# **REDCap eConsent Settings Worksheet for the VCU HRPP**

Instructions: Studies wishing to use REDCap as a platform for electronic Consent (eConsent) should complete and submit this worksheet to the IRB for review of the privacy, confidentiality, appropriateness of the consent process, and review of all associated participant communications that are part of the eConsent.

Studies must also upload the PDF version of all instruments used in the eConsent process into their RAMS-IRB submission.

Any changes to these settings should be submitted to the IRB for review and approval prior to implementation. When submitting a revised version of this worksheet, be sure to upload a Word version of the worksheet to the IRB so that the IRB can readily compare the new version with the previous version.

Note that REDCap uses the term “survey” (and the term is used in this worksheet) instead of “eConsent” because a survey functionality was used when building the eConsent instrument. For assistance, submit a request to consult with the REDCap team at http://go.vcu.edu/bicrequest

## Section 1: eConsent Settings

|  |  |
| --- | --- |
| Study Information: |  |
| Study ID (HM Number): |       |
| Principal Investigator’s Name: |       |
| Does this eConsent process involve any of the following?REDCap eConsent may not be used for FDA-regulated research, to obtain assent signatures from children or decisionally impaired adults, or with foreign participants (i.e., not within the U.S.). Consult your IRB coordinator before using REDCap eConsent with LEP individuals. | [ ]  FDA-regulated research – STOP, REDCap may not be used[ ]  Children[ ]  Decisionally impaired adults[ ]  Foreign participants – STOP, REDCap may not be used[ ]  Persons with limited English proficiency (LEP) – STOP, consult with the IRB before continuing[ ]  None of the above |
| REDCap eConsent Process: |  |
| Which study arm/phase or consent group is this worksheet for?  |       A study involving multiple groups or arms that each have different consent processes may need to complete multiple worksheets if each group will have different settings. |
| Which eConsent template is being used?  | Image Based: A template with passcode verification, which displays inserted images of the IRB, approved consent document.Text Based: A template with passcode verification, which displays text copied from the IRB-approved consent and formatted in REDCap. |
| Will the consent discussion with the potential participant take place in person or remotely? | [ ]  Remote consent discussion[ ]  In person consent discussion [ ]  Either remote or in person consent discussion In what circumstances, would you use remote discussion and when would you use in person discussion?      [ ]  No consent discussion Why will consent discussion not occur?      |
| Will the signing of the eConsent document take place in person or remotely? | [ ]  Remote signing[ ]  In person signing [ ]  Either remote or in person signing In what circumstances, would you use remote discussion and when would you use in person discussion?      [ ]  Waived consent signatures[ ]  Exempt study with no expectation of signed consent/authorization  |
| How will the study team provide a copy of the written eConsent document to each participant to keep for future reference?Each participant should be given a copy of the consent document, not just a weblink, so that they can refer to the information in the future.  |       |
| REDCap eConsent Instrument Settings: |  |
| Will Twilio SMS and Voice Call services for surveys and alerts be enabled? |  |
| When will the survey expire? (optional)Time after which the eConsent will become inactive. |      Note: A period of up to 1 week is recommended to ensure the consent discussion is still fresh in participants’ minds while providing time to consider participation. |
| Will Text-To-Speech functionality be enabled?Allows text on survey page to be read audibly to participants. All text that is spoken is sent to a service hosted at Vanderbilt University that utilizes the IBM Watson Text-to-Speech API service. If the survey utilizes piping, for privacy concerns, data piped from Identifier fields will NOT be sent to the service with the rest of the text but will instead be redacted. | [ ]  No (default setting)[ ]  Yes (IRB preferred setting) Text-to speech will be Language of the text to be spoken:      Note: Enabling text-to-speech can make a text-based consent document more accessible. This setting will likely not function for image-based eConsent templates. This setting does not perform translation and does not take the place of a qualified interpreter for the consent discussion.  |
