# eIC Submission Worksheet

**REQUIRED for:**

* All full board and expedited protocols
* Exempt, flex, NHSR protocols with PHI

**Instructions:**

* Complete all questions.
* If a question is not applicable, indicate N\A and explain.
* Attach this worksheet along with any e-consent to the protocol submission in WVU+kc
* This worksheet is required as of 9/14/2022

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| **Electronic Informed Consent Questionnaire** |
| 1. **Provide link (url) to eTemplate** |
| ***Example Response:*** [*https://redcap.wvctsi.org/redcap/surveys/?s=3HD4TXCCFA*](https://redcap.wvctsi.org/redcap/surveys/?s=3HD4TXCCFA) |
| **Response:** |
| 1. **List template(s) used** |
| ***Example Response:*** *e01 Remote eConsent* |
| **Response:** |
| 1. **If you modified any standard questions (email/survey), please describe the modifications and the reason for the change. Otherwise, write “N/A.”** |
| ***Example Response:*** I added a question required for the research, I modified the survey completion message to provide clear instructions. |
| **Response:** |
| 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 consent document via the Participant Distribution List in REDCap.* |
| **Response:** |
| 1. **How will electronic materials be used for informed consent? If applicable, describe how participants who consented remotely will receive a signed copy of the informed consent document.**  * 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.* |
| ***Example Response:*** *Prospective participants will be consented both in-person and remotely using REDCap. Participants consented remotely will be sent the fully executed consent document via the SEND-IT functionality on REDCap.* |
| **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 and the form, and to 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 #5.* |
| **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 (see link in response to Questions #1) and a link to a website with information regarding the research will be provided to the prospective participant.*  *\*\*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:**   *Notes: The WVU IRB must approve telephone calls and products other than REDCap/HSC Qualtrics. If you are using other products, describe in detail.* |
| ***Example Response:***  *REDCap and the HSC Version of ZOOM* |
| **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’s 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.* |
| **Response:** |
| 1. **How will identification be verified for the person signing the form?** |
| **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:** Consent is happening in-person and we will be able to see the participant sign the document.  **Example**: We are using the identity verification questions in the REDCap template (e07). |
| **Response:** |