

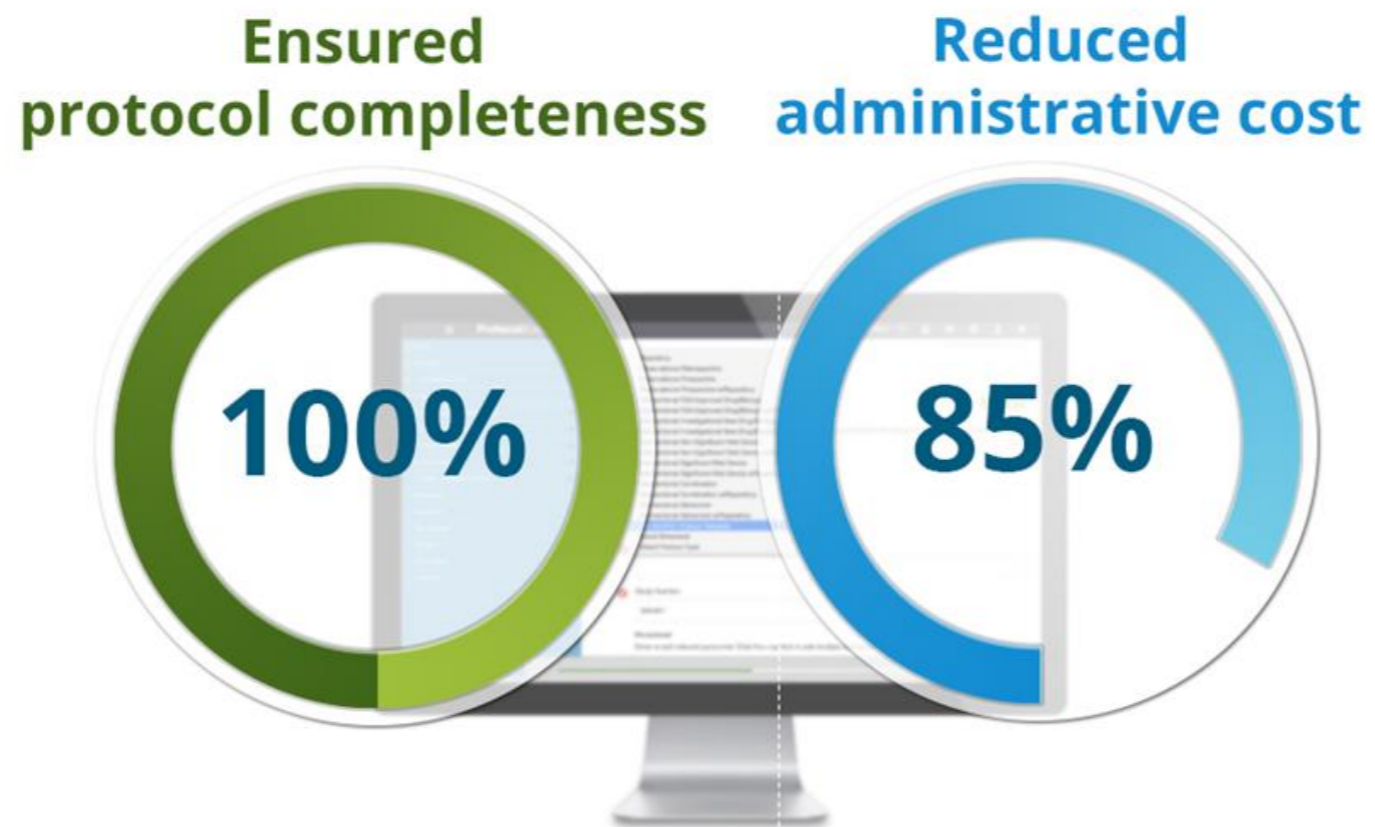


Protocol Builder®

Application Tour

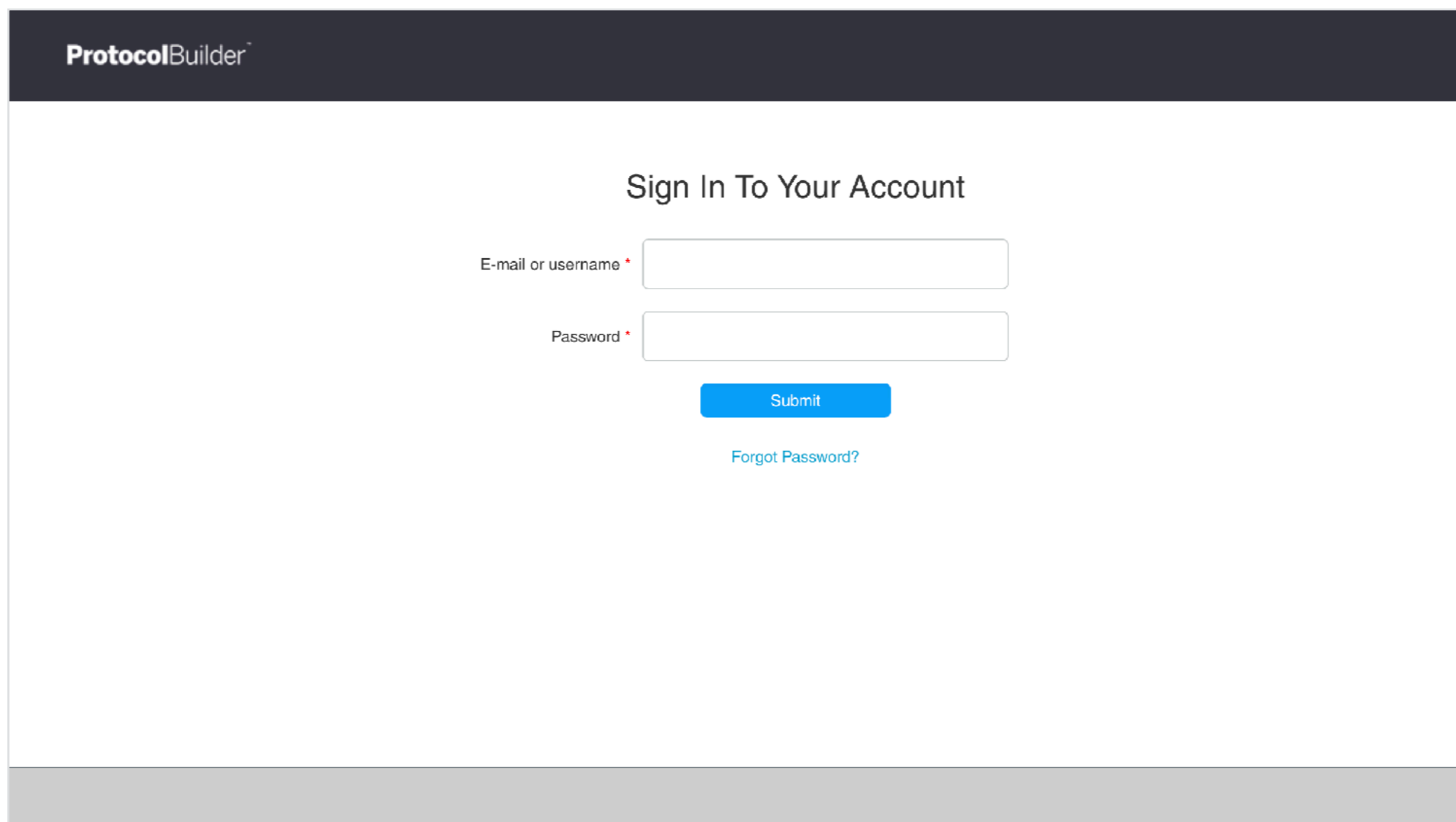
WELCOME TO THE PROTOCOL BUILDER TOUR

Protocol Builder helps make it faster and easier to develop research protocols that comply with IRB and regulatory standards.



SIGN IN

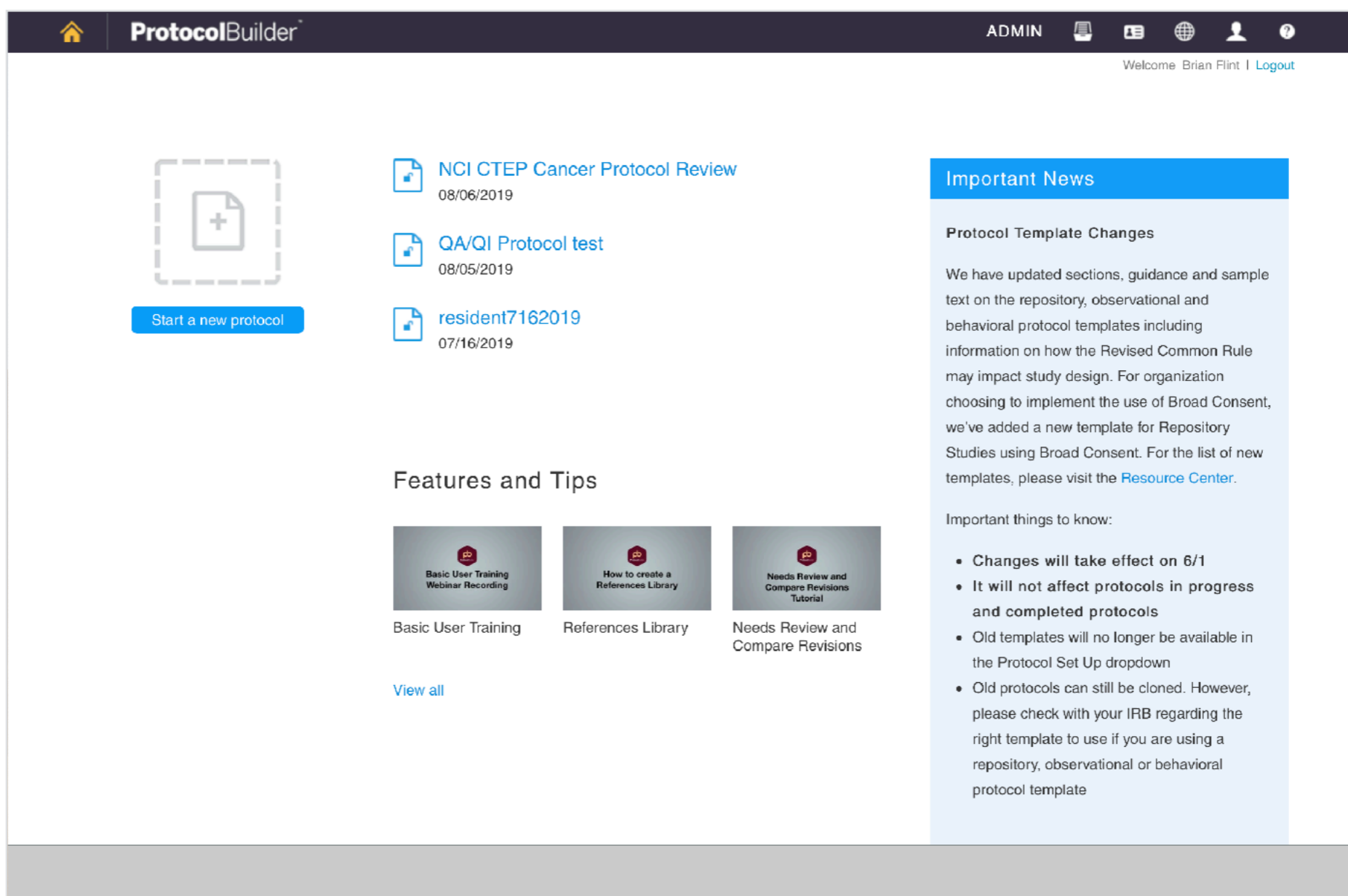
Sign in securely with your email address and password. Click on “Forgot Password” to receive a password reset email.



The screenshot shows the ProtocolBuilder sign-in interface. At the top left, the ProtocolBuilder logo is displayed. The main heading is "Sign In To Your Account". Below this, there are two input fields: "E-mail or username" and "Password", both marked with a red asterisk. A blue "Submit" button is positioned below the password field. A link for "Forgot Password?" is located below the submit button. The entire form is centered on a white background, with a dark grey header and a light grey footer.

