

Research Matters

August 20, 2024

IRB Updates

Update 1: CMPA Approval Requirements

- Approval of CMPA is not required for some recruitment material

Update 1: CMPA Approval Requirements

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

- .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

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.



UT Southwestern
Medical Center
Human Research Protection Program

Protocol Builder

What is Protocol Builder

- 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

- You may use Forgot Password to recover your account

The screenshot shows the ProtocolBuilder home page with several callouts highlighting key features:

- Home:** A callout points to the home icon in the top navigation bar.
- Documents:** A callout points to the document icon in the top navigation bar.
- Contacts:** A callout points to the contact icon in the top navigation bar.
- Resources:** A callout points to the globe icon in the top navigation bar.
- Profile & Reference Library:** A callout points to the user profile icon in the top navigation bar.
- Help Center:** A callout points to the 'HELP' text in the top navigation bar.
- START DOCUMENT:** A callout points to the 'START DOCUMENT' button, which is used to 'Start new document'.
- Recent documents quick list:** A callout points to the list of recent documents, including 'Test Protocol' (08/09/2024) and 'Test' (08/06/2024).
- Important News:** A callout points to the 'Important News' section, which contains 'HELP DESK: 844-563-1042' and contact information.
- Help Desk:** A callout points to the 'HELP DESK' text in the Important News section.
- Featured Tutorials:** A callout points to the 'Featured Tutorials' section, which includes 'New User Training', 'Starting a new protocol', and 'Selecting personnel for a protocol'.

Starting a New Document

The screenshot shows the ProtocolBuilder web application interface. At the top, there is a dark navigation bar with a home icon, the ProtocolBuilder logo, and utility icons for printing, chat, globe, user profile, and a HELP button. Below the navigation bar, the user is greeted with "Welcome Meyad Bird | Logout". The main content area features a large "START DOCUMENT" button with a document icon containing a plus sign. To the right of this button are two document entries: "Test Protocol" dated 08/09/2024 and "Test" dated 08/06/2024. Further right is an "Important News" section with a blue header, containing a "HELP DESK: 844-563-1042" notice with contact information and availability. Below this is a "Features and Tips" section with three cards: "PROTOCOL BUILDER USER TRAINING", "STARTING A NEW PROTOCOL", and "SELECTING PERSONNEL FOR A PROTOCOL", each with a corresponding thumbnail image and a "View all" link at the bottom.

Click START DOCUMENT

Starting a New Document

Document Set Up

i File Name *
 Name document

i Principal Investigator *
Type in the first 3 - 4 letters of the PI's first name and wait for the options to appear in the search box. Click on your selection for PI.
 Select PI's name

i Document Type *
 Select Document Type from templates

If you're unsure, use the [Document Template Assistant](#). **Unsure of template?**

i Document Type *

Select Document Type
Standard Protocol Templates
Behavioral Intervention (incl. benign behavioral intervention)
Biospecimen Collection
Chart Review
Interventional Combination
Interventional FDA Approved Drug/Biologic
Interventional Investigational New Drug/Biologic
Interventional Non-Significant Risk Device
Interventional Significant Risk Device
NIH and FDA Protocol Template for Phase 2 and 3 IND/IDE Clinical Trials
NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans
Observational study of a FDA regulated product
Observational study of individual or group characteristics or behavior, or human factor evaluation
QA/QI
Social Behavioral

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 user will have:
 - Writer/editor
 - Read-only
 - Personnel listing only

Adding Personnel

Personnel

Enter or edit relevant personnel. Click the + symbol to add multiple individuals. If you leave a field blank, it will not appear on the Cover page.

Type in the first 3 - 4 letters of the PI's first name and wait for the options to appear in the search box. Click on your selection for PI .

+	Principal Investigator	Meyad Bird (40936)	Search Database
i	User Role	Writer/Reviewer	←

Type in the first 3 - 4 letters of the Investigator's first name and wait for the options to appear in the search box. Click on your selection for Investigator .

+	Investigator	Erik Soliz - UT Southwestern (42348)	Search Database
i	User Role	Personnel Listing (no access, only listed as study pe	←

Type in the first 3 - 4 letters of the Investigator's first name and wait for the options to appear in the search box. Click on your selection for Investigator .

