Consent Processes and Documentation

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Agenda

- Legally effective informed consent: What is it?
- Processes for obtaining subject consent remotely
- Reporting deviations from the appropriate consent process to the IRB
- Recent updates to the short form consent process
- Documenting the subject’s consent in the research and/or medical record

Caveat

Please refer to the OHSRP website for current information related to consent forms and consent processes. As policies are updated, information in these slides may become outdated.

NIH HRPP Glossary Definition

Legally Effective Informed Consent

Informed consent is legally effective if it is both obtained from the subject or the subject's legally authorized representative (LAR) and documented in a manner that is consistent with the US Department of Health and Human Services (HHS) protection of human subjects regulations, FDA regulations, and with applicable laws of the jurisdiction in which the research is conducted.

“Standard” Informed Consent Process

Per the HHS Policy for the Protection of Human Research Subjects (45 CFR 46), investigators conducting IRB-approved research are expected to obtain legally effective informed consent.

This process generally includes the following:

- Providing a written consent form to the subject
- Going over the consent form with the subject and giving them the opportunity to ask questions
- Obtaining a written signature from the subject (i.e., documentation of informed consent)

Documentation of Informed Consent

Documentation of Informed Consent: Use of a written informed consent document that meets the requirements of 46.116 approved by the IRB (or a short form written informed consent and a written summary) and signed (including in an electronic format) by the subject or the subject's legally authorized representative (45 CFR 46.117(a)-(b))

Challenges

- Investigators may not be in the same location as the subject at the time of initial consent
- Some research activities may need to take place remotely
- Some research activities may need to take place “online” (i.e., on the web) with little or no oral communication between investigators and subjects

Remote Consent

- Refers to a consent process which occurs when the investigator and the subject are not physically co-located (in the same place), the IRB may approve a remote informed consent process
- Remote consent processes include:
  - telephone consent
  - consent using NIH-approved audio-or- video conferencing platforms (“virtual” or “telehealth”) “online” consent form
- Informed consent obtained remotely must meet the same regulatory and policy requirements as an in-person consent process
- The planned method for obtaining consent must be described in the protocol
- The consent process should be documented in the medical or research record

Common Scenarios Involving Remote Consent

Studies which involve:

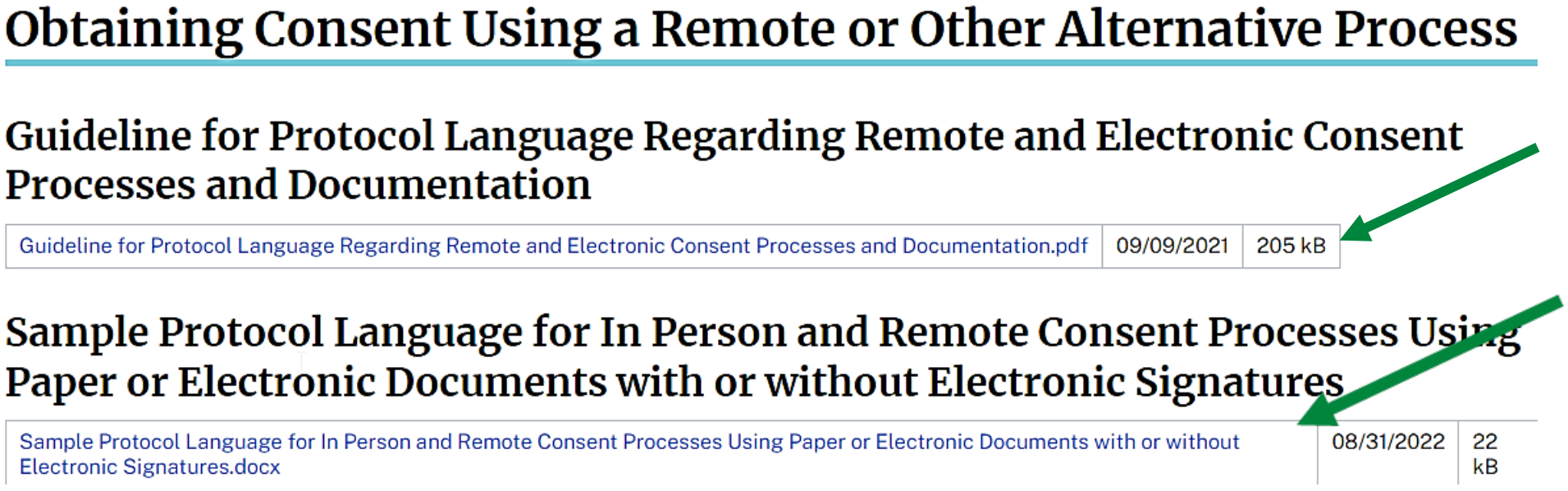
- The collection and shipping of biospecimens, medical records or images from outside of the NIH
- Survey, interview or focus group research via telephone, video conferencing or other web-based technology

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

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Signature vs. No Signature

Signature

- Hand signature: A wet signature on a paper consent form
- Hand signature using a stylus, mouse or finger to handwrite a signature on an electronic consent form is considered to equivalent to collecting a wet signature
- An electronic (digital) signature (i.e., name with time and date stamp) produced by a web-based platform but only if it meets strict specific requirements

These processes are considered "documentation of informed consent"

- ➢ Note: Having the subject type their name in the signature field is **not** acceptable

vs.

No Signature

- IRB approves waiver of documentation of consent

Consent Signatures When Using Telephone or Video Conferencing With Written Documentation of Consent

After the consent process has been conducted and the subject's questions have been answered:

- The subject signs the consent using current date
- The investigator documents the process in medical record/research record in real time on the day of the consent conversation
- 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 subject (It is NOT backdated)

(continued)

Consent Signatures When Using Telephone or Video Conferencing With Written Documentation of Consent

- The investigator should then record another note in the medical record/research record indicating the updated status
- Send a copy to medical records/research record
- Provide a copy of the completed consent form to the subject
- If, after the subject 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 subject has returned a signed and dated informed consent document, unless the IRB has granted a waiver of documentation of consent

Informed Consent with Waiver of Documentation

- What is sometimes known as verbal consent is, in regulatory terms, referred to as informed consent with waiver of documentation
- In this case, the IRB has not waived the requirement for seeking prospective informed consent of the subjects or the parental permission of children who are subjects, but it may waive the requirement for the investigator to obtain a signed consent form when specific criteria are met
- The same regulatory elements of written informed consent are required for verbal consent (all the elements required by the “Common Rule” and NIH IRP policies).

(Continued)

When the Requirement for Documentation of Consent is Waived by the IRB (continued)

- The IRB must still review and approve a written copy of the consent information, e.g., a long form, verbal script, information sheet, etc.
- A "verbal script" is essentially a consent form that will be read to the prospective subject
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or the parents of children who are subjects with a written copy of the consent information or a statement regarding the research
- The investigator must establish a reliable procedure to document that consent was obtained (e.g., in the medical or research record)

Privacy Act Notice – Offsite Consent Template

When subjects will not be registered at the NIH CC or sign the NIH CC Standard Consent Form, there is Privacy Act language which must be communicated to the subject

- Differs from the language in the NIH CC Consent Form template
- The NIH informed consent template for use in off-site research includes this information

Privacy Act Notice – When IRB Waives Documentation of Consent

Information about Certificate of Confidentiality and Privacy Act notification still needs to be conveyed to the subject if . . .

- research is approved for an oral consent process with IRB waiver of documentation of consent (waiver of signature)
- research uses an online consent process with IRB waiver of documentation of consent

Privacy Act Notice – When IRB Waives Documentation of Consent-Examples

Options:

- It could be shared as a written statement mailed or emailed to an offsite subject
- Added as a separate statement for online research when not a CC-registered subject
- If the consent process is entirely oral (by phone or otherwise), the privacy statement could be read to the subject
  - If the consent process is only oral, the investigator should offer to provide a written copy of the notice to the subject
  - Note this option should only be used if the subject will not be registered with the CC and there is no plan to mail or otherwise provide a written consent document to the subject

