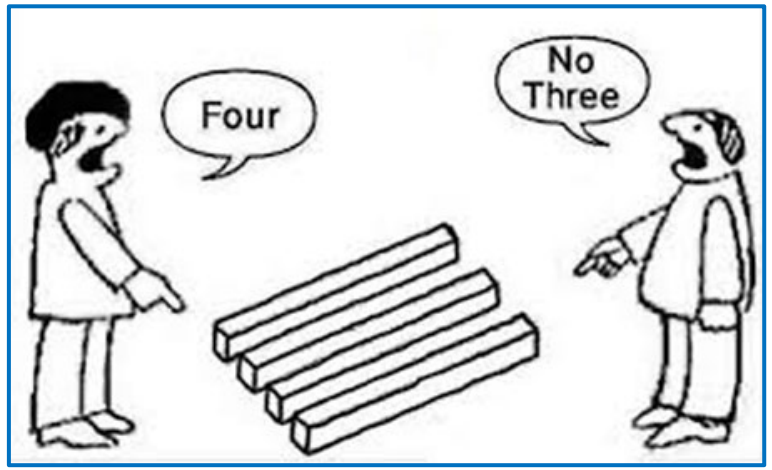
Say: SIS-tik fi-BRO-sus

You may know that you have mucus in your nose, mouth, and lungs, and that it helps keep you healthy. But kids with the condition cystic fibrosis have bodies that make thick, sticky mucus. This causes problems in their lungs and their digestive tract. The condition makes it hard for them to breathe and also to get the nutrition they need from their food.

Revised Common Rule (2018): Changes Related To Informed Consent

- Some of the changes in the Revised Common Rule (2018) related to informed consent were intended to improve the presentation of material in the consent form
- Stemmed from concerns within the research community that consents had become too lengthy and complex
- Among other items, the 2018 Rule added 2 requirements for consent forms included in studies that receive initial approval on and after January 21, 2019
  - **A key information section** must be included at the beginning of the consent form
  - Information must be presented based on the **reasonable person standard**

Reasonable Person Standard- Consider Context and Participant's Viewpoint



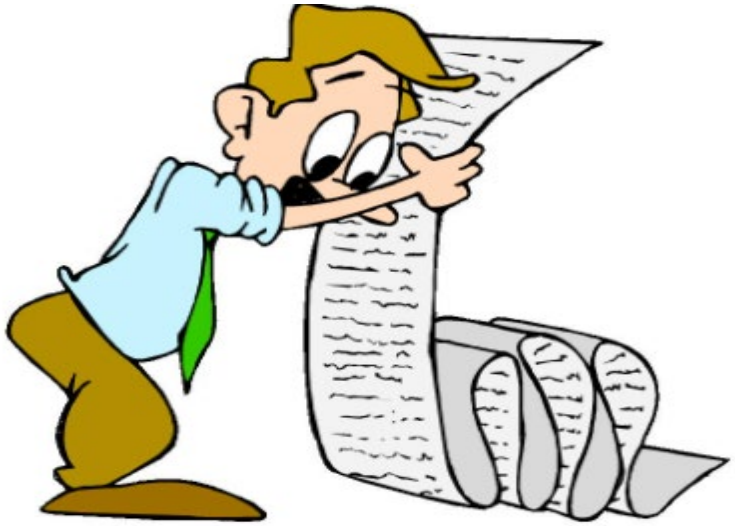
Under what context will prospective participants be provided with the study information?

- Consider cultural group
- What are the participant's cultural and linguistic needs?

Consider the likely participant's:

- Education, familiarity, comfort and ability to communicate about their health concerns and health-related research
- Motivation
- Perception of choices

Assessing a Participant's Understanding of the Study



Assessing a Participant's Understanding of the Study

Topic Area	Question
Purpose	"If you were going to tell a friend what this study was about, what would you say?"
Procedures	"What are the main things you will do or will happen to you while you are in this study?"
Randomization	"Does everyone in this study have to do the same thing?"
	"Tell me in your own words how the researchers will decide whether you get the [intervention] or the [usual care]?"
Risks	"What are the risks, or bad things that might happen to you if or when you join this study?"
Benefits	"What are the benefits, or good things that might happen to you if or when you join this study?"
Voluntariness	"What will happen if you decide you don't want to be in the study?"
	"What can happen if you decide to be in the study but later change your mind?"

