Title: Obtaining E-Consent in REDCap	**Area:** REDCap
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	Pages: 12

1.0 Procedure Description

This SOP describes usage of REDCap to obtain E-Consent for Research Studies.

2.0 Persons Affected

All REDCap researchers using REDCap to obtain consent.

3.0 Procedures

Individuals who are using REDCap to consent anonymous participants may have their e-consent form and data collection instruments within the same project.

If you are consenting non-anonymous participants and your e-consent form requires their signature, or other identifying information, you must have your e-consent form in a separate project from your data collection instruments (See Appendix A, Figure 1).

E-consent form project access should only be granted to the Principal Investigator (PI) or the appropriate and approved delegate(s).

Refer to our Privacy Policy for more information on identifiers and privacy with REDCap.

3.1 Obtaining Consent with REDCap Survey

3.1.1 If not already done, enable “Use surveys in this project” on the Project Setup page. It is the first option under the “Main project settings” tab.

3.1.2 Create/Import/Upload your e-consent form as a data collection instrument within the project. Ensure that is consistent formatting with what your REB has approved. Recommendations will be provided in Section 4.

3.1.3 Enable your e-consent form as a survey in the “Online Designer”.

3.1.4 Ensure that your e-consent form is the first listed instrument in the Online Designer. If you have multiple consents for participants to sign, make sure the one you want them to see first is the topmost data collection instrument.

3.1.5 Click on the “Survey Distribution Tools” under “Data Collection” in the menu on the left of your screen.

3.1.6 Whatever e-consent form you set as your topmost instrument in the Online Designer will now be available via the “Public Survey URL” listed on the Survey Distribution Tools page. Prospective participants can use this link to consent to your study. If you have multiple e-consent forms, see Section 3.2.

3.2 Multiple E-consent forms

3.2.1 If you have multiple e-consent forms for your participants to sign, make sure you have created them as data collection instruments in your Online Designer, and enabled them all as surveys.

3.2.2 In the Online Designer, under Survey options, there is a button for “Survey Queue”. The Survey Queue displays a list of your surveys to a participant all on a single page, in which the queue comprises all surveys that are to be completed (like a 'to-do' list) as well as the surveys that the participant has already completed.

3.2.3 Open the Survey Queue and activate all subsequent e-consent forms from your public survey e-consent form.

3.2.3.1 You also have the option of hiding the Survey Queue from participants. If you do not want them to see the Survey Queue, click the "Keep the survey Queue hidden from participants" box.

3.2.4 Set the logic in the "Display survey in the Survey Queue when…" section. If you do not have any specific logic required, simply click the box "When the following survey is completed:" and select the previous e-consent form. Do this for all remaining e-consent forms.

4.0 E-consent form Design

Your e-consent form must be identical, or as close to identical as possible to the approved REB e-consent form. REDCap may alter the format of the signatures and look of the e-consent form, but all the content should be identical.

4.1 Anonymous Participants

4.1.1 As there are no signatures required for anonymous participants, users can implement radio buttons or dropdowns with "Yes Consent" and "No Consent" options (See Appendix A, Figure 2).

4.2 Non-anonymous Participants "Wet Signature"

4.2.1 Participant "Wet Signatures" can be obtained via the "Signature Field" within REDCap. This field allows participants to draw their signature with their cursor as if they were signing with a pen.

4.2.2 It is also recommended to include text fields so that the participant may enter any other relevant information (first name, last name, date of birth, etc.).

5.0 Auto-Archiver and E-Consent Framework for Non-anonymous Participants

REDCap includes an option in its survey settings that will activate the Auto-Archiver and E-Consent Framework option. **We recommend utilizing this option for consenting non-anonymous participants as it includes some best practice functionality for obtaining consent.**

Enabling this on your e-consent form survey will allow your participants to review their e-consent form survey responses before finally submitting. It will also display language asking the participant if they understand what they are consenting to, and a checkbox to confirm that they do and will consent to participate.

It also will produce a PDF version of their responses on the e-consent form which they can download. This removes the burden on the research team to provide each participant with their signed consent, which is often required by REBs.

The Auto-Archiver will also download this PDF copy of their responses and signed consent to the projects “File Repository”. This enables the research team to download hard copies of the consent, which may also be a requirement of their REBs.