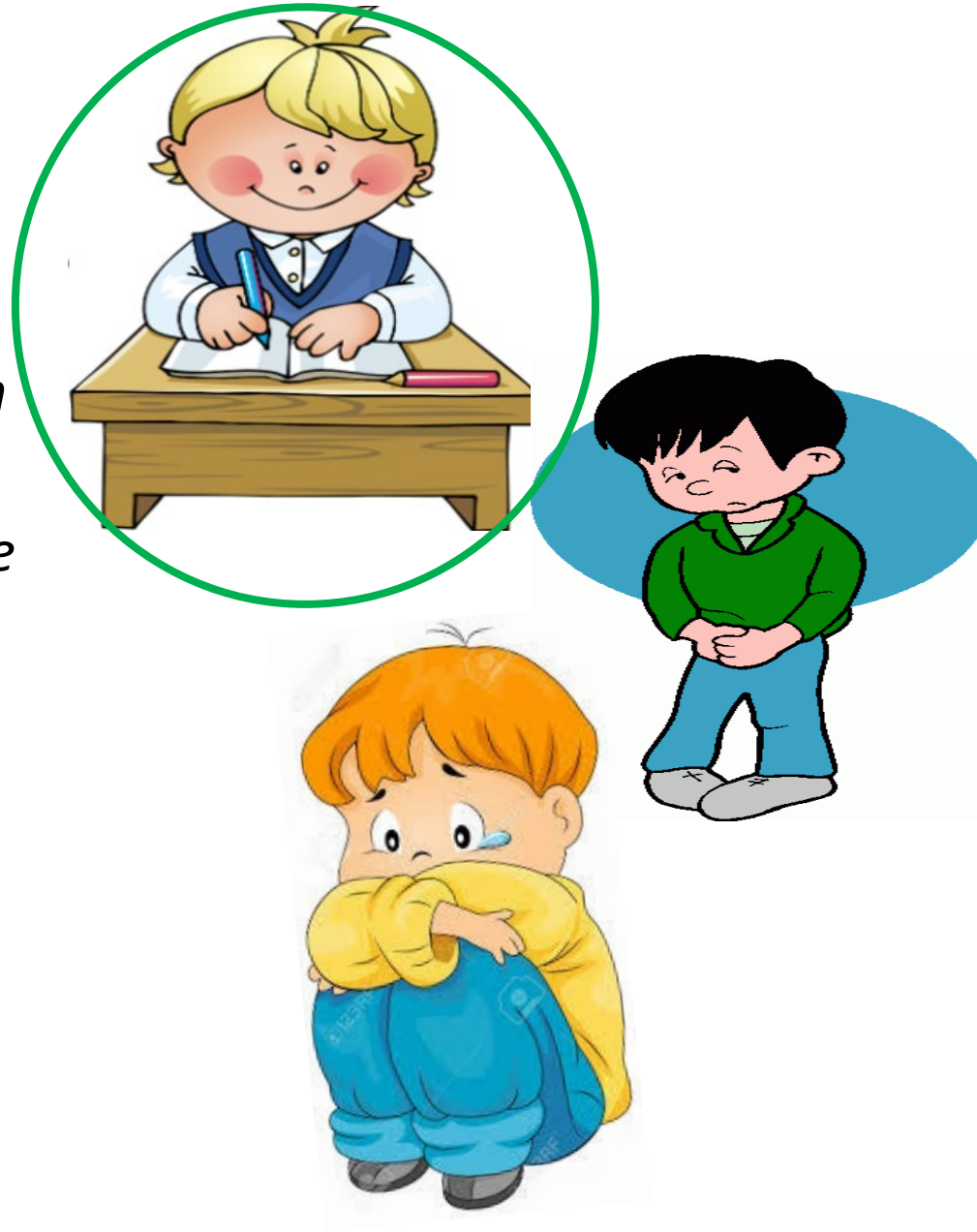
When Study Enrolls Minors: Assent

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.”



Assent from Subjects who are Minors

In cases where the subject 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.*"

Verbal Assent from Minor subjects

If verbal assent is planned, this should be described in the protocol and, 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.

Assent Form

This assent is targeted at 7–13-year-old children

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 ask a question. Then we try to find the answer.

This paper talks about a research study that we are doing and the choice that you have to take part in it. You are being asked to join this research study because [redacted]. We want you to ask us any 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' later.
- You can say 'No' at any time. You will still be able to get good care from a doctor no matter what you decide.

Why are we doing this research?

We are doing this research to find out more about [redacted].

Obtaining Assent from Older Minor Subjects

If you will enroll older minors and do not have a separate assent form, the “Assent” block on the long form ICF can be used. You should describe this plan in the protocol.

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

Remote Consent-by Telephone: Permission from the Parent and Assent from the Minor

The processes for obtaining parental permission from the parent on the IRB approved ICF and obtaining assent from the child are the same as the process for an adult providing consent

- If written assent is required by the IRB, if the child agrees to participate, they sign the IRB approved assent document
- For older minors, if the IRB has approved use of the long form, assent may be documented on the long form along with the parent(s) signature
- If verbal assent is approved by the IRB, this is documented in the consent note in the medical/research record

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 the 2018 Common Rule and 45 CFR 46.116(d) of the pre-2018 Common Rule

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Policy 801 Terminology: Protocol Deviation

A Protocol Deviation (PD): any change, divergence, or departure from the IRB-approved research protocol

- **Major Deviations:** Deviations from the IRB approved protocol that have, or may have the potential to, negatively impact, the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study
- **Minor Deviations:** Deviations that do not have the potential to negatively impact the rights, safety, or welfare of subjects or others, or the scientific integrity or validity of the study

- When NIH is the Reviewing IRB, **major PDs** must be reported to the IRB using the Reportable New Information (RNI) form **within 7 calendar days**
- **Minor PDs are to be reported in aggregate at the time of continuing review (CR)**

Consent Related Deviations: Major vs. Minor

Major Deviations

- Failing to obtain legally effective consent prior to initiating research procedures (including failure to obtained signed consent when required)
- Informed consent obtained by someone other than individuals authorized by the IRB
- Not obtaining consent from a minor when they reach the age of majority, and the now-adult subject continues to be seen/undergoes research procedure and the IRB has not waived the requirement for consent

Minor Deviations

- Use of an expired consent form in which the information contained is not substantively different than the currently approved consent
- A signed copy of the consent form was not given to the subject
- Documentation deficiencies in the consent form such as:
  - A missing investigator signature
  - The subject signs the consent form but does not print their name in the signature block. *Note: A subject who does not sign and date the consent form prior to the initiation of research is considered a **major** deviation*

Reporting Events in PROTECT USING the Reportable New Information Form (RNI)

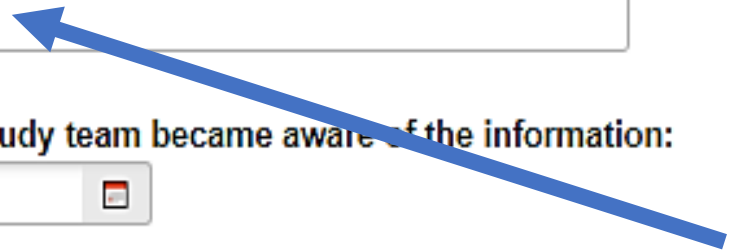
Creating New: IRB Submission

Reportable New Information

1. **RNI short title:** (uniquely identify this new information report)

2. * Date any member of the study team became aware of the information:

3. Date event occurred:



Provide brief descriptive title. This also helps you locate events for auditing purposes. For example:

- Procedures performed before consent
- Error in short form consent process
- Use of short form

(You do not need to enter the protocol # here.)

4. Identify the categories that represent the new information: (check all that apply)

- Non-compliance: Failure of an investigator to follow the applicable laws, regulations, or institutional policies governing the protection of human subjects in research, or the requirements or determinations of the Institutional Review Board (IRB), whether the failure is intentional or not.
- Major protocol deviation: Deviation from the IRB-approved protocol that has, or may have the potential to negatively impact the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study.
- New information that might affect a participant's willingness to enroll or remain in the study. Examples include, but are not limited to: (See examples on RNI form)
- Complaint: Complaint of a subject that cannot be resolved by the research team.
- Death of a subject deemed to be at least possibly due to the research.
- Unanticipated Problem involving risks to subjects or others (See specific criteria on RNI form)
- Short Form Use: Use of the short form consent to enroll a non-English speaking subject.
- Audit: Audit, inspection, or inquiry by a federal agency.
- Confidentiality: Breach of confidentiality
- Unreviewed change: Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- Incarceration: Incarceration of a subject in a study not approved by IRB to involve prisoners.
- Suspension: Premature suspension or termination of the research by the sponsor, investigator, or institution.

5. * Briefly describe the new event:

- Describe the sequence of events in sufficient detail so that it is clear
- Indicate whether or not the event potentially impacts the rights, safety or welfare of the subject or the scientific validity or data integrity
- If the RNI is being submitted outside the required window, explain why
- If procedures were conducted prior to obtaining consent, list what labs/procedures were done and if they were for research

6. * **Describe corrective actions that have already been taken and any additional measures planned:**

- Provide details of steps taken to correct the problem and address any immediate safety concerns or subject rights
- Explain specific steps to be taken to prevent recurrence of the problem in the future
- The corrective action should address the specific **cause** of the event.
- If relevant, indicate if a STARS report was submitted

7. **In the submitter's opinion:**

a. * **Does this information indicate a new or increased risk, or a safety issue?**
○ Yes ○ No Clear

b. * **Does the study need revision?**
○ Yes ○ No Clear

c. * **Does the consent document need revision?**
○ Yes ○ No Clear

If revisions are required, describe them in the text box above for question regarding corrective actions and additional measures.

8. **Related studies and modifications:**

Add the protocol(s) on which event occurred. If the same event affected multiple protocols, list all that were affected.

