UT Southwestern
Medical Center
Human Research Protection Program

Research Matters

August 20, 2024

IRB Updates

Update 1: CMPA Approval Requirements

UT Southwestern Medical Center

- **Approval of CMPA is not required for <u>some</u> recruitment material**

Update 1: CMPA Approval Requirements

UT Southwestern Medical Center

1. If UTSW Logo/branding are required
2. Plans to use official UTSW Social Media platforms for recruitment
3. Exception from Informed Consent Recruitment materials
4. Press/News Releases
5. Key Clinical Trials recruitment material

CMPA Approval Required BEFORE submitting to the IRB

Update 2: Requirements for DUA/DTAs

UT Southwestern Medical Center

- **DUA/DTA will be required for the sharing De-identified data/materials**

This change is being made to restrict liabilities associated with the other entity's use of UTSW data.

Update 2: Requirements for DUA/DTAs

UT Southwestern Medical Center

Data/Material Sharing

01

De-identified Data/Materials

HIPAA Authorization or a Data Use Agreement ("DUA") or an MMTA (if specimens will also be sent) is required unless there is another contract (e.g., CTA) that defines those terms.

02

Limited Data Set

HIPAA Authorization or a Data Use Agreement ("DUA") or an MMTA (if specimens will also be sent) is required unless there is another contract (e.g., CTA) that defines those terms.

03

Protected Health Information (PHI)

A DUA/MMTA is not appropriate for data or materials that include PHI because the disclosure should be covered by the HIPAA Authorization language in the informed consent form or HIPAA Authorization waiver. If the external institution requires an agreement, they may provide one.

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Protocol Builder

What is Protocol Builder

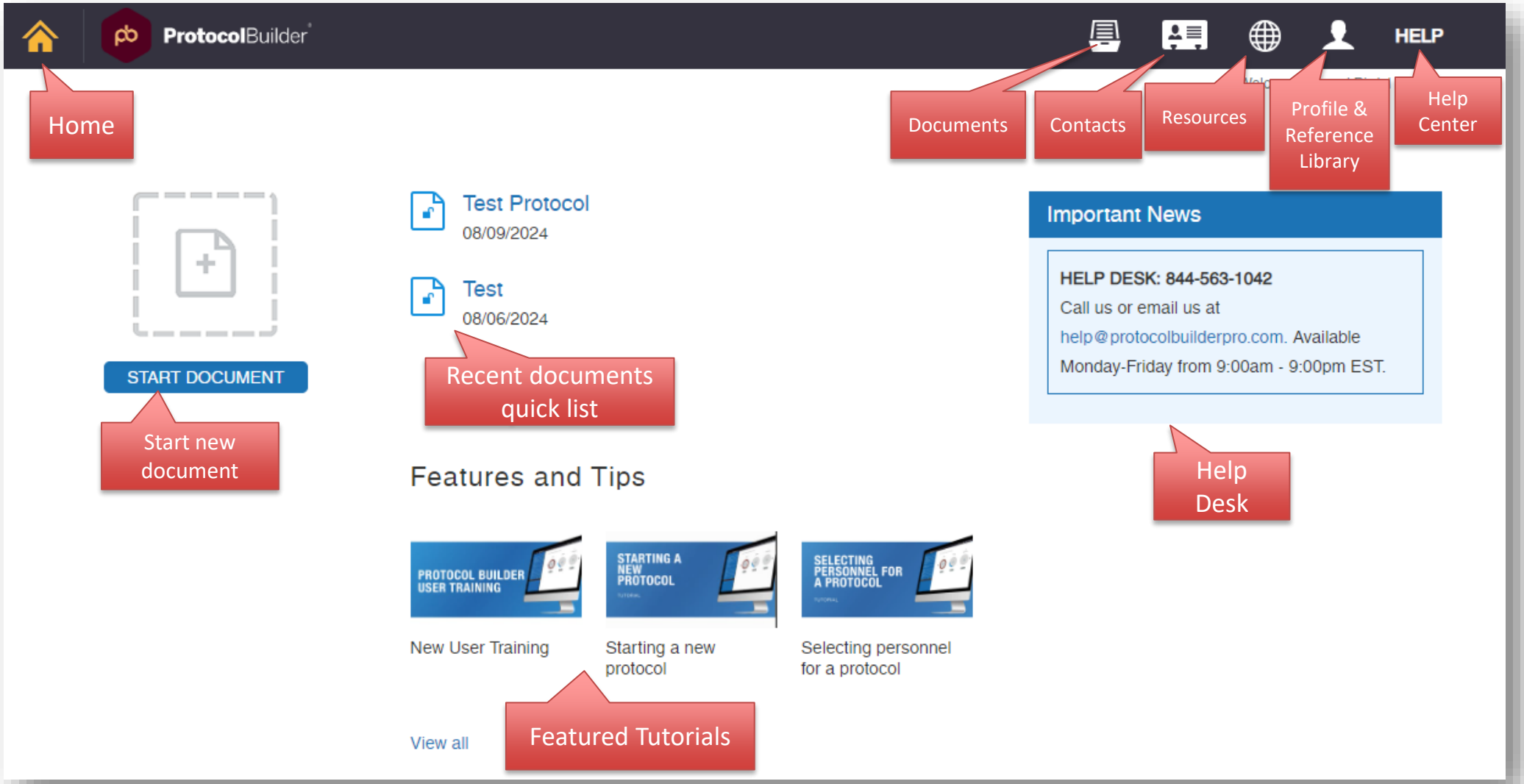
UT Southwestern Medical Center

- Platform built by BRANY
- Makes the process of writing, collaborating, and reviewing protocols more efficient.
- Cloud-based application available 24/7
- Structured writing tool makes writing protocols easier and faster
- Produces a professionally formatted protocol ready for IRB submission
- UTSW will use single sign on so there is no need for a separate user account/password.

Home Page Overview

UT Southwestern Medical Center

- You may use Forgot Password to recover your account



Starting a New Document

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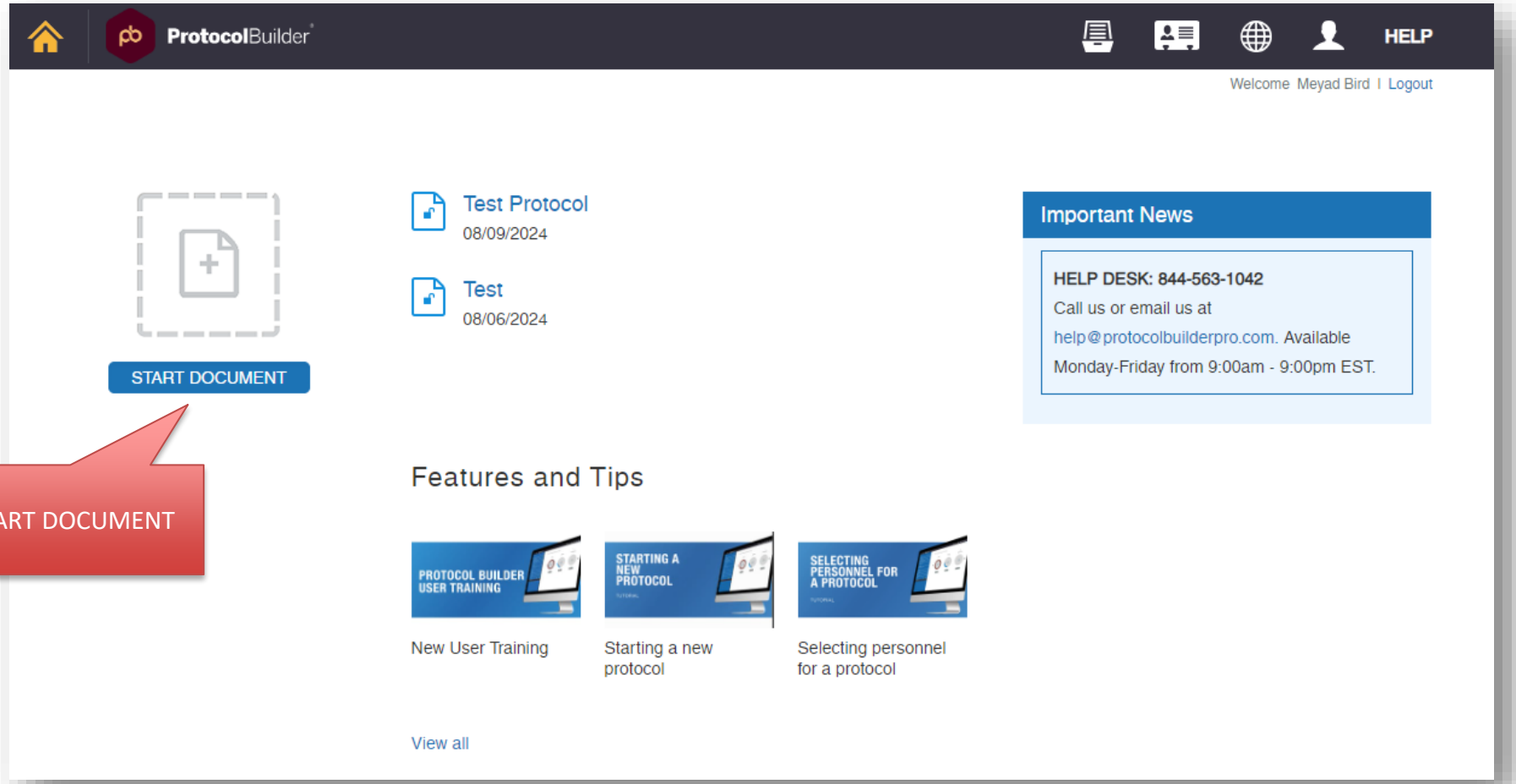
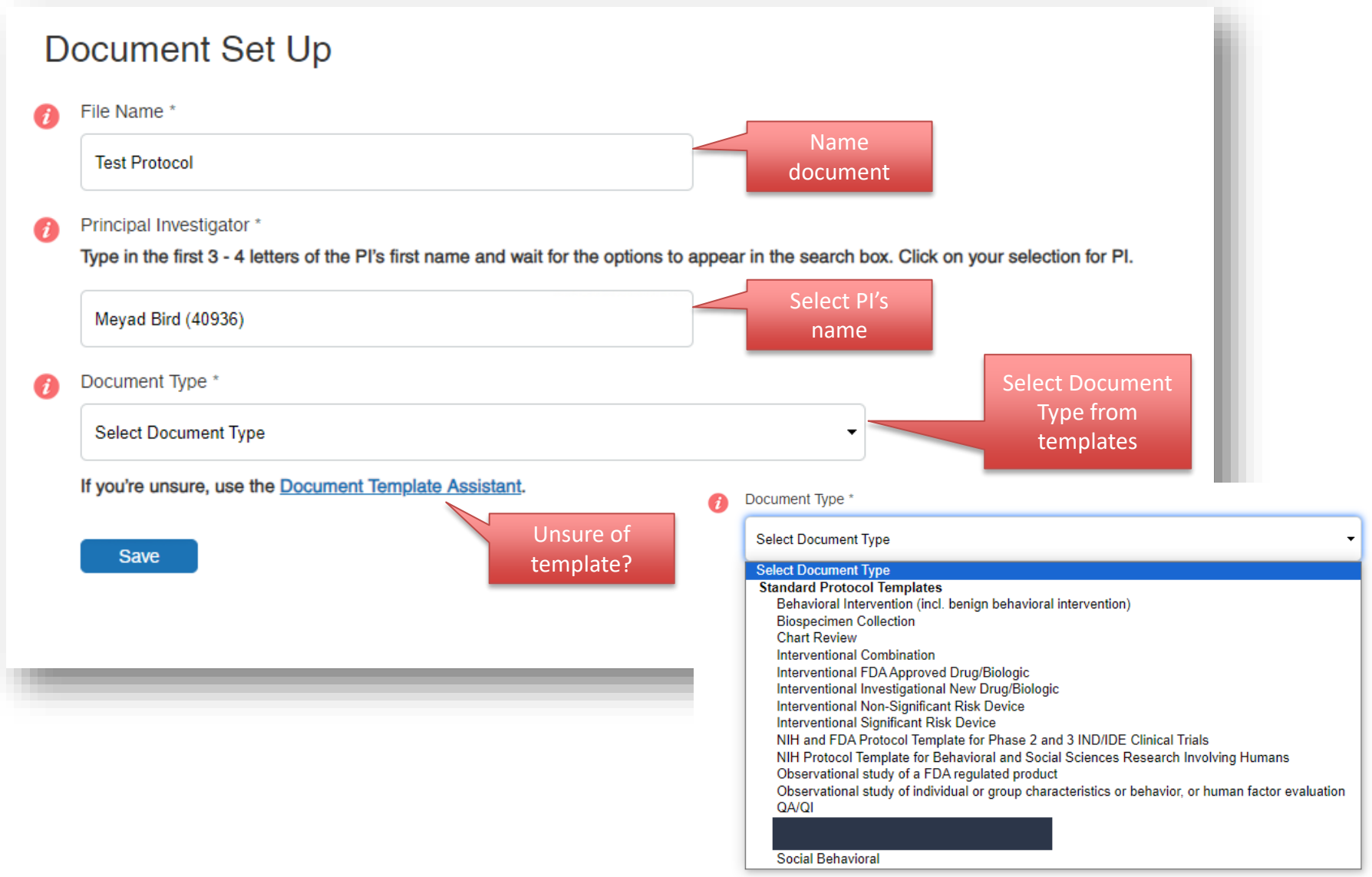