Kass N, Taylor HA, Ali J, Hallez K. A Pilot Study of Simple Interventions to Improve Informed Consent in Clinical Research: Feasibility, Approach, and Results. *Clinical Trials* 2015; (12)1: 54-66.

Visit our NIH PROTECT Help Center page for more information

IRB Templates

Protocol Templates and Forms

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Consent Process Described in the Protocol

Plans for the consent process (how, where, when etc.) need to be anticipated and included in the protocol:

- Where and when will consent be obtained?
- How will coercion or undue influence will be minimized?
- Will consent be done in person, or by telephone/videoconference? Describe the process.
- Will the consent be provided in advance of your discussion?
- Will the consent be provided electronically or in hard copy?
- How much time will the potential subject be provided to consider their participation?
- Who will answer questions from the participant?
- Will the potential participant be provided the opportunity to consult with others (family, friends, private physician) prior to providing consent?

Remote Consent

If the investigators and subjects will not be co-located ("remote research") at the beginning of the study or will never be co-located, the IRB may approve a remote informed consent process. Remote consent processes include:

- telephone consent
- consent using NIH-approved audio-or-video conferencing platforms

The planned method for obtaining consent must be described in the protocol (e.g., if using iMED*, this must be specifically stated in the protocol).

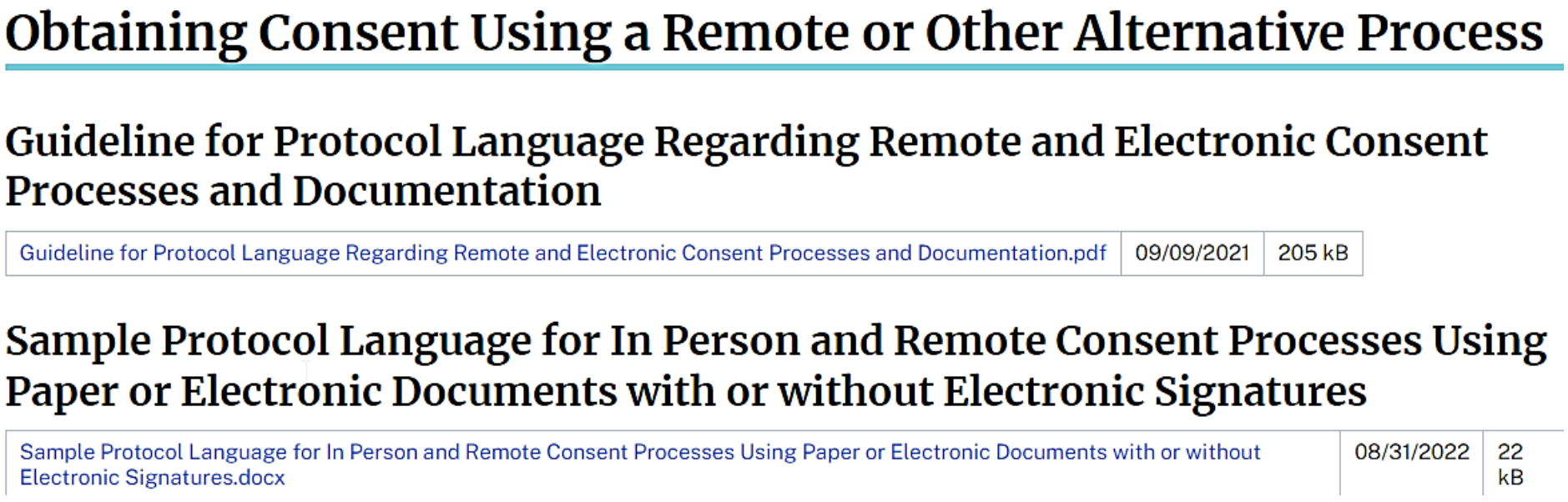
*For more info about iMED, see Electronic Signature Process for Informed Consents (iMedConsent™)

Remote Consent-Describe in the Protocol

For consent processes conducted remotely, the description of the consent process in the protocol should include:

- Whether the ICF will be provided to the participant in advance of consent discussion
- If the ICF will be provided electronically or in hard copy
- Where the participant will be located during the consent process
- How the privacy of the participant will be ensured during the consent process