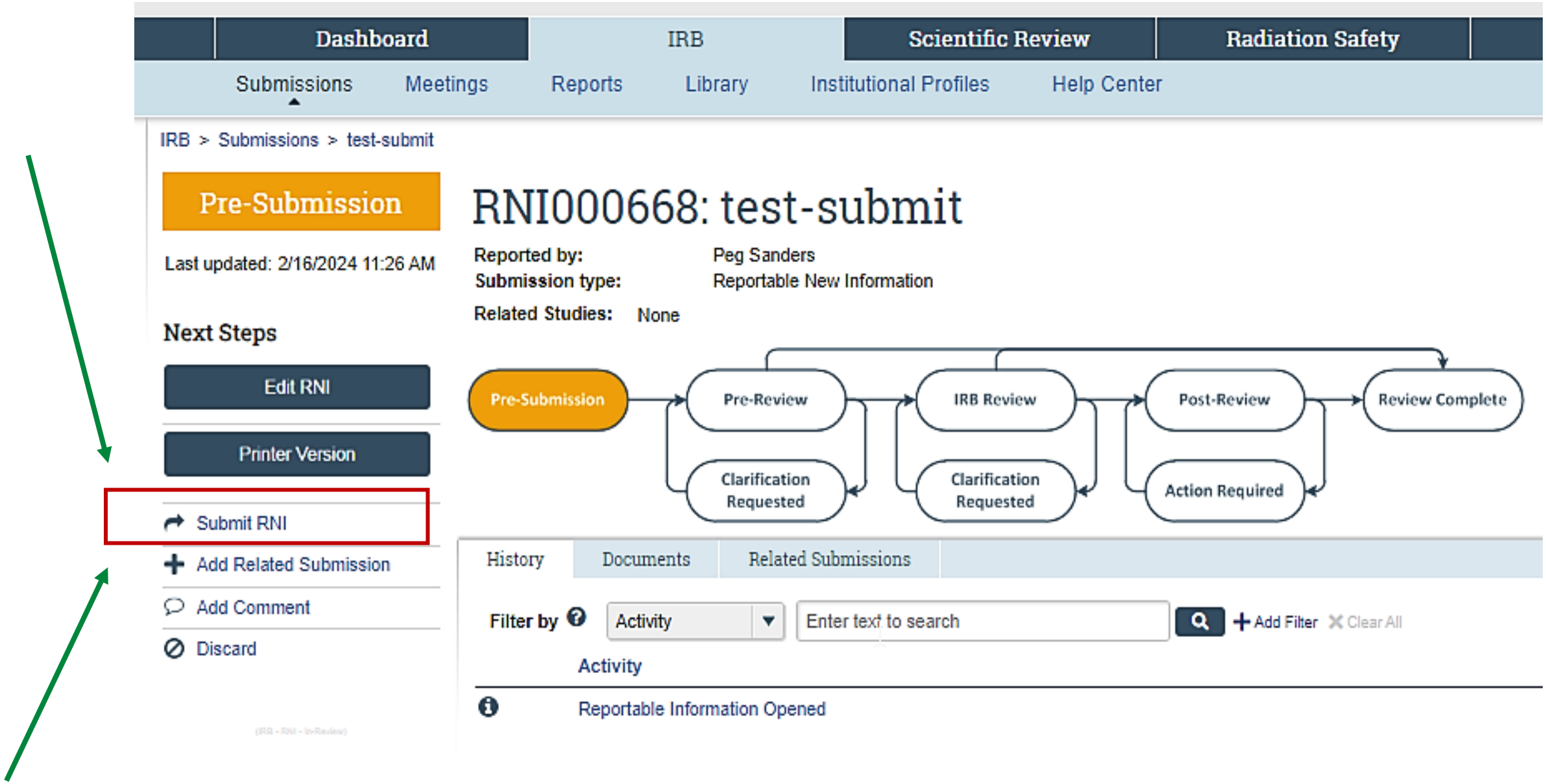
ID	Short Title	Investigator	State	IRB Office
There are no items to display				

9. **Attach files containing supporting information:**

+ Add

Name
There are no items to display

Do NOT Forget to Hit the “Submit RNI” Button!



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What Does the Short Form Consent Actually Say?

INSTITUTE/CENTER:

PRINCIPAL INVESTIGATOR:

STUDY NUMBER:

STUDY TITLE:

You are being asked to participate in a research study. Before you agree, you must first be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

After presenting the summary, the study team will provide you with additional details about the study which must include:

1) the purposes, procedures, and duration of the research;
2) any procedures which are experimental;
3) any reasonably foreseeable risks, discomforts, and benefits of the research;
4) any potentially beneficial alternative procedures or treatments; and
5) how confidentiality will be maintained.

Where applicable, the study team must also tell you about:

1) any available compensation or medical treatment if injury occurs;
2) the possibility of unforeseeable risks;
3) circumstances when the investigator may halt your participation;
4) any added costs to you;
5) what happens if you decide to stop participating;
6) when you will be told about new findings which may affect your willingness to participate;
7) how many people will be in the study;
8) use of your biologic specimens for commercial profit;
9) whether you will be told about your research results;
10) whether the research might include whole genome sequencing; and
11) any future research use of your information or biologic specimens.
12) For clinical trials: A description of this clinical trial will be available on https://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Further, a description of this clinical trial may be available on https://www.clinicaltrials.gov consistent with NIH policy.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact (name) at (phone number) any time you have questions about the research.

You may contact (name) at (phone number) if you have questions about your rights as a research subject or what to do if you are injured.

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.

Signature of Research Participant	Print Name of Research Participant	Date
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:_____.

Short Form Consent (SFC) Process

When the SFC process is used:

- The subject receives no written study specific information in their own language
- They have no documentation to refer to as they decide whether or not to participate or, if they do enroll, to refer to during the study
- Given the ethical and regulatory requirements for obtaining valid informed consent and ensuring the safety of subjects, in many if not most cases, the short form process falls short
- The intent of permitting the short form process has been to provide a mechanism for the *unanticipated or unexpected enrollment* of non-English speaking individuals when there is no IRB approved translated full consent document

(continued)

Short Form Consent (SFC) Process (continued)

- *Unanticipated enrollment* means that the study team could not have reasonably known that they might enroll a person who doesn't speak English
- Typically, at the time a clinic appointment is made, the study team will be aware that a potential subject does not speak English and that an interpreter is needed
  - At this time, the study team should have the informed consent translated into the language of that person
  - The prospective subject's appointment may need to be delayed to obtain the translated document, unless it is clearly in the prospective subject's best interest to not delay and proceed with enrollment using the short form process

Reporting Short Form Consent (SFC) Use via RNI

Process for submitting the RNI for **ALL** uses of the short form

- Inform the IRB of the use of the short form within 7 calendar days by submitting an RNI form in PROTECT
- This should be done for each use of the short form
- Provide the justification for using the short form consent process in the description of the event (for both minimal risk and greater than minimal risk studies)

Reporting SFC Use via RNI-Minimal Risk (MR) Studies

When the protocol is **minimal risk (MR)**:

- Track the number of times the SFC is used in each language and include this information in the submitted RNI form
- If not done previously, when the short form consent is used 3 times for a given language, the short form process may no longer be used for that language, and the consent must be translated for any future subjects that speak that language
- Upon IRB approval, the PI must provide the translated long form to any subjects previously enrolled using the short form consent process who speak that language and who are still on study
- Include this information in a note in the medical/research record

SFC When Study is Greater Than Minimal Risk (GTMR)

- If there is no translated consent document available, enrollment of that individual should be delayed and an IRB approved translated consent should be obtained, UNLESS it is determined by the PI that it is justified to proceed because it is in the prospective subject's best interest to enroll prior to the translation.
- The **best interest of the subject** means that it is necessary to ensure the rights, welfare, and safety of the prospective subject. For example:
  - A trial with therapeutic intent and there is insufficient time to obtain the translation due to the rapidity of disease progression or severity of disease
  - Delaying consent would pose undue hardship on the prospective subject, for example due to travel distance, need for time off work/away from home, etc.

(continued)

SFC Process When Research is GTMR (con't)

- If the PI determines it to be justified to proceed with informed consent prior to translating the consent, and the short form consent process is used, this determination and the reasons for it must be documented in the research record and/or CRIS as part of the consent note.
- Submit an RNI form in PROTECT within 7 calendar days
- Provide the justification for using the short form consent process in the description of the event (item 5 of the RNI form)
- If the non-English speaking person has agreed to participate using the short form process, the consent MUST be promptly translated into the subject's language
- After translation of the long form consent, submit it to the IRB along with the certificate of translation

(continued)

SFC Process – GTMR Studies (con't)

- After IRB approval, the translated long form should be provided to the subject.
- Include this information in a note in the medical/research record
- Ideally, this should occur no later than 30 days following enrollment.
- When the RNI is originally submitted, the Office of Compliance and Training will send a request for clarification asking for a response that reports the date that the translated long form consent is provided to the subject.
- Respond to the request for clarification with the date the translated long form is provided to the subject and the RNI will be closed out

