

## Recent Changes Involving Informed Consent

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Many thanks to Theresa Yu for her assistance with this presentation!



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## Objectives

- Describe the recent changes to the following:
  - Documentation of Research Consent note
  - Witness signature
  - Short form consent process
    - Witness requirement
    - Embedded questions on long form
    - NIH Administrative Section
    - Assent for non-English speaking minors
  - Informed consent process via telephone
- Discuss the new Continuing Review requirement for a recent signed informed consent document



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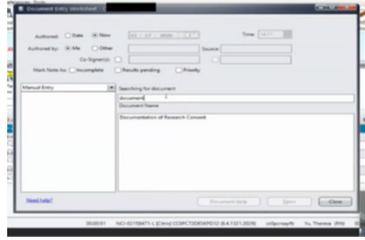
## New CRIS Note: Documentation of Research Consent Process



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## New Consent Note in CRIS

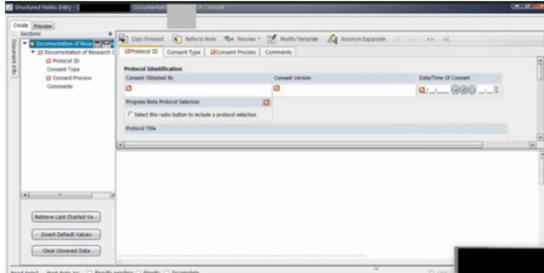
- Went live Jan 21, 2020
- Title: *Documentation of Research Consent*
- Search function




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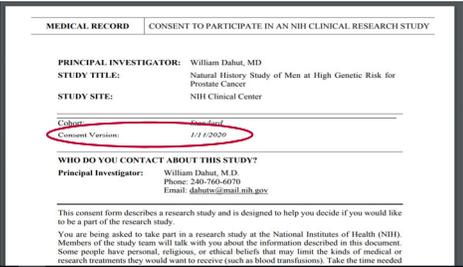
## New Consent Note in CRIS

- New sections for note
  - Protocol ID tab




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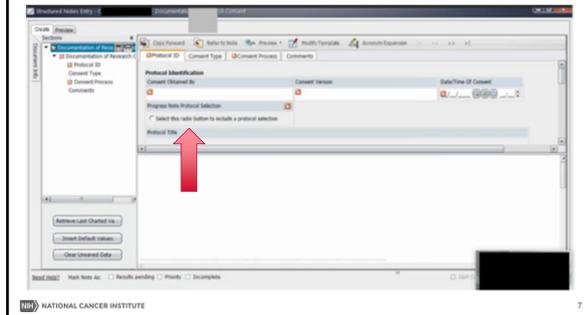
- Use consent version noted on first page




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### New Consent Note in CRIS

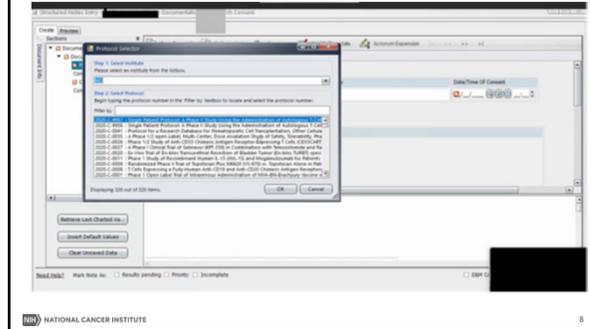
- Protocol ID tab
- Click on button to select from list of protocols



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### New Consent Note in CRIS

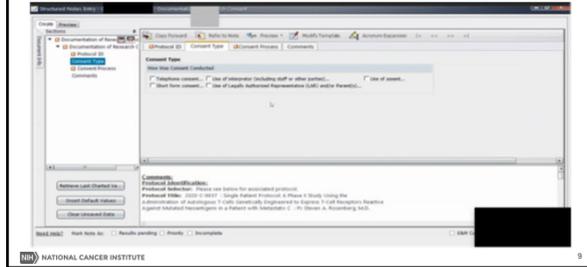
- Enter "NCI" to see list of active protocols



