

Research



Tips to Avoid NC during IC

May 28, 2013



Before

- Make sure your consent matches your protocol
- Set up a filing system that works for you
- Customize your signature page(s)
- Add reminder tabs*
- Highlight*
- Only print what you need for each subject
- Confirm version date
- Don't pre-fill forms
- Review the form
- Know your consent form, know your study (and study staff)

Research

Printed Name of Research Subject

Age

Date of Birth

Signature of Research Subject

Date

Time

(Required unless research subject is under the age of 18 years and assent was not obtained for reason provided below)

Signature of Research Subject's Parent/Legal Guardian

Date

Time

(Required for research subjects under the age of 18 years)

~~Signature of Research Subject's Parent/Legal Guardian~~

~~Date~~

~~Time~~

~~(Required for research subjects under the age of 18 years when study poses more than minimal risk to the subject without the prospect of direct benefit)~~

Comment [11]: Delete this extra signature line if not required.

Signature of Person Obtaining Assent/Consent/Permission

Date

Time

Signature of Interpreter (if applicable)

Date

Time

☒ The child is 5 years of age or younger and assent is not required for participation in this research study.

☐ The child is between the ages of 6-10 years old and has been verbally assented to participate in this research study.

☐ In my opinion, the child is not able to assent to participate in this research study for the following reason:

Comment [12]: Edit Assent lines/boxes if certain ages are not being enrolled. Can also replace with statement "Assent has been waived for this study" and remove signature lines to prevent errors, when applicable.

Signature of Person Obtaining Assent/Consent/Permission

Date

Time



During (1)

- Make sure the appropriate staffer is obtaining consent
- Assure appropriate steps are taken for those who are non-English speaking, illiterate, cognitively impaired, minors, etc.
- Be sure to obtain all signatures and initials from subject or LAR and appropriate staff and don't forget the date

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During (2)

- Complete all optional portions
- Make proper corrections, if there are errors
- Obtain authorization in addition to consent
- Review the form before the subject leaves

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After

- Make notes to file to explain deviations from the norm
- Review the documents before filing
- Have a filing system that works for you and makes sense

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Examples



Research

Jennifer Mc Gaughey
Printed Name of Research Subject

10
Age

5/4/03
Date of Birth

Signature of Research Subject

Date

Time

(Required unless research subject is under the age of 18 years and assent was not obtained for reason provided below)

Signature of Research Subject's Parent/Legal Guardian
(Required for research subjects under the age of 18 years)

5-23-13
Date

Time

Jennifer Mc Gaughey
Signature of Research Subject's Parent/Legal Guardian

5-23-13
Date

10:44
Time

(Required for research subjects under the age of 18 years when study poses more than minimal risk to the subject without the prospect of direct benefit)

[Signature]
Signature of Person Obtaining Assent/Consent/Permission

5-23-13
Date

10:44
Time

Signature of Interpreter (if applicable)

Date

Time

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[Signature]
Signature of Person Obtaining Assent/Consent/Permission

5-23-13
Date

1:23
Time



Hallie Smith
Printed Name of Research Subject

6
Age

9-17-13
Date of Birth

Signature of Research Subject

Date

Time

(Required unless research subject is under the age of 18 years and assent was not obtained for reason provided below)

Signature of Research Subject's Parent/Legal Guardian
(Required for research subjects under the age of 18 years)

Date

Time

Hallie Smith
Signature of Research Subject's Parent/Legal Guardian

9-17-13
Date

1:15 PM
Time

(Required for research subjects under the age of 18 years when study poses more than minimal risk to the subject without the prospect of direct benefit)

[Signature]
Signature of Person Obtaining Assent/Consent/Permission

9/17/13
Date

1:18 PM
Time

Signature of Interpreter (if applicable)

Date

Time

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☐ In my opinion, the child is not able to assent to participate in this research study for the following reason:

Signature of Person Obtaining Assent/Consent/Permission

Date

Time



If there is NC, can I use the data?

Re-Consent	No Re-Consent
Signature missing from consent or assent form	Person Obtaining Consent (POC) was CITI certified, but not study staff and the PI provides a statement that the POC was adequately trained on the study
Signed by someone other than the parent or legal guardian	Any minor issues with date and or time
POC was not CITI certified and not approved study personnel	Expired consent used, but no changes to the risk level or subject care/study visits
Expired consent used and there were changes to the risk level and or subject care/study visits	Missing witness signature (unless required by the regulations or the study sponsor)
POC signature is missing	

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Questions



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