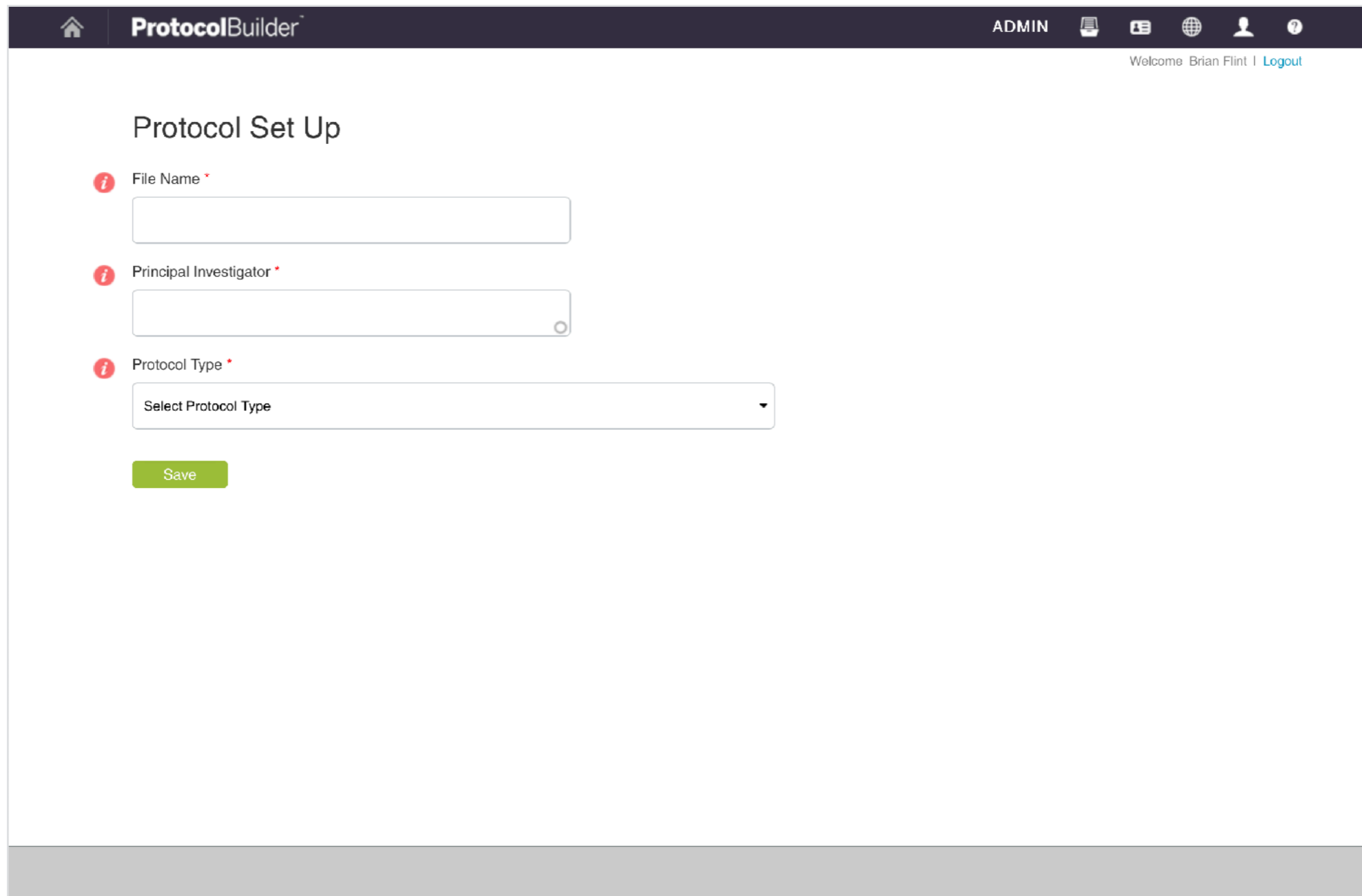
HOME SCREEN

Click to start a new protocol, or open a recently saved protocol from the quick pick list. Or duplicate an existing protocol to repurpose the content and references easily. You will also find links to instructional videos and Important News from Protocol Builder our your IRB.



PROTOCOL SET UP

Set up your protocol quickly by entering basic information. Wait for system to find the PI's name to show up when you enter the first letters of their name.



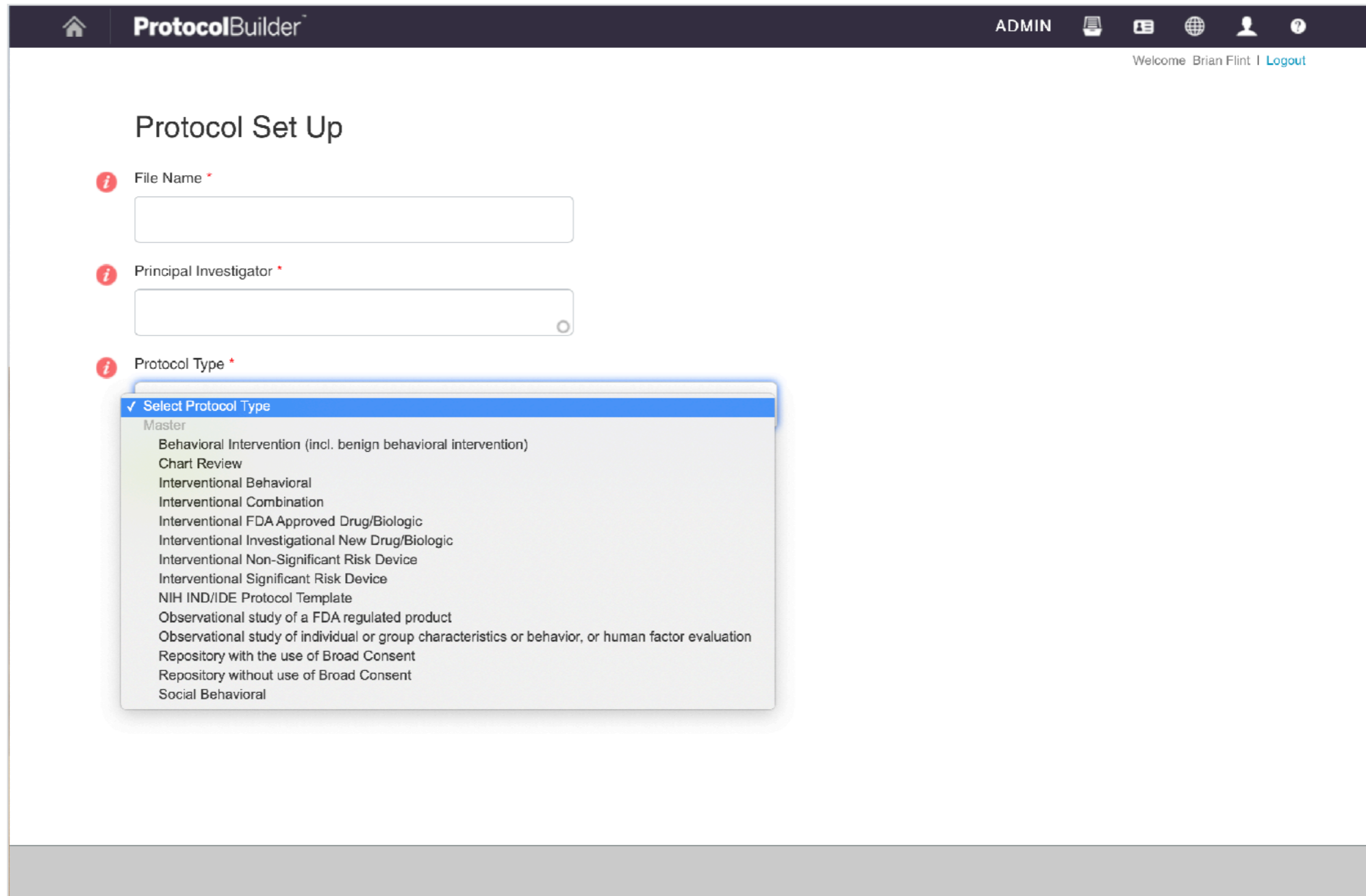
The screenshot shows the 'Protocol Set Up' form in the ProtocolBuilder application. The form is located in the main content area of the dashboard. At the top of the dashboard, there is a dark navigation bar with the ProtocolBuilder logo, a home icon, and the word 'ADMIN'. To the right of the navigation bar, there are several icons: a printer, a calendar, a globe, a user profile, and a help icon. Below the navigation bar, the user is logged in as 'Brian Flint' and has a 'Logout' link. The main content area has a title 'Protocol Set Up' and three required fields, each with an information icon (i) and an asterisk (*):

- File Name ***: A text input field.
- Principal Investigator ***: A text input field with a search icon on the right.
- Protocol Type ***: A dropdown menu with the text 'Select Protocol Type' and a downward arrow.

