How To Guide:
Submit an Initial Study Protocol in iMedRIS

For instructions with * present, be aware that these sub-sections or questions must be completed prior to moving on to the next section.

Even though other sections may be temporarily skipped and the form can be submitted in iMedRIS without filling all fields, the IHMC IRB Analyst may return the submission to the PI if not all applicable study fields are complete for an informed initial review to be conducted.

1. Log in to https://irb.ihmc.us and select "*Create a New Study*".

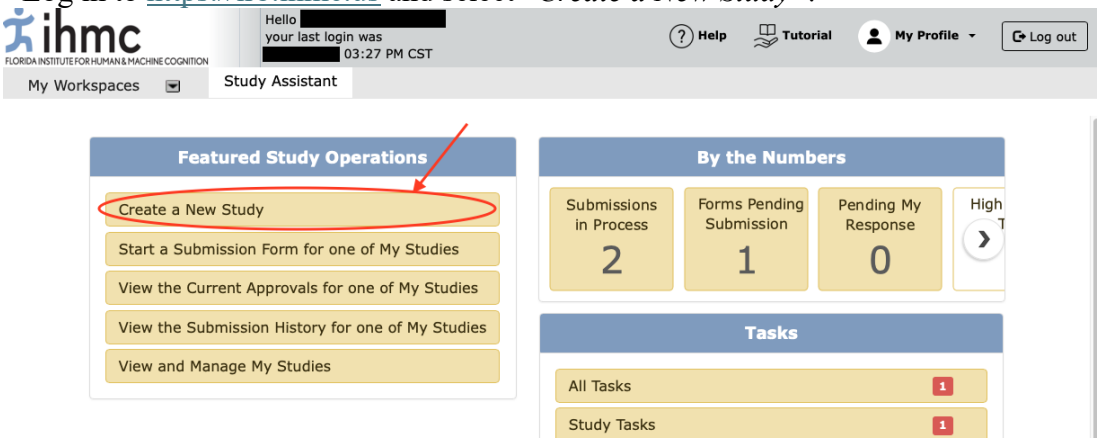

Figure 1: *The My Workspace Study Assistant Dashboard has the "Create a New Study" operation featured.*

2. Start by entering the full title of the study and a short title of the study. *
   - Select "*Save and Continue to Next Section*" to move on to the next section.

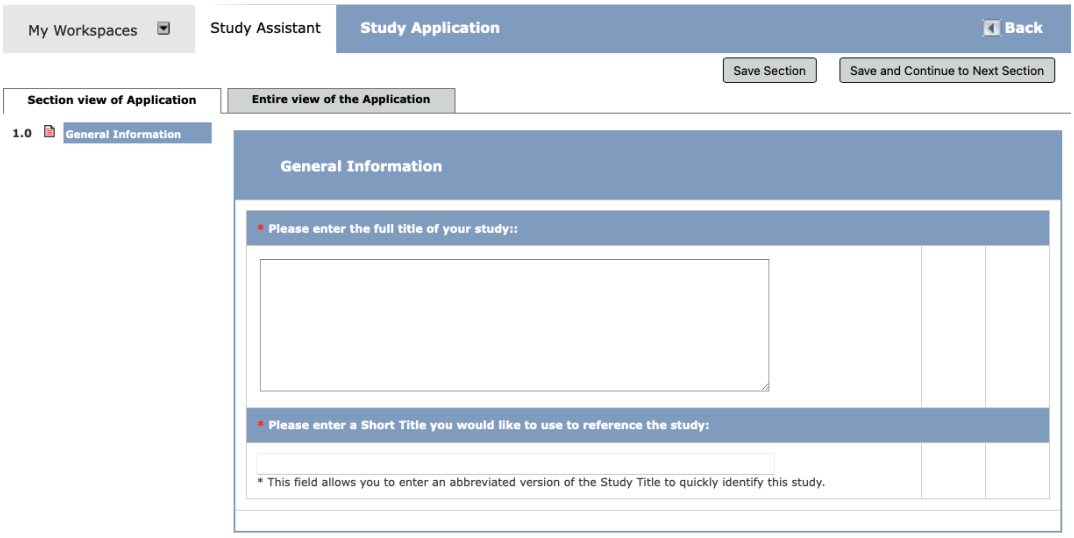

Figure 2: *Both fields in section 1 of the Study Application are required. Be aware that these fields will be how your study is referred to in long and short form.*

The *Section view of the Application* on the left will populate as each section is completed.