4. Identify the categories that represent the new information: (check all that apply)

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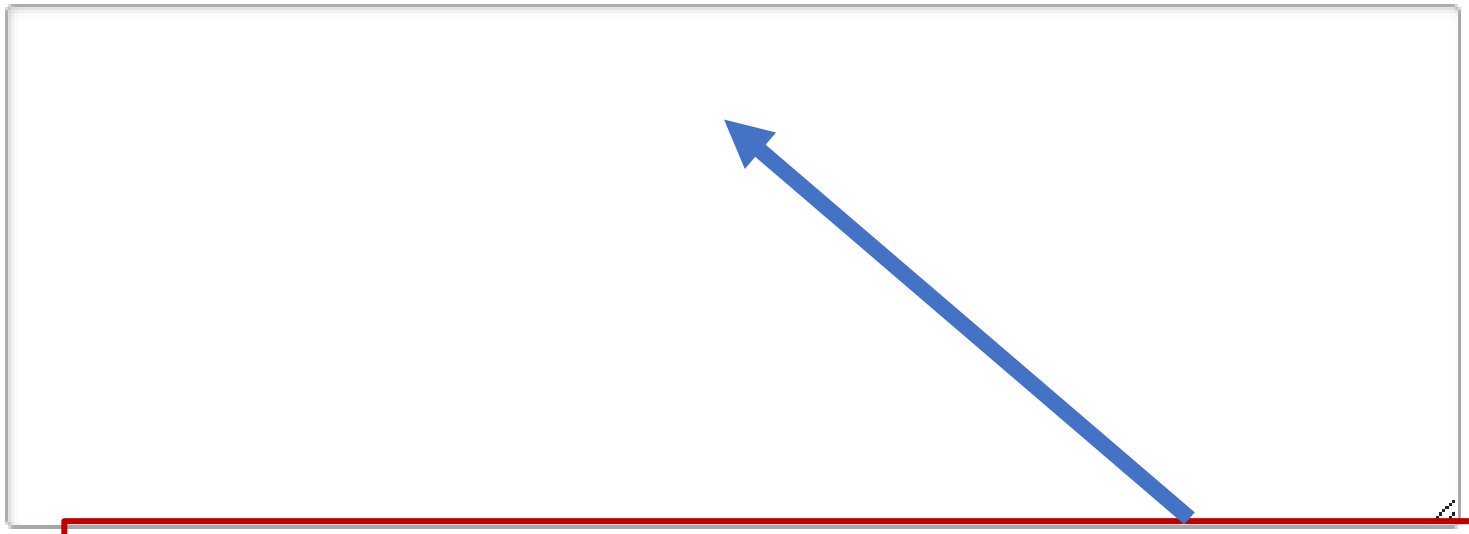

- Include justification for use of the short form process (for both MR and GTMR studies)
- Provide the language of the short form consent document that was used
- If protocol is **minimal risk**, include the number of times the short form consent in that specific language has been used
- If the protocol is **greater than minimal risk,** a request for clarification will be sent when the RNI is submitted asking you to add the date (in item #5) that the relevant translated long form was provided to the subject
- Reply to the request for clarification with the date the subject was provided the IRB approved translated long form

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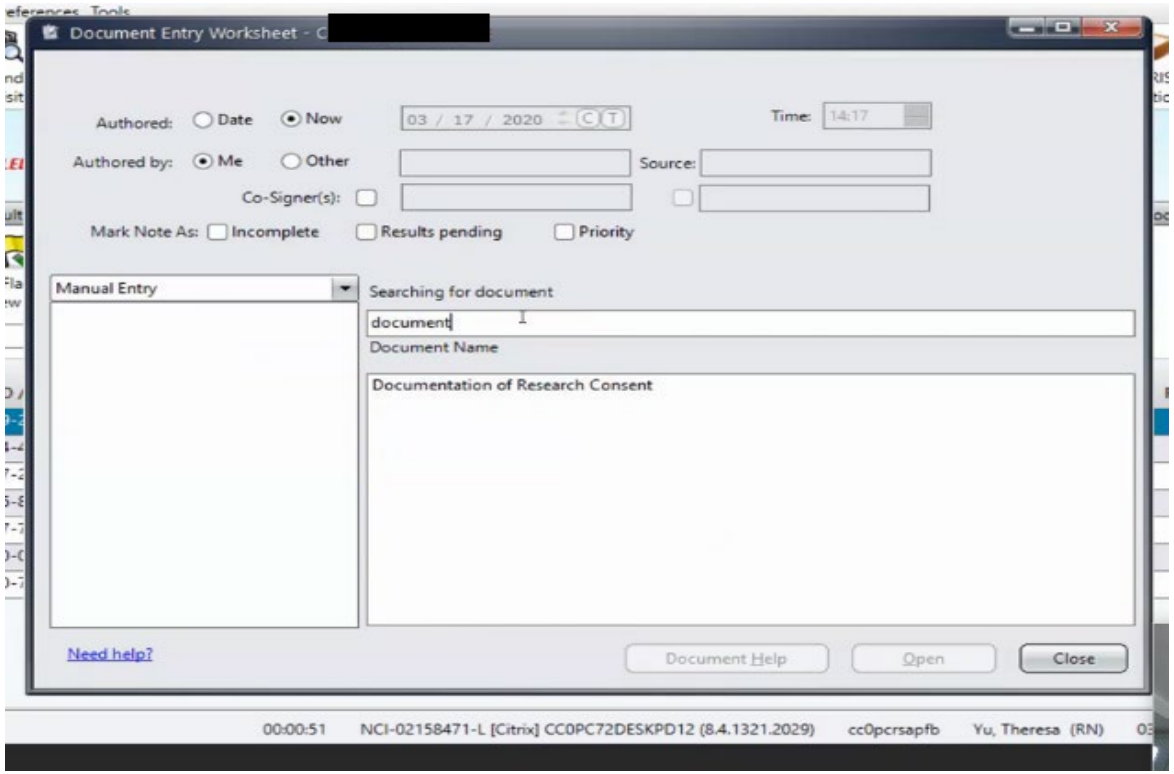
Documentation of IC Process

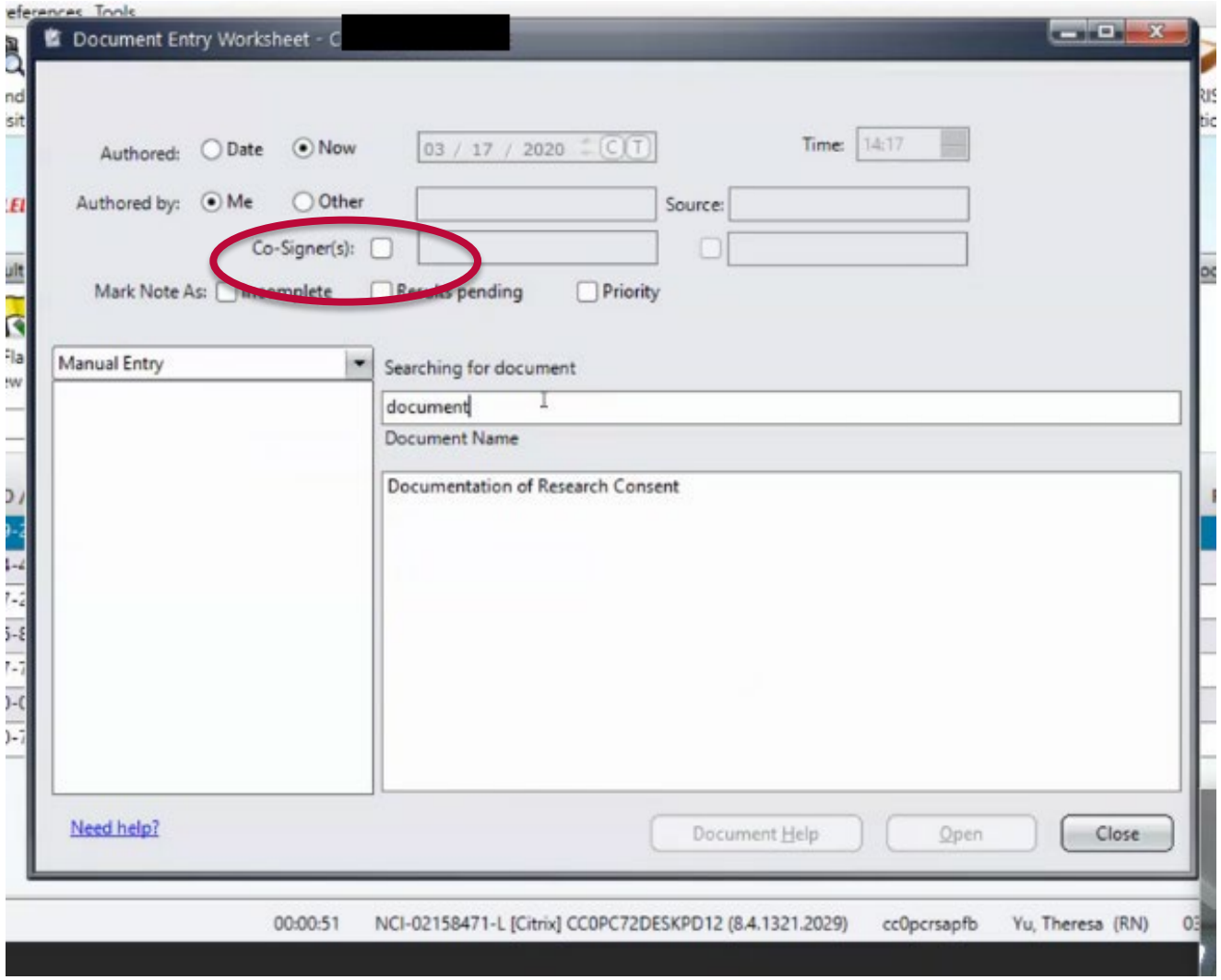
- Should be done by all who discussed the study with the subject
- Specific statement in CRIS addressing the informed consent process
  - HRPP Policy 301
- Typically note will include a statement that:
  - A discussion occurred
  - All questions were reviewed and answered to individual's satisfaction
  - A copy of the signed IC document was given to the subject
- CRIS has an IC process template progress note
- Note in research record for field cohort subjects