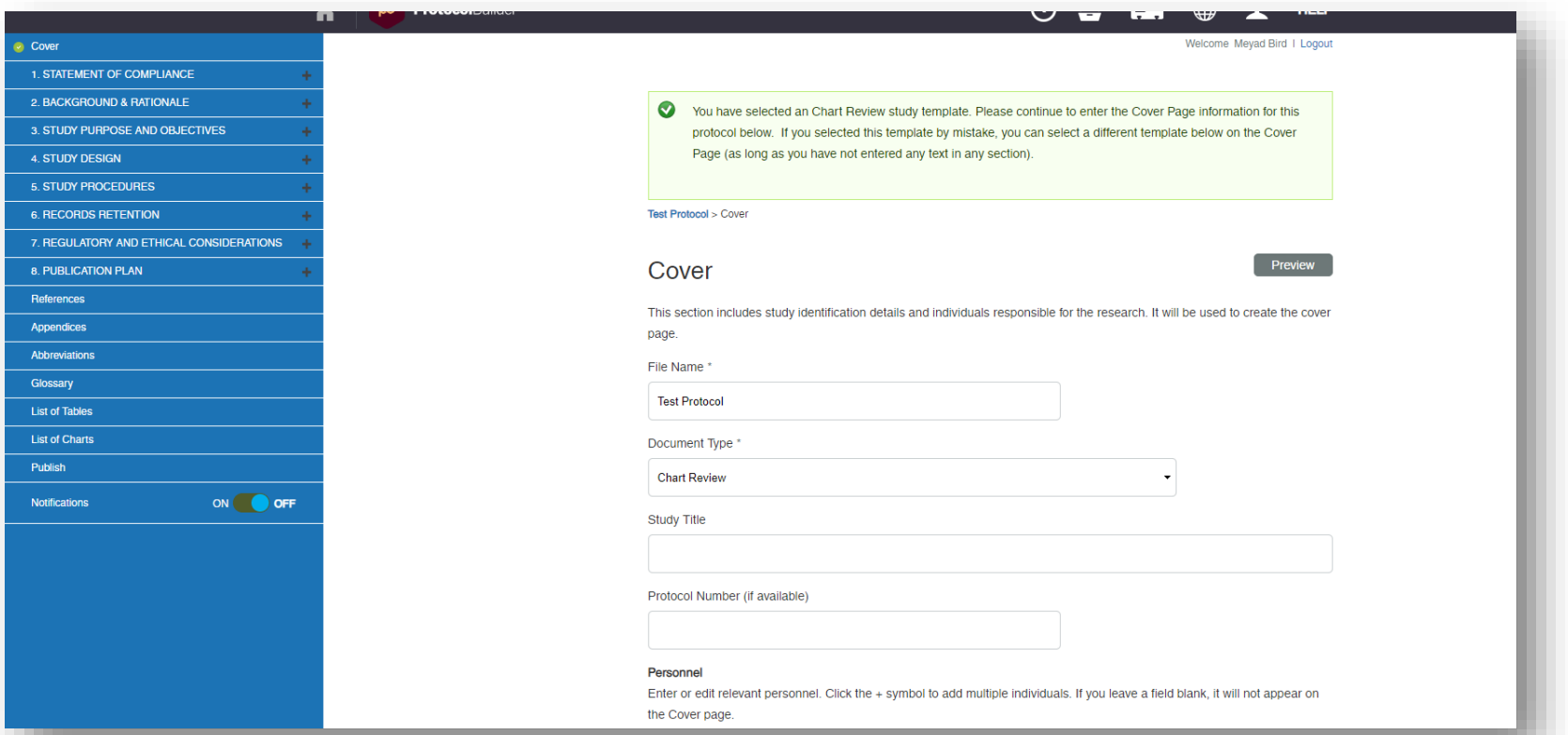
Click START DOCUMENT

Starting a New Document

UT Southwestern Medical Center



Add Study Details and Personnel



- The cover page is where you will enter the study title and other protocol identifiers
- Personnel section: add the people who will collaborate in writing the document or in the study (as well as IRB staff if needed).
- The protocol writer determines the access each use will have:
  - Writer/editor
  - Read-only
  - Personnel listing only

Adding Personnel

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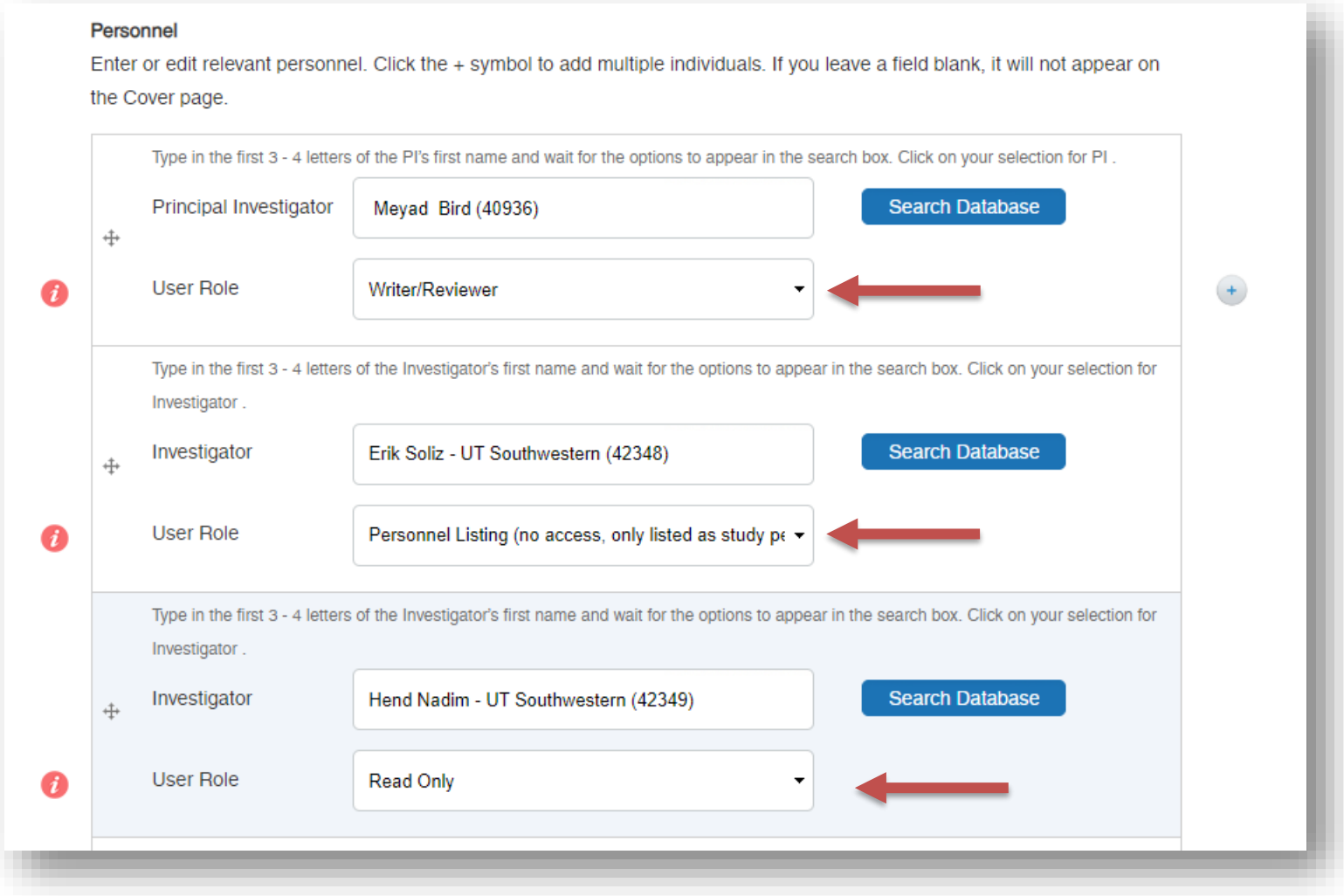

