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## Table 1. Summary of Changes

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Summary of Changes</th>
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<td>01.20</td>
<td>30Nov2018</td>
<td>Original document</td>
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1 UNDERSTANDING GUARDIANSHIP GUIDELINES

The following information provides guidelines to assist research administrators with navigating through guardianship, custody, and unusual familial situations within a participant population when consenting for the ECHO-wide Cohort Data Collection Protocol.

- In general, the ECHO Program does not require legal papers to reflect guardianship. Study personnel may ask, “Are you the guardian of the child?”
- If a pregnant woman consents to study participation but intends to place her baby for adoption, she retains the ability to give consent for the baby until the adoptive parents have legal custody and the child is living with them.
- If a new family has adopted a child, the research administrator may ask the biological mother for contact information for the new adoptive parents. The new adoptive parents would need to consent for ECHO-wide Cohort Data Collection Protocol.
- If a custodial parent is incarcerated, another custodial parent or legal guardian of the child can consent. Do not contact incarcerated persons.
- If a custodial parent loses custody of the minor child, the site must establish who has legal guardianship of the minor child. The legally designated guardian should sign a new permission form.
- In all cases, participation by incarcerated research participants should be deferred until the participant’s release.
- Consenting should not occur if guardianship status is in process or being determined.
- The Respondent Roster for the Child form, located on the ECHOPortal, is completed by cohort study staff to list all respondents who consent to contribute data about an enrolled child. The roster code should be used for the “other respondent” code of form headers if the respondent is neither the participant nor the biological parents of the child.
  - Data collected include the following:
    - Initials
    - Date of birth
    - Date of consent
    - Sex
    - Relationship to child
    - Average number of days per week or days per month this person provides care for the child
  - Relationship-to-child options include the following:
    - Stepparent
    - Adoptive parent
    - Foster parent
    - Full sibling
    - Half sibling
    - Non-biologically related sibling
    - Grandparent
    - Aunt or uncle
    - Cousin
    “Other” relationship may be described on the form.

NOTE: For more details about guardianship guidelines, see Figure 1. Decision Tree for Guardian Consent—provided by the Safe Passage (PASS) Cohort.
Figure 1. Decision Tree for Guardian Consent

- Does the individual identify themselves as the guardian of the child?
  - NO
    - This person should not consent for ECHO-wide Cohort Protocol.
      - Does this person know the guardians of the child and/or have contact information for them?
        - YES
          - Thank the individual
          - Document per Cohort procedures.
        - NO
          - Ask:
            - Is the guardianship status still in process?
            - Is Child Protective Services involved?
            - Is the child currently under a Present Danger Plan?
  - YES
    - Ask:
      - Is the guardianship status finalized?
      - Is the child currently living with this individual?
        - YES
          - This individual may consent for ECHO-wide Cohort Protocol.
            - If multiple children are involved, verify which children are under custody of this individual—consent only for the children under the custody of that individual.
            - If possible, obtain contact information for guardians of the other children who were enrolled in the Cohort Protocol within this same family.
            - Example: If mother has custody of some children who were enrolled in the Cohort Protocol, but not all, she may consent for those who were enrolled in the Cohort Protocol of whom she currently has custody.
        - NO
          - This individual should not consent for ECHO-wide Cohort Protocol.
            - Identify who the individual is in relation to the child and if they know who the current guardian is.
            - Obtain any relevant contact information.
2 ENSURING PARTICIPANT COMPREHENSION

- Ensuring that a potential participant understands the research and the risks and benefits involved is the responsibility of the cohort site principal investigator (PI) or research administrator, not the potential participant.
- During the consent process, the cohort site PI or research administrator should answer and ask questions—asking questions can lead to a more detailed discussion and elicit more questions from the potential participant.
- This type of discussion can help the cohort site PI or research administrator assess the potential participant’s understanding of the study. Asking open-ended and non-directive questions rather than asking for yes or no answers will encourage discussion.

Table 2. Examples of Open- vs Closed-Ended Questions

<table>
<thead>
<tr>
<th>Open-ended</th>
<th>Closed-ended</th>
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<tr>
<td>In your own words, tell me the purpose of the study.</td>
<td>Do you understand the purpose of the study?</td>
</tr>
<tr>
<td>What else would you like to know?</td>
<td>Do you have any other questions?</td>
</tr>
<tr>
<td>Tell me the possible risks of being in the study.</td>
<td>Do you understand the risks of being in the study?</td>
</tr>
</tbody>
</table>

3 REQUIRING SIGNATURES FOR INFORMED CONSENT

After the research administrator has answered all of a participant’s questions and they have agreed to participate in the study, the participant, parent, or legal guardian should sign and date the most current approved informed consent form (ICF).

