|  |
| --- |
| **Use: Review OHRP-46 eIC Worksheet OMR with Signature** |
| **Only Minimal Risk with Signature**  **(Expedited with PHI and Flex with PHi)** |
| 1. **How will the initial email address be obtained?** |
| **Example Response:**  During recruitment, an initial email address will be collected over the phone or during an office visit. This email address will be used to send the Permission to Use Email form using REDCap. The prospective participant will be asked to verify the email that they wish to use for the consent process on the Permission to Use Email form. |
| **Reviewer Considerations:**  There are no specific requirements related to eIC. Refer to acceptable practices during advertising and recruitment. |
| **Notes:** |
| 1. **How will electronic materials be used for informed consent?**  * Remote * In-Person * Both Remote and In-Person |
| **Example Response:**  Prospective participants will be consented both in-person and remotely. |
| **Reviewer Considerations:**  None |
| **Notes:** |
| 1. **FEDERALLY FUNDED RESEARCH: Requirements include that paper-based consent must be offered unless the research cannot be conducted unless all consent is remote, or the IRB approves waiving the paper-based consent.**      1. If a paper-based consent form can not be offered as an alternative, please explain why. 2. Explain how the paper-based form will be provided to a REMOTE  prospective participant and returned to WVU. |
| **Example Response:**  For remote prospective participants who cannot access or use the electronic consent form:   * Two paper copies will be mailed using US Postal Mail. * A self-addressed stamped envelope will be included for the signed returned consent form. * The prospective participant will be instructed NOT to sign the form until they have discussed the research with a WVU Researcher. * A telephone call will be scheduled for the Consenting Researcher to explain the research, the form, and answer any questions. * The prospective participant will sign the forms and mail one copy to WVU. * The Consenting Researcher will sign the form when it is returned to WVU. * Verification of Identity will occur during the telephone call using a passcode provided by the WVU research team. |
| **Response:** |
| **Reviewer Considerations:**  Federal Requirements:  HIPAA – Unsecured electronic transmission of PHI is not permitted unless the participant initiates the transmission and has been informed of the risks. The signed consent form is considered PHI and must be protected via secure transmission.  WVU Policy:  WVU does not permit the unsecured electronic transmission of PHI, whether the participant is informed or uninformed. Consenting prospective participants remotely using a paper-based informed consent form is only possible via US Postal Mail or another mail carrier.  IRB Options:  None |
| 1. **Will all targeted audiences be able to access and use the electronic materials from a personal use perspective (mentally\physically able to use technology) or personal environment perspective (internet access, computer access)?** |
| **Example Response:**  **Example:** The research requires that all participants consent remotely using an electronic consent form.  Prospective participants who cannot consent electronically will not be eligible for participation.  **Example:** For those who cannot use or access an electronic consent form: See the example response in Question #2. |
| **Reviewer Considerations:**  Federal Requirements:  Electronic materials may be used to either supplement or replace paper-based materials and processes to best address the subject's needs throughout the study. For example, some subjects may prefer one method over another. Other subjects may have difficulty navigating or using electronic systems because of, for example, a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills. In such cases, the eIC process may not be appropriate for these subjects. Therefore, subjects should have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process.  The Consenting Researcher can assist the person signing the form with navigation; ADA readers can be used by ensuring the person signing the form downloads the PDF of the consent form to a device and uses a screen reader of their choice. REDCap has a screen reader that can be turned on by the person signing the form as well. The REDCap screen reader will read the text in REDCap but cannot read the uploaded consent form images.  WVU Policy:  Paper-based consent forms must be mailed via postal mail (US Mail, Fed Ex, etc.) Refer to Question #2 above.  IRB Options:  None |
| **Notes:** |
| 1. **Indicate the electronic materials that will be used during the consent process?**   Notes:   * Provide the eConsent materials presented during the consent process (websites, videos, etc.). The WVU IRB must maintain the materials and printouts. * Include the URLs\hyperlinks to all forms and materials – The REDCap survey form link, URLs to websites, etc. * Attach PDFs of all materials, export the REDCap survey form to a PDF, print each page of a website to a PDF, etc. |