Consent Note in CRIS

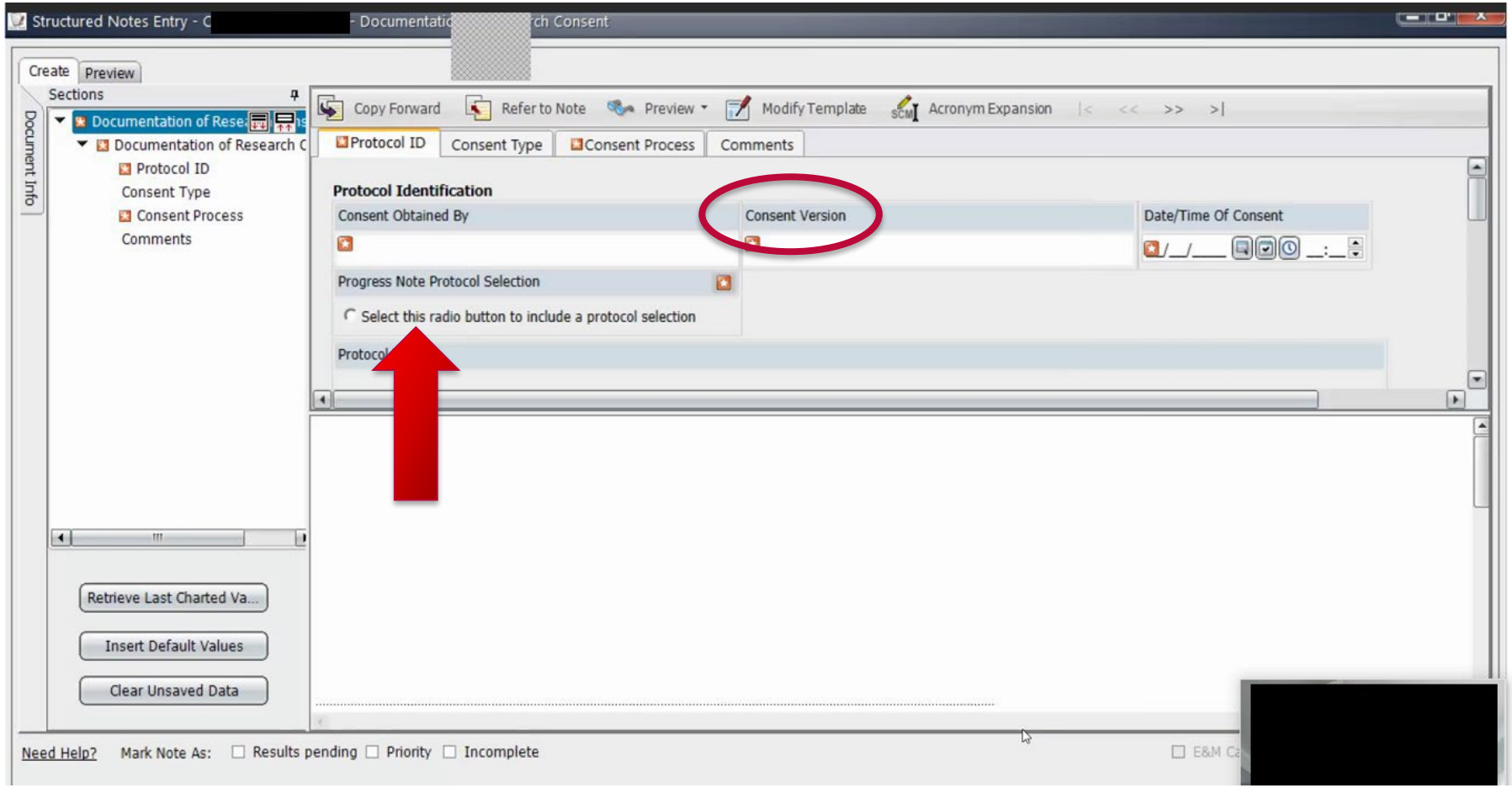
- Structured Note Titled: *Documentation of Research Consent*
  - Search function



Consent Note: Co-signature



Consent Note: Sections of the Note



- On first page

MEDICAL RECORD	CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY

PRINCIPAL INVESTIGATOR: James Gulley, M.D., Ph.D.

STUDY TITLE: Data Collection, Clinical Care and Interventions in CCR, NCI

STUDY SITE: NIH Clinical Center

Cohort: Standard

Consent Version: 08/09/2021

WHO DO YOU CONTACT ABOUT THIS STUDY?

James Gulley, M.D. by phone at 301-480-7164 or by email at gulleyj@mail.nih.gov

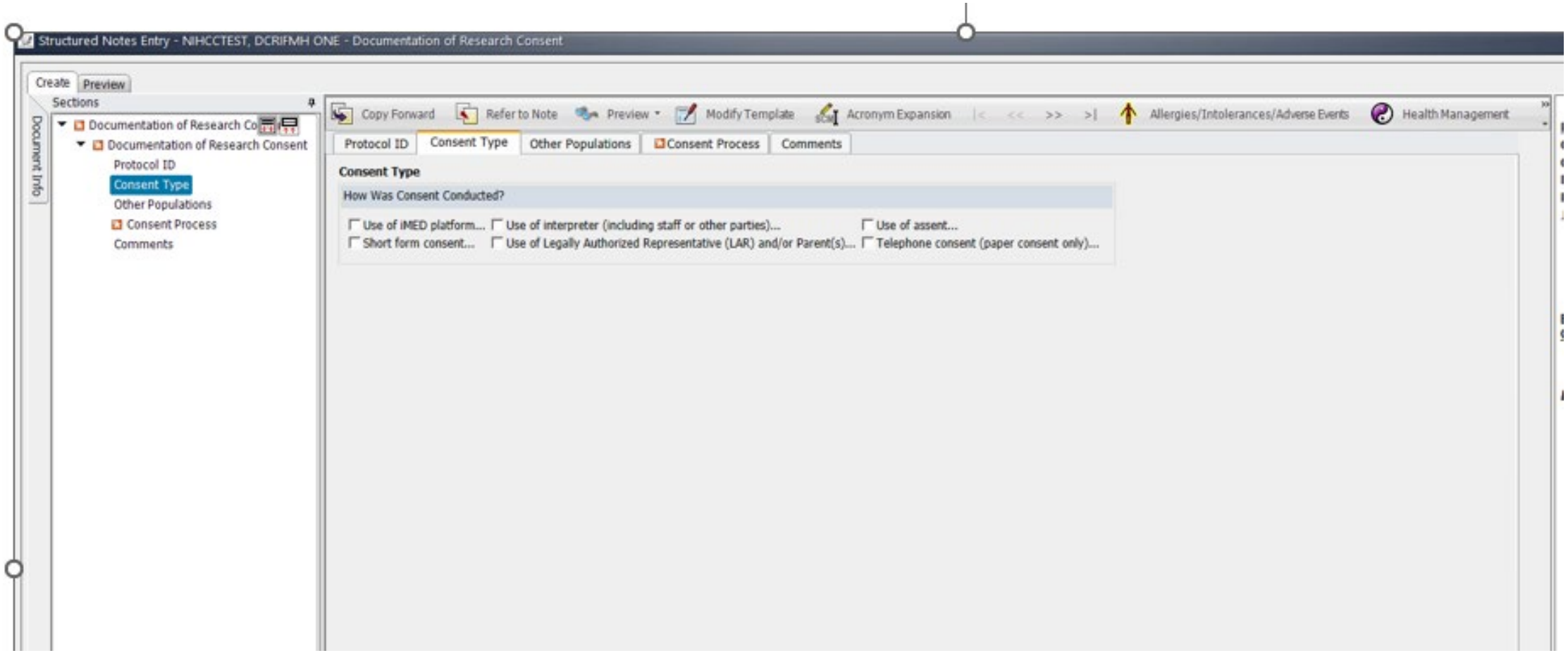
- Footer of each page

PATIENT IDENTIFICATION | **Consent to Participate in a Clinical Research Study**
NIH-2977 (4-17)
File in Section 4: Protocol Consent (1)
Version Date: 08/09/2021
Page 1 of 7