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### New Consent Note in CRIS

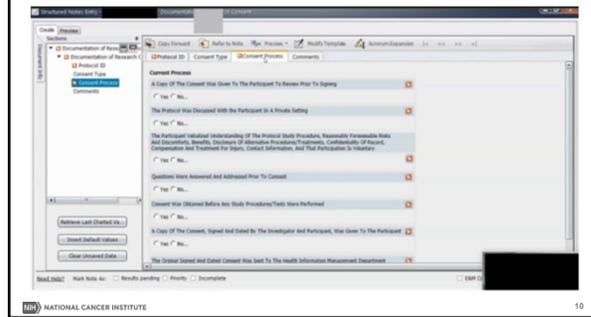
- Click tab or ">" to advance to Consent Type
- Select specific consent situation, if applicable
  - If none apply, click on tab or ">" to advance to Consent Process



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### New Consent Note in CRIS

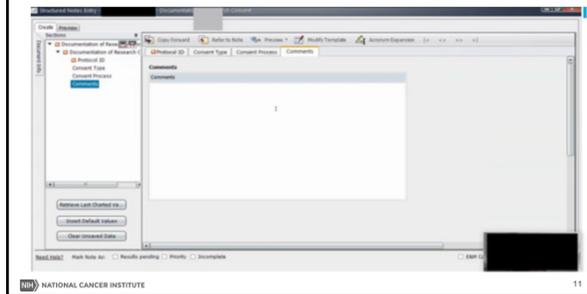
- Consent Process – must select "Yes" or "No"
  - If "No," text box will appear for explanation



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### New Consent Note in CRIS

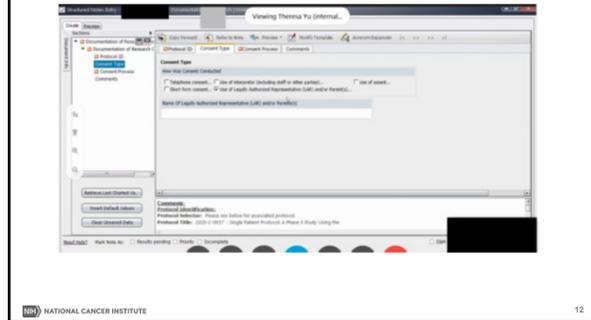
- Comment section for additional information
  - DO NOT repeat information from other section
  - DO NOT include information about eligibility



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### New Consent Note in CRIS

- Use of LAR, including parental consent for minor



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## New Consent Note in CRIS

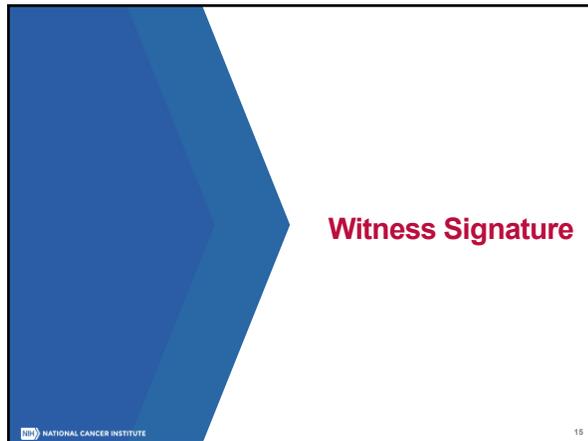
- Use of assent process for minor or adult unable to consent – verbal assent

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## New Consent Note in CRIS

- Use of assent process for minor or adult unable to consent – written assent document

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## Witness Signature

- Effective January 15, 2019, a witness signature is no longer required when using the long-form consent process
  - Including long-form consents translated into another language – a witness is NOT required
- Per Federal Regulations, a witness to the short-form **process** is required
  - Short-form consents for non-English speaking patients
  - Short-form English consent for blind or illiterate patients
  - IRB must approve the use of short-form for blind or illiterate patients

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## Changes to Short Form Consent Process – non-English Speaking

- Witness must be present for the entire informed consent discussion/process and sign both the short form and the long (English) form
  - It is preferable that the interpreter serve as a witness, this is NOT required by regulation
- When telephone interpreter is used, another person who speaks English must be present during the informed consent process and that person will sign as a witness

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### Short Form – Who Signs What?