1. Set up department access. IHMC is the default department. *
    - Make sure to select the department that will be the primary site.
    - Select "*Save and Continue to Next Section*" to move on to the next section.

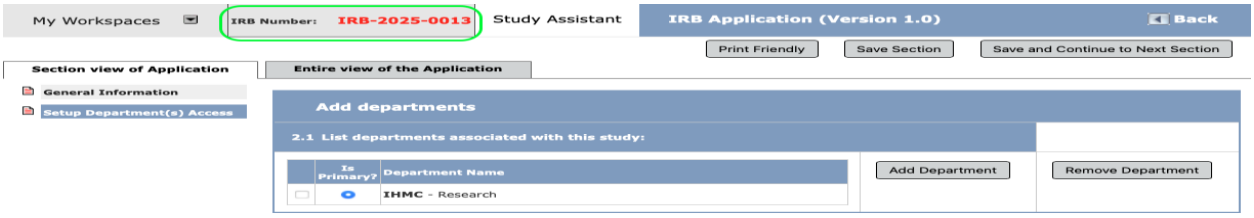

Figure 3: *IHMC automatically populates as the primary department. However, if you are working with additional departments, this is where they will be added. Make note that the study application now has an IRB Number affiliated with it. This is how the study is tracked in the iMedRIS system. It includes IRB, the year of the application's creation, and the order that the application was created (e.g., Figure 3 is application #13 in 2025).*

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2. Assign key study personnel (KSP) access to the study. *