See OHSRP *Guidance: Obtaining Consent Using a Remote or Other Alternative Process*



Obtaining Consent Using a Remote or Other Alternative Process

Guideline for Protocol Language Regarding Remote and Electronic Consent Processes and Documentation

Guideline for Protocol Language Regarding Remote and Electronic Consent Processes and Documentation.pdf	09/09/2021	205 kB

Sample Protocol Language for In Person and Remote Consent Processes Using Paper or Electronic Documents with or without Electronic Signatures

Sample Protocol Language for In Person and Remote Consent Processes Using Paper or Electronic Documents with or without Electronic Signatures.docx	08/31/2022	22 kB

Electronic Consent

Electronic consent is one in which the informed consent document is presented to the prospective participant in an electronic format.

- Electronic signature refers specifically to when the documentation of consent, i.e., the participant's "signature", is digitally generated by the program following the participant clicking on a field of the document.
- A hand signature provided using a finger, stylus, mouse is not considered an "electronic signature" and is acceptable. Having the participant type in their name in the signature field is NOT acceptable.
- When a study uses electronic signatures, it may trigger additional regulatory requirements. For example, if the study is FDA-regulated, the electronic system must be compliant with 21 CFR Part 11.

Describe the Consent Process with Electronic Platform in the Protocol

- Name the electronic platform you plan to use (e.g., iMed, DocuSign, Adobe, etc.), and if it is 21CFR Part 11 compliant.
- Describe how the signature of both the subject and investigator will be obtained
- Describe if you plan to use a true electronic signature or whether signature will be obtained using a stylus/mouse/finger.
- If you are obtaining a true electronic signature for this protocol, describe the process of how you will verify the identity of the subject prior to obtaining consent.