It also allows for research teams to implement version control with their e-consent forms. It is best practice to assign versions to e-consent forms any time changes are made to the e-consent form after recruitment has begun.

See Appendix B for more information on the Auto-Archiver and E-Consent Framework

6.0 Investigator Signature

There are several ways investigators can sign off on participant submitted e-consent forms. The method you will choose will usually be specific to the context of your study. WE-SPARK recommends the following methods:

6.1 "Wet Signature" Method

6.1.1 The "Wet Signature" method involves including a "Signature Field" on your e-consent form. This field allows Investigator(s) to draw their signature with their cursor as if they were signing with a pen.

6.1.2 This is the simplest method but can be time consuming for studies with many participants.

6.2 PI Signature Placeholder Method

6.2.1 For studies recruiting large amounts of participants where physical signatures are not required for each form, researchers can use a PI Signature Placeholder field.

6.2.2 Create a "Descriptive Text" field on your e-consent form and include an image of your PI signature. Choose the "inline image" option to ensure it shows on the page (See Appendix C).

6.3 E-Signature Module in REDCap

6.3.1 For some studies, the "Wet Signature" and the "PI Signature Placeholder" methods may not be sufficient for PI sign off. Authenticity requirements for electronic signatures may vary depending on the study type, sponsors, and REB approvals.

6.3.2 For clinical research studies dealing with strict inclusion/exclusion criteria (disease status, lab results, diagnosis confirmation), and small sample sizes, it is often best practice to utilize the **E-Signature Module.**

6.3.3 The E-Signature module provides the highest authenticity for investigators to sign off on participant consent and data collection forms. By enabling this module, the investigators can go into participant records to lock and e-sign data collection forms.

6.3.4 **The E-Signature is linked to their REDCap account and timestamped, which provides more authenticity than REDCap's "Wet Signature" Fields or any PI Signature Placeholders.**

6.3.5 Currently there is no E-Signature Module SOP. Please contact kylelago@uwindsor.ca if you are interested in implementing the E-Signature module on your REDCap project.

7.0 Review/Revision History

Date	Revision No.	Revision Type (minor edit, moderate revision, complete revision)	Reference Section(s)
2021-March-11	1.0	New procedure drafted	N/A