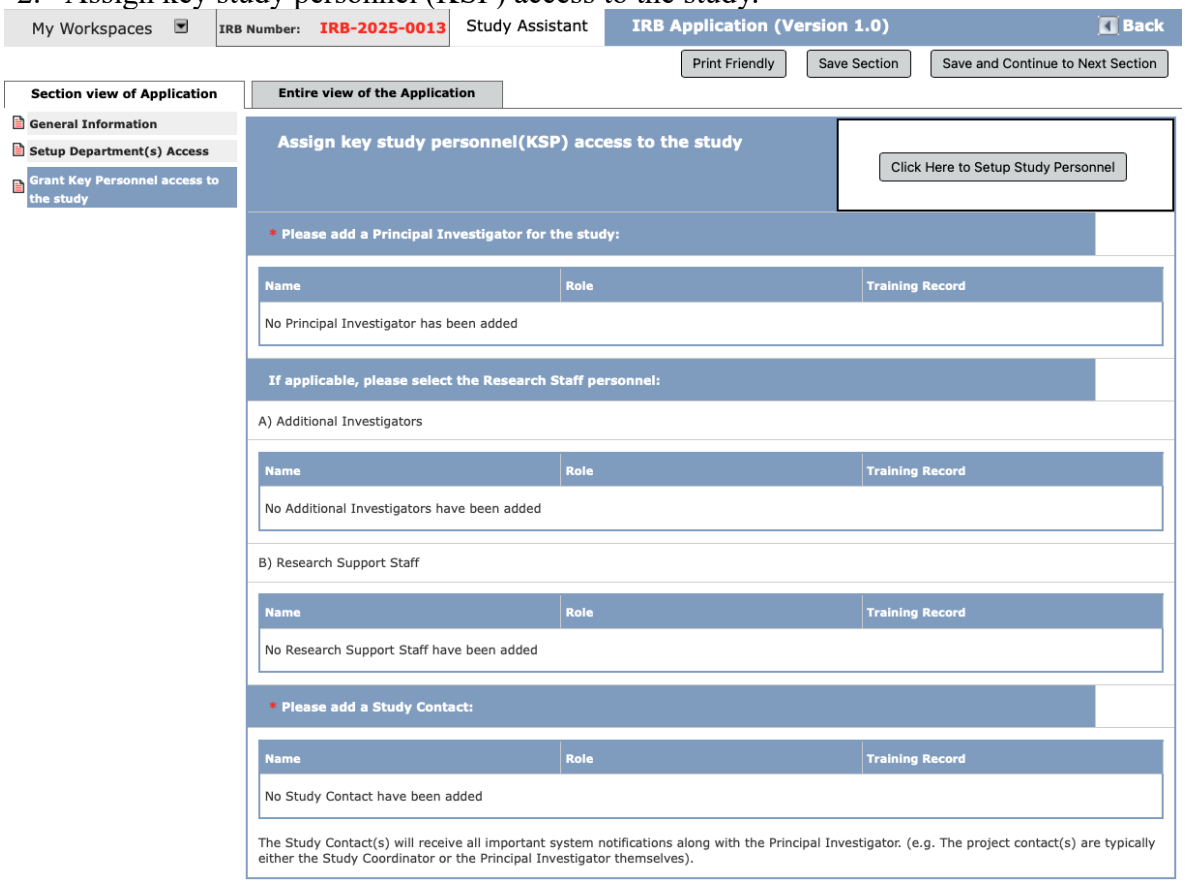

Figure 4: *This is where KSP access is set up in the application. All KSP should be listed here, otherwise they will not appear later in Section 12. KSPs include anyone who will have access to participants, potentially identifiable participant information, or interact with key aspects of human subject research.*

3. Select "*Click Here to Setup Study Personnel"*.
    - Search for the personnel you intend to add to the study.
        - Enter their last name and/or first name
        - Selecting the database you would like to search (iRIS or LDAP).
        - Then, select "*Find User/Search Directory"*.

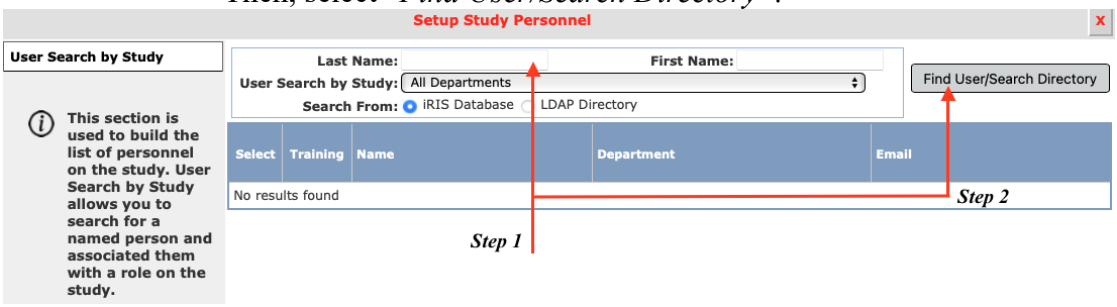

Figure 5: *The first and last name fields and desired database to search are present in a step-by-step search guide.*

4. Select "*Save and Continue"*. Continue to the next section.
5. Once a user is searched through the desired database or directory, click the "*Select*" icon to select the desired personnel.
6. Once the user is selected, select the *Role* that they will fulfill in the protocol.
    - A) Principal Investigator B) Additional Investigator
      C) Research Support Staff D) Study Contact
    - For Additional Investigators and Research Support Staff, make sure to fill the associated drop-down menu to the right.
    - Once complete, select the "*Save"* option at the bottom right.

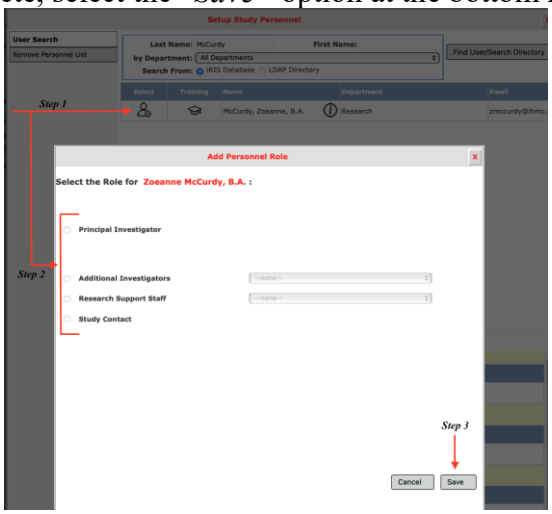

Figure 6: *Step-by-set instruction example on how to select personnel, assign a study role, and save changes. These steps will be repeated for every person that needs to be added to the study personnel list.*

7. Repeat this process for all KSP. Make sure to include all PI(s), research staff, and study contacts.
8. Select "*Close Setup of Study Personnel"*.
9. Select "*Save and Continue"*. Continue to the next section.

