REDCap eConsent v2.0

Configuration and Implementation

(and a quick update on REDCap and 21 CFR Part 11 compliance)

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JHU REDCap: eConsent Framework 2.0

Goals for Today:

- Review the three most common consent types (Megan Singleton).
- Demonstrate the REDCap configuration, primarily focusing on consents requiring legally effective signatures (Scott Carey).

Keep in Mind:

- Studies come in all shapes/sizes in regards to eConsent.
- It is imperative that studies implement their REDCap eConsent configuration in accordance with IRB requirements for that study.
- When you have questions, ASK!
  - Reach out to the REDCap Team (via support request).
    - **NOTE:** eConsent support IS available to Bronze tier projects.
  - Reach out to IRB.

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An important note…

- Today's Presentation will primarily focus on how to use REDCap's e-consent framework when documented consent, requiring a legally effective signature is required.
- Every project is a little different and will have it’s own unique set of requirements.

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What types of research might REDCap be used for to obtain participant consent?**

- **Exempt research** that typically requires a process to inform participants of the study and obtain agreement to participate but does not have to meet all required consent elements (e.g. minimal risk survey study)
- **Minimal Risk research qualifying for a waiver of documentation of consent**
  - All required elements of consent must be included in the consent that is embedded in REDCap
  - Only minimal risk research meeting criteria to waive the signature requirement qualifies
  - The IRB must approve the waiver
  - Does not require signatures but typically has an "I agree" button
  - Doesn't require the REDCap eConsent Framework.

** All planned uses of e-consent require IRB approval

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What types of research might REDCap be used for to obtain participant consent?

- **Research that requires legally effective signature**
  - May be minimal risk or greater than minimal risk
  - Cannot be FDA regulated
  - To have a "legally effective e-signature" REDCap must be configured to include:
    - A mechanism for **Authentication** to verify the person signing is the correct person
      - Provision of a code during the consent conversation that must be unique to the participant and entered as part of the e-consent process is a JHU-approved mechanism for authentication
    - A mechanism where the participant can **document the decision to participate**
      - e.g. Typing name to confirm decision

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What is 21 CFR Part 11 Compliance?

Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). **Part 11**, as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records (Title 21 CFR Part 11 Section 11.1 (a)).
(Wikipedia contributors, 2024)

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Okay… so what does this have to do with a data entry system?

When an FDA sponsored study uses an electronic records system (e.g., REDCap) as the source document (referred to as the "document of record"), the system being used must be thoroughly validated.

This involves very detailed and extensive documentation, testing, validation, and ongoing oversight to ensure the system is accurately representing the data as it was collected. Additionally, every change to the data system source code (patches, version updates, custom code, etc.), requires additional validation.

As you might guess… Part 11 Compliance = **A HEAVY LIFT!!!**

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Can JH REDCap Accommodate FDA Studies Requiring Part 11 Compliance?

No (but it IS on our radar)

- JHU REDCap (here in Baltimore) is **INTENTIONALLY NOT** Part 11 compliant.
  - We make far too many code customizations.
  - Maintaining compliance would be impossible.
- Will JH REDCap eventually be Part 11 Compliant?
  - It's possible and has been discussed.
  - If it happens, it would be a SEPARATE instance of REDCap.
  - This instance would have limited customizations.
  - No timeline has been established for a JH REDCap instance that is Part 11 Compliant

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Is there a currently available option for e-consent for FDA-regulated research?

- YES !

DocuSign

- Has been used here at Johns Hopkins for quite awhile.
- Requires IRB approval
- Can be used for FDA 21 CFR Part 11 studies.
- Accommodates multiple "in-line" signatures.

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REMINDER

IRB eConsent requirements vary from project to project.
It is important that the PI and study team understand clearly what IRB has approved (and NOT approved) as it relates to eConsent.

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- Recently, REDCap released a major eConsent Framework update that changes how REDCap eConsent is configured.
- This framework will be particularly useful for studies that require legally effective signature as part of the documented consent.
- Several new features and improvements:
  - More easily accommodate multiple signatures (participant , study coordinator, LAR, PI…).
  - Better accommodates eConsent "versioning".
  - Dynamically display different eConsent PDF's when a project is using the Multi-Language Management feature (based on participants language preference).
  - Dynamically display site-specific eConsent PDF's when multi-site studies are using Data Access Groups (DAGs).