Appendix A

Figure 1. Separate project for consenting non-anonymous participants

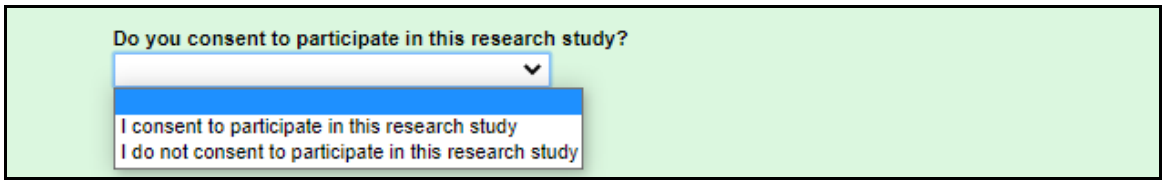
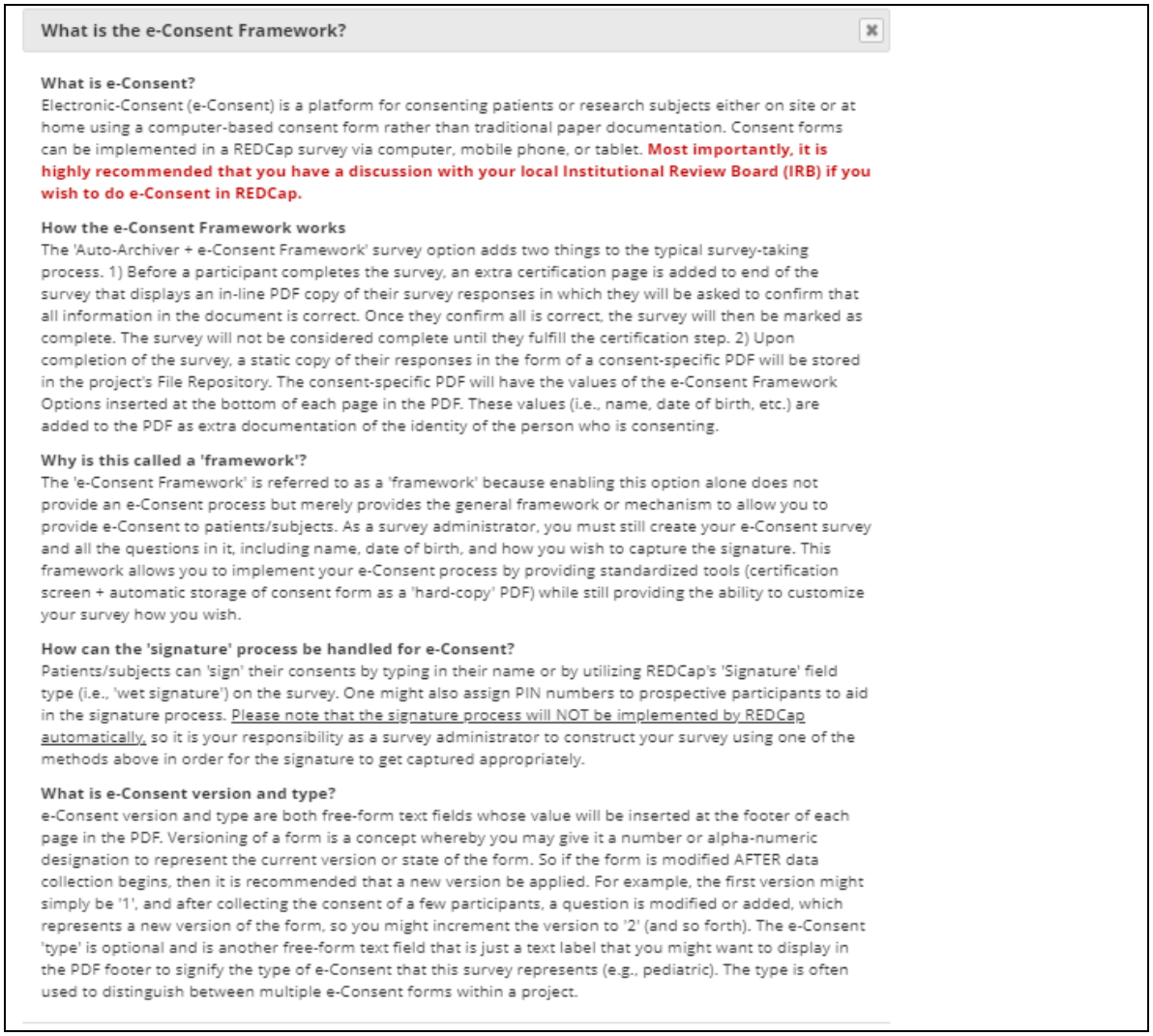


Figure 2. Consent option example for anonymous participants

Appendix B



What is the e-Consent Framework?

What is e-Consent?
Electronic-Consent (e-Consent) is a platform for consenting patients or research subjects either on site or at home using a computer-based consent form rather than traditional paper documentation. Consent forms can be implemented in a REDCap survey via computer, mobile phone, or tablet. **Most importantly, it is highly recommended that you have a discussion with your local Institutional Review Board (IRB) if you wish to do e-Consent in REDCap.**

How the e-Consent Framework works
The 'Auto-Archiver + e-Consent Framework' survey option adds two things to the typical survey-taking process. 1) Before a participant completes the survey, an extra certification page is added to end of the survey that displays an in-line PDF copy of their survey responses in which they will be asked to confirm that all information in the document is correct. Once they confirm all is correct, the survey will then be marked as complete. The survey will not be considered complete until they fulfill the certification step. 2) Upon completion of the survey, a static copy of their responses in the form of a consent-specific PDF will be stored in the project's File Repository. The consent-specific PDF will have the values of the e-Consent Framework Options inserted at the bottom of each page in the PDF. These values (i.e., name, date of birth, etc.) are added to the PDF as extra documentation of the identity of the person who is consenting.