| Select the identity verification process the study will use and describe any identifiers that will be used for obtaining signatures remotely:Note: Currently, only the Passcode verification option has a REDCap eConsent template available.  | [ ]  Verification during in-person consent discussion and signing - verified by the study team during e-consent registrationIf not using an in-person consent discussion and signing, select one or more of the following verification methods:[ ]  Verification with an Established Passcode: An agreed upon passcode is communicated between the participant/LAR and the study team. To create a more secure code, do not base the code on any direct identifiers and create a unique code for each participant.How will a passcode for each participant be selected (i.e., random numbers, alphanumeric code, etc.)?      If the eConsent template’s email notification will not be used to send the passcode to the participant, how will it be communicated to them?      [ ]  Verification with Known Information: The study team adds questions to answer at the time of accessing the eConsent form. These questions should be pre-established security questions. The responses should be agreed upon by both the study team and the participant/LAR during an in person or remote (video conference or telephone) conversation. To use this verification method, submit a request to consult with the REDCap team at http://go.vcu.edu/bicrequestI confirm that the REDCap team was involved in developing the study’s eConsent instrument. \* [ ] When will the study team have a discussion with the potential participant to decide upon these security question?      [ ]  Verification with a Passcode Based on Known Information: A study team who has already collected sufficient demographic data can verify authentication without agreeing to a prior known passcode or information by informing the participant/LAR that a combination of their demographic data will be used as their passcode. The information should already be known by both parties. To use this verification method, submit a request to consult with the REDCap team at http://go.vcu.edu/bicrequestI confirm that the REDCap team was involved in developing the study’s eConsent instrument. \* [ ] List the set of all possible demographic variables the study team might use:      From what source will you obtain this information?      If a participant asks about how you obtained this information about them, what will you say?      [ ]  Verification with Identity Document Upload: A government specific identity verification would be required. The study team could verify identity using a government issued ID during the video conference by taking an image or screenshot during the conversation, or implement a post-process verification method, which requires the participant/LAR to upload a picture or scanned version of a specific identity document such as a passport or state issued ID card to accompany the e-Consent submission. This method would require manual document review by the study staff to ensure the information matches what is expected. To use this verification method, submit a request to consult with the REDCap team at http://go.vcu.edu/bicrequestI confirm that the REDCap team was involved in developing the study’s eConsent instrument. \* [ ] List all government-issued documents/IDs the study team might use:      Describe the method the study team will use to verify identity with this document:      Who on the study team (by role) will have access to this document?       |
| Survey Termination Options: |  |
| After participants complete the eConsent, what will they see/do next in REDCap? | [ ]  Auto-continue to next survey: Which survey will be presented next?       |
|  | [ ]  Redirect to a URLProvide the webpage URL:      |
|  | [x]  Survey Completion Text(default option)Displayed after survey is completed as 'thank you' text [x]  I will use the IRB-preferred completion text:Thank you for your response.If you have chosen to receive a copy of your signed eConsent document, it will be emailed to you from the study team.[ ]  I will use customized completion text:      |
| Will you use REDCap’s survey settings to send a confirmation email?Sending confirmation emails through this REDCap setting is not necessary if the study team will use the template’s notifications/alerts. | [x]  No (default setting)[ ]  Yes - provide the following information: Subject Line:      Message Text:      Include a PDF of completed survey as attachment? Include an attached file? What document will be attached?       |
| Identifiers Used (eConsent Framework settings) |  |
| What identifiers (if any) will be inserted into the footer of the PDF consent form? | [ ]  I will not insert any identifiers (IRB preferred)[ ]  I will insert "First Name" and "Last Name" (default)[ ]  I will insert a date of birth field Justify why date of birth is necessary for consent:      [ ]  I will insert another identifier – describe and explain why it is necessary for consent:       Note: To protect privacy, use of identifiers should be limited. The fields selected will be inserted on all pages of the consent document, which means they would be visible by unauthorized persons if confidentiality or privacy were to be breached. |

## Section 2: Interactive Elements

[ ]  I am not using any interactive elements (Go to Section 3)

Instructions: The sections below represent the anticipated interactive elements that study teams will use most frequently. The IRB will need to review all interactive elements that will be used in the eConsent.