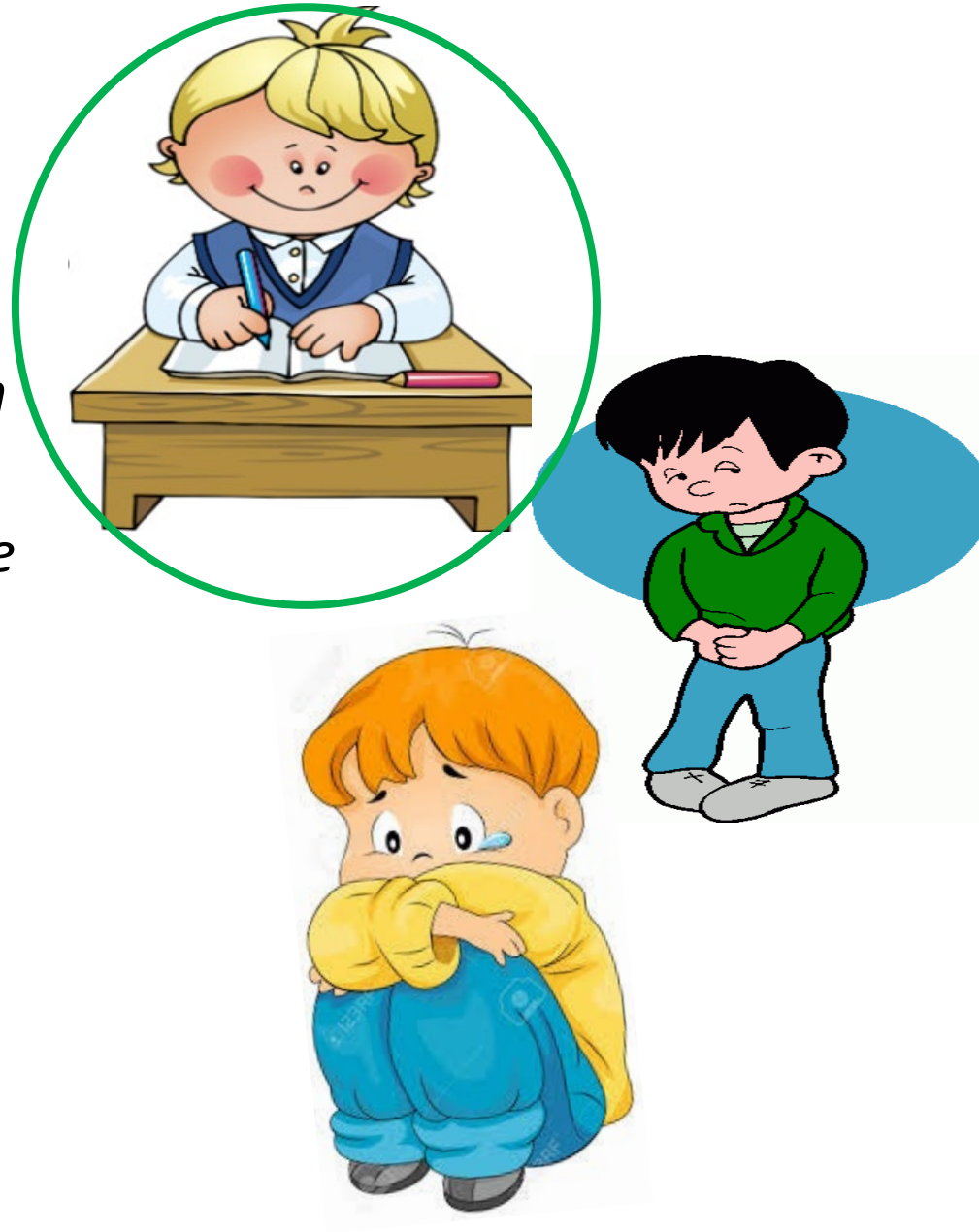
When Study Enrolls Minors: Assent

Assent in terms of the federal regulations means:

- *. . .” a child’s affirmative agreement to participate in research.*
- *Mere failure to object should not, absent affirmative agreement, be construed as assent.*”

For the various categories of research that involves minors the IRB must find that:

“Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians” . . . “when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.”



When Minors will be Subjects (Protocol Template)

- Describe how parental permission will be obtained.
- The IRB expects that the investigator will submit a proposal in the protocol, describing which age groups will be able to provide assent, and which will not provide assent.
- If applicable, describe the process for obtaining assent of the subjects (e.g., verbal assent, written assent.)
- Written assent should be obtained whenever possible.
- Note that in situations where there is joint custody of a child, both parents must sign consent. If only one parent can be present at NIH, the other parent's consent can be obtained by telephone via the procedure you describe.
- Address consent processes for children who become adults during a study.

When is Consent Needed for Screening?

- Under the pre-2018 Common Rule regulation (45 CFR 46)
  - unless the research qualified for specific exemptions, prospective consent from the potential subject for recording of their identifiable private information being obtained for recruitment was required, unless waived by the IRB.
- For protocols subject to the revised (2018) Common Rule **only**
  - an IRB may approve certain screening or recruitment activities, or activities to determine eligibility, prior to obtaining informed consent. These include:
    - Obtaining information through oral or written communication with the prospective subject, OR
    - Obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
  - In this event, the PI does not need to request a waiver of consent, but these activities that will occur prior to obtaining informed consent must be clearly described in the IRB approved protocol. The solicited information should be limited to the minimum necessary for screening, or to determine study eligibility.

Obtaining Informed Consent- THE PROCESS

The Consent Process: How are we doing?

January – April 2021 (iRIS)

- 162 REFs submitted
- 34 (21%) were related to consent process problems

(mid) Jan-April 2023 (PROTECT):

- 126 RNI forms submitted:
- 48 (**38%**) were related to consent process problems

Enrollment of non-English Speaking Subjects- Ethics

Belmont report

“An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered judgment, when there are no compelling reasons to do so.”

Enrollment of non-English Speaking Subjects-Regulations

HSR regulations relating to language of the consent form state:

"The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative." § 46.116(a)(3)

- When obtaining the consent of non-English speaking subjects, consent must be obtained using an IRB-approved translated long form consent or, if enrollment of a non-English speaking subject is not anticipated, an IRB-approved short form consent in the language of the subject.*
- When non-English speaking subjects are **anticipated** to enroll in the research:
  1. The PI must submit a certified translated long form consent document* in the language of the anticipated subjects to the IRB for approval.
  2. IRB approval of the certified translation must be obtained before the translated long form consent document is used.

*A resource for obtaining a translation is the NIH Library.

Translations

Translations

Translations FAQ

Contact

Julio Santana
Translation Project Coordinator
santanaj@ors.od.nih.gov
301-827-4057

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301-827-4075

Translations

The NIH Library's Translations Service provides written translations of materials and certificates of accuracy NIH employees and contractors in support of their employment and/or research. Eligible translation request are fulfilled free of charge for the covered languages listed below. A translation request is eligible (1) if it concerns an NIH employee's work duties, or (2) if it concerns patient care at NIH.