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Key Ingredients: (where legally effective signature is required)

- Must be specifically approved by IRB to use REDCap for eConsent.
- Must have an opportunity for a consent conversation w/ consenter (in-person, Zoom, Teams).
- Must implement an authentication method (such as an eConsent survey access code).
- Must display the IRB-Approved eConsent version (typically the approved PDF is displayed).
- Must collect eConsent datapoints required by IRB. This often includes items such as:
  - Date of Consent
  - Indication of intention to participant
    - Example: "I have reviewed the informed consent document above with the study coordinator and I agree to participate in the XYZ study.")
  - Participant First & Last Name
  - Participant Signature
  - Study Coordinator Name & Signature

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REDCap eConsent Framework (2.0) Overview:

- The eConsent instrument uses a generic descriptive text field as a "placeholder" field for displaying the appropriate PDF version.
- Multiple versions of the consent PDF can be accommodated and dynamically displayed based on various conditions, such as:
  - Language selected via Multi-Language Management configuration (MLM)
  - Site specific versions for multi-site projects using Data Access Groups (DAGs)
  - Other conditions
- Additional signatures require separate survey(s) for attestation.
  - This is where the setup is a little less intuitive than DocuSign.
  - Once understood, it should not be an issue.
  - Additional signatures may include: study coordinator, LAR, PI, interpreter.

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SIGNATURES:

- A valid eConsent (**documented electronic consent)** requires not only the participant signature, but also the signature of the person facilitating the eConsent of the participant, such as the study coordinator (may include other signatures, as well).
- When doing a remote/online eConsent with a participant, the participant eConsent survey can only accommodate a single signature.
- The study coordinator signature occurs on a second (paired) survey.
- When the participant completes (submits) the eConsent, the study coordinator is sent a link where they can add their signature via a separate survey.
- The two can then be merged into a single PDF.

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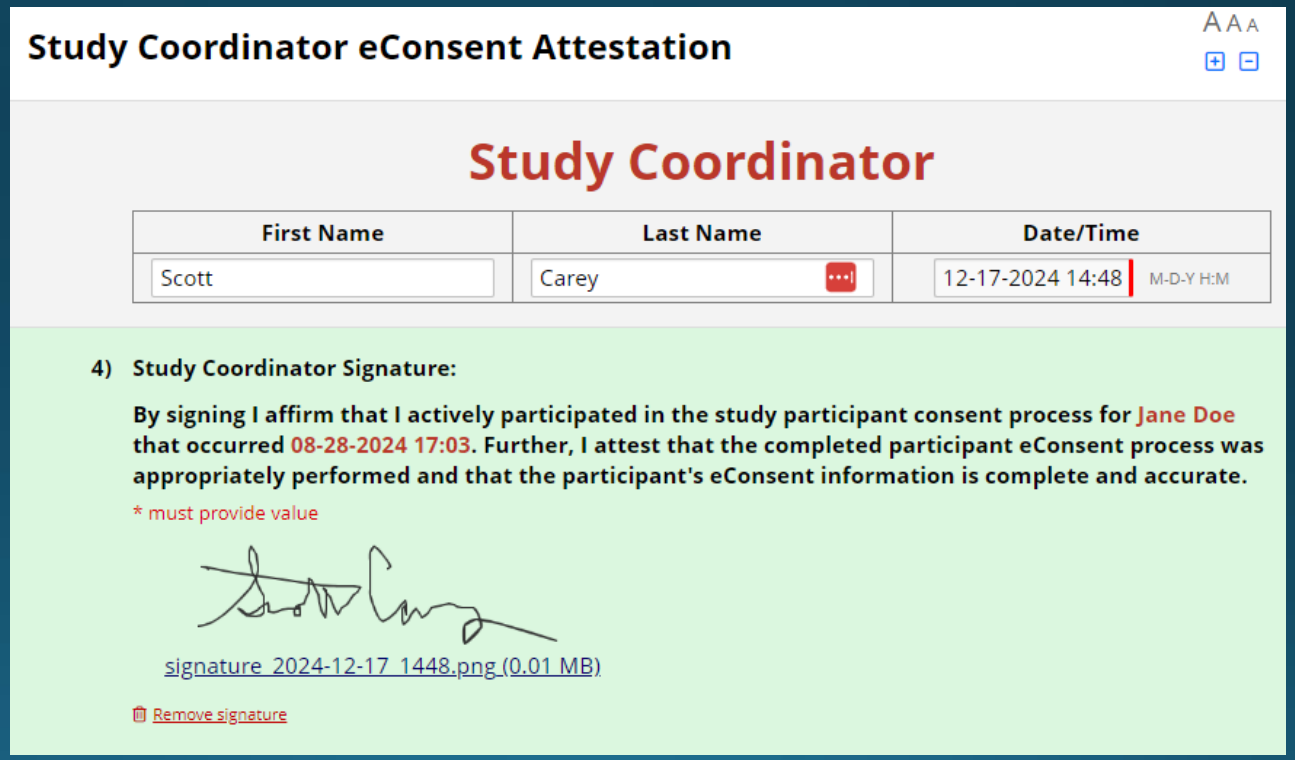
Sample Study Coordinator / PI Attestation Signature