- Short form is signed by the patient and the witness
- Long form is signed by the investigator and the witness
  - Patient signature line is left blank on long form

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### Short Form – Embedded Questions in Long Form

- Investigator obtaining consent answers on behalf of the patient
- Interpreter asks the patient the embedded question(s) and tells the investigator their response
  - Investigator indicates the response on the long form by initialing the patient's response using the investigator's initials
- If patient declines to answer, the embedded question(s) are left blank
- Neither the interpreter nor the patient should record a response for the embedded questions
- The *Documentation of Research Consent* note must clearly explain the review and response of embedded questions

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### NIH Administrative Section

- Both the long form and the short form have a NIH Administrative Section to document the use of an interpreter during the informed consent process
  - Long form section is in English
  - Short form section is in the language of the short form
- Section on long form is completed by the investigator
- Section on short form is completed by the interpreter or investigator
  - If using the telephone language line, the investigator should select the second option on BOTH forms and include the ID code

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### NIH Administrative Section

- "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: \_\_\_\_\_."
- Both forms must contain the same selection
  - If there is an error, the research team can correct, date and initial correction. You do not need to provide another copy to patient if a correction is made.

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### Informed Consent Templates

- "Old" IC template
  - Will NOT contain NIH Admin Section
- "New" IC template
  - Contact PSO if your ICD does not contain NIH Admin Section

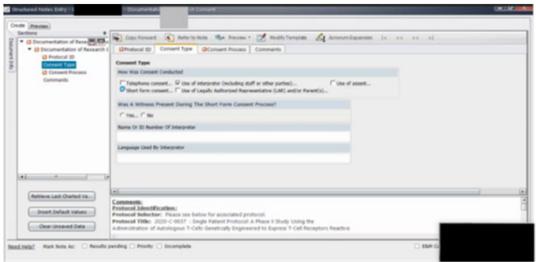
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### New Consent Note in CRIS

- Use of short form with interpreter
  - If "No" is selected for witness, a text box will appear for explanation

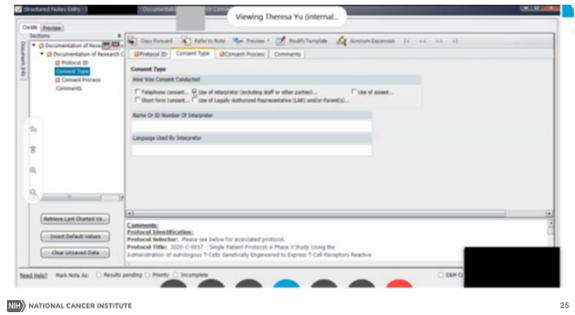


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### New Consent Note in CRIS

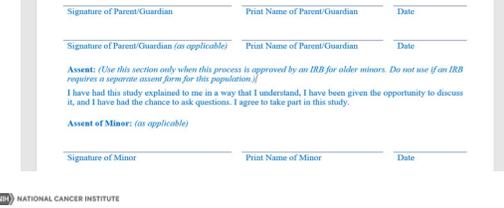
- For translated long form, only select "Use of interpreter"



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### Assent for non-English Speaking Minors – Translated Long Form

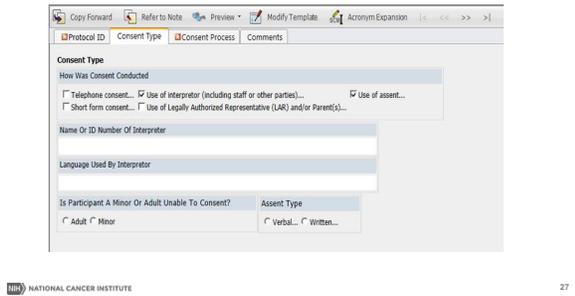
- If the protocol requires written assent and the long form has been translated into another language, the minor can sign the Assent Section on the long form