Below the fields is a green 'Save' button.

PROTOCOL SET UP

Choose the protocol type to set up the table of contents and guidance that will guide you through the process of writing the protocol.



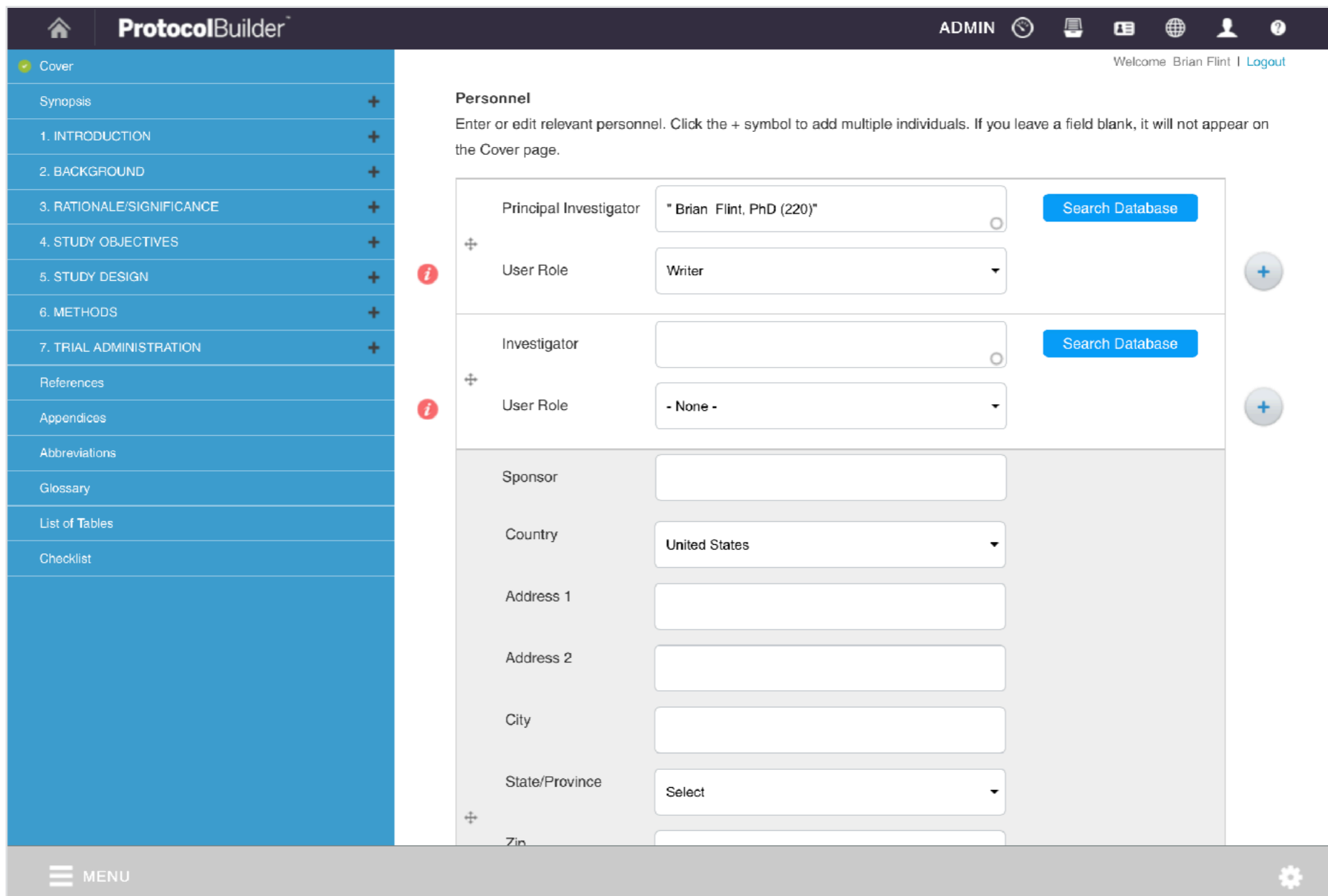
COVER PAGE

Enter the key information about the protocol that will show up on the cover page (the file name will not show on the final protocol output).

The screenshot displays the ProtocolBuilder web application interface. On the left is a blue sidebar menu with the following items: Cover (selected), Synopsis, 1. INTRODUCTION, 2. BACKGROUND, 3. RATIONALE/SIGNIFICANCE, 4. STUDY OBJECTIVES, 5. STUDY DESIGN, 6. METHODS, 7. TRIAL ADMINISTRATION, References, Appendices, Abbreviations, Glossary, List of Tables, and Checklist. The main content area is titled 'Cover' and includes a 'Preview' button. Below the title is a descriptive paragraph: 'This section includes study identification details and individuals responsible for the research. It will be used to create the cover page.' The form contains several fields: 'File Name *' with the text 'New Protocol'; 'Protocol Type *' with a dropdown menu showing 'Interventional Investigational New Drug/Biologic'; 'Study Title' with an empty text box; 'Protocol Number (if available)' with an empty text box; 'Investigational Product' with an empty text box; 'IND Number' with an empty text box; and 'Clinical Phase' with a dropdown menu showing '- None -'. The top navigation bar includes 'ADMIN' and various utility icons. The bottom of the page features a 'MENU' button and a settings gear icon.

COVER PAGE

Start typing in a name and Protocol Builder will search for it in your organization's list of users. Simply select the name when it appears. Make sure you choose the access role you want to them have for your protocol: "Writers" can edit, "Reviewers" can only read and comment. At the bottom of the personnel list you will find the Research Admin box for IRB, HRPP or other personnel you want to share the protocol with, but do not want to show on the cover page.



SEARCH FOR PERSONNEL

If the name is not found, click “Search Database”. Type in an email address to search the entire Protocol Builder database. If the user is in the system fields will show populated. If the user is not in the system, you can enter the information manually and an email invitation to join the protocol will be sent out.

