

WVU OHRP Combo e04 HIPAA Authorization and e07 Permission to use Email

THE INSTRUCTIONS ASSUME BASIC KNOWLEDGE OF QUALTRICS. Tutorials and Help are available through Qualtrics on the main page. Researchers using HSC Qualtrics can contact Qualtrics Support 24/7. Researchers using WVU Qualtrics can contact the WVU ITS Help Desk for basic assistance.

Considerations for this eTemplate:

- Approved for the following protocols: **Only Minimal Risk – Expedited and Flex protocols with PHI or PII.**
- Combines the e07 Permission to Use Email form into the form so both forms are presented to the participant at the same time.
- Consenting Researcher Signature: Qualtrics has limited capability to provide the "Participant Copy" and cannot easily provide the capability for the "Consenting Researcher's Signature". The WVU IRB waives the requirement to provide the consenting researcher's signature for Only Minimal Risk research.
- Participant Copy: The participant copy of the consent form is provided in two steps:
 1. The participant downloads the attached PDF (this is an unsigned copy of the consent form)
 2. The email containing the eSignature and the Qualtrics responses (sent immediately after the participant signs electronically)

PREPARING FOR THE PROTOCOL SUBMISSION & CUSTOMIZING THE eTemplate

1. WVU IRB SUBMISSION REQUIREMENTS

- Provide the link (url) for eTemplate in the *eIC Submission Worksheet*: Use the Survey Distributions option
- Attach an exported file of the Qualtrics eTemplate:
Survey>Tools>Import\Export function to obtain a file to attach to the protocol submission. Attach the Word file to WVU +kc

2. CUSTOMIZE THE eTEMPLATE

All requests for modification must be clearly described in the *eIC Submission Worksheet* when submitting the protocol to the WVU IRB.

- Changes Requiring WVU IRB Approval:
All modifications to the eTemplate
Logos must be approved by WVU University Relations.
Email Trigger Messages, End of Survey Messages (Anything the participant/LAR will be presented with)

- **Items that Cannot Be Changed:**
Colors, text, or style - University Relations requires specific color schemes for ADA compliance.
End of Survey Messages
The Email Triggers
3. **CUSTOMIZE THE TRIGGERS TO ADD THE RESEARCHER EMAIL ADDRESS(ES) FOR RESEARCHER EMAIL NOTIFICATIONS:**
Modify the "Research Participant Consent Form Response" trigger to indicate the email address(es) of the researcher(s) that should be notified when the completed forms are returned:
 - Click the Tools drop-down menu above and select Triggers -> Email Triggers>
 - Send Research Participant Consent Form Response to: researcher@example.edu
 - Change researcher@example.edu to a valid email address
 - Trigger email messages can be modified if needed; change must be approved by the WVU IRB.
 4. **REVIEW SURVEY OPTIONS:**
 - Survey Experience: Back Button and Save/Continue are set and cannot be changed without IRB approval.
 - Survey Protection: The default is set "By Invitation Only" – This can be changed depending on the type of research.
 - Survey Protection: Prevent Ballot Box Stuffing and Prevent Indexing, Secure Participants' Files are set as defaults but can be changed for the type of research with WVU IRB approval. (Secure Participants' Files is required for OMR with signature)
 - Survey Termination: Custom Messages are set. The message can be changed with WVU IRB approval.
 - Items not mentioned above can be modified.
 5. **DETERMINE DISTRIBUTION METHOD:**
 - Click on the Distributions menu option on the top menu bar and configure accordingly.
 - Note that anonymous surveys will require a change in the Survey Protection options above.
Use Qualtrics Help to determine the best method to distribute the form.
 - **Sending the link outside of Qualtrics using WVU/HSC/WVU Medicine email is NOT permitted.**
 6. PREVIEW and TEST the Survey Form
 7. PUBLISH
 8. Obtain the distribution link and the exported file (from Step 1) and include them in the eIC worksheet

AFTER THE WORD (PAPER-BASED) CONSENT FORM IS APPROVED BY WVU IRB:

1. ATTACH A PDF OF WVU IRB APPROVED and WATERMARKED CONSENT DOCUMENT
 - Attach the watermarked PDF of the WVU IRB-approved Informed Consent document to the applicable survey field in the standard eTemplate.
 - The PDF is required for ADA compliance (screen readers) and also to provide a copy to the participant. The PDF download is the only option for the participant to receive a copy of the paper consent form. The uploaded images in the next step are not provided to the participant.
2. UPLOAD IMAGE FILES OF THE APPROVED and WATERMARKED CONSENT DOCUMENT
 - To enable the user to view the consent form on the screen, the PDF must be converted to an image file (JPG or PNG).
 - Refer to the WVU OHRP website for instructions on how to export the PDF to an image file.
 - Upload each image file (there will be one file per page) and add a page break.
 - Create as many question fields and page breaks needed for the total number of pages.
3. PI RESPONSIBILITY
 - Test the eTemplate to be sure all changes work and email notifications work.
 - Spell check
 - Verify that you have not made changes that require IRB approval (all messages and survey questions that the participant/LAR will be presented with)