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### New Consent Note in CRIS

- Use of assent – translated long form
- Select "Verbal" Assent



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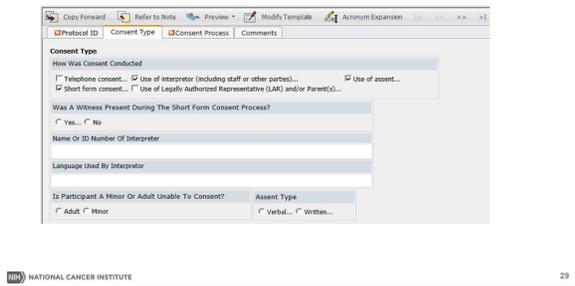
### Assent for non-English Speaking Minors – Short Form Process

- If the protocol requires assent and you are using the short form process, the minor can verbally agree (or not) to participate
- The non-English-speaking minor DOES NOT sign the English assent document because the minor cannot read what he/she is signing
- The *Documentation of Research Consent* note must describe the assent process, including that the minor does not speak/read English and cannot sign any document

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### New Consent Note in CRIS

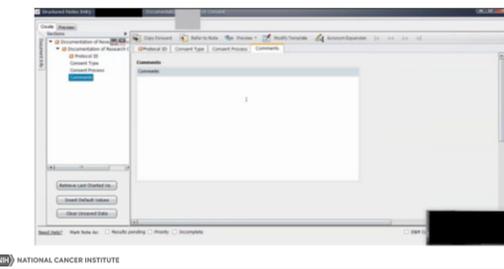
- Use of assent process
- If short form process with non-English speaking minor and no translated assent document, select "Verbal"



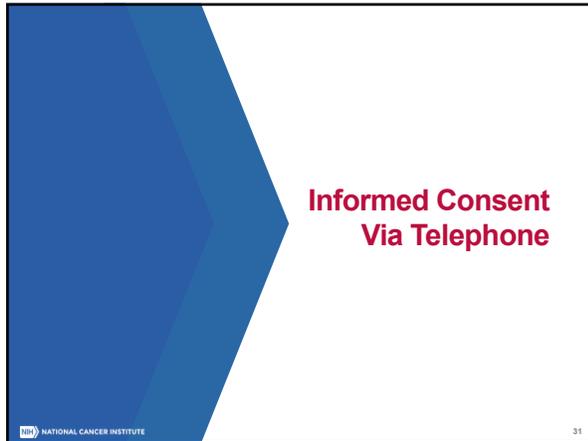
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### New Consent Note in CRIS

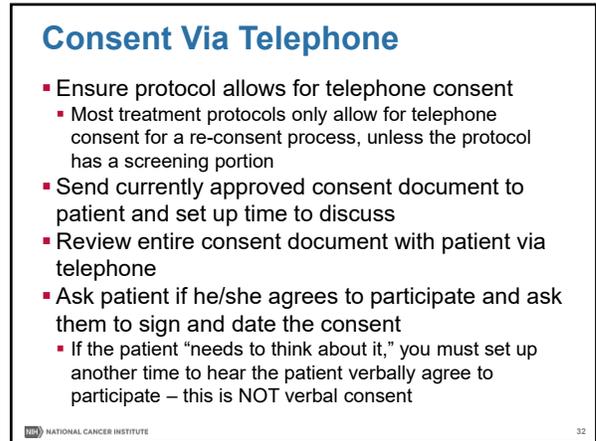
- Use of assent process – non-English speaking minor
- Explain in Comments section that minor does not speak English so verbal assent was obtained