Writing the Protocol

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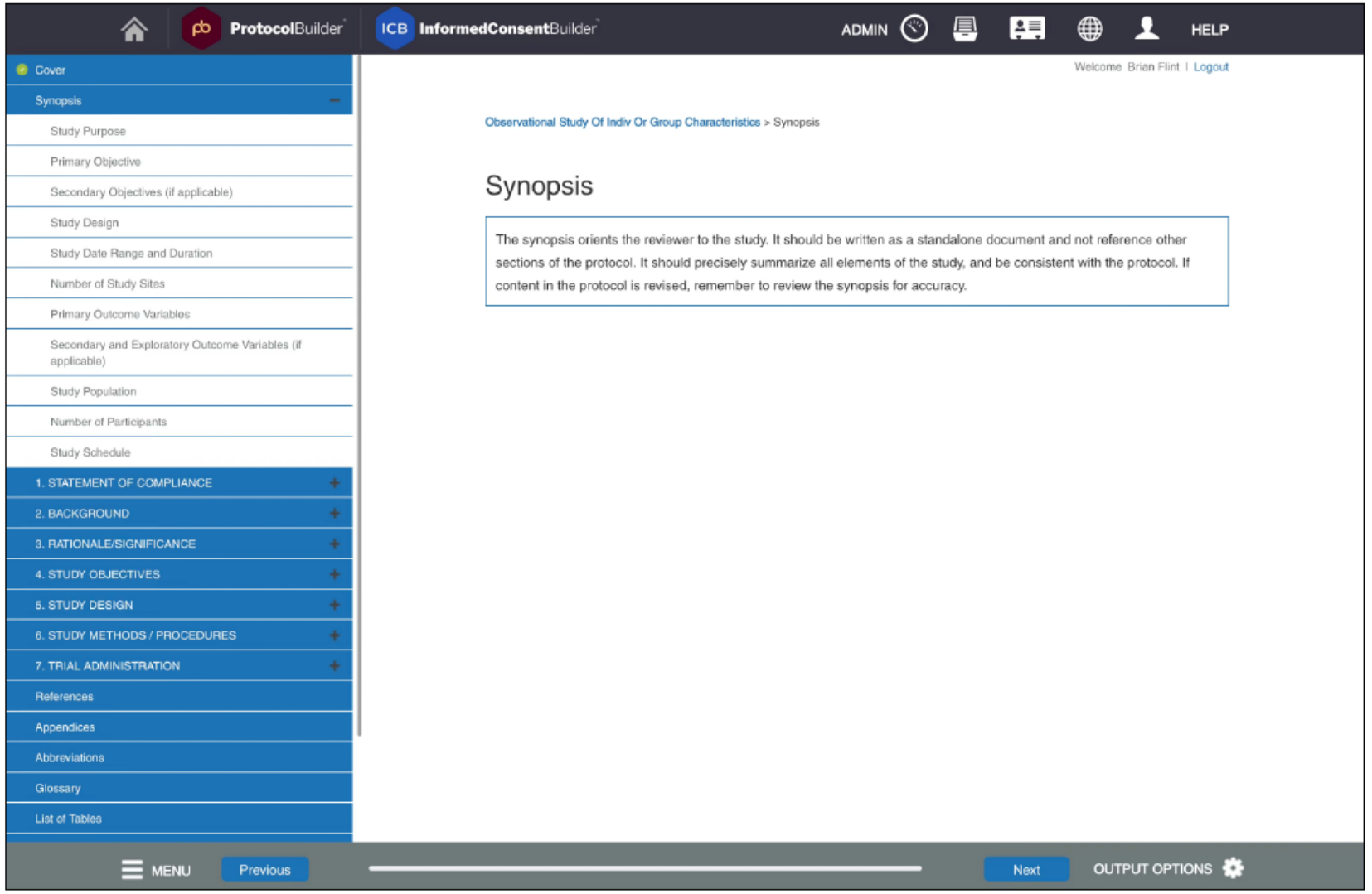
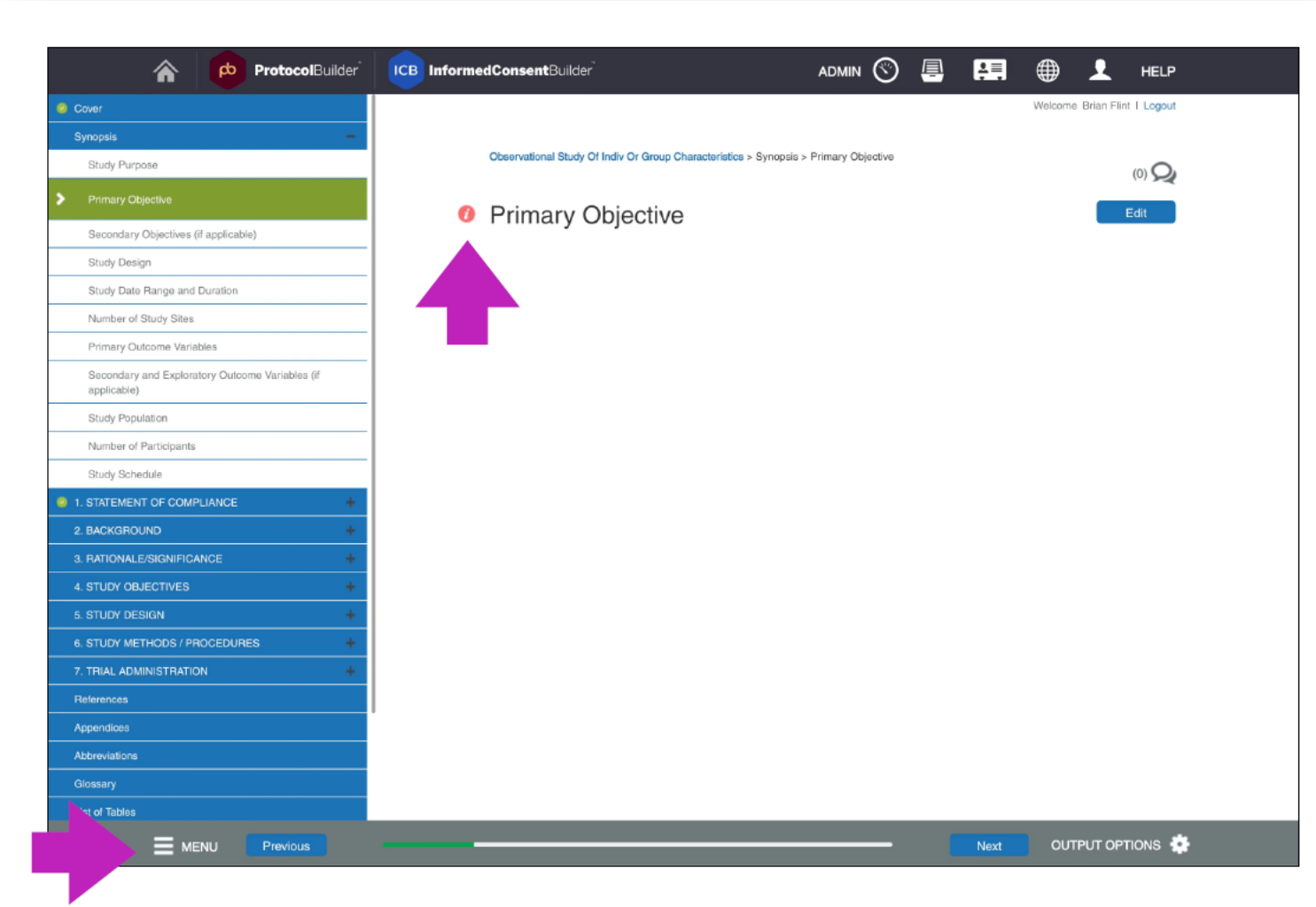


The best practice for writing protocols is to outline the study in the synopsis first. – Protocol Builder was built to be a guided experience through the protocol using the next and previous buttons. But this process may not work for everyone so you can navigate to any section first

Writing/Editing Screen



The menu can be collapsed to focus on writing. The I Icon has tips that provide guidance for writing that section. Some sections have links that connect the synopsis to the corresponding protocol to save time. Many sections have sample text to provide structure or more precise language that may be required. Just click to insert and start editing.