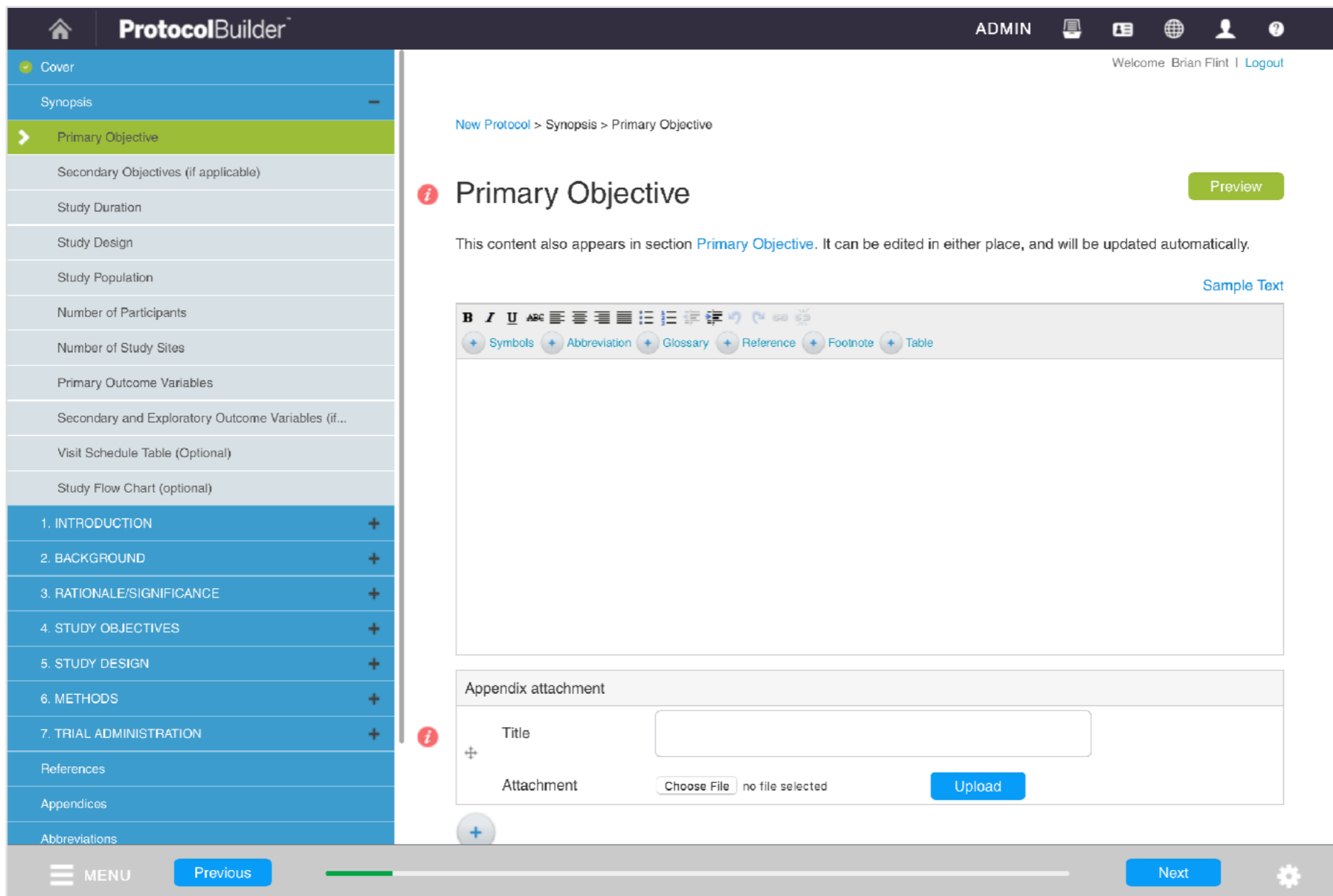
The screenshot displays the ProtocolBuilder web application interface. A modal window titled "User Found" is open, containing the following fields and instructions:

- Instructions:** "Click Submit if Correct. We found this user in our database. If this is correct, please select Submit and we will send an email invitation to collaborate on this protocol. If not, you can reenter the email address and search again."
- Email ***: Input field containing "Kirvine@brany.com" with a "Search" button to its right.
- Prefix**: Empty input field.
- First Name ***: Input field containing "Kim".
- Middle Name**: Empty input field.
- Last Name ***: Input field containing "Irvine".
- Suffix**: Empty input field.
- Phone**: Empty input field.
- Organization**: Empty input field.
- Title**: Empty input field.
- Buttons:** "Cancel" and "Submit" buttons at the bottom of the modal.

The background interface shows a sidebar menu with items like "Cover", "Synopsis", "1. INTRODUCTION", "2. BACKGROUND", "3. RATIONALE/SIGNIFICANCE", "4. STUDY OBJECTIVES", "5. STUDY DESIGN", "6. METHODS", "7. TRIAL ADMINISTRATION", "References", "Appendices", "Abbreviations", "Glossary", "List of Tables", and "Checklist". The top navigation bar includes "ADMIN", "Welcome Brian Flint", and "Logout".