10. Complete Section 1.0. This includes the following sub-sections:
    - 1.1 | Type of research *
    - 1.2 | Review level *
    - 1.3 | Medical Monitor (*only for Full-Committee Review Level*)
    - 1.4 | Ombudsman (*only for Full-Committee Review Level & if required*)
    - 1.5 | Expedited Review Categories (*only for Expedited Reviews)*
    - 1.6. | Exempt Review Categories (*only for Exempt Reviews)*
    - 1.7 | Data security *
    - 1.8 | Clinical Trial (*Specify if a clinical trial and NCT number if applicable*)
    - 1.9 | Clinical Trial Phase (*Specify clinical trial phase or N/A*)
    - 1.10 | Financial interests *
11. Select "*Save and Continue to Next Section".*

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12. Complete Section 2.0. This includes the following sub-sections:
    - 2.1 | Representative Protocol Materials
        - Insert images and/or descriptions of any drugs, devices, supplements, systems, questionnaires, etc., that study participants will be administered/will use/interact with as part of the protocol
    - 2.2 | Drugs and/or Biologics *
    - 2.3 | Drugs/Agents Listed
    - 2.4 | Medical Devices *
    - 2.5 | Non-Significant Risk (NSR) Determination Request & Explanation
    - 2.6 | Listed Study Medical Devices/In-Vitro Diagnostics
    - 2.7 | Expanded Access or Compassionate Use Protocol Status
13. Select "*Save and Continue to Next Section".*

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14. Complete Section 3.0. This includes the following sub-sections:
    - 3.1 | Federal Funding *
    - 3.2 | Sponsors
    - 3.3 | Funding Document *

If you do not have federal funding secured but intend to, select "No" for subsection 3.1

15. Select "*Save and Continue to Next Section".*

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16. Complete Section 5.0. This includes the following sub-sections:
    - 5.1 | Enrollment Target (*if using multiple participant groups, indicate group N)*
    - 5.2 | Total Participants (*For multicenter studies only)*
    - 5.3 | Sample Size Justification

Only specify total participants in subsection 5.2 if it is a **multicenter study**

17. Select "*Save and Continue to Next Section".*

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18. Complete Section 6.0. This includes the following sub-sections:
    - 6.1 | Determination of Eligibility
    - 6.2 | Recruitment Plan
    - 6.3 | Recruitment Statement
    - 6.4 | Consent Methods * (*multiple options may be selected*)
    - 6.5 | Consent Process

- 6.6 | Participant Identifiers & Destruction Plan
- 6.7 | Time Commitment for Participants *
- 6.8 | Alternatives Designation & Description *
- 6.9 | Post-Participation Debriefing Summary

19. Select "*Save and Continue to Next Section"*.

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20. Complete Section 8.0. This includes the following sub-sections:
    - 8.1 | Description of Hypotheses to be Tested & Study Design *
    - 8.2 | Listed Primary Objectives
    - 8.3 | Listed Secondary Objectives
    - 8.4 | Listed Exploratory Objectives (*if applicable*)
    - 8.5 | How the Study will Answer Posed Research Questions
    - 8.6 | Summarized Rationale & Background *
    - 8.7 | Citations (*in APA formatting*)
21. Select "*Save and Continue to Next Section"*.

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22. Complete Section 8.0. This includes the following sub-sections:
    - 9.1 | Participant Exposure to Radiation *
23. Select "*Save and Continue to Next Section"*.

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24. Complete Section 10.0. This includes the following sub-sections:
    - 10.1 | Research-Related Risks * (*Any anticipated risks & minimization steps*)
    - 10.2 | Resources (*Select all that apply & provide a description*)
    - 10.3 | Benefits * (*Select all that apply & describe any others*)
    - 10.4 | Risks & Benefits (*Describe risks in relation to benefits*)
    - 10.5 | Data & Safety Monitoring * (*DSMP & plan details if applicable*)
    - 10.6 | Remuneration
25. Select "*Save and Continue to Next Section"*.