+	Investigator	Hend Nadim - UT Southwestern (42349)	Search Database
i	User Role	Read Only	←

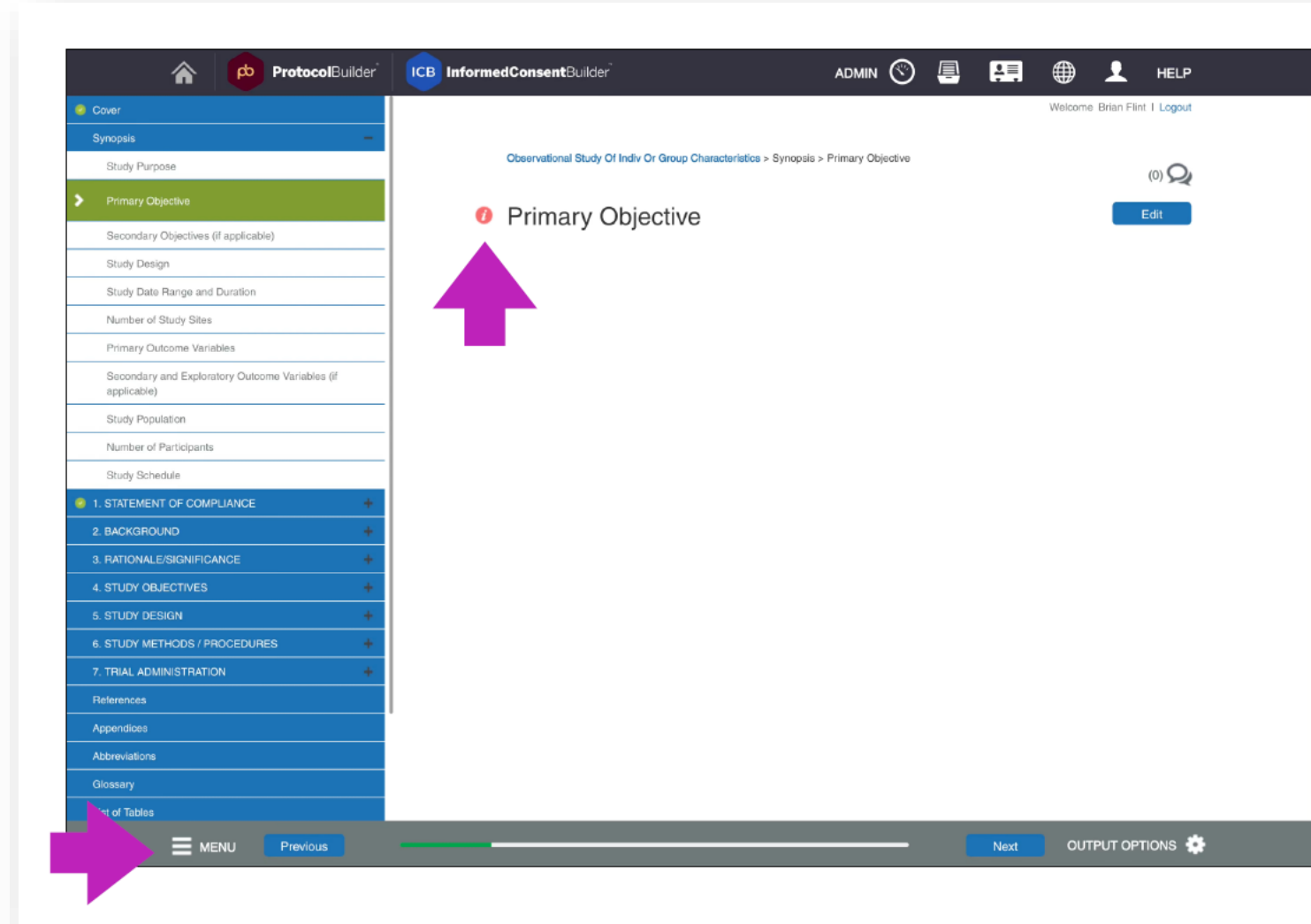
Writing the Protocol

The screenshot displays the ProtocolBuilder web application interface. The top navigation bar includes a home icon, the ProtocolBuilder logo, the Informed Consent Builder (ICB) logo, and utility icons for ADMIN, a clock, a printer, a document, a globe, a user profile, and HELP. A user greeting "Welcome Brian Flint | Logout" is visible in the top right. The left sidebar contains a table of contents with sections like Cover, Synopsis, Study Purpose, Primary Objective, Secondary Objectives, Study Design, Study Date Range and Duration, Number of Study Sites, Primary Outcome Variables, Secondary and Exploratory Outcome Variables, Study Population, Number of Participants, Study Schedule, and numbered sections 1 through 7 (STATEMENT OF COMPLIANCE, BACKGROUND, RATIONALE/SIGNIFICANCE, STUDY OBJECTIVES, STUDY DESIGN, STUDY METHODS / PROCEDURES, TRIAL ADMINISTRATION), followed by References, Appendices, Abbreviations, Glossary, and List of Tables. The main content area shows the "Synopsis" section for an "Observational Study Of Indiv Or Group Characteristics". A text box contains the following text: "The synopsis orients the reviewer to the study. It should be written as a standalone document and not reference other sections of the protocol. It should precisely summarize all elements of the study, and be consistent with the protocol. If content in the protocol is revised, remember to review the synopsis for accuracy." The bottom navigation bar features a MENU icon, a "Previous" button, a "Next" button, and an "OUTPUT OPTIONS" button with a gear icon.

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.