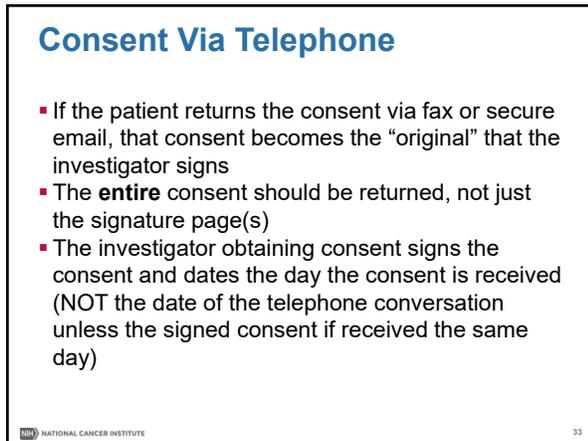
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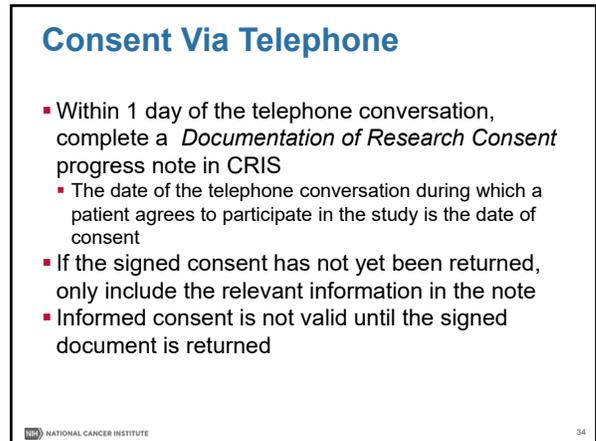
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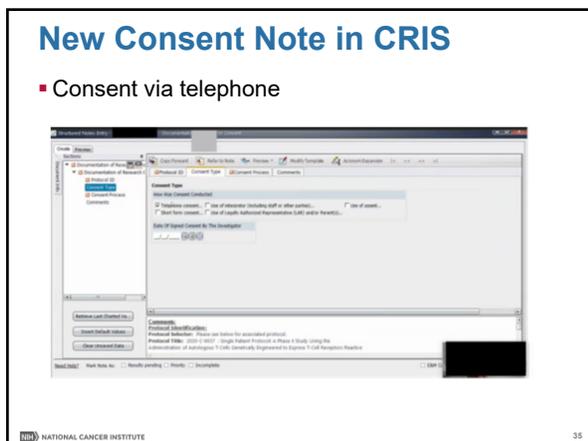
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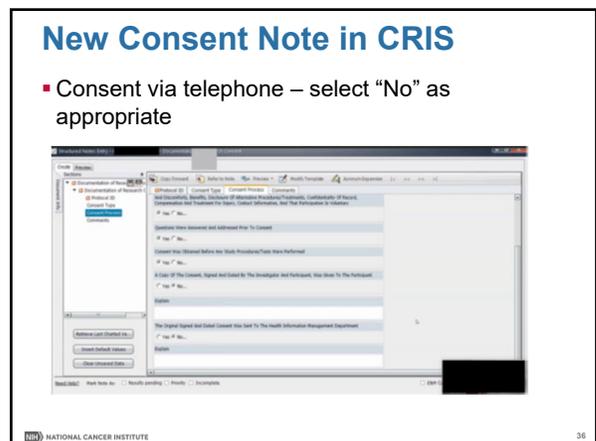
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### Consent Via Telephone

- When signed consent is returned, write a research nurse note and indicate that:
  - Signed consent was returned
  - Investigator signed document
  - Copies were made of the fully-signed document and one was sent to the patient
  - Original fully-signed document was sent to HIMD for scanning into CRIS
- Register the patient with the CRO within 24 hours of the signed consent being returned

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### Consent via Telephone – Short Form Process

- Send both the short form in the patient's preferred language and the English long form to the patient
- A witness to the entire telephone process must be present with the investigator obtaining consent – this can be the interpreter or another staff
- Discuss the consent with the patient via phone, using the interpreter
- Patient signs and dates the short form only and sends to the investigator
- Investigator and witness sign the long form on the day the patient agrees to participate
- Complete the NIH Admin Section on long form