Assent for younger children no longer includes the child’s signature. Assent for older children should be signed by the child, though that will depend on each individual child’s abilities.

- **HIPAA (Health Insurance Portability and Accountability Act) Research Authorization**: At the same time the research administrator obtains written consent for participation, if the institutional review board (IRB) requires a separate HIPAA research authorization, the participant should also sign and date this document.
- **Cohort Site PI or Research Administrator**: The research administrator who oriented and consented the participant must also sign and date the ICF.
  - Usually, the cohort site PI or research administrator, participant, and impartial witness (when required) sign at the same time.
  - The cohort site PI or research administrator’s signature cannot pre-date the participant’s signature.
- **Copy of Consent Form**: Research administrator should provide the participant with a signed copy of the ICF for reference (e.g., scheduling of procedures and emergency contact information).
4 MAINTAINING AND RETAINING SOURCE DOCUMENTS

Research administrators are responsible for retaining all regulatory documents and source documents, including all ICFs and assent forms signed by participants. The site will maintain the original ICF and provide a copy of the signed ICF to the study participant, parent, and/or legal guardian.

- For minor children, research administrators should:
  - Evaluate and document current capacity to give assent in the study record, prior to the assent discussion.
  - Include documentation on how they evaluated competency. Because “assent” means a child’s affirmative agreement to participate in research, (45 Code of Federal Regulations [CFR] 46.402[b]), the child must actively show their willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.
  - Indicate the time and date that they obtained consent or assent from the participant and/or parent/legal guardian.

- For all participants, research administrators should document the following:
  - Time and date of the consent discussion, according to institutional policy.
  - Name of person conducting the consent discussion and the names of the persons involved in the consent discussion (e.g., parent, minor child, guardian, witness).
  - Statement confirming that research administrators performed no study-specific procedures prior to obtaining informed consent, parental/guardian permission, and/or assent.
  - Statement confirming that research administrators gave the participant a copy of the signed ICF and/or assent documents.

5 CONSENTING REMOTELY

- If the potential participant cannot be present for an in-person visit, research administrators may complete the consent discussion via telephone or via electronic consent (e-consent).
- Research administrators should provide applicable consent documents to the potential participant via email, mail, fax, etc., prior to the consent discussion. Research administrators may utilize e-consents via an IRB-approved, HIPAA-compliant, computer-based platform rather than the traditional paper-based documentation.
- Research administrator must review the ICF and conduct a complete consent discussion with the participant over the telephone.
- Independent witness (an individual at the research site) must participate in the telephone call to attest to the understanding of the potential participant.
- Participant must sign and date the ICF and return the signed and dated ICF to the site as instructed via email, mail, fax, etc., within 24 to 48 hours of the discussion. The person conducting the consent discussion and the independent witness must sign the ICF and note that the discussion occurred via telephone.
- Research administrator should provide a copy of the signed ICF to the participant via email, mail, fax, etc.
- Cohorts should consult their IRB for specific information and site-based policies relevant to the use of e-consent.
6 RECONSENTING: INFORMED CONSENT PROCEDURES

A study participant (or parent or legal guardian) who has already signed an ICF may need to sign an amended or new ICF for any of the following reasons:

- ICF is revised due to changes in study procedures
- ICF is revised due to changes in the risks or safety of the study (all active participants must sign the revised ICF)
- Child participating in the ECHO-wide Cohort Data Collection Protocol attains the legal age of an adult

7 REQUIRING A WITNESS

A witness can be another adult household member, a relative, or a neighbor, but not the research administrator. If the participant has requested the presence of another person, such as their spouse or partner, the additional person can record a signature in the witness box on the signature page as long as the witness space is not needed for another witness, such as an interpreter.

The following situations require the presence of a witness to document that the participant has given informed consent:

- If the participant uses either a spoken or sign-language interpreter to translate the consent information, then that individual also must sign the ICF as a witness. The signature indicates that the site provided all information to the participant.
- If the participant being asked to sign the ICF cannot read or write or is physically limited in their ability to write so that they must make a mark such as an “X,” then a witness must sign to corroborate that they witnessed the participant signing with a mark.