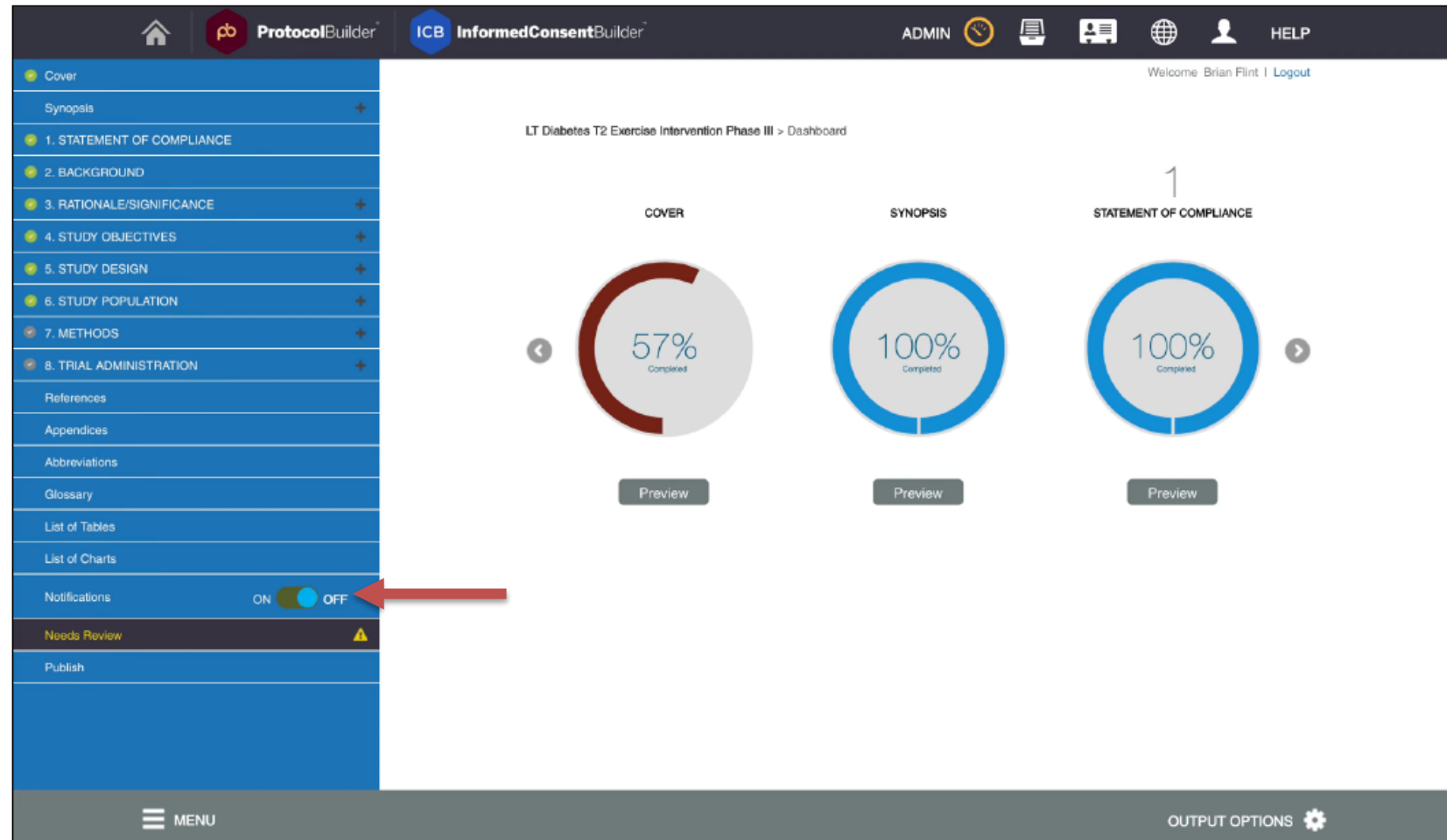


Saving Sections

The screenshot displays the Informed Consent Builder interface. The left navigation bar shows a list of sections. The section '4.2 Primary Objective' is highlighted with a green background and a grey checkmark, indicating it is a draft. The main content area shows the text of the section, a rich text editor, and an appendix attachment form. Red arrows point to the draft status in the navigation bar, the section title, and the 'Needs Review' indicator at the bottom.

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

The screenshot displays the ProtocolBuilder web application interface. The top navigation bar includes a home icon, the ProtocolBuilder logo, and utility icons for clock, printer, chat, globe, user profile, and HELP. A user greeting 'Welcome Meyad Bird | Logout' is visible in the top right. The left sidebar contains a table of contents with sections: Cover (selected), 1. STATEMENT OF COMPLIANCE, 2. BACKGROUND & RATIONALE, 3. STUDY PURPOSE AND OBJECTIVES, 4. STUDY DESIGN, 5. STUDY PROCEDURES, 6. RECORDS RETENTION, 7. REGULATORY AND ETHICAL CONSIDERATIONS, 8. PUBLICATION PLAN, References, Appendices, Abbreviations, Glossary, List of Tables, List of Charts, Publish, and Notifications (with a toggle switch set to OFF).

The main content area shows the 'Cover' page for a 'Test Protocol'. The breadcrumb 'Test Protocol > Cover' is at the top. The title 'Cover' is centered, with 'Edit' and 'Next' buttons to the right. The page contains a list of fields and their values:

File Name:	Test Protocol
Document Type:	Chart Review
Study Title:	Test Protocol1234
Document Number (if available):	STU-XXXX-XXXX
Principal Investigator:	Meyad Bird
Investigator:	Erik Soliz Hend Nadim
Document Version:	Draft
Last Modified:	17 Aug 2024 10:06:47PM EST

A red arrow points to the 'Last Modified' timestamp.