Why is this called a 'framework'?
The 'e-Consent Framework' is referred to as a 'framework' because enabling this option alone does not provide an e-Consent process but merely provides the general framework or mechanism to allow you to provide e-Consent to patients/subjects. As a survey administrator, you must still create your e-Consent survey and all the questions in it, including name, date of birth, and how you wish to capture the signature. This framework allows you to implement your e-Consent process by providing standardized tools (certification screen + automatic storage of consent form as a 'hard-copy' PDF) while still providing the ability to customize your survey how you wish.

How can the 'signature' process be handled for e-Consent?
Patients/subjects can 'sign' their consents by typing in their name or by utilizing REDCap's 'Signature' field type (i.e., 'wet signature') on the survey. One might also assign PIN numbers to prospective participants to aid in the signature process. Please note that the signature process will NOT be implemented by REDCap automatically, so it is your responsibility as a survey administrator to construct your survey using one of the methods above in order for the signature to get captured appropriately.

What is e-Consent version and type?
e-Consent version and type are both free-form text fields whose value will be inserted at the footer of each page in the PDF. Versioning of a form is a concept whereby you may give it a number or alpha-numeric designation to represent the current version or state of the form. So if the form is modified AFTER data collection begins, then it is recommended that a new version be applied. For example, the first version might simply be '1', and after collecting the consent of a few participants, a question is modified or added, which represents a new version of the form, so you might increment the version to '2' (and so forth). The e-Consent 'type' is optional and is another free-form text field that is just a text label that you might want to display in the PDF footer to signify the type of e-Consent that this survey represents (e.g., pediatric). The type is often used to distinguish between multiple e-Consent forms within a project.