- Should include:
  - Date
  - Study Coordinator Name
  - Study Coordinator Signature
  - Statement of attestation



Study Coordinator eConsent Attestation

AAA

Study Coordinator

First Name	Last Name	Date/Time
Scott	Carey	12-17-2024 14:48 M-D-Y H:M

4) **Study Coordinator Signature:**

By signing I affirm that I actively participated in the study participant consent process for Jane Doe that occurred 08-28-2024 17:03. Further, I attest that the completed participant eConsent process was appropriately performed and that the participant's eConsent information is complete and accurate.

* must provide value

signature_2024-12-17_1448.png (0.01 MB)

Remove signature

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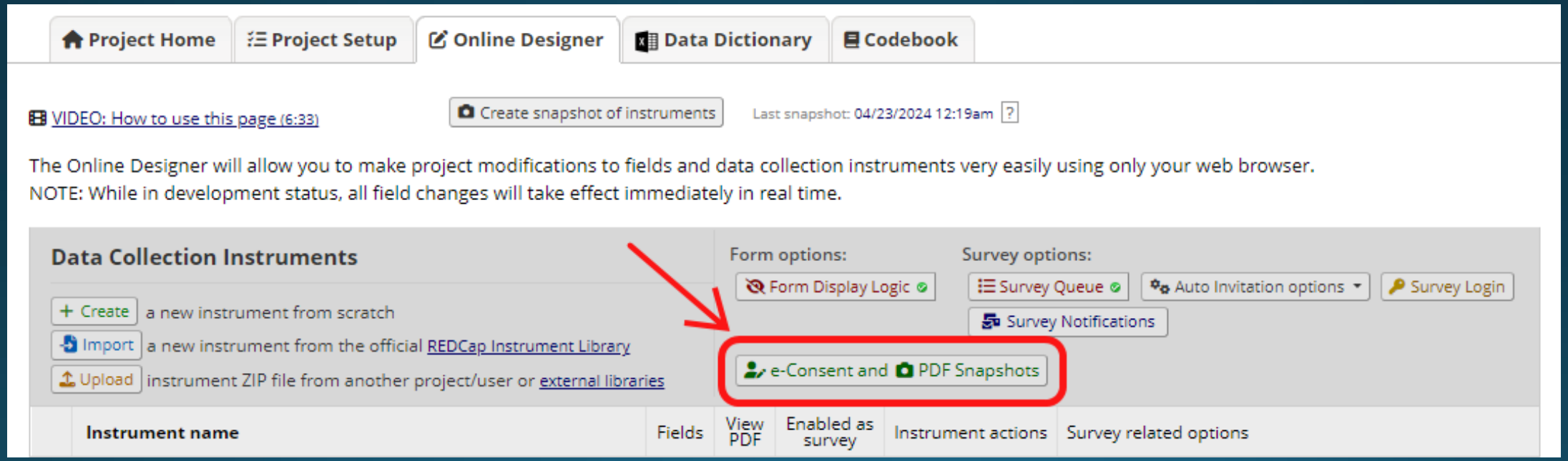
REDCap eConsent 2.0 Configuration

Once the necessary eConsent / Attestation surveys have been created, the next step is to enable the eConsent functionality. The eConsent configuration page now is accessed from the Online Designer page.