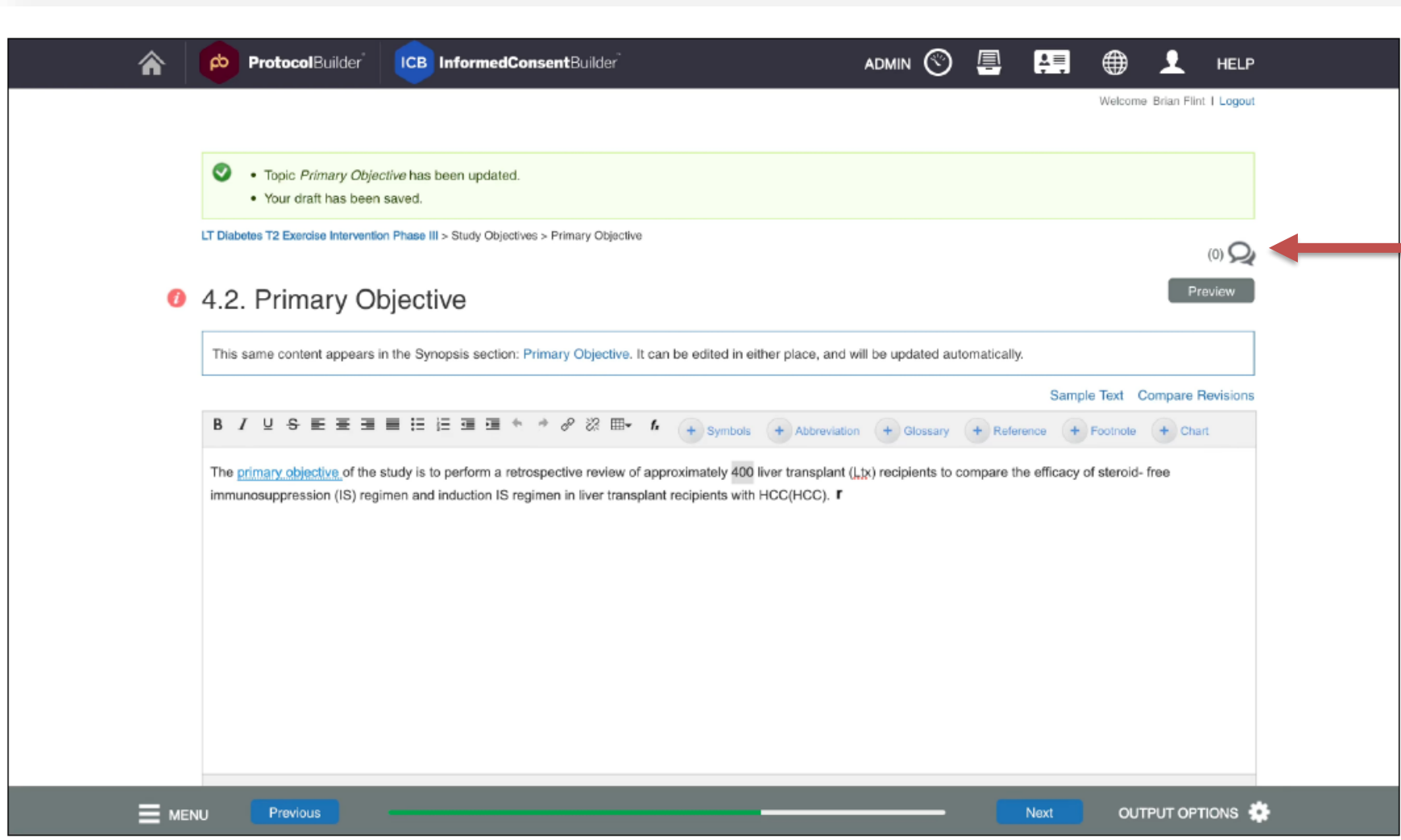
Make sure that you have set up the personnel contained in the Cover page. If the person you want to add does not show up in the options, click on search database to search by email. New users can be set up in the search pop-up if there is not a match for the email.

Needs Review List

The screenshot shows the Informed Consent Builder interface. On the left, a sidebar lists various sections, with '4.2 Primary Objective' highlighted in green and labeled as 'Needs Review'. The main content area displays a draft of this section. At the top, a green notification bar indicates that the topic 'Primary Objective' has been updated and the draft has been saved. Below this, the text reads: 'This same content appears in the Synopsis section: [Primary Objective](#). It can be edited in either place, and will be updated automatically.' A rich text editor toolbar is visible, followed by a paragraph of text: 'The [primary objective](#) of the study is to perform a retrospective review of approximately 400 liver transplant (Ltx) recipients to compare the efficacy of steroid-free immunosuppression (IS) regimen and induction IS regimen in liver transplant recipients with HCC(HCC). r'. A red arrow points to the 'Needs Review' section in the sidebar.