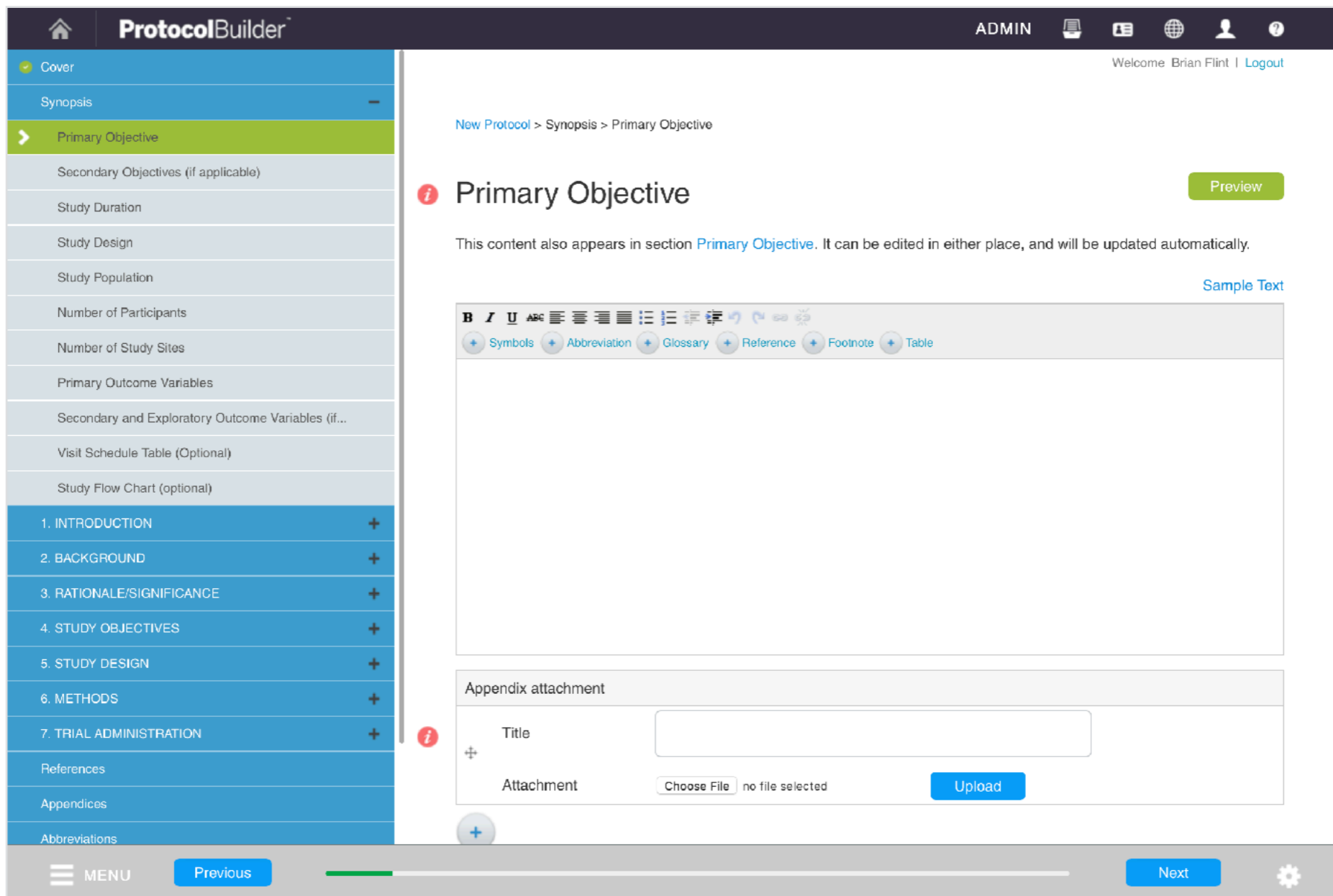
WRITING THE PROTOCOL

Once the set up is completed, you can start writing the protocol sections. We suggest starting with the Synopsis sections as part of your first draft. The tool will automatically populate those sections that are the same in body of the protocol, so you don't have to type them in twice.



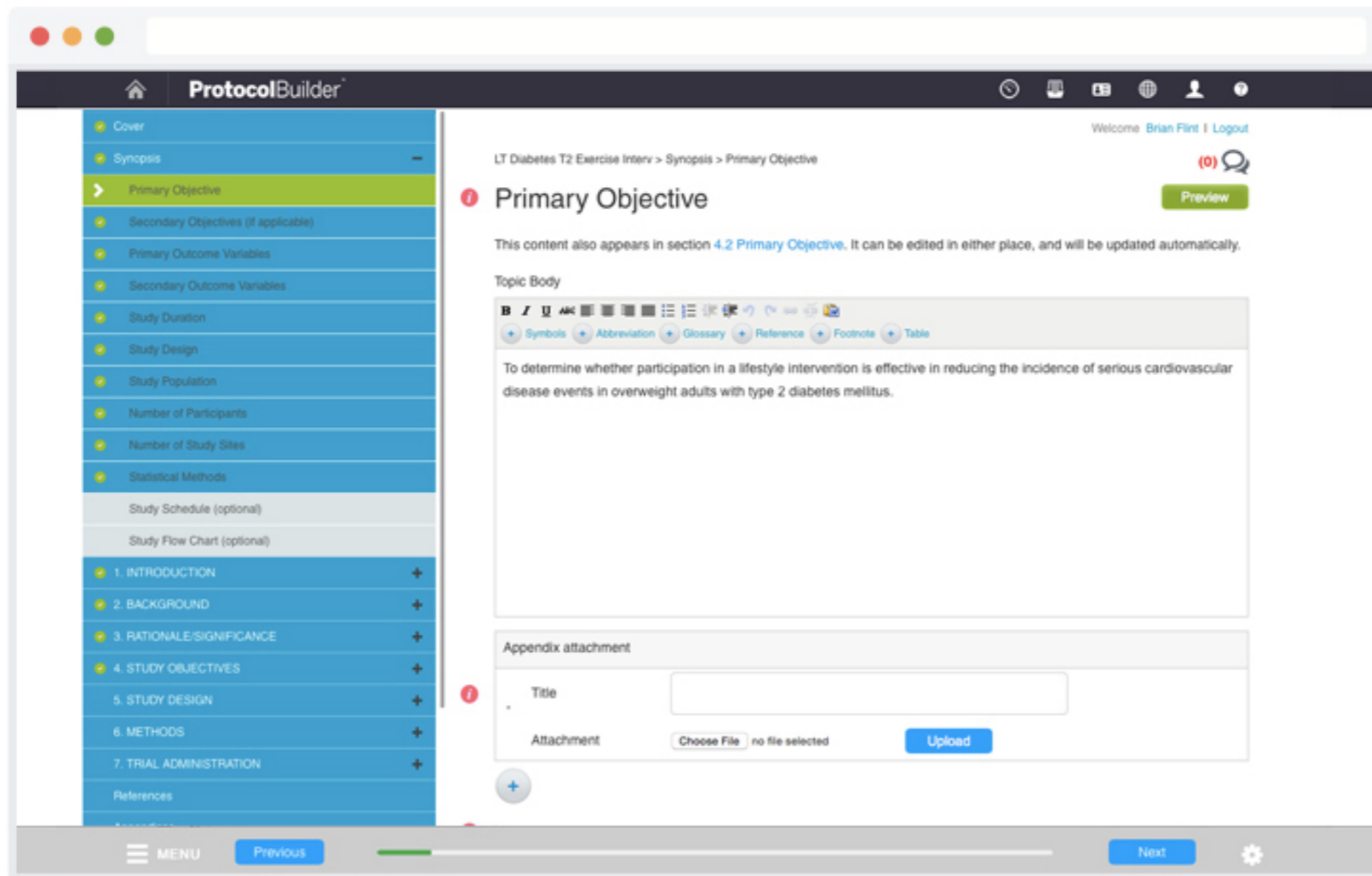
WRITING THE PROTOCOL - CONTENTS MENU

You can jump straight to the section you want to work on using the left hand navigation that contains all protocol sections. As you go working on the sections you will see a check mark appear: a grey checkmark means it is still a draft, a free checkmark means it is complete.



CONTENTS MENU

If you'd like to jump to a specific section of a protocol, open the Contents Menu and click the name of that section.



WRITING THE PROTOCOL - TOOL TIP GUIDANCE

Click on the “i” icons anywhere to display the guidance for completing the section.