Figure 3. Auto-Archiver and E-Consent Framework Information

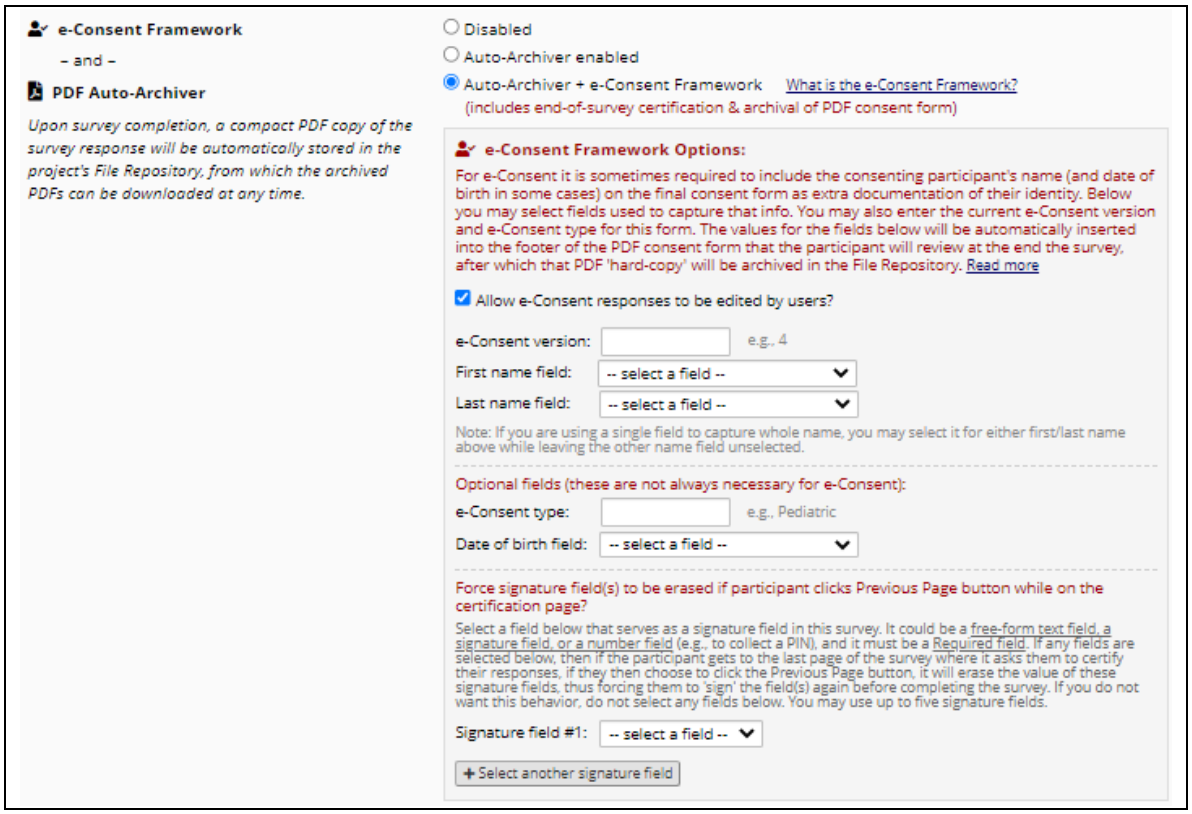


Figure 4. Auto-Archiver and E-Consent Framework options in "Survey Settings"