Saving Sections

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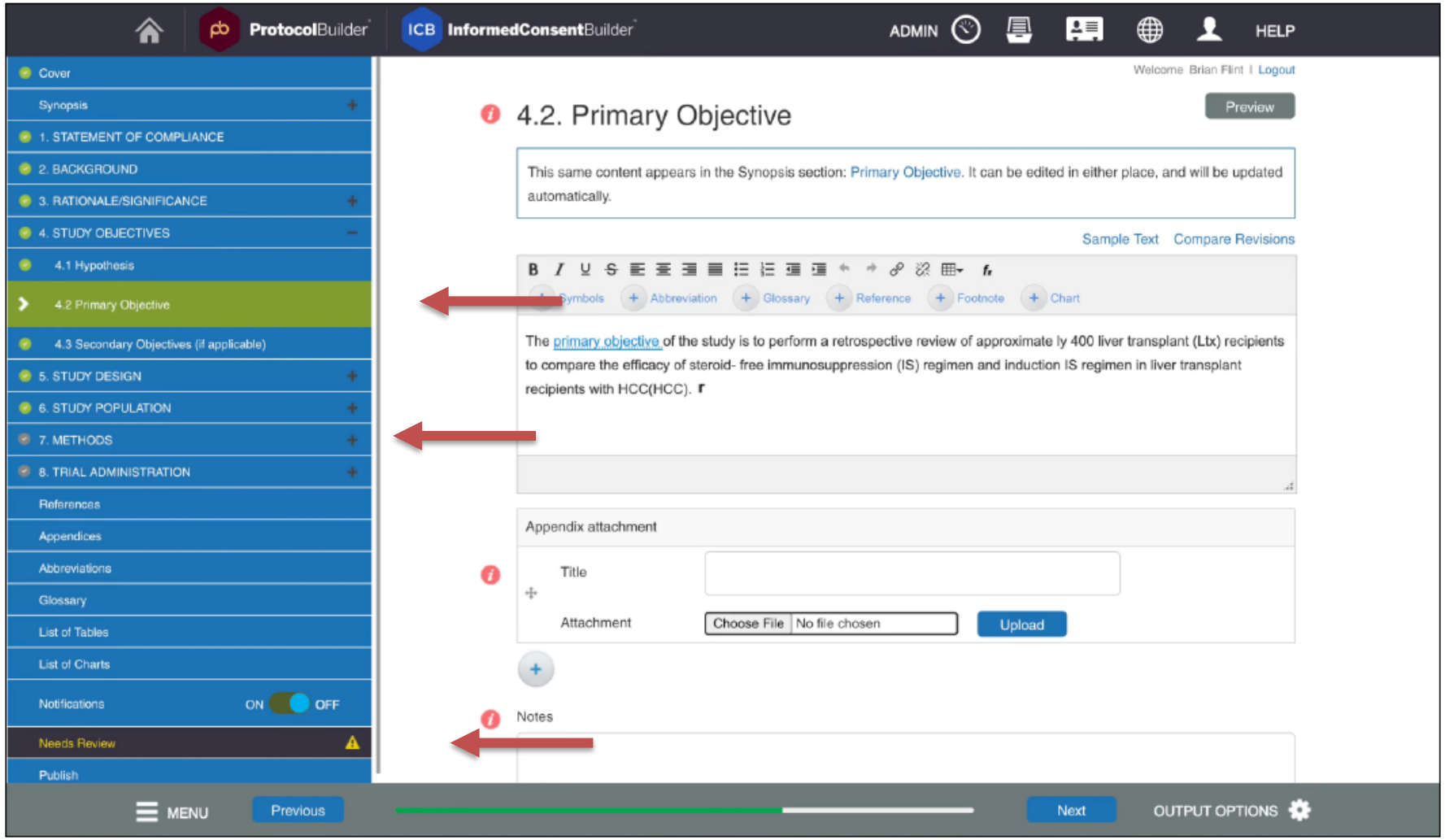
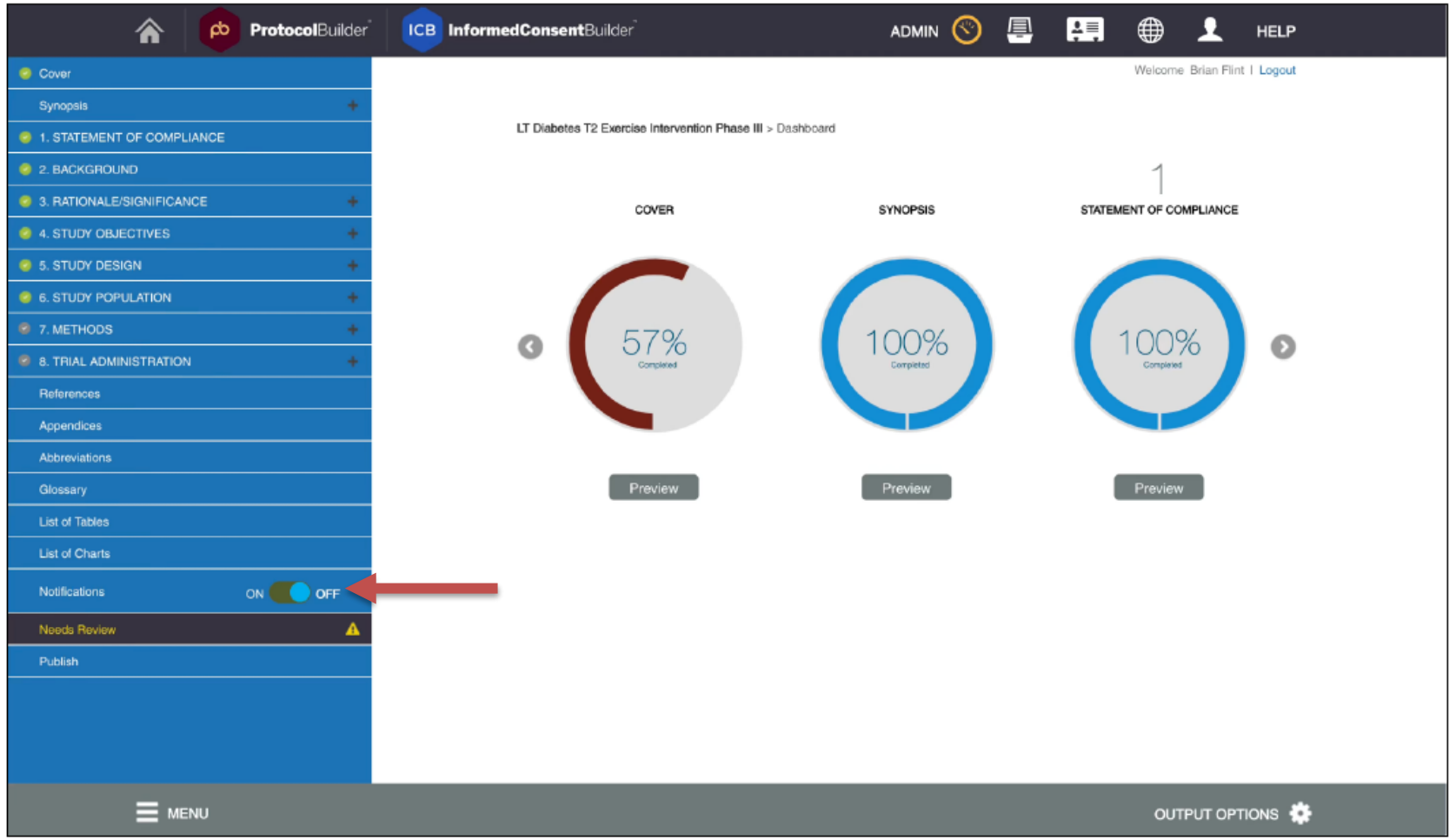


Sections can be saved as draft or complete. Alerts can be sent to collaborators when sections are ready – make sure to turn on notifications. Draft sections show up in the needs review list. When sections are saved, they are indicated so with a grey checkmark in the navigation bar. When it's complete, it turns green.

Progress Dashboard



Displays progress for each section. Alerts can be sent to collaborators when sections are ready – make sure to turn on notifications.

Collaboration

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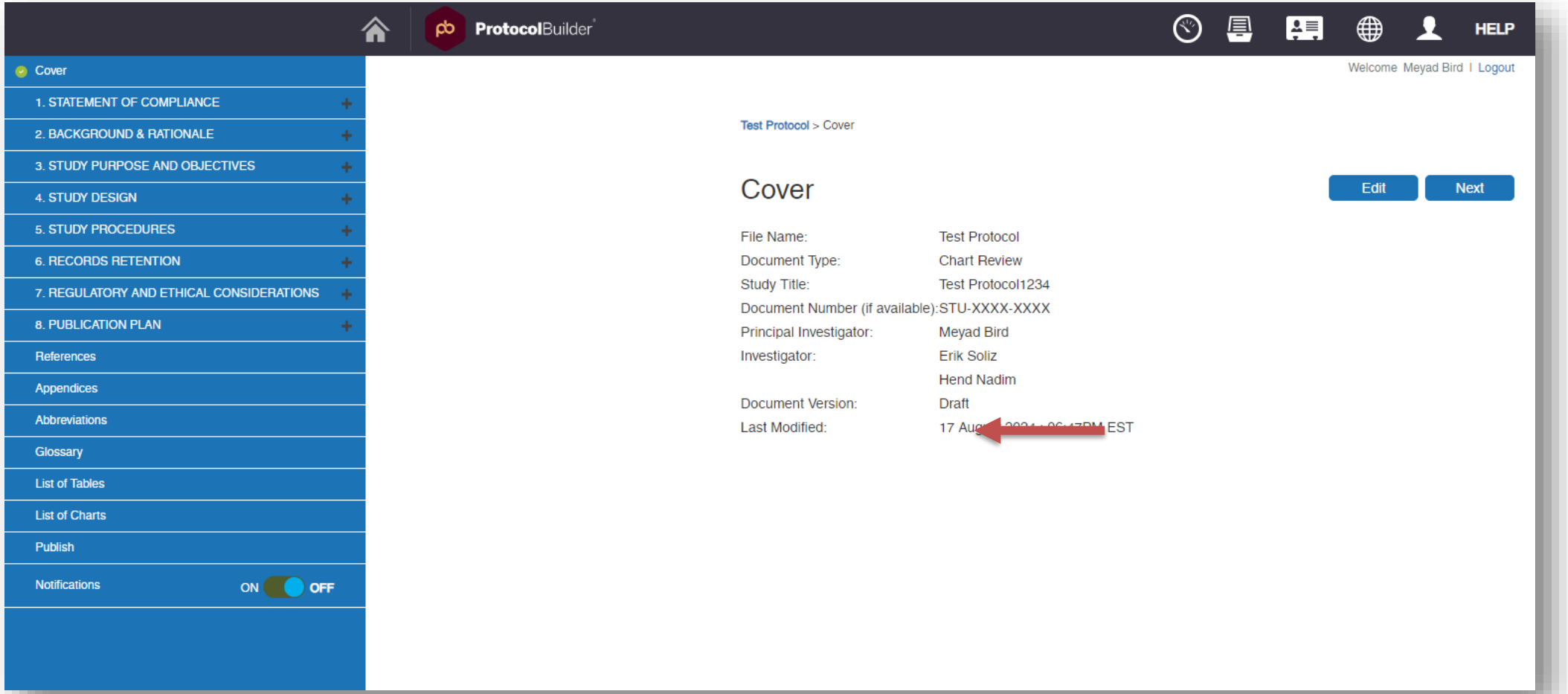

Make sure that you have set up the personnel contained in the Cover page. If the person you want to add does not show up in the options, click on search database to search by email. New users can be set up in the search pop-up if there is not a match for the email.

Needs Review List

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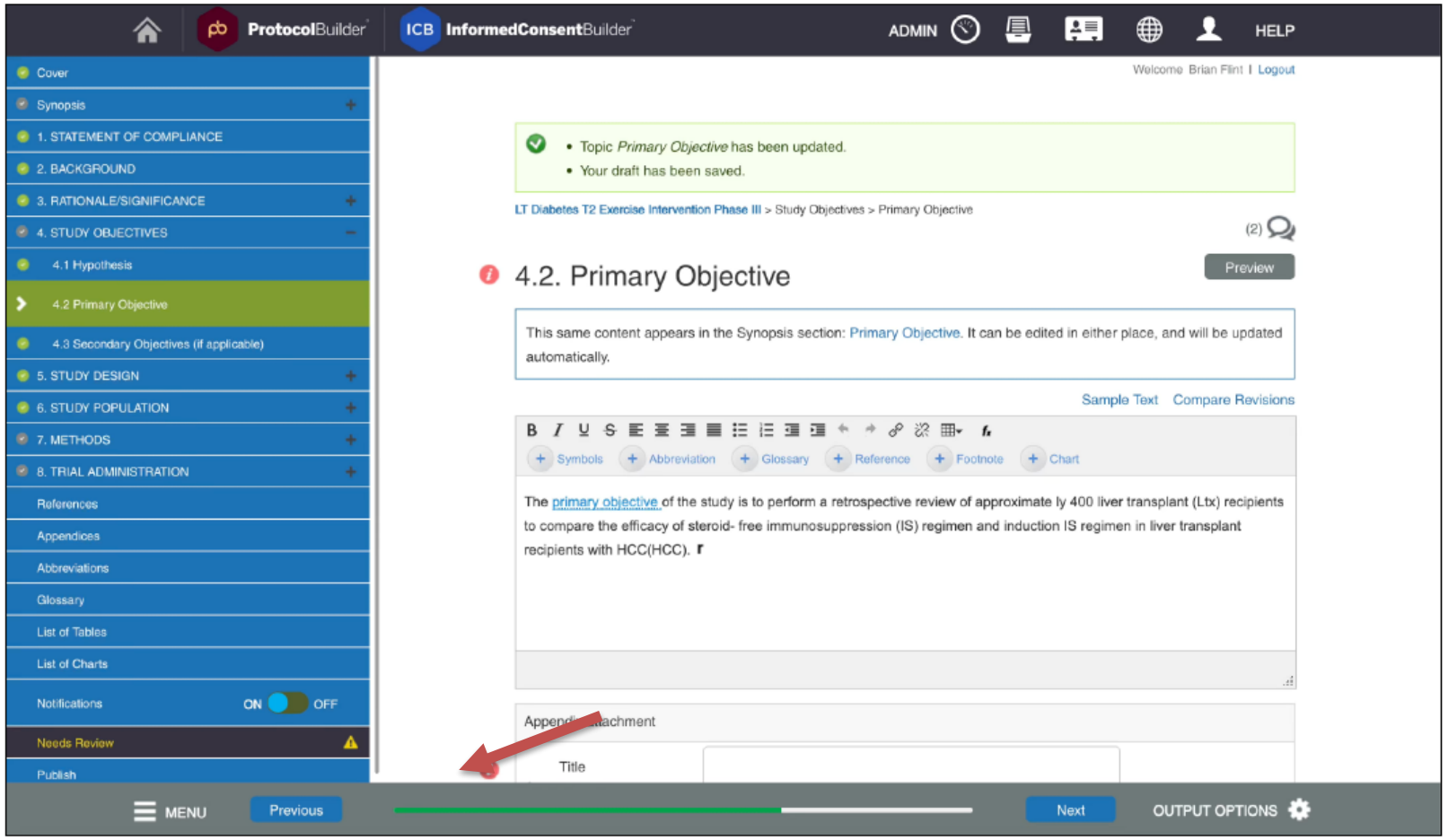

