* Complete all questions. If a question is not applicable, indicate N\A, and explain.
* Attach this worksheet to the protocol submission in WVU+kc
* This worksheet is required as of 1/4/21.
* [Refer to the Electronic Informed Consent guidance on the WVU OHRP website](https://human.research.wvu.edu/guidance/informed-consent/electronic-consent)

|  |
| --- |
| **More Than Minimal Risk - Requires a Signature**  **(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. |
| **Response:** |
| 1. **How will consent Occur?**  * Remote (participant\LAR\Legal Guardian Alone) * Remote (participant\LAR\Legal Guardian with Witness) * In-Person (participant\LAR\Legal Guardian with Consenting Person) * Both Remote and In-Person   If a witness is used, please indicate the reason for the Witness. Note that the Witness is not the Consenting Person. |
| **Example Response:**  Prospective participants will be consented both in-person and remotely. |
| **Response:** |
| 1. **Will all targeted audiences be able to use eIC remote or in-person from a personal use perspective (mentally\physically able to use technology) or personal environment perspective (internet access, computer access)?**     Federal requirements include that paper-based consent must be offered unless the research cannot be done unless all consent is remote (requires IRB approval).    A) If a paper-based ICF be not be offered as an alternative, please explain why.    B) Explain how the paper-based form will be provided to the prospective participant and returned to WVU (NOTE email attachments cannot be used.) |
| **Example Response:**  **Example:** The research requires that all participants consent remotely using eIC.  **Example:** For those who cannot use the eIC, two copies of the paper-based ICF will be mailed using postal mail along with a stamped and addressed return envelope.  **Example:** The unsigned form will be sent using email using SECURE EMAIL controls  with instructions stating that the form cannot be signed and emailed back. The consent form will be sent from within REDCap for signature if there is an agreement to move forward with the consent process. |
| **Response:** |
| 1. **Indicate the eIC materials that will be used during the consent process?**   Notes:   1. Provide all eConsent materials presented during the consent process (websites, videos, etc.). The IRB must maintain the materials and printouts. 2. Include the URLs\hyperlinks to all forms and materials – The REDCap survey form link, URLs to websites, etc. 3. Attach PDFs of all materials, print the REDCap survey form to a PDF, print each page of a website to a PDF, etc. |
| **Example Response:**  The eICF and a link to a website with information regarding the research will be provided to the prospective participant.  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 eICF |
| **Response:** |
| 1. **Are ALL prospective participants capable of using the e-materials provided? If not, please explain how special needs will be accommodated for both remote and in-person consent**. |
| **Example Response:**  Remote eIC: Age may hinder the use of technology; the Consenting Person (via ZOOM) or other Witness will assist the prospective participant in using the technology.  In-Person eIC: Age may hinder the use of technology; the Consenting Person will assist the prospective participant in using the technology. |
| **Response:** |
| 1. **List the products that will be used to obtain eIC:**   **Options: REDCap, HSC version of ZOOM** |
| **Example Response:**   * REDCap and the HSC Version of ZOOM * A Sponsor product and process * Other products will be used, describe in detail. |
| **Response:** |
| 1. **How and when will the consent information be provided for the prospective participant to review and assess?** (For both remote and in-person consent). *Note that this question is not related to explaining the research and the consent to the prospective participant. 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 eIC:** The REDCap eTemplate link will be sent 7 days before the HSC Zoom session occurs for the consent process. 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 conference 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 eIC:** The Consenting Person will provide the consent form ahead of a scheduled visit using REDCap. If the form's review must happen during the visit, a paper-copy or eICF will be provided based on preference for review. XX amount of time will be provided for review and discussion with others as needed. |
| **Response:** |
| 1. **For REMOTE eIC, will an HSC Zoom session be used to explain the research, the consent form, answer questions, verify identity, and witness the signature?** |
| **Example Response:**  **Remote eIC:** 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 Persons will address questions and concerns during a scheduled phone\video call and explain whom to contact for additional questions if needed.  **In-Person eIC:** The consenting researcher will explain the research and the form in-person. The process will be the same as the paper consent process. An HSC Zoom video session will take place with each prospective participant.  **OR (IRB must approve)**  Some prospective participants cannot use ZOOM; the proposed alternative method is to make a private telephone call to explain the research and the consent form and use the answers of three personal questions built-in to the REDCap Permission to Use Email form. The answers to the questions will be asked when the eICF is sent via REDCap,  **OR (IRB must approve)**  A witness of the prospective participants choosing will witness the eSignature and sign the REDCap eICF using the added witness signature block. |
| **Response:** |
| 1. **How will the prospective participant's understanding be gauged during remote and in-person eIC?** |
| **Example Response:**  **Example:** During the review of the consent form, the Consenting Person will pause after each page of the form and ask for verification of understanding and will observe via the video session the participant's reaction to the information and the questions. The process will be the same for in-person eIC without the video session.  **Example:** Additional questions will be added to the REDCap form to ensure understanding of the key aspects of the research. |
| **Response:** |
| 1. **How will Identification be verified for the person signing the form at the time of signature?** |
| **Example Response:**  **Example**: Identity Verification will be accomplished by the consenting researcher viewing an official ID such as a birth certificate, passport, or driver's license while on the ZOOM session. If an official ID is not available, the consenting researcher witnessing the signature will be the alternative for verifying identity.  **Example**: Since an official ID may not be readily available, the answers to three questions will be used. The questions will be asked in the Permission to use Email Form in REDCap, and the prospective participant will be asked to enter them when they click on the REDCap consent form link. Contact information will be provided should the prospective participant forget the answers to the questions. |
| **Response:** |