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26. Complete Section 11.0. This includes the following sub-sections:
    - 11.1 | Research PHI
    - 11.2 | Protecting Privacy *
    - 11.3 | Certificate of Confidentiality
    - 11.4 | Sharing of Research Results
    - 11.5 | Data Disclosure
    - 11.6 | Data Security
    - 11.7 | HIPAA Applicability – Study Locale
    - 11.8 | HIPAA Applicability – PHI Data *
    - 11.9 | HIPAA – Permission to Access Sensitive Data
    - 11.10| HIPAA Applicability – Does HIPAA Apply?
27. Select "*Save and Continue to Next Section"*.

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28. Complete Section 12.0. For each KSP in the Department Access Setup Section, do the following in Section 12.0:
    - Select the personnel from the KSP Name drop-down list.
    - If the personnel will obtain informed consent, check the applicable checkbox.
    - Briefly describe their study responsibilities (e.g., data collection, management, analysis, etc.).
    - Specify personnel qualifications, licensure, and training.
    - Provide a current CITI training link to their CITI Completion Report.

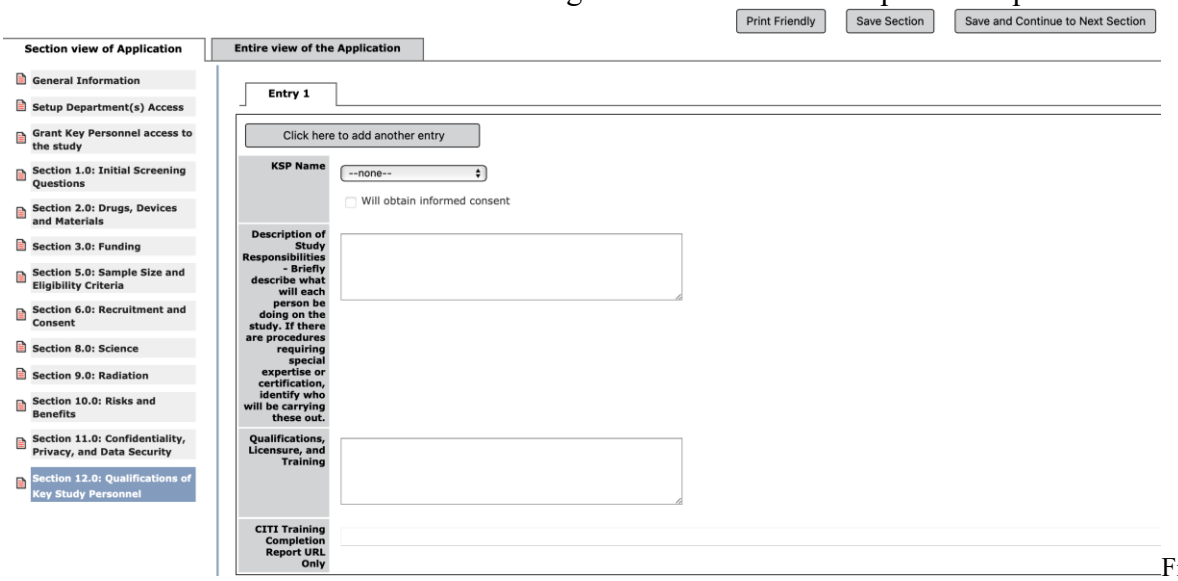

Figure 7: *This is what the first entry will look like for Section 12.0. After every entry, another tab will populate beside "Entry 1".*

29. Repeat these steps for all KSP.

- If the study involves invasive/risky procedures requiring special training or certification, identify <u>who</u> will be conducting these procedures and provide details about their qualifications and training.
- Make sure that the CITI Completion Report link is <u>active</u> and does not direct to the Completion Certificate.
- Make sure **<u>all</u>** KSP included in the Setup Department Access section are present in section 12.0 and have active certifications. For guidance on required certifications, reach out to the IHMC IRB Administrator or IHMC IRB Chair.

