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| **Use: Review OHRP-45 eIC Worksheet MMR** |
| **More Than Minimal Risk**  **(Full Board Protocols)** |
| 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     Note: A witness is not required unless Alteration of Informed Consent is requested, or a sponsor requires a witness.  WVU requires that the Consenting Researcher witness the signature during the required video session. |
| **Example Response:**  Prospective participants will be consented both in-person and remotely. |
| **Reviewer Considerations:**  If a Witness is required for the consent process, ensure that the eTemplate includes an eSignature field for the Witness signature, name and date. |
| **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 PDFs are attached to the protocol submission.    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 ZOOM**    Notes:  The WVU IRB must approve telephone calls and other products. |
| **Example Response:**   1. REDCap and the HSC Version of ZOOM 2. 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 is required * REMOTE: An HSC Zoom session is required to verify the signature of the person signing the form and to explain the research and answer questions. * The IRB can approve a telephone call to be conducted in a private location if Zoom is not possible for the prospective participant.   IRB Options: None |
| **Notes:** |
| 1. **How and when will the consent information be provided for the prospective participant to review and assess.**   Note:  The question addresses the requirement**to allow for sufficient time for the prospective participant to review the consent information,**discuss the information with others, and ask the consenting researcher questions. |
| **Example Response:**  **Remote:** The link to the REDCap form will be sent <enter the number of days> days before the HSC Zoom session occurs.  The following instructions will be provided in the REDCap email template:    1. Review the form  2. Discuss the information with others as needed  3. DO NOT sign the form until you are on the ZOOM video session with the researcher.    When on the ZOOM video session, the consenting researcher will review the research, the consent form and answer any questions that arise.    **In-Person:** The Consenting Researcher will provide the consent form ahead of a scheduled visit using REDCap. If consent occurs during the same visit, a paper-copy or the REDCap form will be provided based on preference for review.  <Specify the amount of time> will be provided for the prospective participant to review the form and discussion with others as needed. |
| **Reviewer Considerations:**  Federal Requirements:  Whether the eIC is obtained from the subject on-site or remotely, the eIC process must provide sufficient opportunity for the subject to consider whether to participate (see 45 CFR 46.116 and 21 CFR 50.20).  The investigator should have methods in place to ensure that the eIC process allows subjects the opportunity to consider whether or not to participate and to ask questions.  WVU Policy:  Defer to the Federal Requirements  IRB Options:  Researchers can send the consent form as information using OHRP e08 through REDCap. The template includes the question "Are you interested in participating in this research?" The template does not have signature fields. If the response is Yes, the Permission to Use Email form and the electronic consent form can be sent automatically within REDCap after a specified period of time. The email with the consent form instructs the prospective participant not to sign the form until they are the Zoom video session with the Consenting Researcher. |
| **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 and the form during a scheduled HSC ZOOM video session. Those authorized on the approved protocol as Consenting Researchers will address questions and concerns during a scheduled video session.  **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 help ensure privacy and confidentiality.  WVU Policy:  A video session is required using the HSC version of Zoom . HSC Zoom is the only approved product for video sessions with a prospective research participant.  IRB Options:  If Zoom cannot be used, a telephone call with confidentiality and privacy controls can be approved. |
| **Notes:** |
| 1. **How will the prospective participant's understanding be gauged during remote and in-person using an electronic consent form?** |
| **Example Response:**  **Example:** During the consent form review, the Consenting Researcher will pause after each page of the form and ask questions and observe the prospective participant reactions and demeanor during the video session reaction. The process will be the same for in-Person consent using the REDCap form, without the video session.  **Example:** Additional questions will be added to the REDCap form to ensure understanding of the key aspects of the research. For instance, after the page that indicates the number of visits required, a question has been added: "How many visits are required to complete the research." |
| **Reviewer Considerations:**  Federal Requirements:  To assist the subject in understanding the material, the eIC may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration.  The eIC should be appropriate for the intended audience, taking into consideration the subject's age, language, and comprehension level.  The eIC may contain various methods to help an investigator assess the subject's understanding of the information being presented during the eIC process.  For example, the eIC may include optional questions at any time during the eIC discussion that can be used to help educate the subject about the information presented, as well as assess the subject's understanding of the informed consent materials.  Such optional questions and other methods may be used as tools to gauge subject comprehension of key study elements and highlight areas where the subject might need further explanation and discussion before signing the informed consent to enter the study.  WVU Policy: None  IRB Options: The IRB may elect to require optional questions within the REDCap form to help gauge understanding for some protocols or protocols that target protected populations. |
| **Notes:** |
| 1. **How will Identification be verified for the person signing the form:**   Notes:  If a formal ID is not possible, the IRB can approve other reasonable methods to verify identity: a passcode provided by the researcher, the answers to three person questions (asked using the Permission to Use Email form) |
| **Example Response:**  **Example**: The Consenting Researcher will ask to see a formal ID such as a birth certificate, passport, or driver's license while on the ZOOM session of the person signing the form.  **Example**: Since an official ID may not be readily available, the Permission to Use Email eTemplate with three personal questions will be used. |
| Federal Requirements:  FDA regulations do not specify any particular method for verifying the identity of an individual and accepts many different methods. For example, verifying someone's identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. In addition, use of security questions to confirm an individual's identity can also be considered.  If any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR (see 21 CFR 11.100(b)).  Federal OHRP encourages investigators to apply a risk-based approach to the consideration of subject identity. For example, social-behavioral minimal risk research will not typically warrant such verification. In addition, informed consent may be waived for minimal risk research meeting the requirements at 45 CFR 46.116(d).  WVU Policy:  Verification of Identity is required for all MMR research – Full Board Clinical and non-clinical trials,  An HSC ZOOM session is required to: view a formal ID (birth certificate, passport, driver's license) and witnessing the signature on the video session.  The answers to three personal questions can be used (built-into a Permission to Use Email eTemplate in REDCap).  FDA research at WVU requires the use of the HSC Zoom video session to verify a formal ID.  IRB Options:  If formal IDs are not readily available, the IRB can approve any of the following:   1. Consenting Person witnessing the signature. 2. The use of the answers to three personal questions asked in the REDCap Permission to Use Email eTemplate. |
| **Notes:** |