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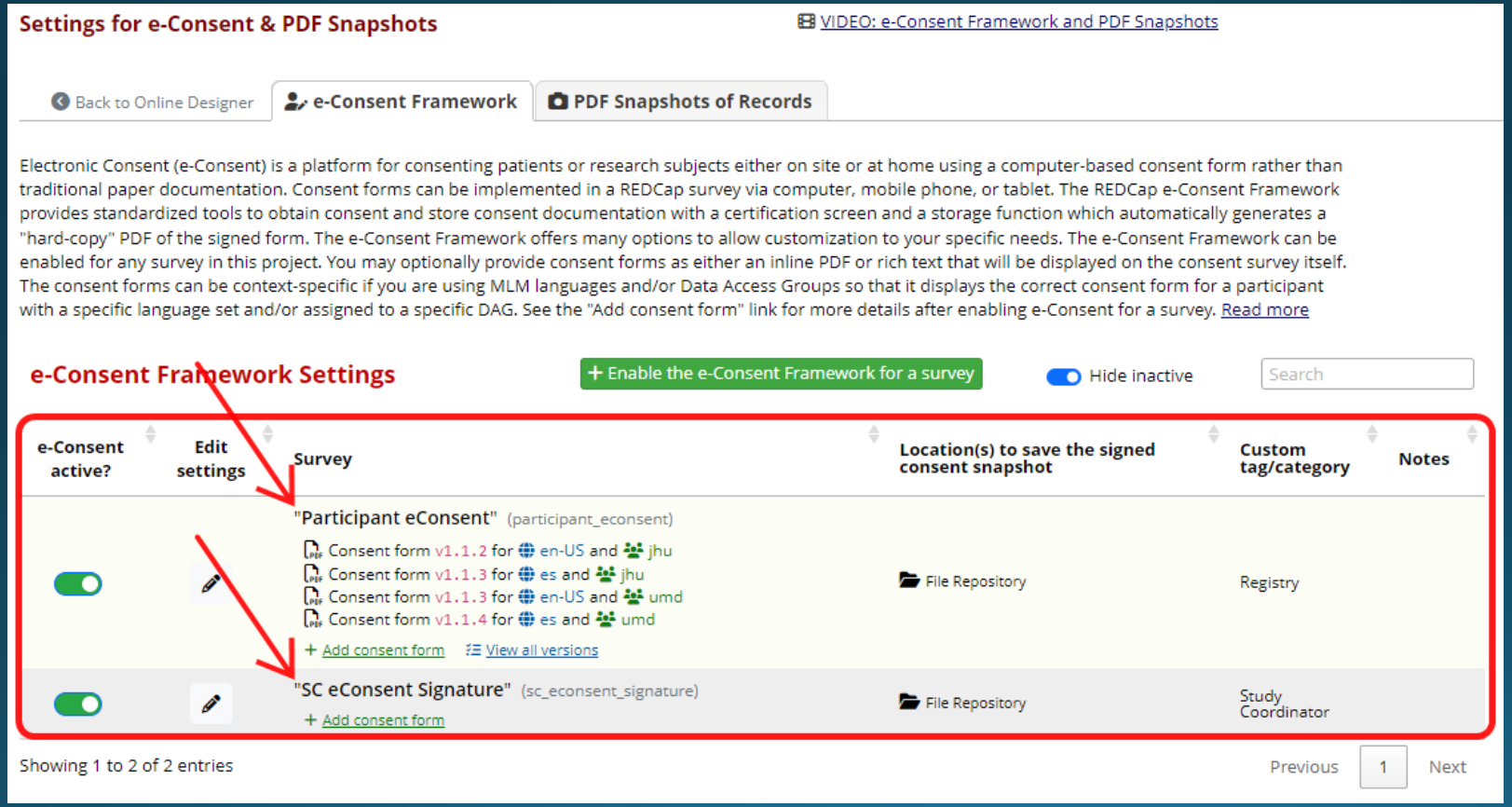
REDCap eConsent Configuration

Instruments involved in the eConsent are added here (participant consent, coordinator attestation…)