30. Select "*Save and Continue to Next Section*".

31. You will receive notice that the *Initial Review Submission Packet* was created.
    - Select "*Save and Continue to Next Section".*
32. You will receive notice that the *Application* has been attached.
    - If you need to edit any section, you go back and make changes at any time. However, remember to **save each section**.
33. Select "*Save and Continue to Next Section".*
34. You are brought to the *Informed Consent, Assent, or HIPAA Forms* section. Here you will attach the informed consent(s), assent(s), or HIPAA Forms for the protocol.
35. To add a consent, select the "*Add a New Consent"* button.

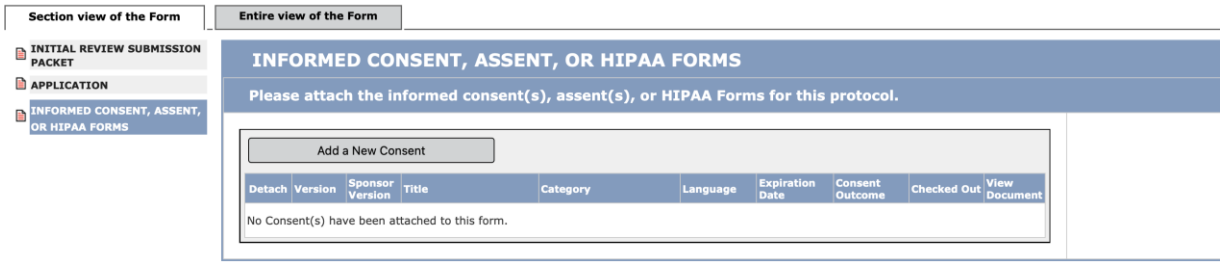

Figure 8: *The initial appearance of the Informed Consent, Assent, or HIPAA Forms section. Note the change in the left-hand menu pane after the Initial Submission Application was attached.*

36. The Study Consent Add Selection Method pop-up will appear. Select the best applicable option.
    - *Uploading an already existing electronic document you have is recommended, as this is easier than utilizing the online builder tool which can be faulty with iMedRIS application updates.*

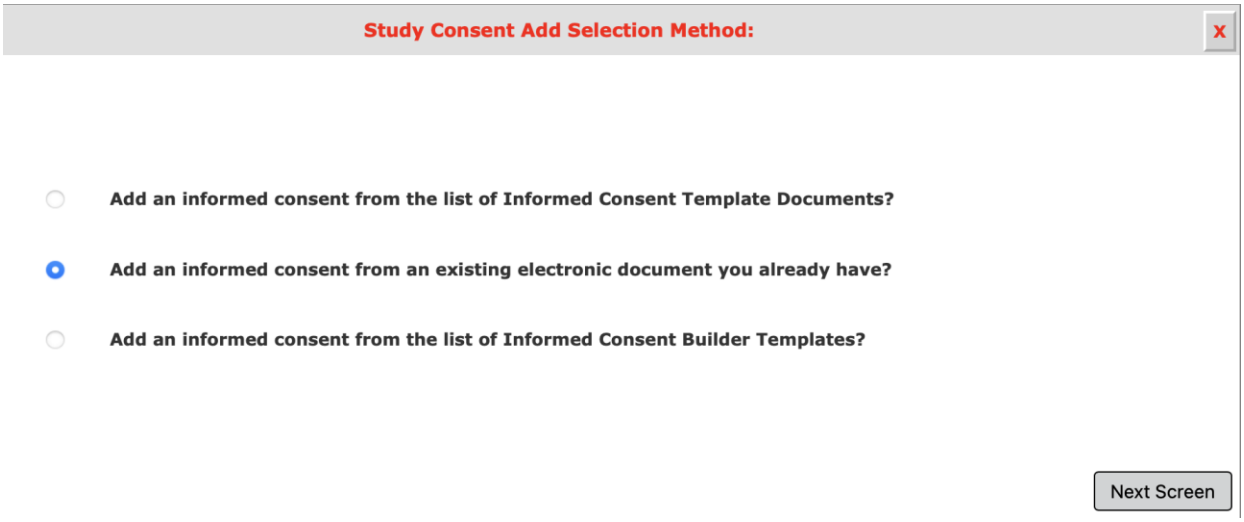

Figure 9: *The Consent selection method pop-up window that appears.*

37. Select "*Next Screen*".

38. If the second option, adding an existing electronic document, was selected, the Study Consent Add pop-up window appears. Enter all the following fields:
    - Consent Title *
    - The consent to be uploaded *
    - Version Number * (*this should start at 1.0*)
    - Version Date * (*this should be the date of upload of this version)*
    - Category (*Specify if it is a Consent, Assent, HIPAA Form, Other, etc.)*
    - Document Language *