Who is Eligible for Translations

The NIH Library's Translations Service provides written translations of materials and certificates of accuracy NIH employees and contractors in support of their employment and/or research. Eligible translation request are fulfilled free of charge for the covered languages listed below. A translation request is eligible (1) if it concerns an NIH employee's work duties, or (2) if it concerns patient care at NIH.

What We Do

The Translations Service translates the following types of documents:

- Personal documents: diplomas, certificates, licenses, financial and health statements
- Medical and scientific documents: consents, medical records, lab results, and questionnaires
- Articles: cited journal articles related to NIH research or the field of medicine in general

If your document does not fit into one of these categories, we can refer you to the appropriate service for yo materials.

Languages and Costs

Languages offered in house free of charge

- French into English
- Spanish into English
- English into Spanish

All other language combinations are covered by our contractors and paid for by your Institute or Center (IC). will arrange for the translation of an language combination. Translations are usually priced by the word, and rates vary depending on the language, level of difficulty, and turnaround time.

If we are unable to complete your in-house translation request within your expected timeframe, we can assis you by getting bids for your translation project among our vetted contractors for the most competitive rate w assuring a quality product, and then managing the translation contracting practice.

How to Request a Translation

To request a translation, **complete the translations form**. You will be contacted about submitting your documents.

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To request a translation, **complete the translations form**. You will be contacted about submitting your documents.

Consent Process When a Translated Long Form is Used

- In this case, an interpreter is also used to facilitate the discussion and answer the participant's questions, and the investigator obtaining consent and the participant 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.

Unexpected Enrollment of Non-English Speaking Subjects

When a non-English speaking subject seeks to enroll unexpectedly, and there is no IRB-approved long form consent document in the language of the subject:

1. The investigator must use an IRB-approved **short form consent** document in the language of the subject, if one is available, or
2. If there is no IRB-approved short form consent document in the language of the subject, the NIH PI must submit a certified translation of the short form consent* in the language of the subject that meets the regulatory requirements for approval by the IRB *before* it is used.

At the discretion of the IRB, the PI may be directed to translate the English informed consent document into a foreign language.

*A resource for obtaining a translation is the NIH Library.

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Use of Interpreters

Interpreter: When obtaining short form consent (or when the subject requires an interpreter for long form consent discussion) a professional interpreter, who is in-person, should be used or, alternatively, a professional interpretation can be conducted via a phone interpretation service.

- Use of an adult family member for interpretation is not permitted unless a professional medical interpreter cannot be located. The research record must document the reasons for using a family member and the attempts made to locate a professional interpreter.

Use of Witnesses for the Short Form Consent Process

Witness must be present for the entire oral consent presentation when short form is used.

- Either the interpreter or a second individual (fluent in both languages) can serve as the witness.

The intent of the witness is not **only** to attest that the person signed the consent (act as a "witness to the signature"). They are attesting that

- the information was accurately explained to the subject (or their legally authorized representative)
- all the subject's questions were answered

and

- consent was provided voluntarily

Witness

Witness

- The witness must be fluent in the language of the subject and in English. In the very rare instance that the interpreter is unable to act as the witness and the witness is not fluent in both the language of the subject and English, then the witness should verify with the interpreter that:
  - the subject understands the information presented
  - all questions have been satisfactorily addressed, and
  - the subject agrees to participate.
- The witness, or investigator obtaining informed consent, should document this as a note in the record documenting the short form consent procedure.

Required Signatures & Process For Short Form Consent

- The **investigator** obtaining consent must sign and date the English long form.
- **Subject** signs and dates only the short form consent.
- **Witness** must sign and date both the short form and the English long form/written summary used as the basis of translation.
  - Interpreter may sign as the witness.
  - When the interpreter cannot sign as the witness, another party who speaks English and the language of the subject, and who is present for the entire oral consent presentation, must sign as a witness.

Each person (investigator, subject, witness) signs the form they are able to read.