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Multiple PDF's can be assigned to a single DTF to be displayed dynmically (e.g., based on selected language, site…)

e-Consent active?	Edit settings	Survey	Location(s) to save the signed consent snapshot	Custom tag/category	Notes
		"Participant eConsent" (participant_econsent) Consent form v1.1.2 for en-US and jhu Consent form v1.1.3 for es and jhu Consent form v1.1.3 for en-US and umd Consent form v1.1.4 for es and umd + Add consent form View all versions	File Repository	Registry	
		"SC eConsent Signature" (sc_econsent_signature) + Add consent form	File Repository	Study Coordinator	

Showing 1 to 2 of 2 entries Previous 1 Next

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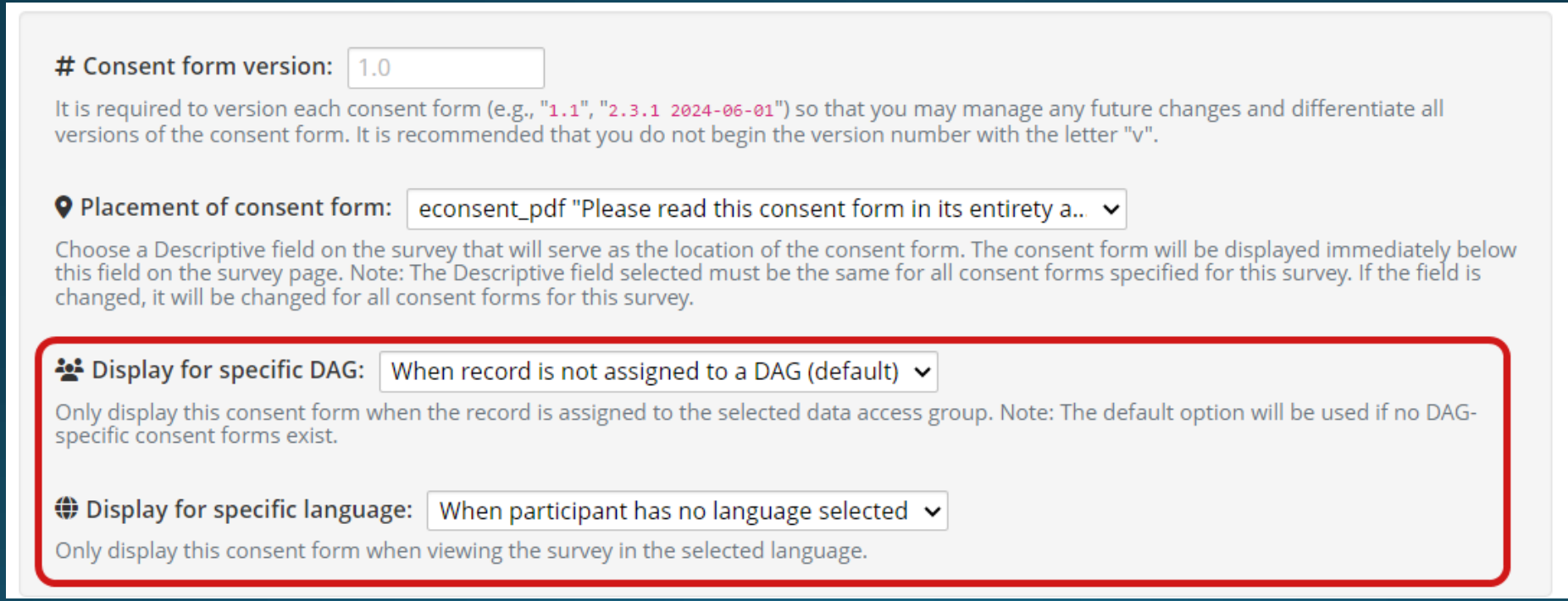
When adding Consent Forms, they can be tagged for specific DAG's or Languages.



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Let's take a closer look… (live demo)

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References

Frequently Asked Questions About Electronic and Remote Consent. (n.d.). Www.hopkinsmedicine.org. https://www.hopkinsmedicine.org/institutional-review-board/guidelines-policies/guidelines/remote-consent-and-eletronic-consent

Wikipedia contributors. (2024, November 23). *Title 21 CFR Part 11*. Wikipedia. https://en.wikipedia.org/wiki/Title_21_CFR_Part_11

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