List any/all videos that are embedded into the consent information (add rows as needed):

Content must be educational in nature. Promotional videos are unlikely to be approved by the IRB as the intention of including interactive elements is to promote comprehension of the consent form. Provide the weblink to the video if it can’t be uploaded; study-specific videos must be uploaded for review. Several videos explaining common medical procedures are available from the STRIDE Project at: https://www.youtube.com/channel/UCKOqWFdtVU7XsxWs2fpfvNQ

| Section of the consent document where the video will be located | Video name | Indicate if the video file is uploaded or if can’t be uploaded, give the weblink |
| --- | --- | --- |
|  |  | Uploaded / Not uploaded – weblink:  |
|  |  | Uploaded / Not uploaded – weblink:  |
|  |  | Uploaded / Not uploaded – weblink:  |
|  |  | Uploaded / Not uploaded – weblink:  |
|  |  | Uploaded / Not uploaded – weblink:  |

Provide any/all photos, images, figures, graphics, etc. that are embedded into the consent information (add rows as needed):

Content must be educational in nature. Promotional content is unlikely to be approved by the IRB as the intention of including interactive elements is to promote comprehension of the consent form. For more on alt-text and image accessibility, see [https://wiki.vcu.edu/display/TFour/Image+accessibility](https://wiki.vcu.edu/display/TFour/Image%2Baccessibility)

| Section of the consent document where the image will be located | Copy/paste image into the table cell | Alt-text for the image |
| --- | --- | --- |
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Provide any/all hover text (i.e., mouseover, tooltip, rollover text) that will be used in the consent information (add rows as needed):

Content must be educational in nature. Promotional content is unlikely to be approved by the IRB as the intention of including interactive elements is to promote comprehension of the consent form. For a lay terminology resource, see https://www.nccn.org/education-research/nccn-oncology-research-program/informed-consent-language-database

| Section of the consent document where the hover text will be located | Word or phrase that will trigger the hover text | Copy/paste into the table cell the text that will be displayed |
| --- | --- | --- |
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Provide any/all other interactive elements (i.e. comprehension questions, activities, etc.) that will be used in the consent information (add rows as needed):

Content must be educational in nature. Promotional content is unlikely to be approved by the IRB as the intention of including interactive elements is to promote comprehension of the consent form. For example, a study might incorporate questions from the Informed Consent Evaluation Instrument available in the Informed Consent accordion at https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/

| Section of the consent document where the interactive element will be located | Describe the interactive element |
| --- | --- |
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## Section 3: REDCap eConsent Notifications to Participants

The REDCap eConsent templates have several notifications/alerts built in to facilitate the consenting process. The language and settings indicated in this worksheet are the IRB preferred settings and text that will maximize privacy and confidentiality. Default settings and text have been pre-filled but may be edited.

|  |  |
| --- | --- |
| Title of this Alert: | Participant eConsent Email[ ]  This alert will not be used because the study will only use in-person consent  |
| Alert Schedule | Describe when the alert will be sent: Send immediately |
|  | Sent on what schedule and how many times? Every time the registration form is saved |
| Message Settings | Alert Type:  |
|  | Email Subject Line: Consent document ready for review  |
|  | Email Message Text (select one):[x]  Template default text (IRB preferred): You are invited to participate in a study. Please follow the link below to review the consent form. [survey-link:econsent] To securely login to your consent form that is unique to you, please enter the passcode that will be sent in a separate email. That passcode is unique to you, and *must not be shared.*If you have any questions, contact the study team before signing at [study team phone and email address]To opt-out of the study and not receive any more notifications, contact the study team directly.[ ]  Customized text:       |
|  | [x]  Prevent piping of data for Identifier fields?To protect privacy, the box for “Prevent piping of data for Identifier fields” should be CHECKEDIf unchecked, describe what identifiers will be used and why they are necessary:       |
|  | List any attachments that will be sent with the email: None |