The Needs Review list is a worklist of sections in draft mode that need review and completed sections that have been review. Each section listing gives you a link to either edit or review revisions.

Commenting Tool

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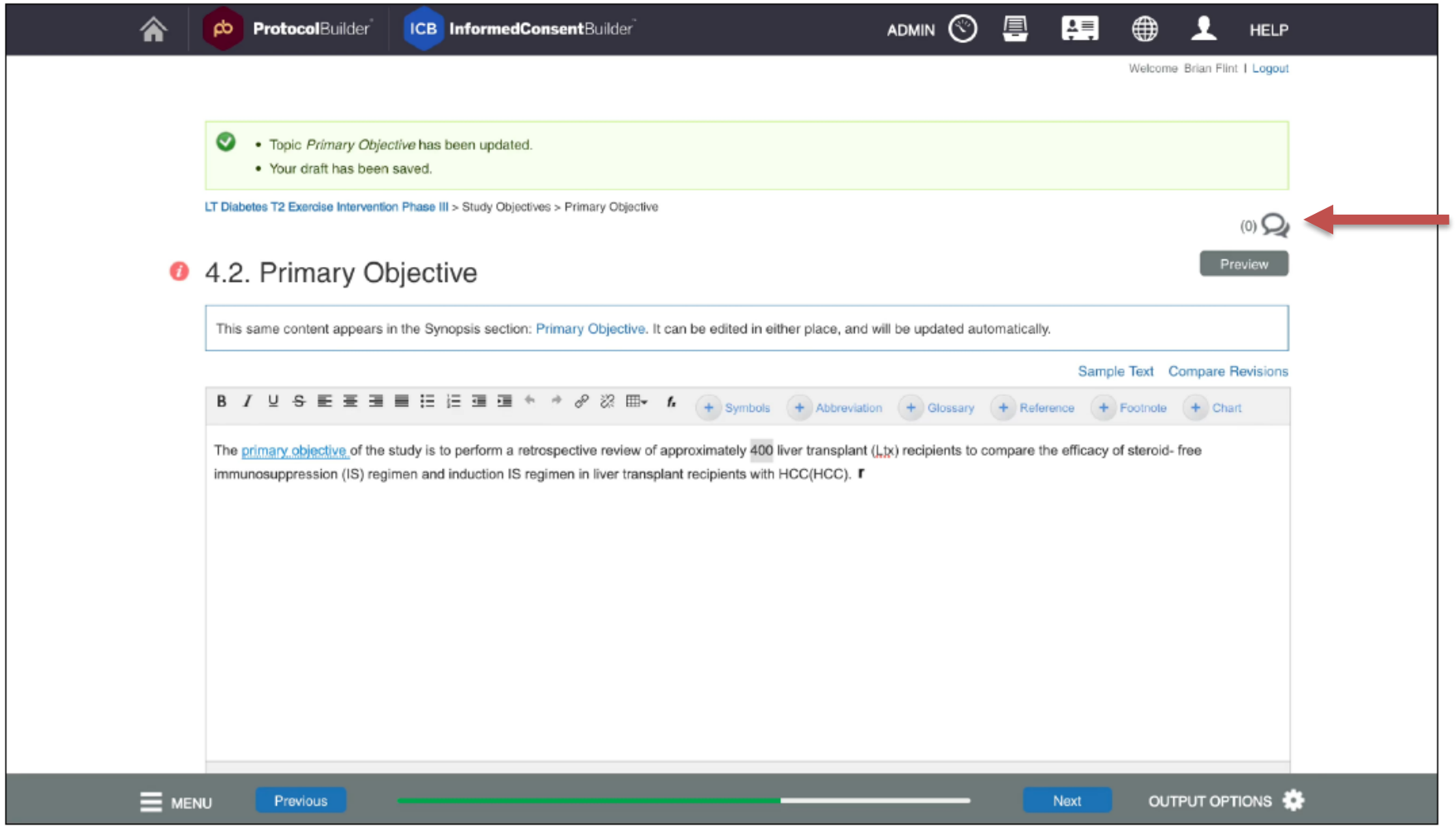

Click on the commenting tool icon to open the commenting panel. Highlight the sentence or words to comment on, type the comment in the text field. The tool will insert a numbered pin after the text highlighted. Comments can be replied to, deleted, or resolved.

Finishing and Publishing

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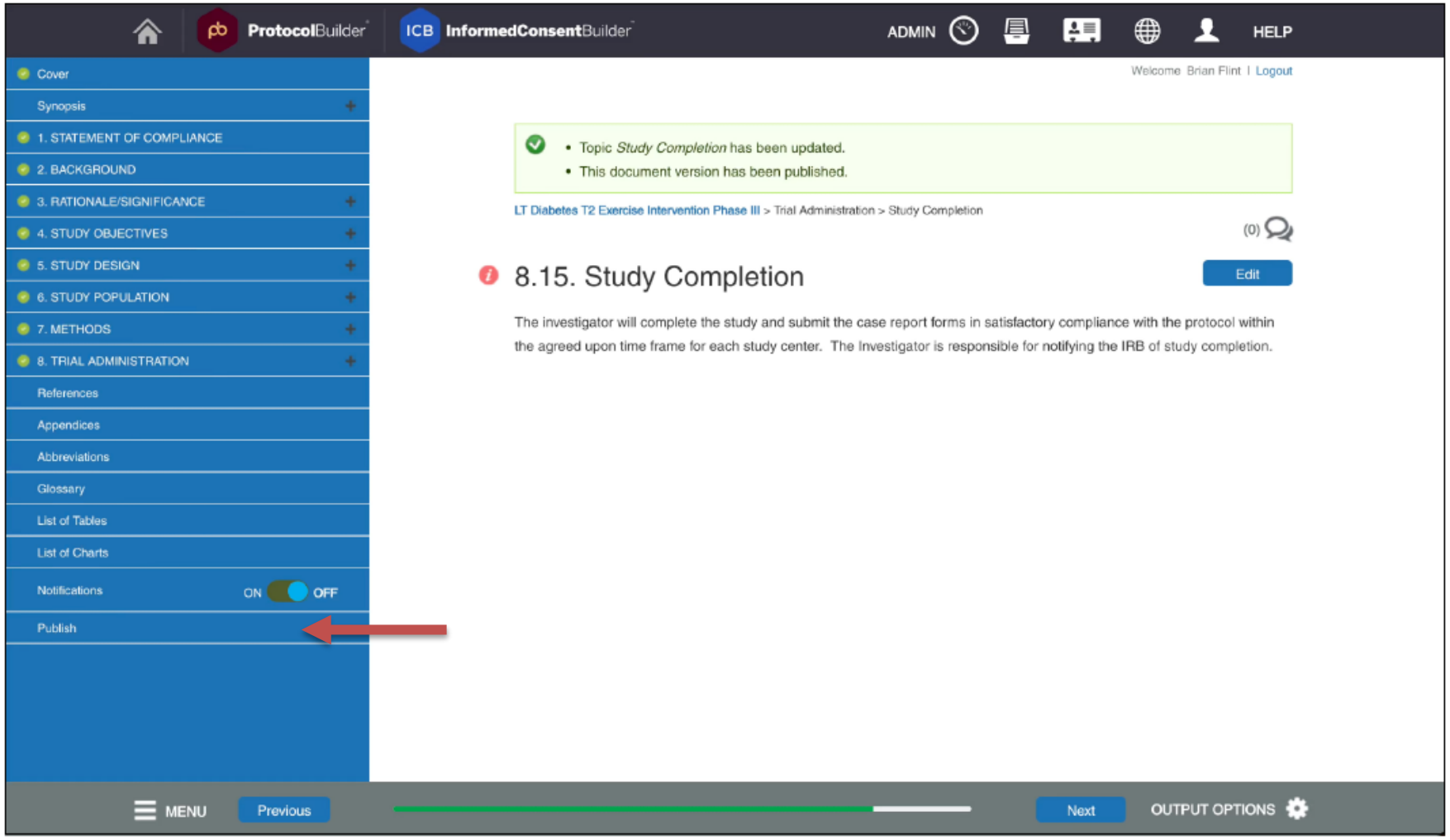

Make sure that all sections have green checks and that the dashboard marks all sections complete. Click the publish tab. Preview the entire document on a scrollable page or invite to review. Publish a version and view prior versions. Output options, include Word, PDF, all which include appendices.

