**REQUIRED** FOR PROTOCOL SUBMISSIONS WHEN WVU IS THE IRB of RECORD:

* 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)** |
| **Link (url) to eTemplate:**  Example: <https://redcap.wvctsi.org/redcap/surveys/?s=3HD4TXCCFA> |
| **eTemplate Used:**  Example: WVU OHRP Combo e07 Permission to Use Email and e01 MMR/OMR |
| **Did you modify and standard questions (email/survey) messages in the eTemplate Y/N?**  **If Yes, please describe the modifications and the reason for the change.**  Example: I added a question required for the research, I modified the survey completion message to provide clear instructions. |
| 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. |
| **Response:** |
| 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 using REDCap. A witness is not required |
| **Response:** |
| 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 will 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:** |
| 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. |
| **Response:** |
| 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.  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. |
| **Response:** |
| 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. |
| **Response:** |
| 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. |
| **Response:** |
| 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. |
| **Response:** |
| 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." |
| **Response:** |
| 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 questions known by both the researcher and the participant. |
| **Example Response:**  **Example**: The Consenting Research will ask to see a formal ID such as a birth certificate, passport, or driver's license while on the ZOOM session.  **Example**: Since an official ID may not be readily available, a passcode will be provided to the prospective participant in the Permission to Use Email form. |
| **Response:** |
| 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. The Permission to Use Email Form contains three questions that can be used dor this purpose or deleted if they are not needed. Additionally a passcode provided by the researcher can be used. |
| **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 questions will be used. |
| **Notes:** |