IRB NUMBER: 04C0165
IRB APPROVAL DATE: 09/07/2021

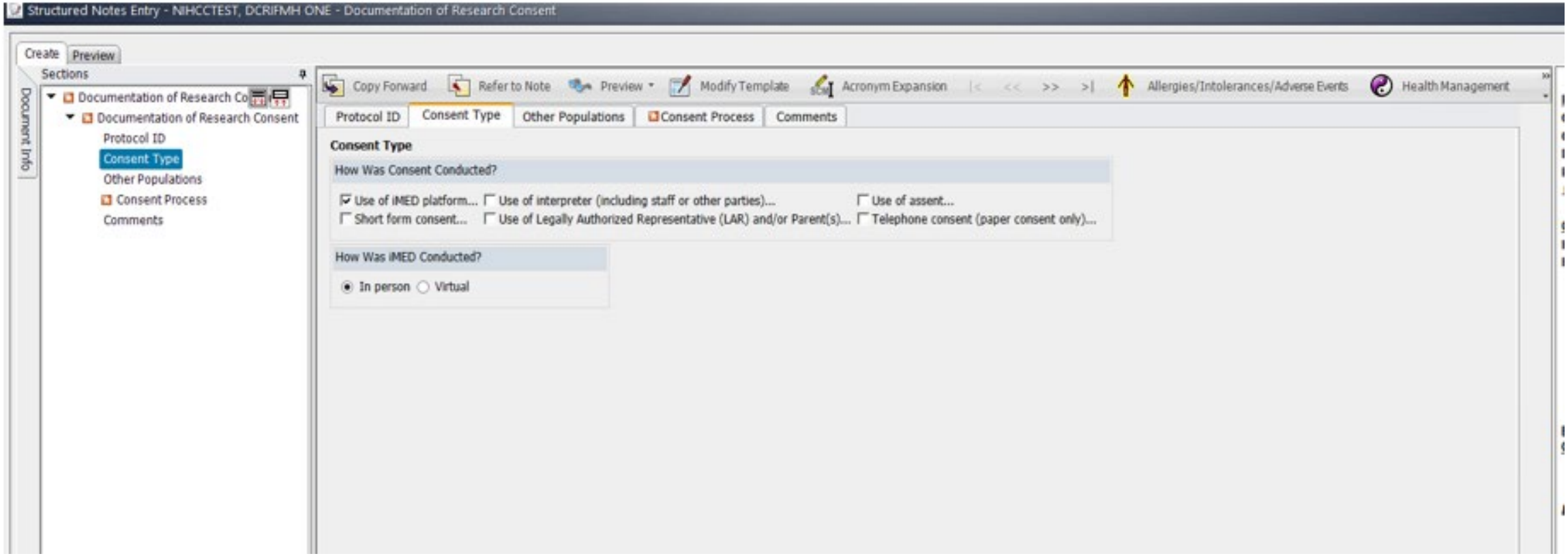
Consent Note: Consent Type

- Select ALL specific consent situation(s), when applicable
  - Only if in-person paper consent can this tab be skipped



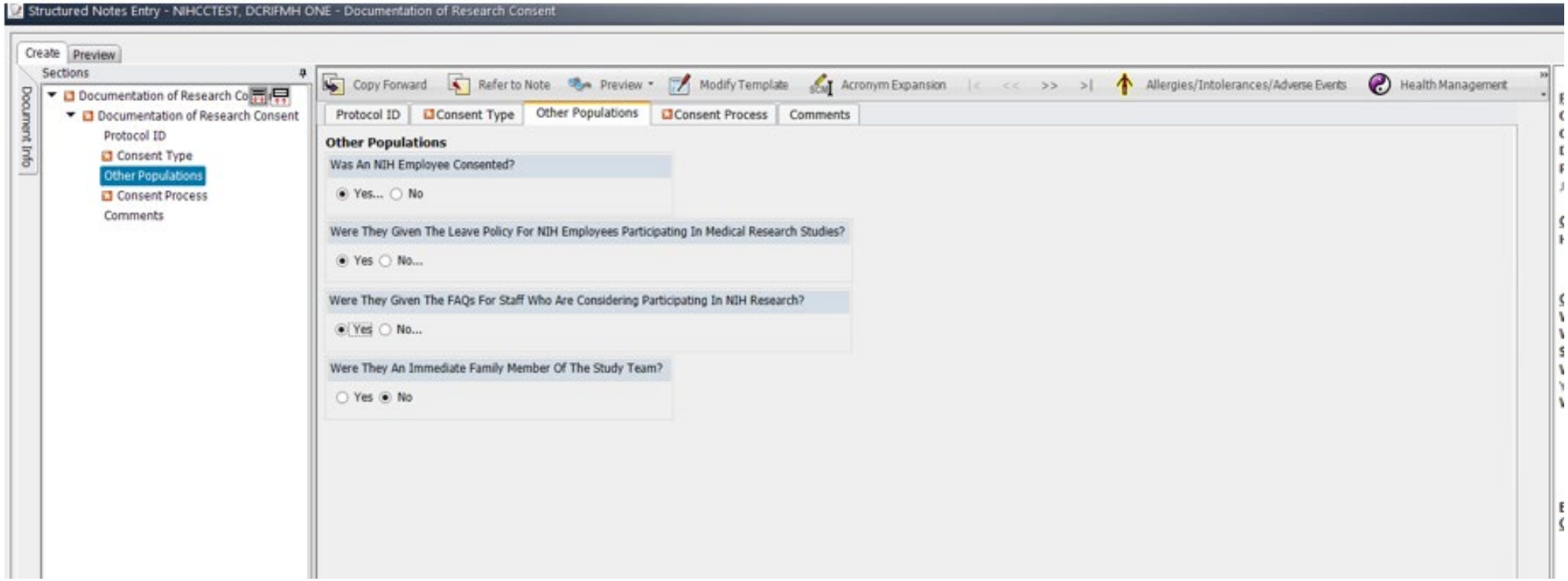
Consent Note: Use of iMed Platform

- In person
- Virtual – includes telephone consent



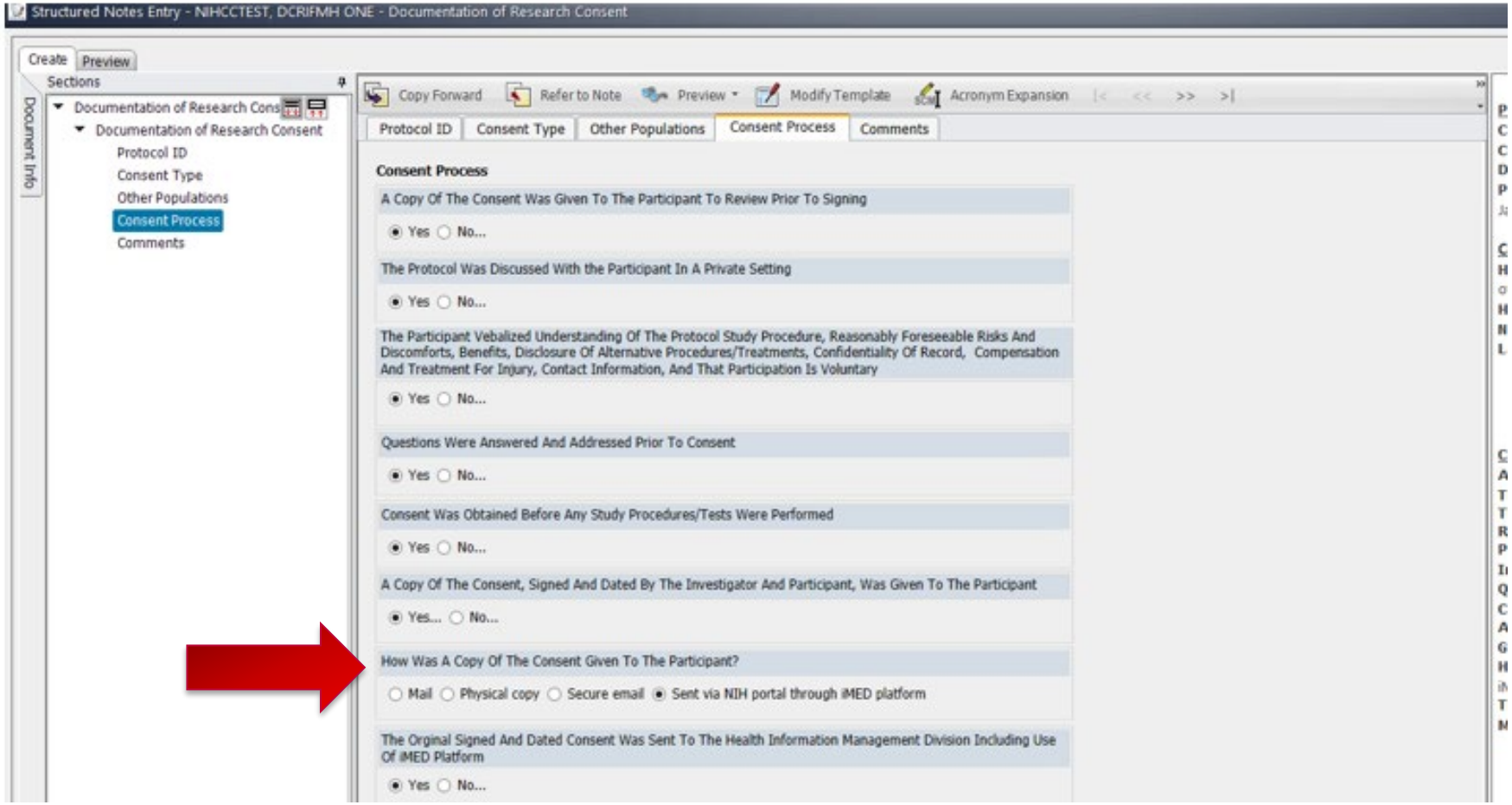
Consent Note: Other Populations

- Enrollment of NIH Staff
  - NIH HRPP Policy 404 has requirements
- Enrollment of family members of protocol study team
  - Restrictions on who can obtain consent