8 CONSENTING THOSE WITH SPECIAL NEEDS

8.1 Consenting Those with Hearing Impairments

If a participant is hearing-impaired, the research administrator must take an individualized approach, similar to arranging for an interpreter of other languages. In such cases, follow these guidelines:

- Work with the local institution to arrange for a sign-language interpreter or any other assistive technology (e.g., overhead projectors, FM systems, auditory devices with amplification features, speech-to-text software).
- Interpreter is required to sign the ICF as a witness.

8.2 Consenting Those with Vision Impairments

Similarly, if the participant is visually impaired, the research administrator should take an individualized approach. In such cases, the research administrator or designated caregiver may read the information verbatim to the participant and record the participant’s responses as received. The research administrator should document the consent process according to cohort procedures.

8.3 Consenting Speakers of Other Languages

Research administrators must present the ICF to the participant in their preferred language. If such a document is not available in the participant’s language and the participant uses only that
language, then the study site must assign a trained multilingual study staff member for the enrollment and all subsequent visits.

Sites will provide translated versions of the ICF and assent forms for participants who are not fluent in English. The Coordinating Center anticipates providing universal Spanish translation of the ICF and assent documents for cohort sites using the ECHO single IRB. Cohort sites using a local IRB as the IRB-of-record are responsible for their own translations.

When using an interpreter, follow these guidelines:

- Interpreters should translate the study staff member’s explanation about study participation as well as the questions and answers between the study staff member and the participant.
- Interpreters should not paraphrase the information or answer questions themselves.
- Interpreter is required to sign the ICF as a witness.

Research administrators will submit all translations to IRBs for review and approval, when available.

If the participant is legally blind, illiterate, or does not read/understand English and there is no ICF available in their native language, the research administrator should take the following steps:

- Have an impartial witness observe the consent process.
- Present the ICF orally by a person fluent in the participant's language.
- Allow sufficient time for the participant and the person obtaining consent to ask and answer questions to ensure the participant comprehends the consent information.

8.4 Assisting Those with Limited Literacy

It is essential that a participant have the opportunity to hear or read all of the details provided in any available participant-facing study material provided through the Coordinating Center or the cohort. Cohorts should check with the IRB-of-record for any special requirements for consenting participants with limited literacy.

If the research administrator encounters someone with a limited ability to read, they should follow these guidelines:

- Offer to read the information to the participant if they have difficulty reading or are moving through the document very slowly.
- If the participant asks the research administrator to read written information materials to them, the research administrator should agree to the request.
- Research administrator must read the entire ICF to the participant.
- Research administrator should have someone else present during the consent process who will sign the ICF as an impartial third-party witness (someone not connected with the study, such as a staff member not involved in the particular research or a patient advocate).
- If the participant is unable to sign their name, an “X” is acceptable as long as an impartial third party can witness and sign the ICF.

NOTE: For more information about situations that require a witness, see Section 7.
9 HANDLING BARRIERS TO PARTICIPATION

Potential participants may voice hesitancy to participate in research. If a potential participant expresses one or multiple concerns regarding participation, it is important to determine the actual concerns of the individuals. Using open-ended, non-directive questioning can help to clarify the fears and concerns. Common concerns about participating in research include:

- Cultural or religious beliefs
- Fear of research or of the unknown; being a “guinea pig”
- Previous experiences with research
- Lack of understanding
- Privacy issues
- Time and travel involved in the research procedures
- Use or long-term storage of biologic samples (such as genetic sampling)

Once there is a clear understanding of the concerns, the research administrator can work to address them individually through further explanation, education, problem solving, and flexibility. For example, if a participant has religious objections to the collection of biologic samples, they may opt out of that part of the study and participate in other parts. If time and travel are a barrier, then home or virtual visits may be a better alternative.

Research administrators who are involved in recruitment of participants must have a thorough understanding of the study and be ready to address various concerns. If the potential participant has concerns that the administrator cannot address or is uncomfortable with addressing, the research administrator should escalate these concerns to senior study staff members or the cohort site PI.

It is imperative that the research administrator does not try to pressure or coerce the participant into agreeing to the study, but thoughtfully addresses concerns that may help the individual remain open to participation. The research administrator should document all discussions regarding the participant’s concerns in the study records. If the potential participant declines the study, the research administrator should inform them that they are welcome to come back for another evaluation if they changes their mind. The research administrator should give the potential participant the site’s contact information.