Advanced Editing/Automate Features

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FORMATTING REFERENCE SECTIONS WITH AUTO NUMBERING

INSERTING FOOTNOTES

AUTO LIST OF TABLES AND LISTS OF CHARTS

APPENDICES ATTACHMENTS AND LIST OF APPENDICES

LISTS OF ABBREVIATIONS AND GLOSSARY TERMS

SUMMARY OF CHANGES AFTER PUBLISHED PROTOCOL

References Library

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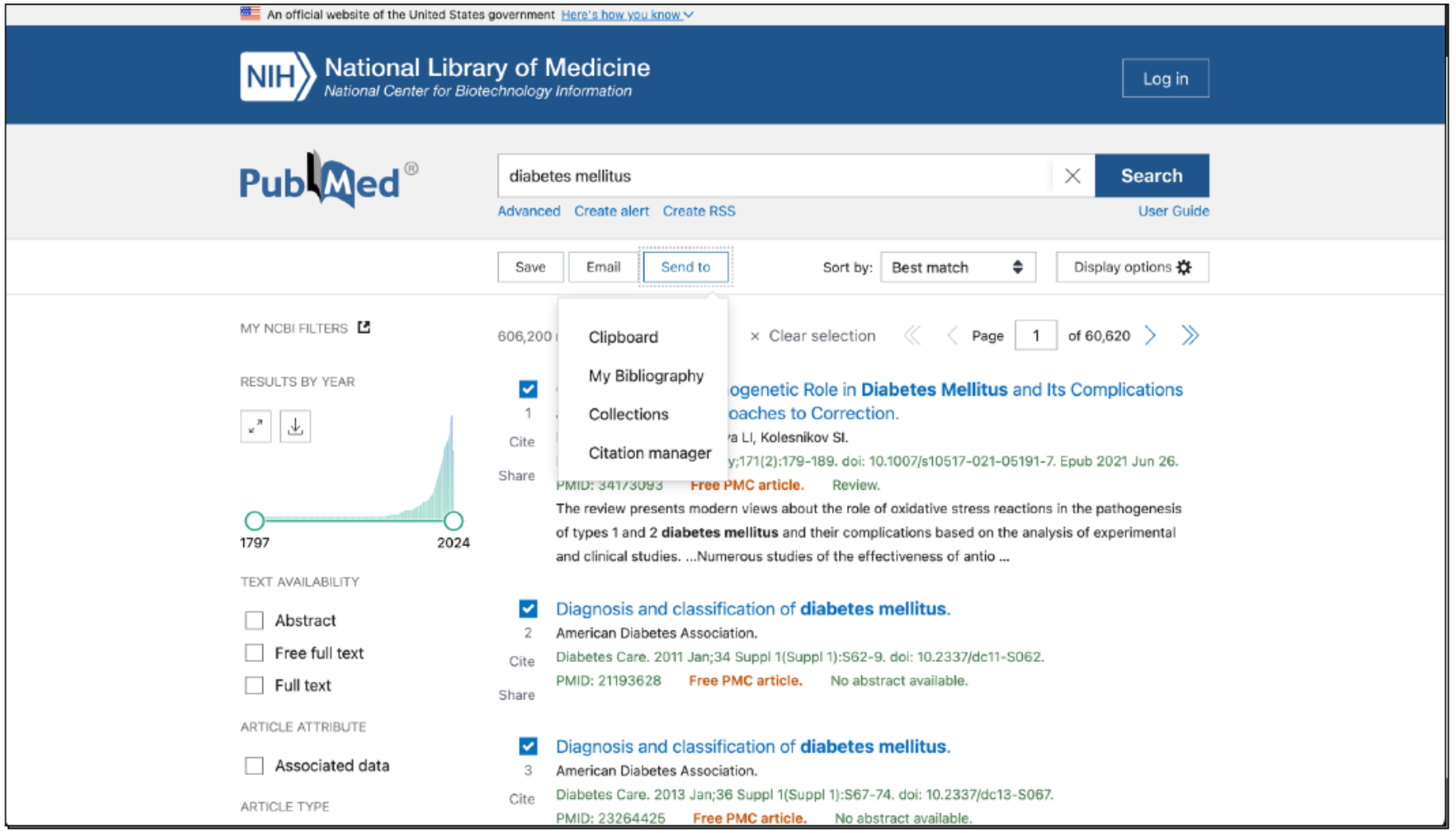
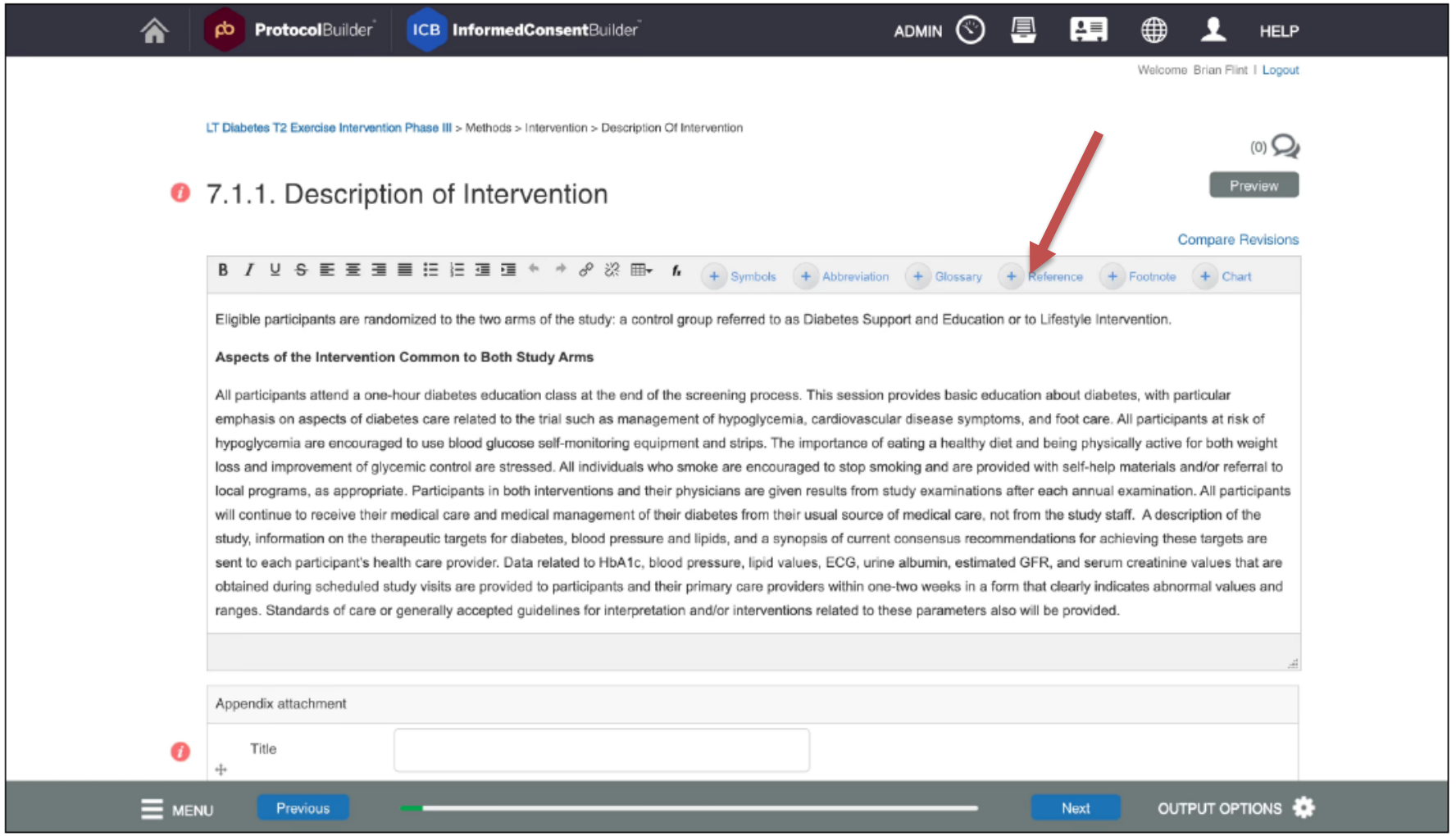


Protocol builder can maintain a library of citation imported from a variety of sources, pubmed, endnote, Mendeley, etc. Must ensure that the file is on .NBIB or .RIS format. Navigate to the profile a the top of the navigation bar. Upload the file to create your reference library.

Insert References



Place the cursor where you want to insert the reference. Click on references icon, find the reference you need and click insert. Tool with insert ‘R” they will be numbered upon output. Reference section will automatically be built. Citation can also be added manually.

Footnotes

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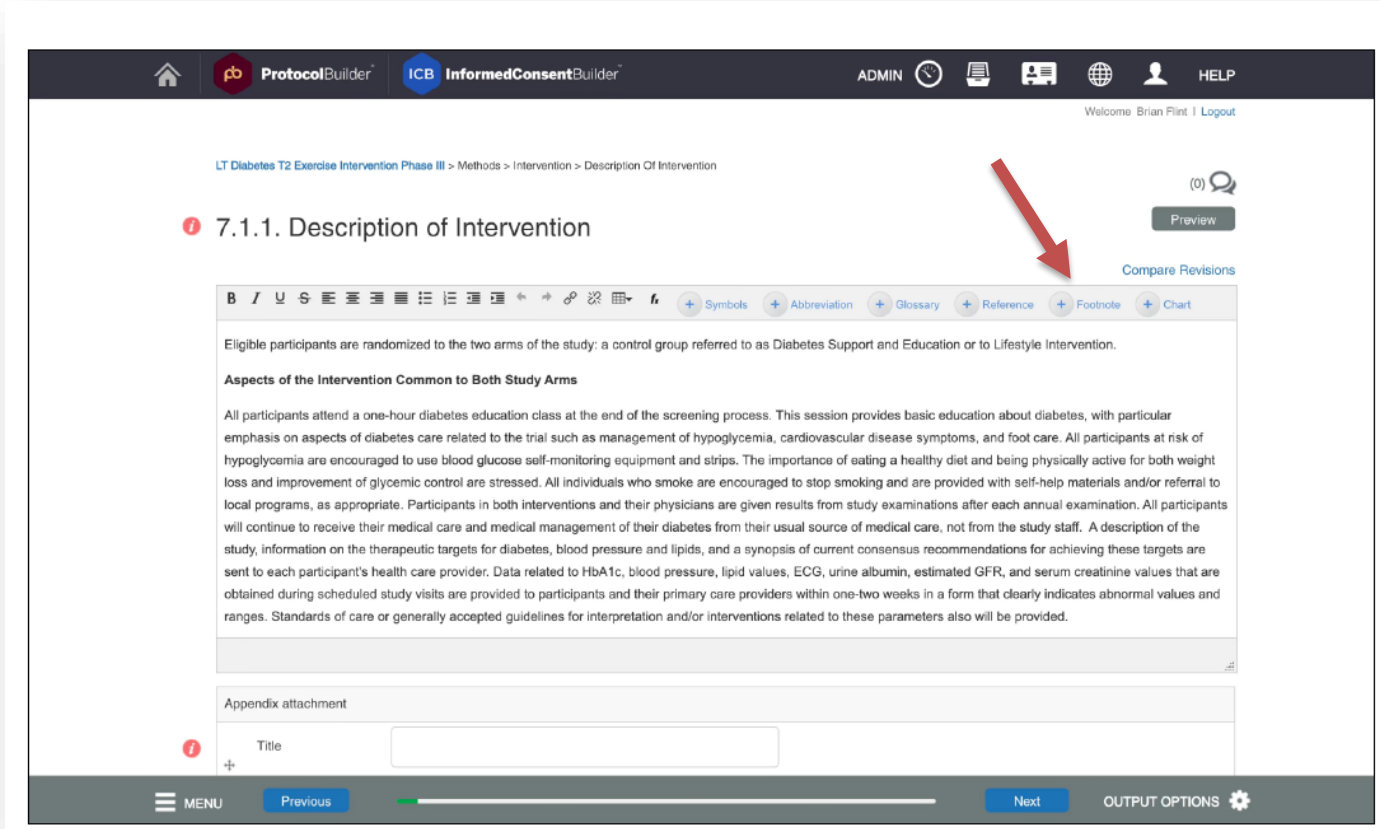