The screenshot displays the ProtocolBuilder web application interface. On the left, a yellow tooltip box contains the following text: "State the main purpose for performing the study. It should be clear, detailed but limited in scope. Keep in mind the primary objective will help determine the sample size." The main content area is titled "Primary Objective" and includes a "Preview" button. Below the title, there is a text editor with a rich text toolbar and a list of options: Symbols, Abbreviation, Glossary, Reference, Footnote, and Table. At the bottom of the main area, there is an "Appendix attachment" section with a "Title" input field, an "Attachment" field with a "Choose File" button and "no file selected" text, and an "Upload" button. The interface also features a top navigation bar with "ADMIN" and user information, and a bottom navigation bar with "Previous" and "Next" buttons.

WRITING THE PROTOCOL - SAMPLE TEST

To save time Protocol Builder provides, where possible, sample text that can be inserted and edited.

The screenshot displays the ProtocolBuilder web application interface. On the left is a navigation sidebar with a list of sections: Cover, Synopsis, Primary Objective (highlighted), Secondary Objectives (if applicable), Study Duration, Study Design, Study Population, Number of Participants, Number of Study Sites, Primary Outcome Variables, Secondary and Exploratory Outcome Variables (if...), Visit Schedule Table (Optional), Study Flow Chart (optional), 1. INTRODUCTION, 2. BACKGROUND, 3. RATIONALE/SIGNIFICANCE, 4. STUDY OBJECTIVES, 5. STUDY DESIGN, 6. METHODS, 7. TRIAL ADMINISTRATION, References, Appendices, and Abbreviations. The main content area shows the breadcrumb path 'New Protocol > Synopsis > Primary Objective' and a yellow 'Insert' dialog box. The dialog box contains the following sample text: 'The primary objective of this study is to determine whether the [insert exposure, presenting sign, comorbidity, treatment option] reduces, increases, etc. outcome measure [insert outcome measure] in population [insert population description].'. The interface also includes a top navigation bar with 'ADMIN' and user information, and a bottom navigation bar with 'Previous', 'Next', and 'MENU' buttons.

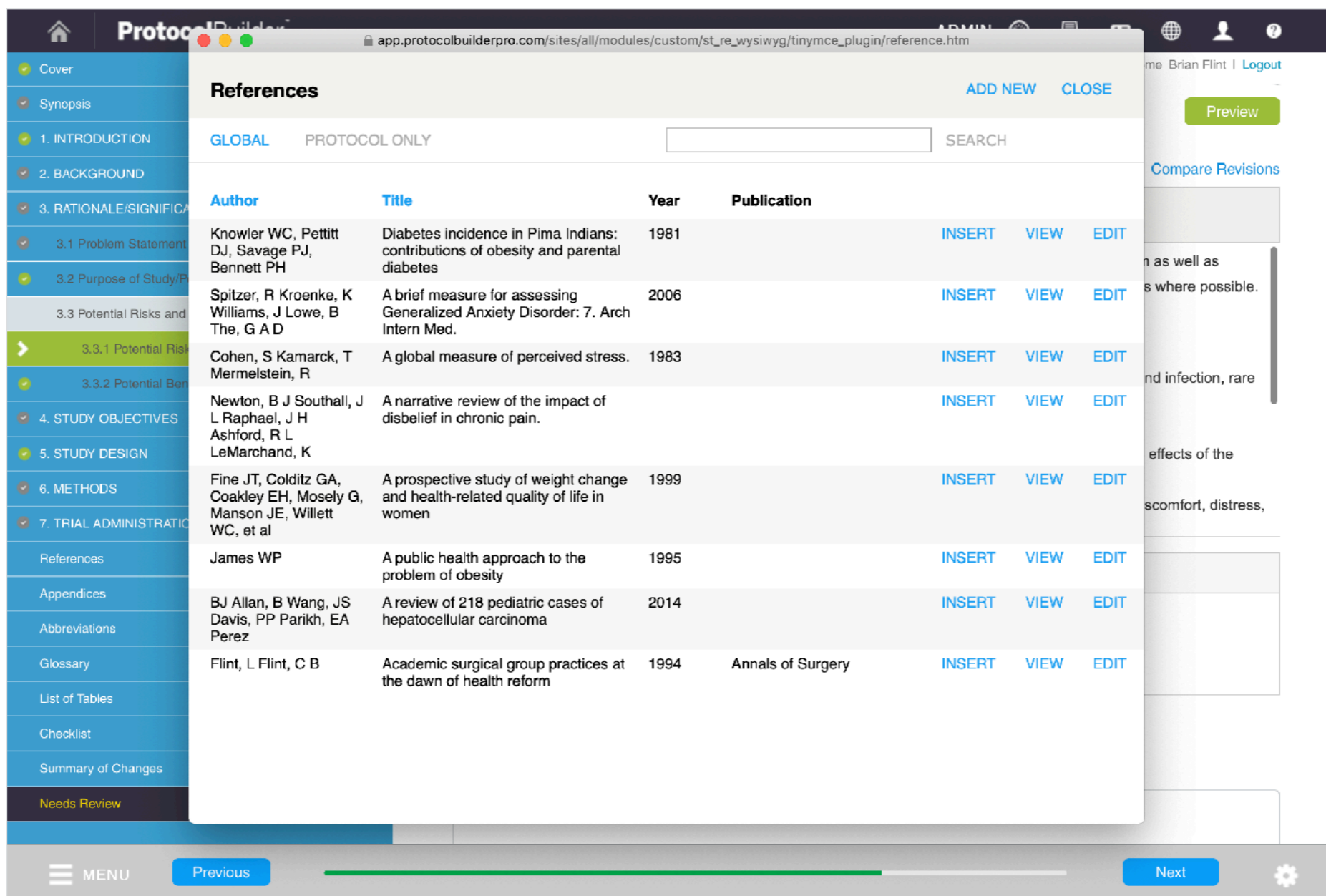
WRITING THE PROTOCOL - EDITING TOOLS

As you're writing, you can click the editing toolbar buttons to format text.

The screenshot displays the ProtocolBuilder web application interface. At the top, the 'ProtocolBuilder' logo is on the left, and 'ADMIN' with various utility icons is on the right. A navigation sidebar on the left lists sections like 'Cover', 'Synopsis', and a numbered list of protocol sections: '1. INTRODUCTION', '2. BACKGROUND', '3. RATIONALE/SIGNIFICANCE', '4. STUDY OBJECTIVES', '5. STUDY DESIGN', '6. METHODS', '7. TRIAL ADMINISTRATION', 'References', 'Appendices', and 'Abbreviations'. The main content area shows a text editor with a rich text toolbar containing icons for bold, italic, underline, text color, background color, bulleted list, numbered list, link, unlink, and insert. Below the toolbar are buttons for '+ Symbols', '+ Abbreviation', '+ Glossary', '+ Reference', '+ Footnote', and '+ Table'. The text editor contains 'Sample Text'. Below the editor is an 'Appendix attachment' section with a 'Title' input field, an 'Attachment' input field with a 'Choose File' button and 'no file selected' text, and an 'Upload' button. At the bottom, there is a 'MENU' icon, 'Previous' and 'Next' buttons, and a settings gear icon.