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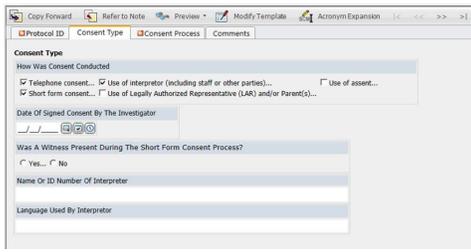
### Consent via Telephone – Short Form Process

- Within 1 day of the telephone conversation, document telephone consent process in CRIS – see slide 34
- When the signed short form consent is received, the same witness signs that consent and dates the day the short form is returned (NOT the date of the telephone conversation)
- Complete NIH Admin Section on short form
- Make copies of all signed documents (short and long forms) and send one copy to the patient
- Send original to HIMD for scanning into CRIS
- Document the return of the signed short form in CRIS – see slide 37

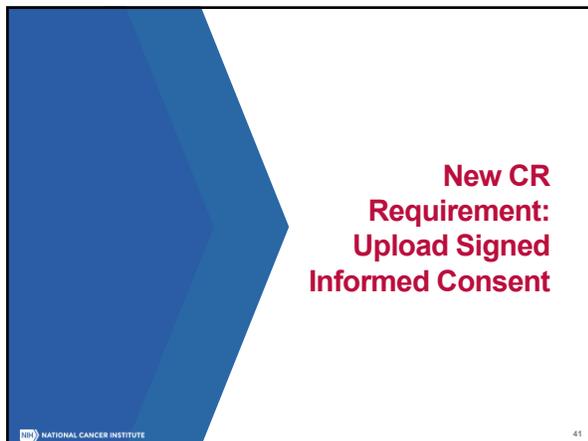
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### New Consent Note in CRIS

- Consent via telephone with short form and interpreter



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**New CR Requirement:  
Upload Signed  
Informed Consent**

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### CR Requirement

- Last ICD signed – each version, including assent, if used since last CR
  - If informed consent was not obtained during the CR period, please note this in the CR summary
- Must redact patient information (name, MR# and date of birth) from each page
  - On signature page, make sure to redact printed patient name and partially redact signature
- Do not redact investigator signature or any signature dates

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### Redact in Adobe

**MEDICAL RECORD** | **CONSENT TO PARTICIPATE IN AN NIH CLINICAL RESEARCH STUDY**

**Adult Research Participant:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

\_\_\_\_\_  
Signature of Research Participant

\_\_\_\_\_  
Print Name of Research Participant

2-3-20  
Date

**Legally Authorized Representative (LAR) for an Adult Unable to Consent:** I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I am legally authorized to make research decisions on behalf of the adult participant unable to consent and have the authority to provide consent to this study. As applicable, the information in the above consent was described to the adult participant unable to consent who agrees to participate in the study.

\_\_\_\_\_  
Signature of LAR

\_\_\_\_\_  
Print Name of LAR

\_\_\_\_\_  
Date

**Investigator:**

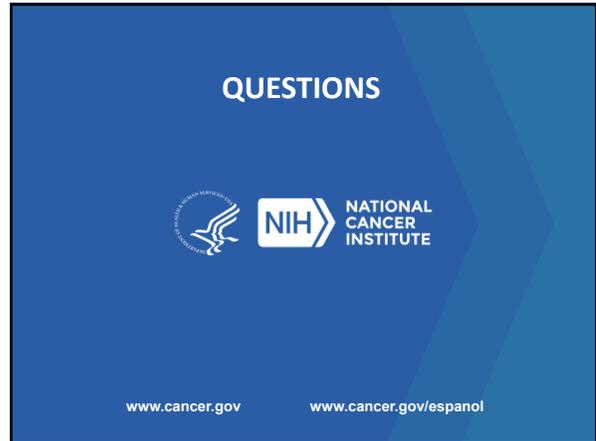
\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Print Name of Investigator

2/3/20  
Date

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