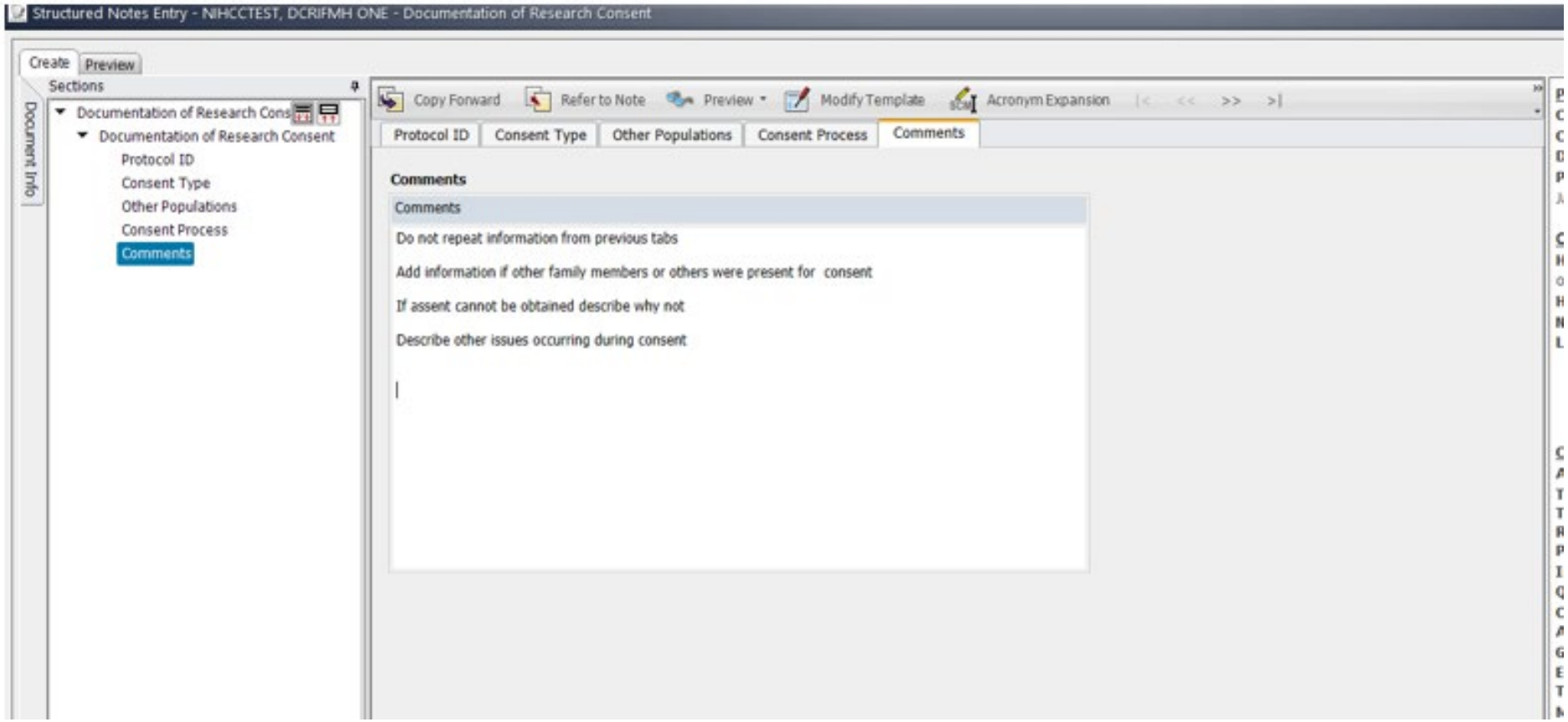
Consent Note: Consent Process

- Must select “Yes” or “No”
  - If “No,” text box will appear for explanation



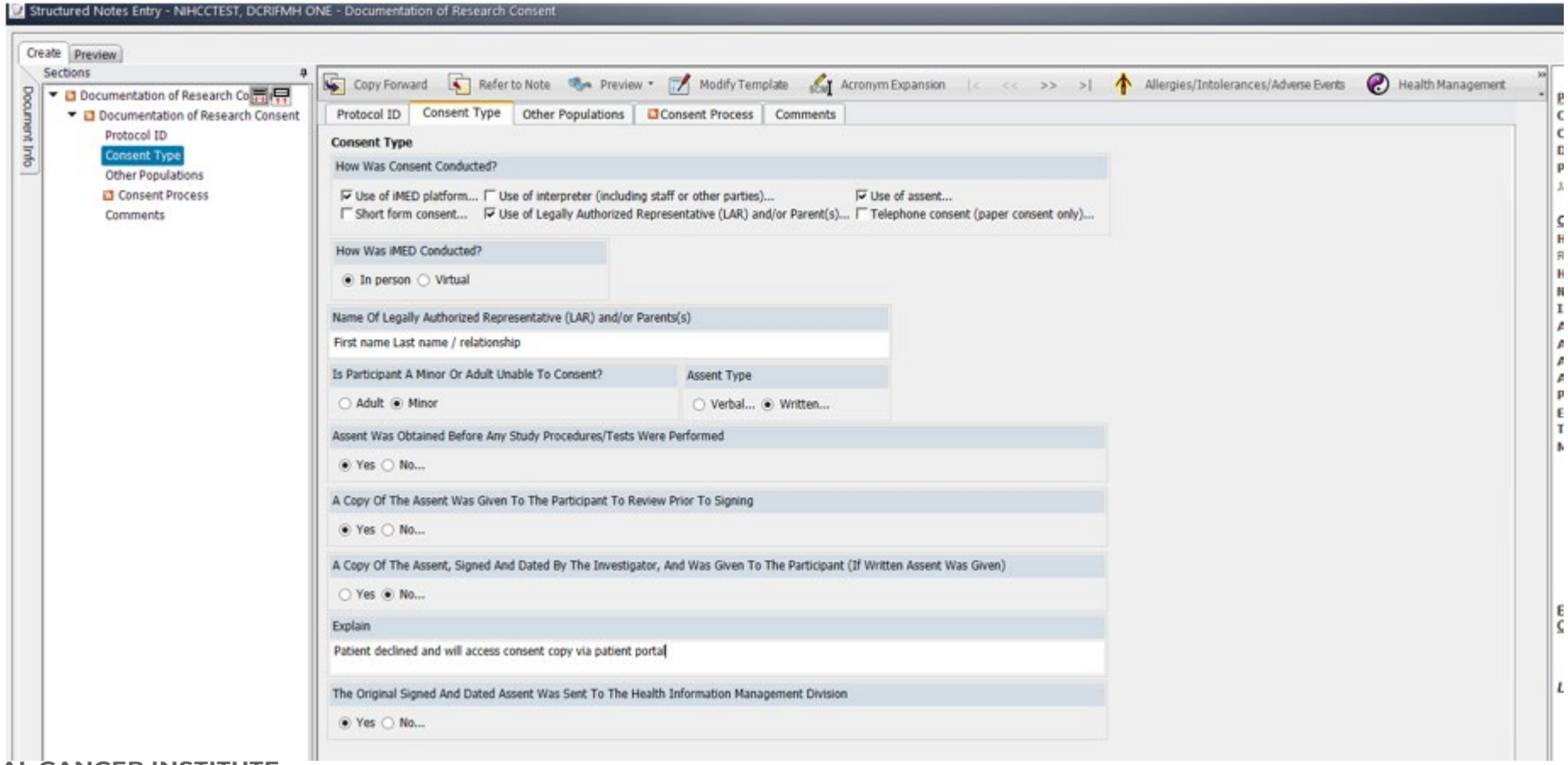
Consent Note: Comments

- For additional information
- DO NOT repeat information from other sections
- DO NOT include information about eligibility
- If assent cannot be obtained, describe why