(continued)

Required Signatures & Process For Short Form Consent (con't)

- The subject must be provided a copy of the signed short form consent as well as a copy of the signed English long form/written summary that was used as the basis of translation.
- The research team must complete the administrative section of the short form consent, as well as the administrative section of the English long form/written summary, stating who witnessed the short form consent procedure.
- The consent process must be documented in the subject's medical or research record.

English long form consent

Investigator:

Investigator obtaining consent

Signature of Investigator	Print Name of Investigator	Date

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Interpreter or separate witness to the entire consent process

Signature of Witness	Print Name of Witness	Date

Required signatures on the short form

Example: Spanish short form

Firmar este documento significa que se le explicó verbalmente el estudio de investigación, incluida la información anterior, y que acepta participar voluntariamente.

Participant signature/printed name/date

Firma del participante de la investigación	Nombre en letra imprenta del participante de la investigación	Fecha

Interpreter or separate witness to the entire consent process:

Signature	**Printed name**	**Date**
Firma del testigo*	Nombre en letra imprenta del testigo	Fecha

In English: Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate

Administrative Block When an Interpreter is Used*

Signature of Witness	Print Name of Witness	Date

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: _____.

*This is how the administrative block appears on the English long form consent. On a translated long form or the appropriate short form, it will appear in the language of the non-English speaking subjects.

When There Is An Investigator on the Protocol Who is Truly Fluent in the Language of the Subject

- If there is an IRB approved **translated long form** in that language, the investigator may obtain consent and no witness is needed. The investigator and the subject sign the translated long form as would be the case with the English long form used with an English speaking subject
- 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 cannot act as the witness, so the second option in the administrative block is checked, and the investigator's name is noted on the provided line.
  - In such cases, there must be a separate individual present to observe the entire consent process who signs as the witness.

Bilingual Investigator- Short Form Process

information here is for the bilingual witness to the short form process

Signature of Witness | Print Name of Witness | Date

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: Name of bilingual investigator obtaining consent .

If the investigator obtaining consent is fluent in English and subject's language, that investigator's name is entered here. A separate witness is still required when the short form is used.

Conducting and Documenting Consent Obtained from English-Speaking Blind or Illiterate Participants

Consent should be obtained from an English-speaking participant who is blind or illiterate using the long-form study consent form.

- The consent form should be read verbatim to the participant unless they prefer to use another type of assistive technology to facilitate the process (e.g., screen-reader)
- The participant may make their mark on the participant line.

Witness should sign below if either:

1. **A short form consent process has been used to enroll a non-English speaking subject or**
2. **An oral presentation of the full consent has been used to enroll a blind or illiterate subject**

Signature of Witness	Print Name of Witness	Date

Assent from Subjects who are Minors

In cases where the participant is a minor, Policy 402 states "*When the IRB determines that assent is required, it shall determine whether and how assent must be documented. The assent process may be either verbal or written.*"

Documenting Assent

If the IRB approves a **verbal assent** process, the investigator who obtains verbal assent should document this in the consent note in the medical/research record.

Obtaining Assent from Older Minor Subjects

Parent/Guardian of a Minor Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I give permission for my child to take part in this study.

Signature of Parent/Guardian	Print Name of Parent/Guardian	Date
Signature of Parent/Guardian	Print Name of Parent/Guardian	Date

Assent: I have had this study explained to me in a way that I understand, I have been given the opportunity to discuss it, and I have had the chance to ask questions. I agree to take part in this study.

Assent of Minor:

Signature of Minor	Print Name of Minor	Date

IRB Approved Written Assent Form

PRINCIPAL INVESTIGATOR:

STUDY TITLE:

STUDY SITE:

Cohort:

Assent Version

What is a research study?

Research studies help us learn new things. We can test new ideas. First, we we try to find the answer.

This paper talks about a research study that we are doing and the choice tha in it. You are being asked to join this research study because . We w questions that you have. You can ask questions any time.

Important things to know…

- You get to decide if you want to take part.
- You can say 'No', or you can say 'Yes'.
- No one will be mad at you if you say 'No'.
- If you say 'Yes', you can always change your mind and say 'No' lat
- You can say 'No' at any time. You will still be able to get good matter what you decide.

Why are we doing this research?

We are doing this research to find out more about .