| **Example Response:**  The REDCap form and a link to a website with information regarding the research will be provided to the prospective participant.  The links and attachments are provided below:    Provide the link to the REDCap Survey Form  Provide the link to the website that will be presented during consent  Attach PDF files of both the website contents (all pages) and the REDCap form. |
| **Reviewer Considerations**:  Federal Requirements:  The investigator should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including any videos and Web-based presentations, which the subject will receive and view during the eIC process.  The IRBs must maintain and retain copies of materials that have been reviewed in accordance with 45 CFR 46.115 and 21 CFR 56.115.  The IRBs should also review any optional questions or methods used to gauge subject comprehension of key study elements. The IRB should also review the usability of the eIC materials to ensure that they are easy to navigate.  If the program uses hyperlinks to convey study-related information, IRBs should review the contents to which subjects are referred in order to determine if the study-related information that has been supplied is accurate and appropriate.  Because Web sites are often modified over time, IRBs must maintain the version of the Web site information that contains the study-related information that the IRB reviews and approves, either electronically or as a hard copy (see 45 CFR 46.115 and 21 CFR 56.115).  WVU Policy: Defer to Federal Regulations  IRB Options: None |
| **Notes:** |
| 1. **List the products that will be used to obtain electronic informed consent:**   **Options: REDCap, HSC version of Qualtrics.** |
| **Example Response:**  Example: REDCap  Example: Other products will be used, describe in detail. |
| **Reviewer Considerations:**  Federal Requirements:  Products used must meet federal regulatory requirements for electronic signature, HIPAA and the federal HHS\FDA eConsent guidelines.  For FDA-regulated clinical investigations, the electronic system that supports the eIC must be secure with restricted access (see 21 CFR 11.10 and 11.30) and should include methods to ensure confidentiality regarding the subject's identity, study participation, and personal information after informed consent has been obtained.    If the entity holding the subject's personal information is a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law No.104-191) or acting as a business associate of a HIPAA-covered entity, the requirements in the HIPAA Privacy, Security, and Breach Notification Rules apply (see 45 CFR parts 160 and 164). For example, the subject's information within an electronic system must be encrypted, unless the entity documents why encryption is not reasonable and appropriate in their specific circumstances and implements a reasonable and appropriate equivalent measure.  HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject's personal representative) is a valid electronic signature under applicable laws and regulations. The Electronic Signatures in Global and National Commerce Act (E-Sign Act) (Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form.  The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a subject (or a subject's personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.  WVU Policy:   * REDCAp or the HSC version of Qualtrics.   IRB Options:  As applicable require:   * A private telephone call * An HSC Zoom session ( The WVU version of Zoom cannot be used for PHI) |
| **Notes:** |
| 1. **How will the Consenting Researcher explain the research, the consent form, and answer questions?** |
| **Example Response:**  **Remote:** The consenting researcher will explain the research. The HIPAA Authorization during pre-screening activities or a telephone call\zoom video session will be scheduled to explain the research and the HIPAA Authorization included in the consent form.  **In-Person:** The Consenting Researcher will explain the research and the form in-person. The process will be the same as the paper consent process. |
| **Reviewer Considerations:**  Federal Requirements:  Communication with Prospective Participants for the consent process may be accomplished by in-person discussions with study personnel or through a combination of telephone calls, video conferencing with a remotely located investigator or study personnel.  When video conferencing is used during the eIC process, investigators and study personnel should remind subjects to conduct the eIC discussion in a private location to ensure privacy and confidentiality.  WVU Policy:  Use WVU Approved products for communications with remote prospective participants.  Non-Federally Funded – Consider the risk related to the research.  IRB Options:  A telephone call with confidentiality and privacy controls can be recommended as needed or an HSC Zoom session. |
| **Notes:** |