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



The screenshot displays the Informed Consent Builder interface. At the top, there is a navigation bar with icons for home, ProtocolBuilder, ICB InformedConsentBuilder, ADMIN, a clock, a document, a list, a globe, a user profile, and HELP. Below the navigation bar, a green notification box contains the following text: "Topic Primary Objective has been updated." and "Your draft has been saved." Below the notification, the breadcrumb trail reads "LT Diabetes T2 Exercise Intervention Phase III > Study Objectives > Primary Objective". A red arrow points to a commenting tool icon (a speech bubble with a pin) and a "Preview" button. Below this, the section title "4.2. Primary Objective" is displayed. A text box contains the text: "This same content appears in the Synopsis section: Primary Objective. It can be edited in either place, and will be updated automatically." Below the text box, there are links for "Sample Text" and "Compare Revisions". A rich text editor toolbar is visible, including buttons for Bold, Italic, Underline, Strikethrough, Text Color, Background Color, Bulleted List, Numbered List, Indent, Outdent, Undo, Redo, Link, Unlink, Table, and a "f" icon. Below the toolbar, the text reads: "The primary objective of the study is to perform a retrospective review of approximately 400 liver transplant (LTX) recipients to compare the efficacy of steroid-free immunosuppression (IS) regimen and induction IS regimen in liver transplant recipients with HCC(HCC). ¶". At the bottom of the interface, there is a footer with a MENU icon, a "Previous" button, a progress bar, a "Next" button, and an "OUTPUT OPTIONS" button with a gear icon.

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

The screenshot displays the Informed Consent Builder (ICB) interface. The top navigation bar includes a home icon, the ProtocolBuilder logo, the ICB InformedConsentBuilder logo, and utility icons for ADMIN, a clock, a document, a person, a globe, and HELP. A user greeting 'Welcome Brian Flint | Logout' is visible in the top right. A left-hand sidebar menu lists various document sections: Cover, Synopsis, 1. STATEMENT OF COMPLIANCE, 2. BACKGROUND, 3. RATIONALE/SIGNIFICANCE, 4. STUDY OBJECTIVES, 5. STUDY DESIGN, 6. STUDY POPULATION, 7. METHODS, 8. TRIAL ADMINISTRATION, References, Appendices, Abbreviations, Glossary, List of Tables, List of Charts, Notifications (with an ON/OFF toggle), and Publish. A red arrow points to the 'Publish' tab. The main content area shows a green notification box with a checkmark and two bullet points: 'Topic Study Completion has been updated.' and 'This document version has been published.' Below this is a breadcrumb trail: 'LT Diabetes T2 Exercise Intervention Phase III > Trial Administration > Study Completion'. The section title is '8.15. Study Completion' with an 'Edit' button. The text below reads: 'The investigator will complete the study and submit the case report forms in satisfactory compliance with the protocol within the agreed upon time frame for each study center. The Investigator is responsible for notifying the IRB of study completion.' At the bottom, there is a 'MENU' icon, 'Previous' and 'Next' buttons, a progress bar, and an 'OUTPUT OPTIONS' button with a gear icon.

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.

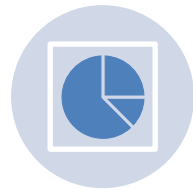
Advanced Editing/Automate Features



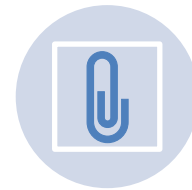
FORMATTING
REFERENCE SECTIONS
WITH AUTO
NUMBERING



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

An official website of the United States government [Here's how you know](#)

NIH National Library of Medicine
National Center for Biotechnology Information

Log in

PubMed®

diabetes mellitus Search

Advanced Create alert Create RSS User Guide

Save Email Send to Sort by: Best match Display options

MY NCBI FILTERS

RESULTS BY YEAR

TEXT AVAILABILITY

ARTICLE ATTRIBUTE

ARTICLE TYPE

606,200

Clipboard x Clear selection << < Page 1 of 60,620 > >>

My Bibliography

Collections

Citation manager

1
Cite
Share

PMID: 34173093 **Free PMC article.** Review.