Assent and PI Responsibilities

- All investigators are responsible for complying with IRB requirements for obtaining and documenting parental permission and assent, as applicable, or they must provide a justification for requesting a waiver of parental permission and/or assent.
- When child subjects reach the age of majority, investigators must seek legally effective informed consent from the now-adult subject or withdraw the subject from the research.
  - Alternatively, the investigator may request a waiver of consent from the IRB for the subject's continued participation if the ongoing research meets the criteria for a waiver specified in federal regulations.*
  - If the now-adult subject is unable to provide legally effective informed consent, the requirements of Policy *3014-403 Research Involving Adults Who Lack Decision-making Capacity to Consent to Research Participation* must be followed.

* 45 CFR 46.116(f)(3) of 2018 Common Rule & 45 CFR 46.116(d) of pre-2018 Common Rule

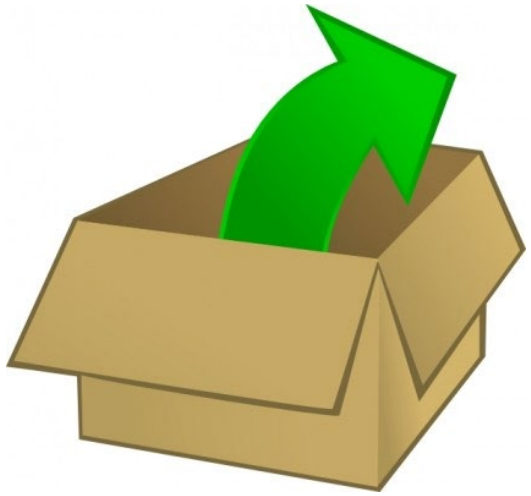
Remote Consent-by Telephone

- No witness needed if English long form is used with English reading/speaking subject.
- After the consent discussion has occurred and the participant's questions have been answered, the participant signs the consent in real time using current date.
  - Ideally the consent is mailed it back to the investigator obtaining consent.
  - If not mailed, it can be scanned and returned (and not returned as photos).
  - ALL pages must be returned.
- On the day of the consent conversation, the investigator obtaining consent documents the process in CRIS/medical record (or the research record if there is no medical record) in real time

(continued)

Remote Consent-by Telephone-continued

- When the signed/dated consent form is returned to the investigator who conducted the consent discussion, the investigator signs and dates the consent form with the date they received the signed the consent from the participant.
- The investigator should then record another note in CRIS/research record indicating the updated status and send a copy to medical records (or research record if there is no medical record)
- Unless documentation is waived by the IRB, a copy of the signed informed consent document must be provided to the subject who signed it.



Remote Consent-by Telephone-continued

- If, after the participant has signed the consent form, specimens and/or data are collected locally for research purposes, no analyses of these specimens and/or data may occur until the investigator has verified that the participant has returned a signed and dated informed consent document, unless the IRB has granted a waiver of documentation of consent.

Resources and Links

45 CFR 46.116: General requirements for informed consent

45 CFR 46.117: Documentation of informed consent

21 CFR 50 Subpart B: Informed Consent of Human Subjects

NIH Policy 300: Investigator Responsibilities

NIH Policy 301: Informed Consent

NIH Policy 402: Research Involving Children

OHSRP FAQs: General and Short Form Consent Processes

IRB Templates (OHSRP templates and guidance for protocols, consent/assent/short forms)

Resource Information and Tools to Improve Consent Form Readability (OHSRP website)

earch mandate.

Find my IRB Team | New to the NIH IRB? | PROTECT Help and Support

1

OTECT Help Center page for more information

NIH Investigator Manual for Human Subjects Research

2

NIH Investigator Seminar Series

NIH Investigator Seminar Series information

Topic	Session date/time/link	Slides	Recorded Video
Determining Whether Your Project Might Require an Exemption or IRB Review, Including Submission of a Secondary Research Protocol	Monday, February 13, 2023 3:00 - 4:00 PM https://nih.zoomgov.com/j/1611460087	Download	Recorded Video
IRB role, function & authority	Monday, March 13, 2023 3:00 - 4:00 PM https://nih.zoomgov.com/j/1612436847	Download	Recorded Video
Planning your protocol	Monday, April 17, 2023 3:00 - 4:00 PM https://nih.zoomgov.com/j/1607113363	Download	
Informed Consent	Monday, May 8, 2023 3:00 - 4:00 PM https://nih.zoomgov.com/j/1616411372	3	


Thank You

QUESTIONS ?