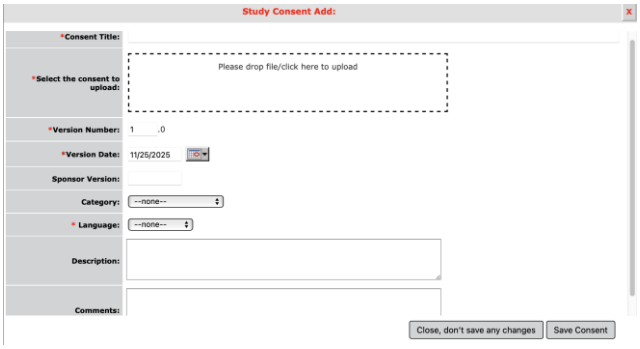

Figure 10: *The Study Consent Add pop-up. Descriptions and comments are optional, though useful tools.*

39. Select "*Save Consent"*.
40. Repeat this process for any other consents, assents, or HIPAA forms.
41. When done, select "*Save and Continue to Next Section"*.

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42. You are brought to the *Additional Study Documents* section. Here you will attach any additional study documents for the protocol (e.g., recruitment materials, flyer, web posting, funding documents, debrief form, etc.).
43. Choose one of the two options presented to add a document(s):
    - The "*Add a New Document*" option uploads a single document. Required are:
        - Uploaded Document
        - Version Number
        - Version Date
        - Category
        - "*Save Document"* selection.

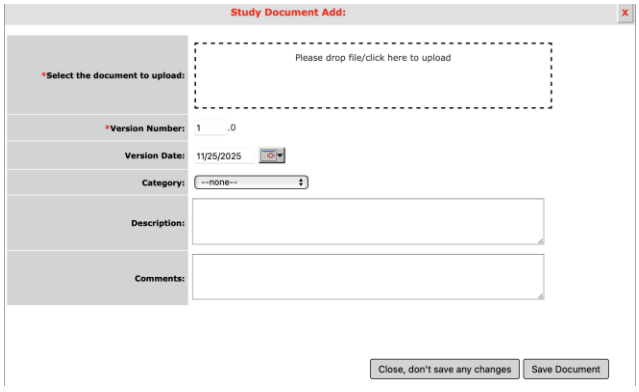

Figure 11: *The Description and Comment(s) sections are optional. While the Category and Version Date sections are optional as well, these help with version control and tracking efforts.*

- The "*Add Multiple Documents*" option uploads several documents at once (up to five). Required are:
  - Uploaded Document
  - Version Number
  - Version Date
  - Category
  - "*Save Document"* selection.

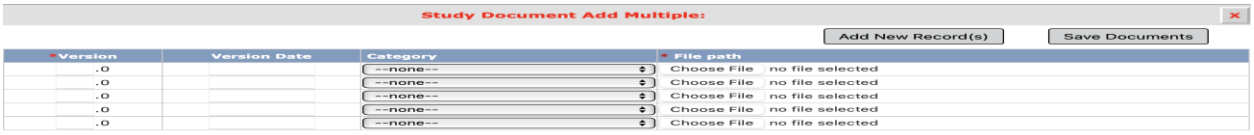

Figure 12: *The Multiple Document addition pane allows for up to five documents to be uploaded. It does not include a section for a Description or Comments.*

44. Once done uploading additional documents, select "*Save and Continue to Next Section*".

45. The next screen will show "*Form has been Completed*".
    - Select "*Submit and Notify PI to Sign-Off*".
      - The Study's PI will have to sign off on the form. Once signed off, the submission will be routed to the IHMC IRB Administrator.
    - Exit the form.