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)

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| **Only Minimal Risk - Requires a Signature****(Expedited with PHI and Flex with PHI)** |
| **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?**
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| **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 or HSC Version of Qualtrics>. 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
 |
| **Example Response:**Prospective participants will be consented both in-person and remotely using <<REDCap or HSC Version of Qualtrics>.  |
| **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 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.
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| **Example Response:**For remote prospective participants who cannot access or use the electronic consent form:1. Two paper copies will be mailed using US Postal Mail.
2. A self-addressed stamped envelope will be included for the signed returned consent form.
3. The prospective participant will be instructed NOT to sign the form until they have discussed the research with a WVU Researcher.
4. A telephone call will be scheduled for the Consenting Researcher to explain the research, the form, and answer any questions.
5. The prospective participant will sign the forms and mail one copy to WVU.
6. The Consenting Researcher will sign the form when it is returned to WVU.
7. Verification of Identity will occur during the telephone call using a passcode provided by the WVU research team.
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| **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)?**

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| **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: 1. Provide the eConsent materials presented during the consent process (websites, videos, etc.). The WVU IRB must maintain the materials and printouts.
2. Include the URLs\hyperlinks to all forms and materials – The <REDCap or HSC Version of Qualtrics> survey form link, URLs to websites, etc.
3. Attach PDFs of all materials, print the <REDCap or HSC Version of Qualtrics> export the REDCAp\Qualtrics survey form to a PDF, print each page of a website to a PDF, etc.
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| **Example Response:** The <REDCap or HSC Version of Qualtrics> 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 or HSC Version of Qualtrics> Survey Form Provide the link to the website that will be presented during consentAttach PDF files of both the website contents (all pages) and the <REDCap or HSC Version of Qualtrics> form. |
| **Response:** |
| 1. **List the products that will be used to obtain electronic informed consent:**

**Options: <REDCap or HSC Version of Qualtrics>. The WVU version of Qualtrics cannot be used for research involving PHI.**Notes:The WVU IRB must approve telephone calls and other products. |
| **Example Response:** * <REDCap or HSC Version of Qualtrics>
* Other products will be used, describe in detail.

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| **Response:** |
| 1. **How will the Consenting Researcher explain the research, the consent form, and answer questions**
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| **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.  |
| **Response:** |