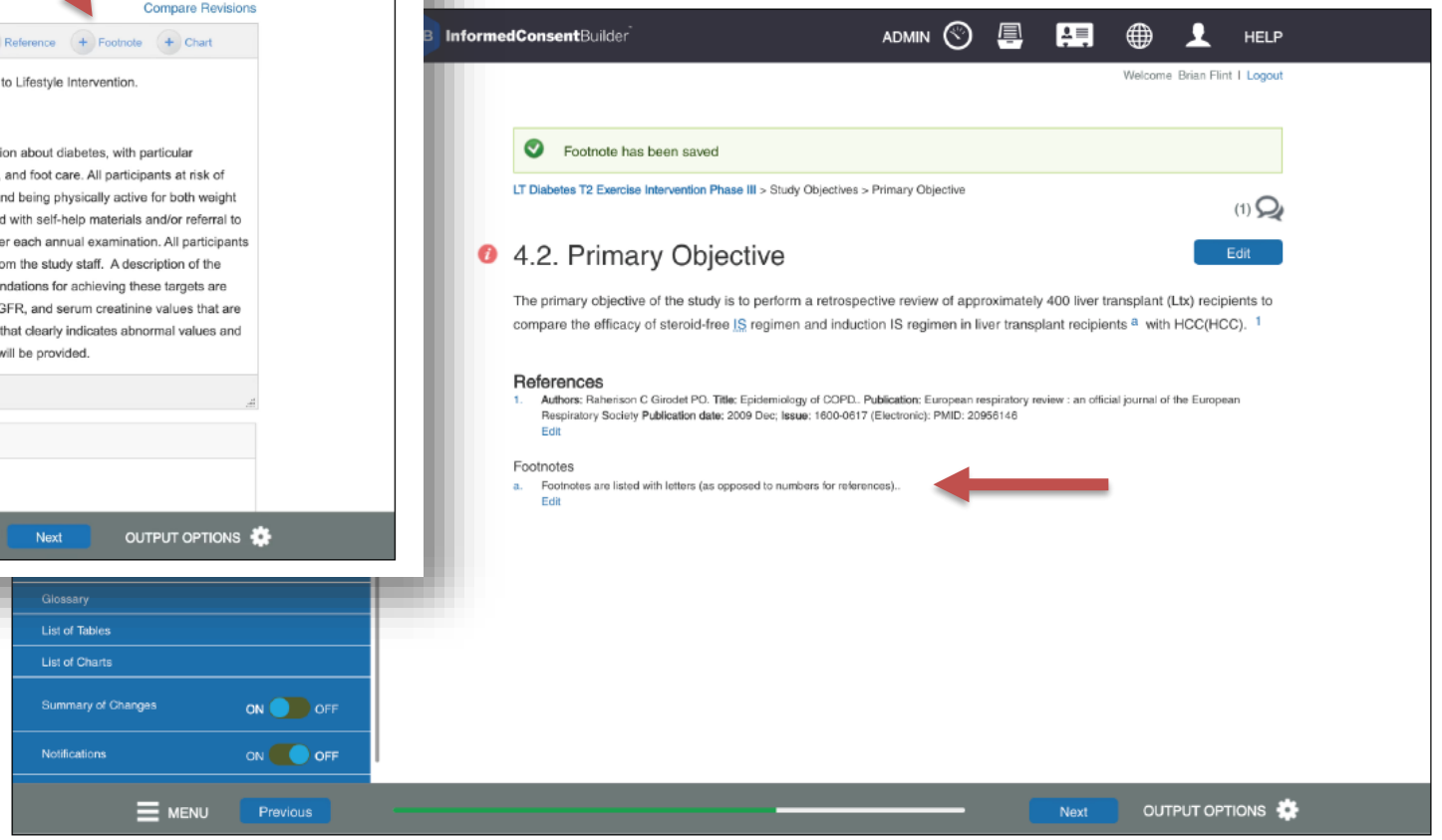

Place the cursor where you want to insert the footnote. Type in the footnote in the popup and footnote will be listed using letters (as opposed to numbers).

List of Tables/Charts

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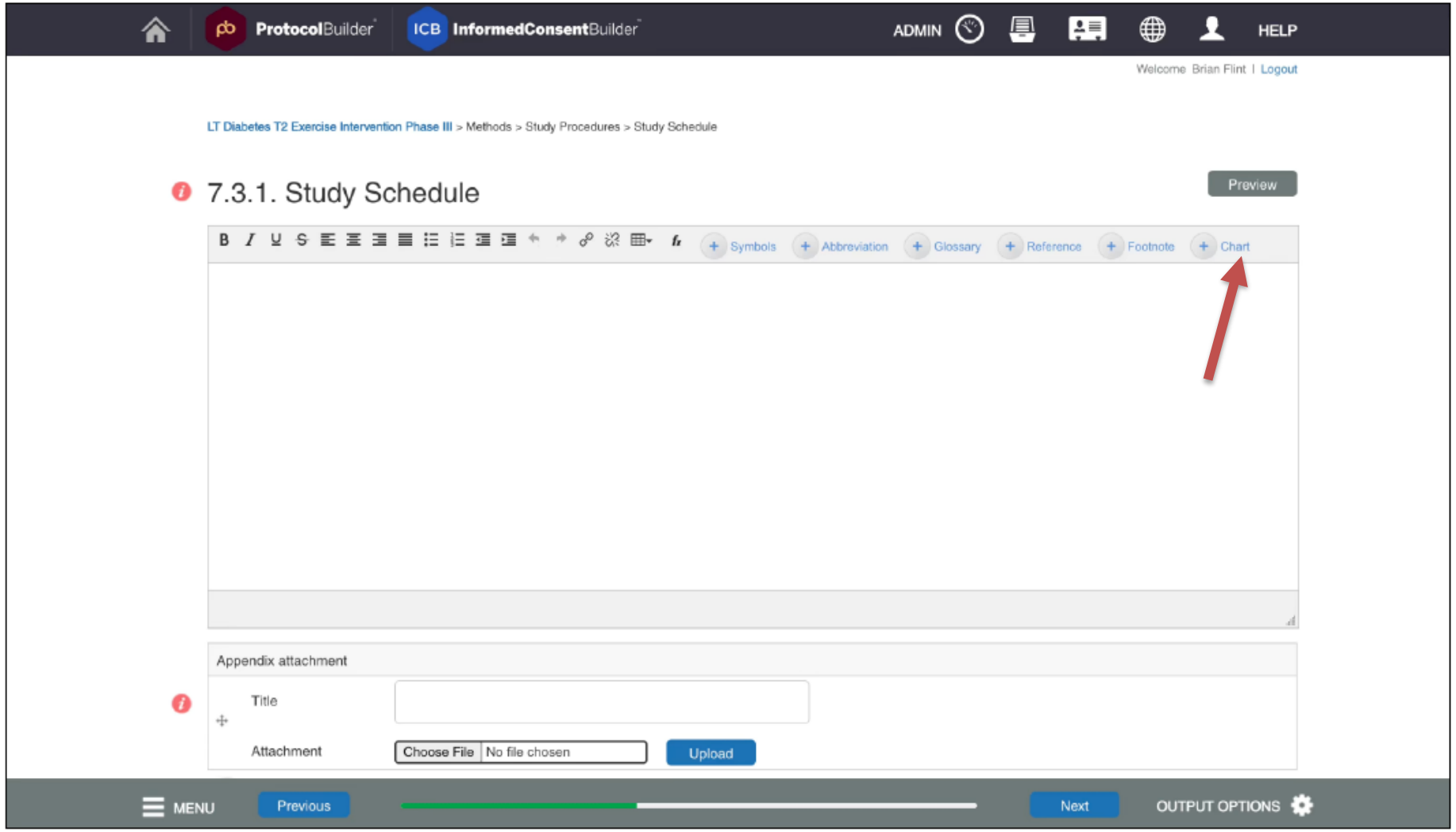
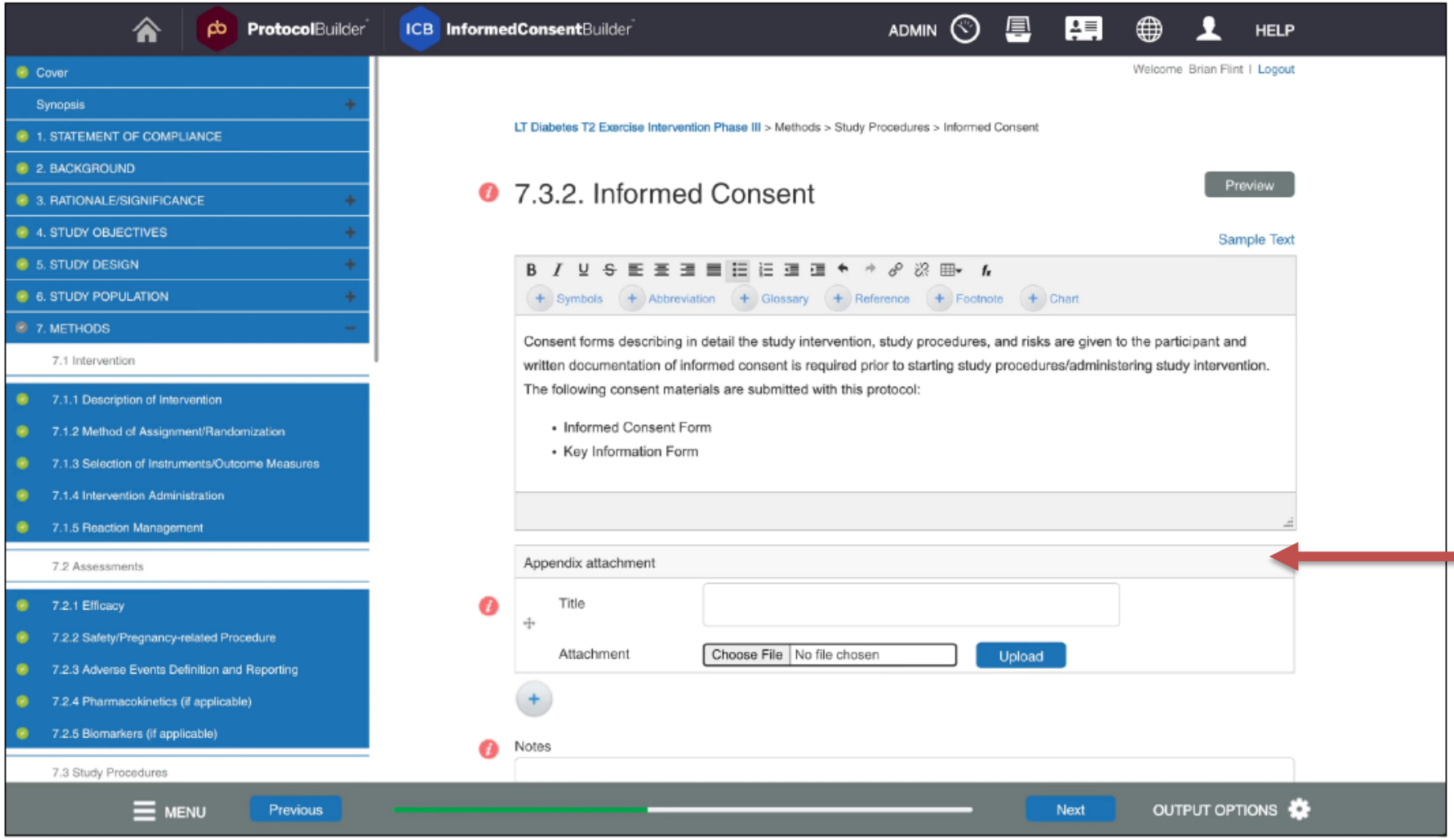