The review presents modern views about the role of oxidative stress reactions in the pathogenesis of types 1 and 2 **diabetes mellitus** and their complications based on the analysis of experimental and clinical studies. ...Numerous studies of the effectiveness of antio ...

Diagnosis and classification of diabetes mellitus.

2
Cite
Share

American Diabetes Association.
Diabetes Care. 2011 Jan;34 Suppl 1(Suppl 1):S62-9. doi: 10.2337/dc11-S062.
PMID: 21193628 **Free PMC article.** No abstract available.

Diagnosis and classification of diabetes mellitus.

3
Cite
Share

American Diabetes Association.
Diabetes Care. 2013 Jan;36 Suppl 1(Suppl 1):S67-74. doi: 10.2337/dc13-S067.
PMID: 23264425 **Free PMC article.** No abstract available.

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 at the top of the navigation bar. Upload the file to create your reference library.

Insert References

The screenshot shows the Informed Consent Builder interface. At the top, there are navigation icons for home, ProtocolBuilder, and ICB InformedConsentBuilder. The user is logged in as Brian Flint. The current page is titled "7.1.1. Description of Intervention". A red arrow points to the "Reference" button in the rich text editor toolbar. Below the toolbar, there is a text area containing the following text:

Eligible participants are randomized to the two arms of the study: a control group referred to as Diabetes Support and Education or to Lifestyle Intervention.

Aspects of the Intervention Common to Both Study Arms

All participants attend a one-hour diabetes education class at the end of the screening process. This session provides basic education about diabetes, with particular emphasis on aspects of diabetes care related to the trial such as management of hypoglycemia, cardiovascular disease symptoms, and foot care. All participants at risk of hypoglycemia are encouraged to use blood glucose self-monitoring equipment and strips. The importance of eating a healthy diet and being physically active for both weight loss and improvement of glycemic control are stressed. All individuals who smoke are encouraged to stop smoking and are provided with self-help materials and/or referral to local programs, as appropriate. Participants in both interventions and their physicians are given results from study examinations after each annual examination. All participants will continue to receive their medical care and medical management of their diabetes from their usual source of medical care, not from the study staff. A description of the study, information on the therapeutic targets for diabetes, blood pressure and lipids, and a synopsis of current consensus recommendations for achieving these targets are sent to each participant's health care provider. Data related to HbA1c, blood pressure, lipid values, ECG, urine albumin, estimated GFR, and serum creatinine values that are obtained during scheduled study visits are provided to participants and their primary care providers within one-two weeks in a form that clearly indicates abnormal values and ranges. Standards of care or generally accepted guidelines for interpretation and/or interventions related to these parameters also will be provided.

Below the text area, there is an "Appendix attachment" section with a "Title" input field.

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.

The screenshot shows the InformedConsentBuilder interface. The breadcrumb trail is "LT Diabetes T2 Exercise Intervention Phase III > Methods > Intervention > Description Of Intervention". The main heading is "7.1.1. Description of Intervention". A red arrow points to the "Footnote" option in the toolbar, which is highlighted in blue. Other toolbar options include Bold, Italic, Underline, Text Color, Background Color, Bulleted List, Numbered List, Indent, Outdent, Link, Unlink, Table, Image, Symbols, Abbreviation, Glossary, Reference, and Chart. The main text area contains a paragraph about randomization and a section titled "Aspects of the Intervention Common to Both Study Arms" with a detailed description of the intervention. At the bottom, there is an "Appendix attachment" section with a "Title" input field.

The screenshot shows the InformedConsentBuilder interface after a footnote has been saved. A green notification bar at the top says "Footnote has been saved". The breadcrumb trail is "LT Diabetes T2 Exercise Intervention Phase III > Study Objectives > Primary Objective". The main heading is "4.2. Primary Objective". Below the heading is a paragraph describing the primary objective of the study. Underneath is a "References" section with one reference listed. At the bottom, a "Footnotes" section is visible, with a red arrow pointing to a footnote listed with the letter "a".

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).

The screenshot shows the "OUTPUT OPTIONS" menu. It includes options for "Glossary", "List of Tables", "List of Charts", "Summary of Changes" (ON/OFF), and "Notifications" (ON/OFF). The "Summary of Changes" and "Notifications" options have toggle switches. The bottom of the menu shows "MENU", "Previous", "Next", and "OUTPUT OPTIONS" with a gear icon.