|  |  |
| --- | --- |
| Title of this Alert: | Passcode Email[ ]  This alert will not be used because the study will only use in-person consent |
| Alert Schedule | Describe when the alert will be sent: Send immediately |
|  | Sent on what schedule and how many times? Every time the registration form is saved |
| Message Settings | Alert Type:  |
|  | Email Subject Line: eConsent Passcode for a VCU Research Study  |
|  | Email Message Text (select one):[x]  Template default text: Hello,Please enter the passcode provided below to open the eConsent form sent in a separate email.  This passcode is unique to you and *must not be shared* with anyone else.* Passcode (enter [registration form’s passcode])

[ ]  Customized text:       |
|  | [x]  Prevent piping of data for Identifier fields?To protect privacy, the box for “Prevent piping of data for Identifier fields” should be CHECKEDIf unchecked, describe what identifiers will be used and why they are necessary:       |
|  | List any attachments that will be sent with the email: None |

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| --- | --- |
| Title of this Alert: | Send Copy of eConsent |
| Alert Schedule | Describe when the alert will be sent: Send immediately |
|  | Sent on what schedule and how many times? Just once (default) |
| Message Settings | Alert Type:  |
|  | Email Subject Line: Copy of your eConsent  |
|  | Email Message Text (select one):[x]  Template default text: Hello,You have agreed to receive a copy of your eConsent via email.  Attached you will find your signed eConsent document.If you have any questions. please contact the research team at:Phone: [study team’s direct phone number]Email: [study team’s email address]Thank you.[ ]  Customized text:       |
|  | [x]  Prevent piping of data for Identifier fields?To protect privacy, the box for “Prevent piping of data for Identifier fields” should be CHECKEDIf unchecked, describe what identifiers will be used and why they are necessary:       |
|  | List any attachments that will be sent with the email: PDF of the executed eConsent  |

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| --- | --- |
| Title of this Alert: | Confirmation Email to Participant[ ]  This alert will not be used because the study will only use in-person consent |
| Alert Schedule | Describe when the alert will be sent: Send immediately |
|  | Sent on what schedule and how many times? Just once (default) |
| Message Settings | Alert Type:  |
|  | Email Subject Line: eConsent Confirmation Email  |
|  | Email Message Text (select one):[x]  Template default text: Hello,Thank you for your interest in the research study. If you have chosen to receive a copy of your signed eConsent document it will be emailed to you from the study team in a separate email.Please DO NOT REPLY to this email.If you have any questions. please contact the research team at:Phone: [study team’s direct phone number]Email: [study team’s email address]Thank you.[ ]  Customized text:       |
|  | [x]  Prevent piping of data for Identifier fields?To protect privacy, the box for “Prevent piping of data for Identifier fields” should be CHECKEDIf unchecked, describe what identifiers will be used and why they are necessary:       |
|  | List any attachments that will be sent with the email: none  |

Provide any other alerts/notifications related to eConsent that will be sent to study participants:

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| --- | --- |
| Title of this alert: |       |
| Alert Schedule | Describe when the alert will be sent:       |
|  | Sent on what schedule and how many times?       |
| Message Settings | Alert Type:  |
|  | Email Subject Line:       |
|  | Email Message Text:      |
|  | [x]  Prevent piping of data for Identifier fields?To protect privacy, the box for “Prevent piping of data for Identifier fields” should be CHECKEDIf unchecked, describe what identifiers will be used and why they are necessary:       |
|  | List any attachments that will be sent with the email:       |
| Title of this alert: |       |
| Alert Schedule | Describe when the alert will be sent:       |
|  | Sent on what schedule and how many times?       |
| Message Settings | Alert Type:  |
|  | Email Subject Line:       |
|  | Email Message Text:      |
|  | [x]  Prevent piping of data for Identifier fields?To protect privacy, the box for “Prevent piping of data for Identifier fields” should be CHECKEDIf unchecked, describe what identifiers will be used and why they are necessary:       |
|  | List any attachments that will be sent with the email:       |