The app also allows you to list tables and charts. Place cursor where you want the table to start, click the chart icon name the chart/table and a list of tables and charts will be created automatically.

Appendices



The app also allows you to attach files that belong with the protocol and create the list of appendices. Appendices can be added in the sections or directly to the appendices tab. Name the appendix and upload the file. The list of appendices will be created automatically.

Abbreviations and Glossary

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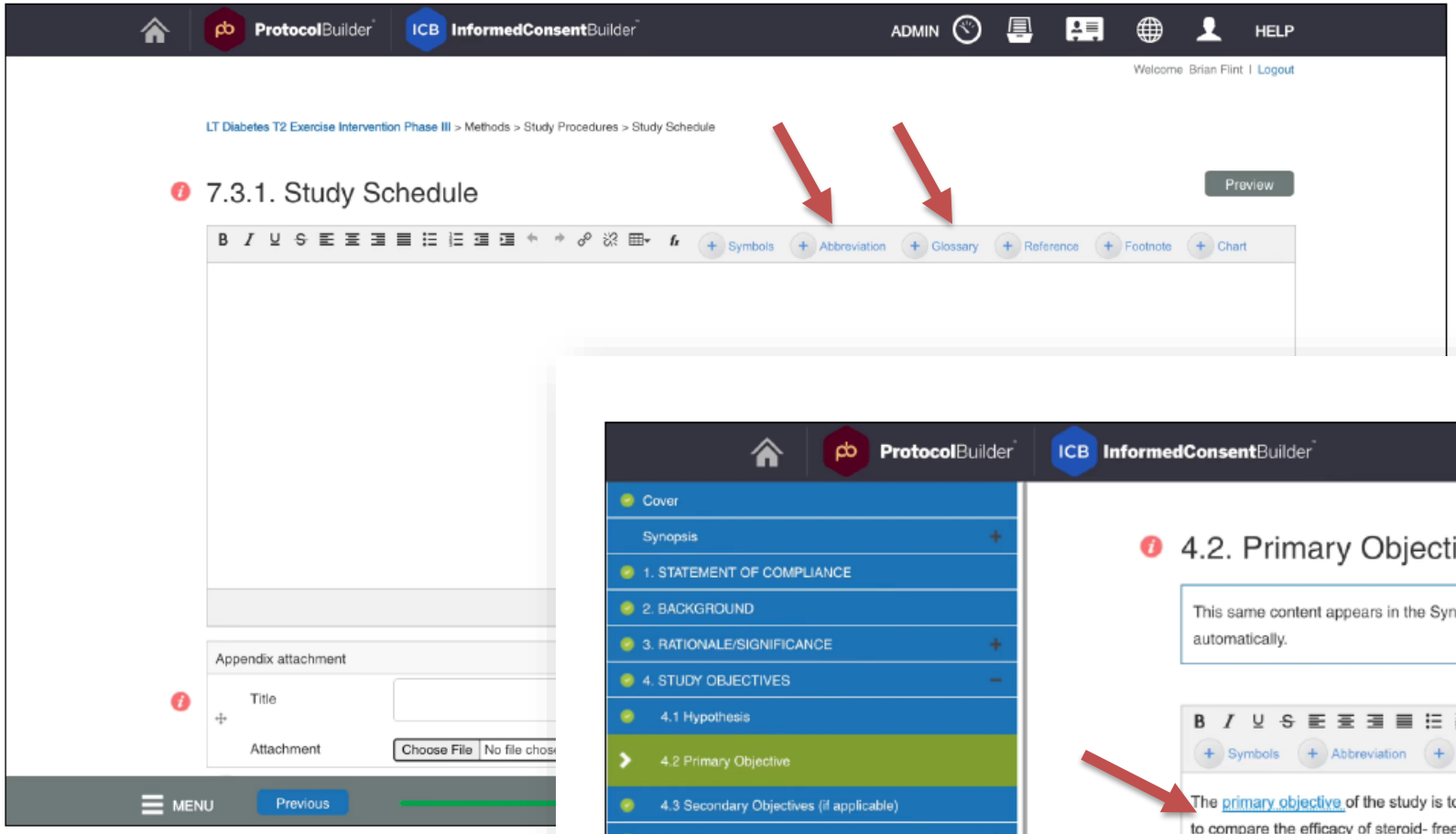
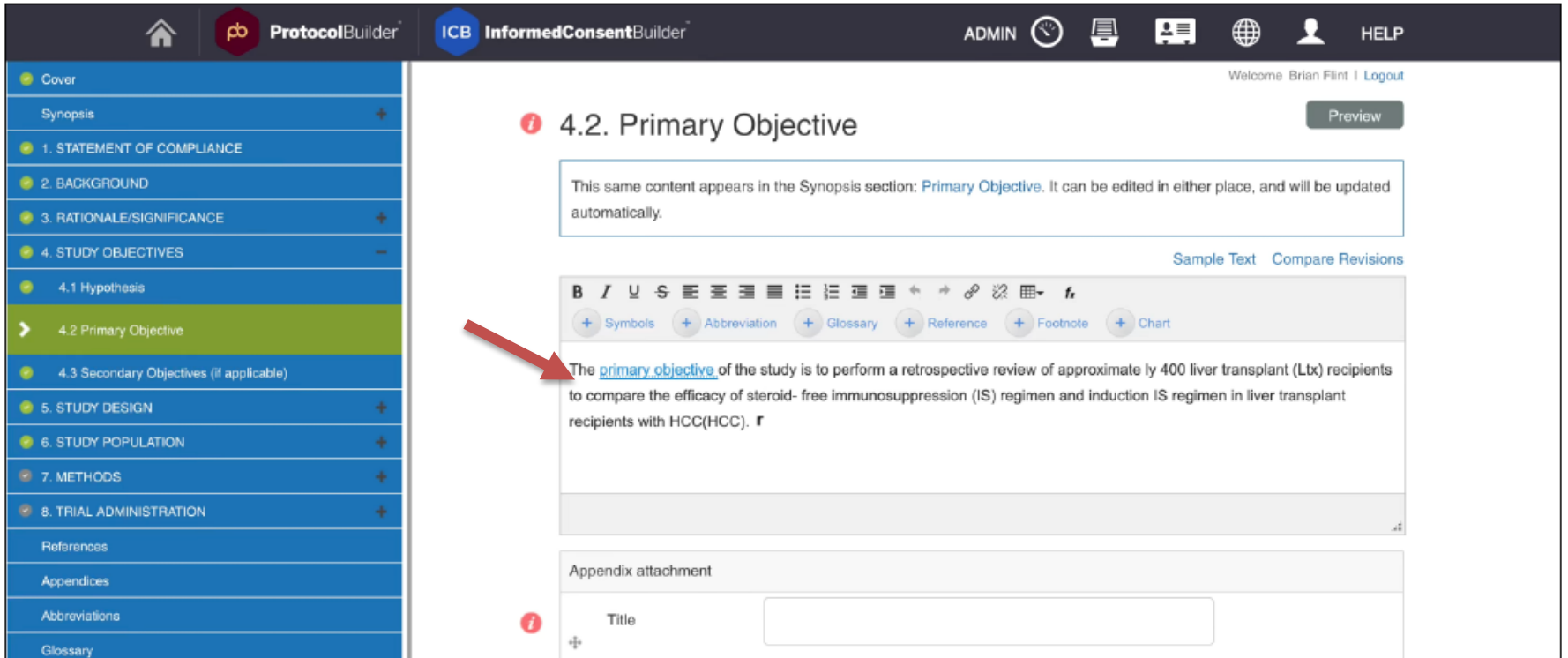
You can create a list of abbreviations and glossary terms. Highlight the abbreviations or glossary term, click on the icons and type the abbreviations or glossary details. Highlighted terms will turn blue and a list will be automatically created.





Summary of Changes

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Section	Change	Rationale
5 Study design	Added Cohort 2	Cohort 2 is being introduced to meet Aim 2
7 Methods	Added Procedure for Cohort 2	Procedures necessary for Cohort 2

Once a protocol version is published, a summary of changes will be created for subsequent versions. Turn the summary of changes on the navigation. Add and overall summary o changes box. Add rationale for each individual change that summarize the tracked changes. The summary of changes will be included in the protocol output.

Protocol Templates

UT Southwestern Medical Center

- Behavioral Intervention
- Biospecimen Collection
- Chart Review
- Interventional Combination
- Interventional FDA Approved Drug/Device
- Interventional Investigational New Drug/Device
- Interventional Non-Significant Risk Device
- Interventional Significant Risk Device
- NIH and FDA Protocol Template for Phase 2 & 3 IND/IDE Clinical Trials
- NIH Protocol Template for Behavioral and Social Science Studies
- Observational Study of FDA Regulated Products
- Observational Study of Individual or Group Characteristics or Behavior
- QA/QI
- Social/Behavioral
- UTSW SCCC Template
- UTSW Population Science Protocol Template

When with Protocol Builder Launch?

UT Southwestern Medical Center

- **Finalizing subscription**
- **Projected Launch Date: September 2024**

Questions?

Thank You!

- **We'd love to hear your feedback.** We invite you to provide your evaluation of Research Matters and of the Human Research Protection Program.

- Visit: https://ais.swmed.edu/redcap/surveys/?s=3PRJFCFJJW