List of Tables/Charts

The screenshot displays the Informed Consent Builder (ICB) interface. At the top, there is a navigation bar with icons for home, ProtocolBuilder, and ICB InformedConsentBuilder, along with user options like ADMIN, HELP, and a welcome message for Brian Flint. The main content area shows a breadcrumb trail: LT Diabetes T2 Exercise Intervention Phase III > Methods > Study Procedures > Study Schedule. Below this, the section title '7.3.1. Study Schedule' is visible, accompanied by a 'Preview' button. A rich text editor toolbar is shown with various icons and buttons for 'Symbols', 'Abbreviation', 'Glossary', 'Reference', 'Footnote', and 'Chart'. A red arrow points to the 'Chart' button. Below the editor is an 'Appendix attachment' section with a 'Title' input field, an 'Attachment' field with a 'Choose File' button and 'No file chosen' text, and an 'Upload' button. The bottom navigation bar includes a 'MENU' icon, 'Previous' and 'Next' buttons, and an 'OUTPUT OPTIONS' button with a settings icon.

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 screenshot displays the ICB Informed Consent Builder interface. The top navigation bar includes 'ProtocolBuilder' and 'ICB Informed Consent Builder' logos, along with 'ADMIN', 'HELP', and user information. A left sidebar contains a table of contents with sections like 'Cover', 'Synopsis', '1. STATEMENT OF COMPLIANCE', '2. BACKGROUND', '3. RATIONALE/SIGNIFICANCE', '4. STUDY OBJECTIVES', '5. STUDY DESIGN', '6. STUDY POPULATION', and '7. METHODS'. The main content area is titled '7.3.2. Informed Consent' and features a rich text editor with a toolbar containing options like Bold, Italic, Underline, and various list and link functions. The text in the editor reads: 'Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting study procedures/administering study intervention. The following consent materials are submitted with this protocol: Informed Consent Form, Key Information Form'. Below the editor is an 'Appendix attachment' form with a 'Title' field, an 'Attachment' field with a 'Choose File' button and 'No file chosen' text, and an 'Upload' button. A red arrow points from the text box on the right to the 'Appendix attachment' form. At the bottom, there is a 'MENU' button, 'Previous' and 'Next' navigation buttons, and an 'OUTPUT OPTIONS' button with a gear icon.

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

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.

The screenshot shows the ProtocolBuilder interface for the '7.3.1. Study Schedule' section. The top navigation bar includes 'ProtocolBuilder' and 'ICB InformedConsentBuilder' logos, along with 'ADMIN', 'HELP', and a user profile icon. The breadcrumb trail reads 'LT Diabetes T2 Exercise Intervention Phase III > Methods > Study Procedures > Study Schedule'. The main content area displays the section title '7.3.1. Study Schedule' and a toolbar with icons for Bold, Italic, Underline, Strikethrough, Bulleted List, Numbered List, Indent, Outdent, Undo, Redo, and a rich text editor. The 'Abbreviation' and 'Glossary' icons in the toolbar are highlighted with red arrows.

The screenshot shows the ProtocolBuilder interface for the '4.2. Primary Objective' section. The top navigation bar is identical to the previous screenshot. The breadcrumb trail reads 'LT Diabetes T2 Exercise Intervention Phase III > Methods > Study Procedures > Study Schedule > 4.2. Primary Objective'. The main content area displays the section title '4.2. Primary Objective' and a text box containing the text: 'This same content appears in the Synopsis section: [Primary Objective](#). It can be edited in either place, and will be updated automatically.' Below the text box is a toolbar with icons for Bold, Italic, Underline, Strikethrough, Bulleted List, Numbered List, Indent, Outdent, Undo, Redo, and a rich text editor. The 'Abbreviation' icon in the toolbar is highlighted with a red arrow. The bottom of the screen shows an 'Appendix attachment' section with a 'Title' field and a '+ Choose File' button.

Summary of Changes

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

- 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?

- **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>