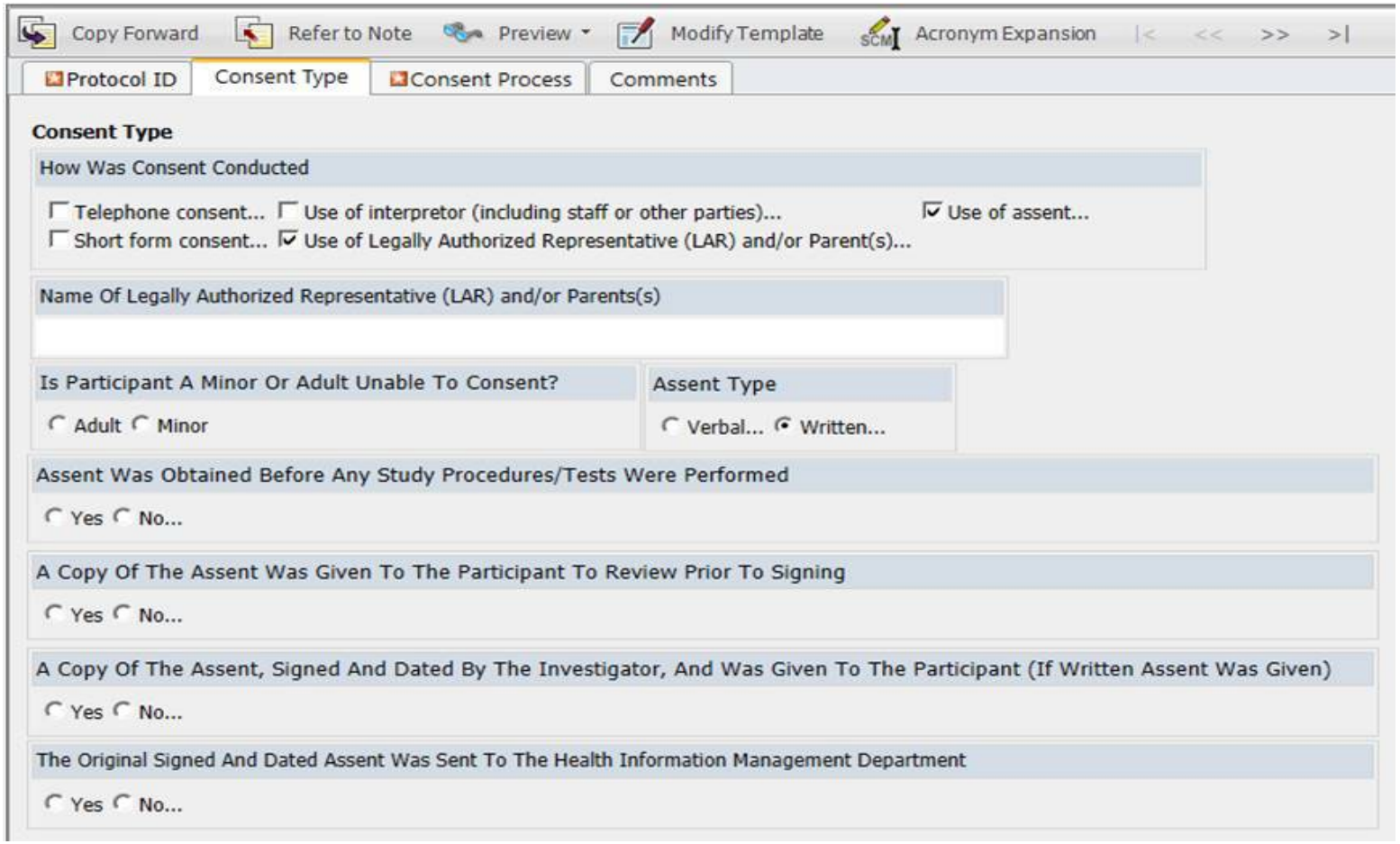


Consent Note: Enrollment of Child or Adult Unable to Consent

- Use of LAR and/or parents
- Assent process: verbal or written

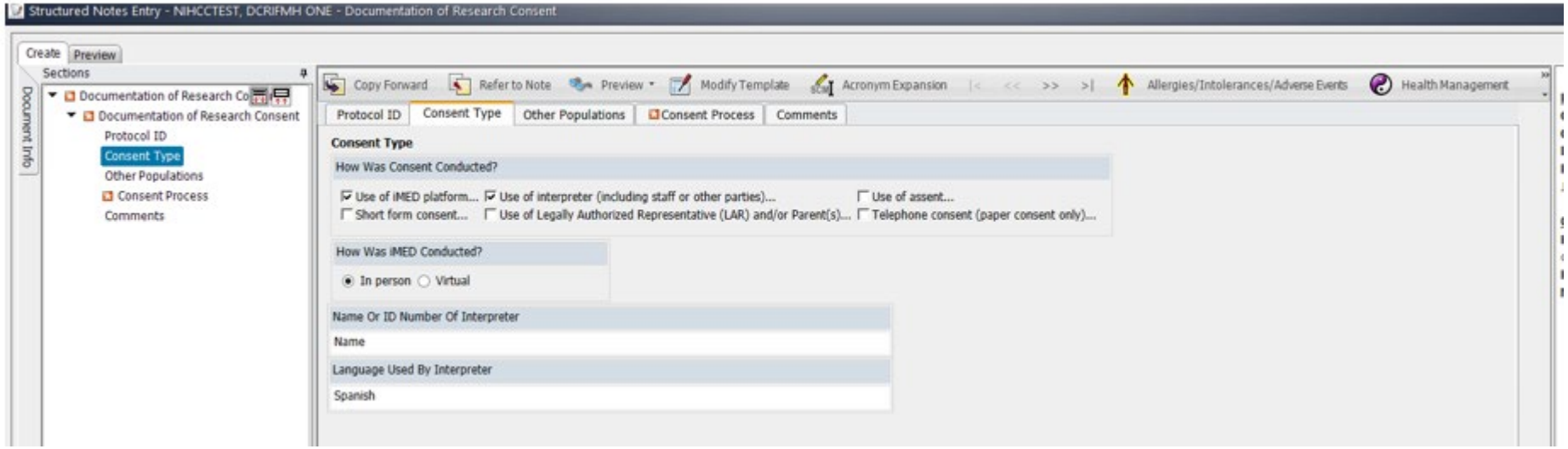


Consent Note: Written Assent

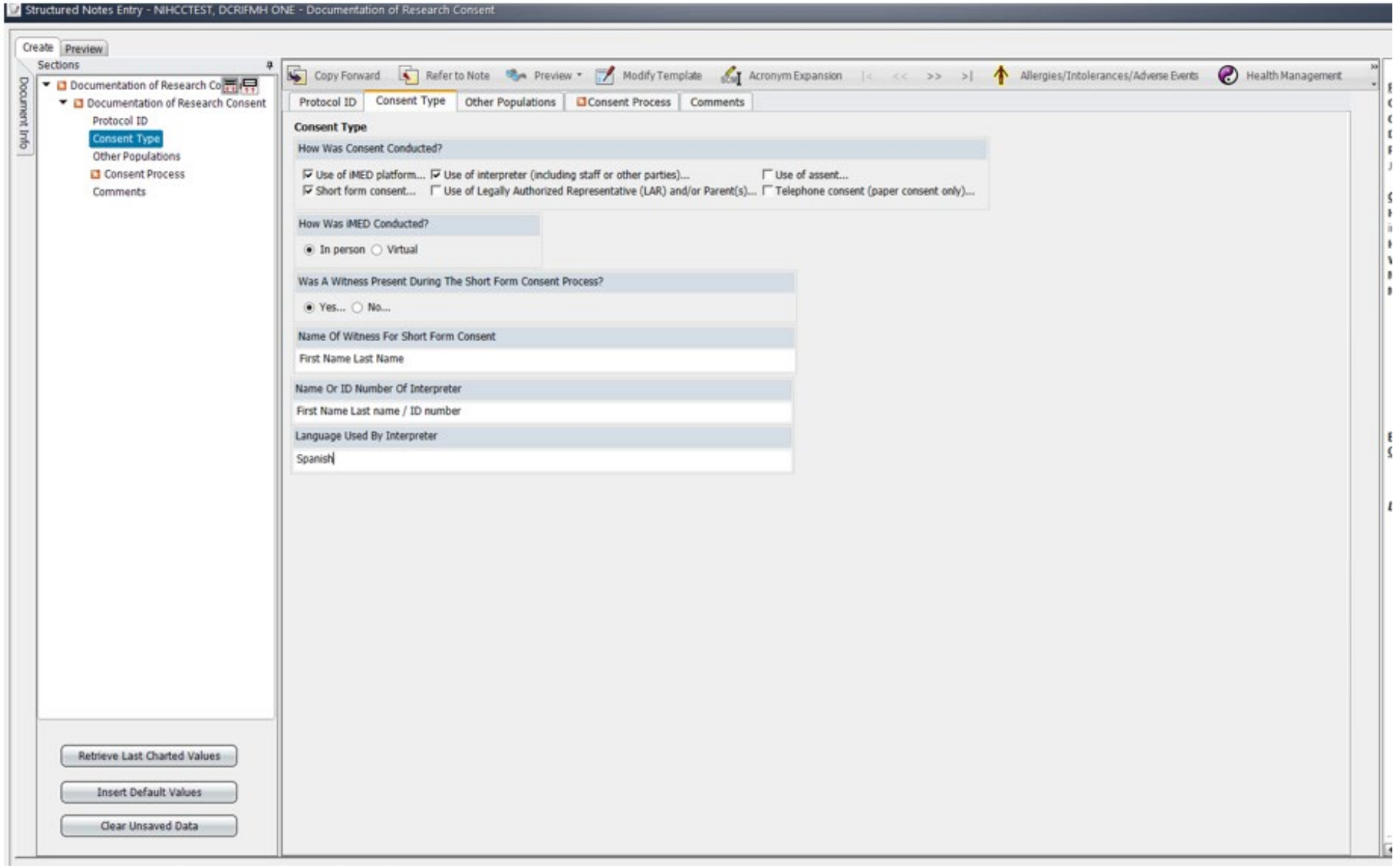


Consent Note: Long Form Translation

- Only select “Use of interpreter”
- If study team member is bilingual, must still select “Use of Interpreter”



Consent Note: Short Form



Additional Information

- NIH HRPP Policies:
  - 3014-301 - Informed Consent
  - 3014-303 - Intramural Research Program Telehealth Requirements
- OHSRP Guideline-Enrolling Non-English Speaking Subjects (1.31.2024)
- OHSRP Guidance for Protocol Language Regarding the Consent Process and Remote Consent
- OHSRP FAQs: "General and short form consent processes"
- CITI course: Informed Consent: A Focus on the Process (can be added as an optional session to view via the user's NIH CITI account accessed here)
- Investigator Seminar Series May 5, 2023: *Consent Forms and Processes: What Investigators Need to Know.* Slides and Video

Thank You!