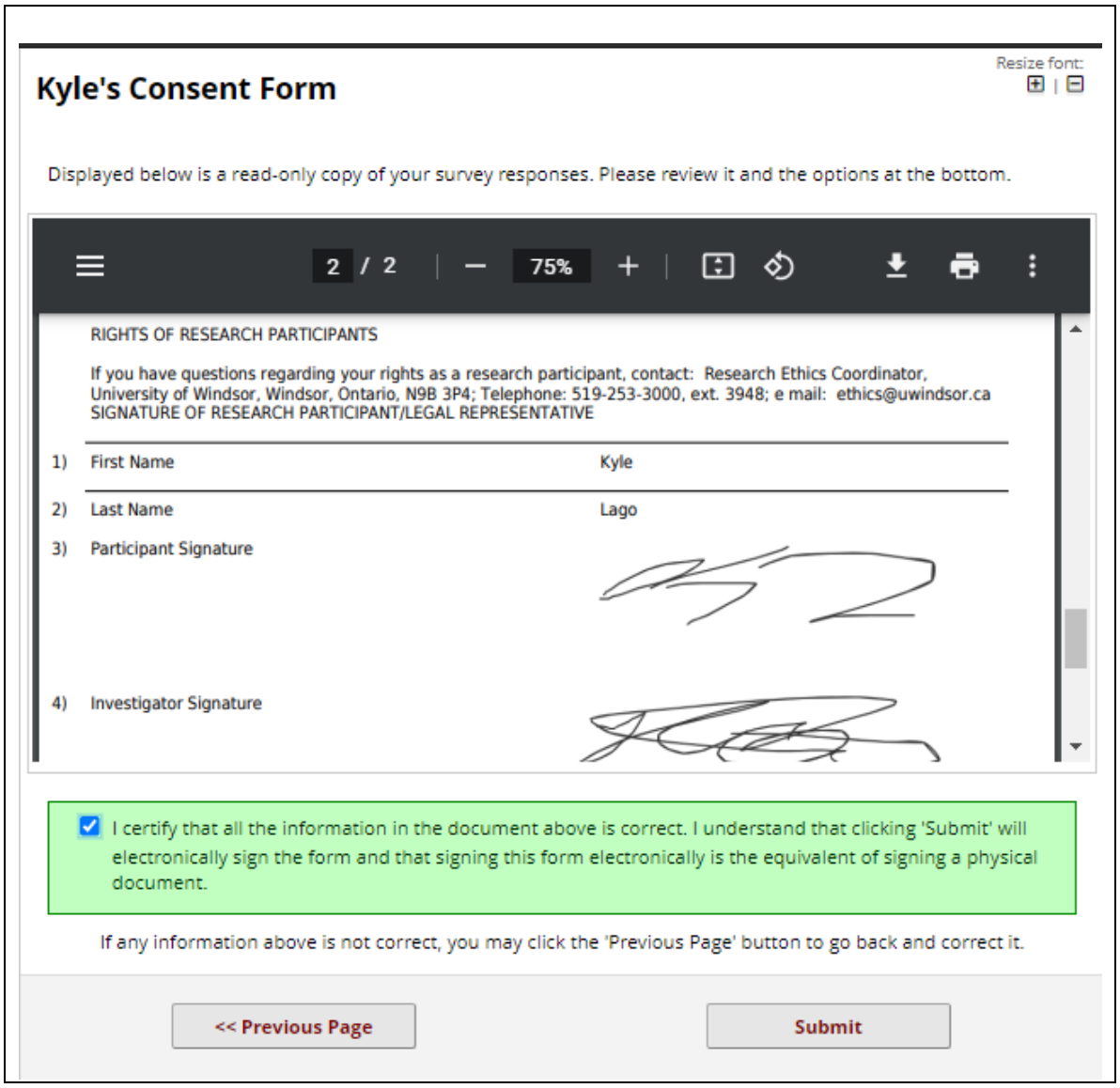


Figure 5. Example of E-Consent Framework on a E-consent form Survey.

Appendix C

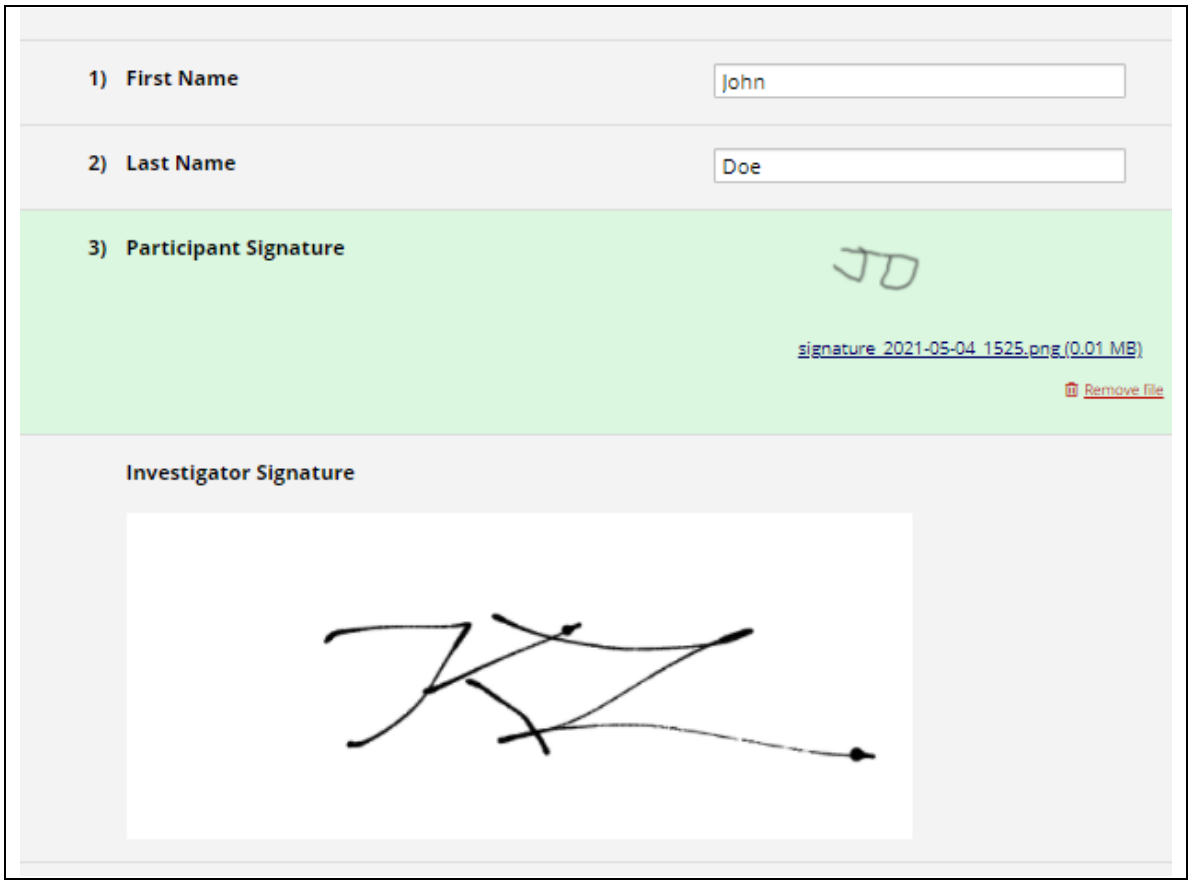


Figure 6. Example of Investigator Signature Placeholder Field