WRITING THE PROTOCOL - REFERENCES

As you're writing, you insert references you've improved into your References Library. Protocol Builder will take care of formatting them, numbering them and adding them to the References page at the end of the protocol.

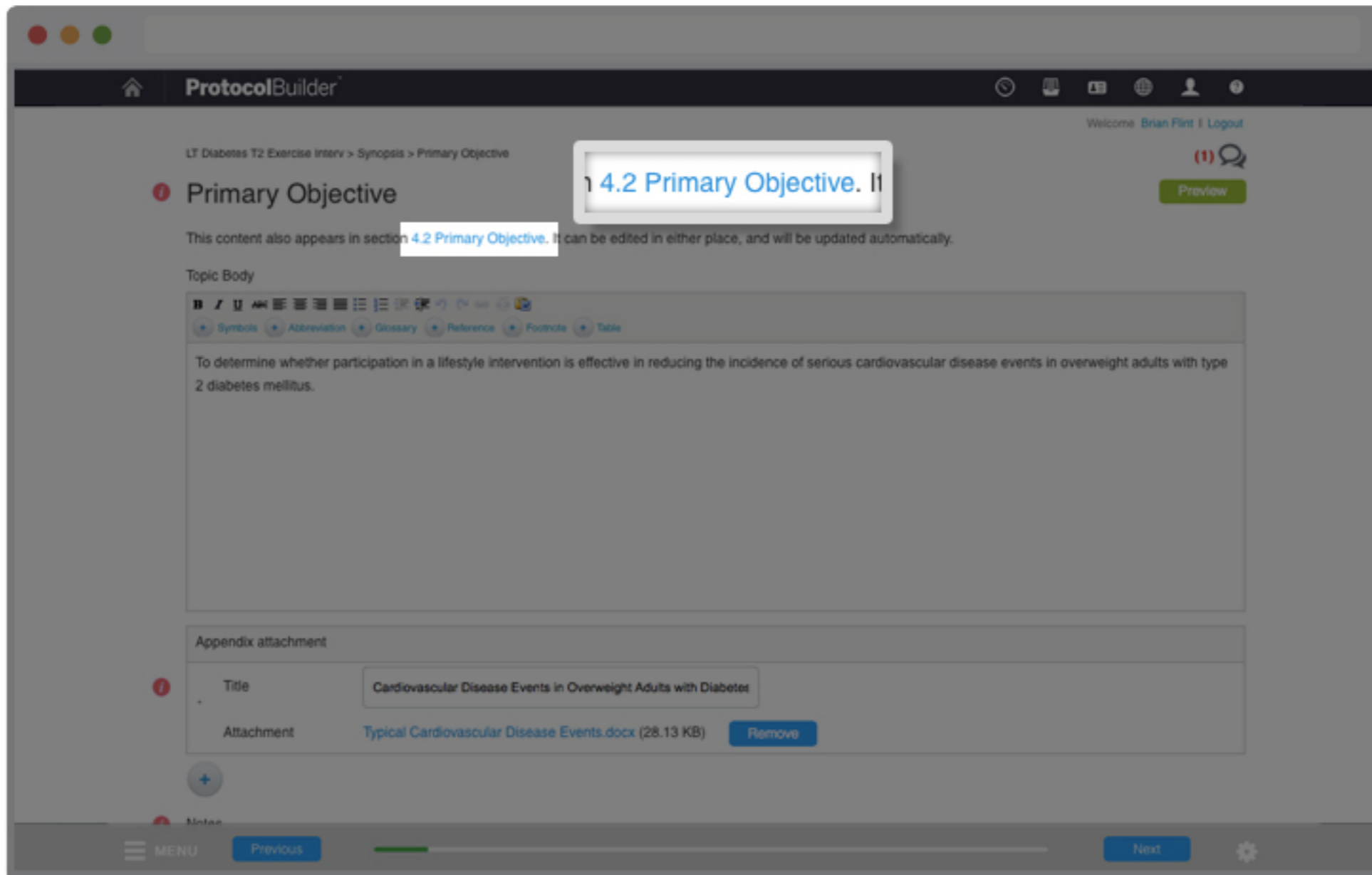


The screenshot displays the Protocol Builder interface. On the left is a sidebar with a list of protocol sections: Cover, Synopsis, 1. INTRODUCTION, 2. BACKGROUND, 3. RATIONALE/SIGNIFICANCE (with sub-sections 3.1 Problem Statement, 3.2 Purpose of Study/Purpose, 3.3 Potential Risks and Benefits, and 3.3.1 Potential Risks and Benefits), 4. STUDY OBJECTIVES, 5. STUDY DESIGN, 6. METHODS, and 7. TRIAL ADMINISTRATION. The 'References' section is highlighted in the sidebar. The main content area shows a 'References' modal window with a search bar and a table of references. The table has columns for Author, Title, Year, and Publication, with 'INSERT', 'VIEW', and 'EDIT' buttons for each row. The bottom navigation bar includes a 'MENU' icon, 'Previous' and 'Next' buttons, and a settings gear icon.

Author	Title	Year	Publication	INSERT	VIEW	EDIT
Knowler WC, Pettitt DJ, Savage PJ, Bennett PH	Diabetes incidence in Pima Indians: contributions of obesity and parental diabetes	1981		INSERT	VIEW	EDIT
Spitzer, R Kroenke, K Williams, J Lowe, B The, G A D	A brief measure for assessing Generalized Anxiety Disorder: 7. Arch Intern Med.	2006		INSERT	VIEW	EDIT
Cohen, S Kamarck, T Mermelstein, R	A global measure of perceived stress.	1983		INSERT	VIEW	EDIT
Newton, B J Southall, J L Raphael, J H Ashford, R L LeMarchand, K	A narrative review of the impact of disbelief in chronic pain.			INSERT	VIEW	EDIT
Fine JT, Colditz GA, Coakley EH, Mosely G, Manson JE, Willett WC, et al	A prospective study of weight change and health-related quality of life in women	1999		INSERT	VIEW	EDIT
James WP	A public health approach to the problem of obesity	1995		INSERT	VIEW	EDIT
BJ Allan, B Wang, JS Davis, PP Parikh, EA Perez	A review of 218 pediatric cases of hepatocellular carcinoma	2014		INSERT	VIEW	EDIT
Flint, L Flint, C B	Academic surgical group practices at the dawn of health reform	1994	Annals of Surgery	INSERT	VIEW	EDIT

WRITING THE PROTOCOL - LINKED SECTIONS

If you are working on a working on a Synopsis section that is repeated later these sections will be linked so you don't have to re-enter information or make the changes in two places.



NEEDS REVIEW LIST

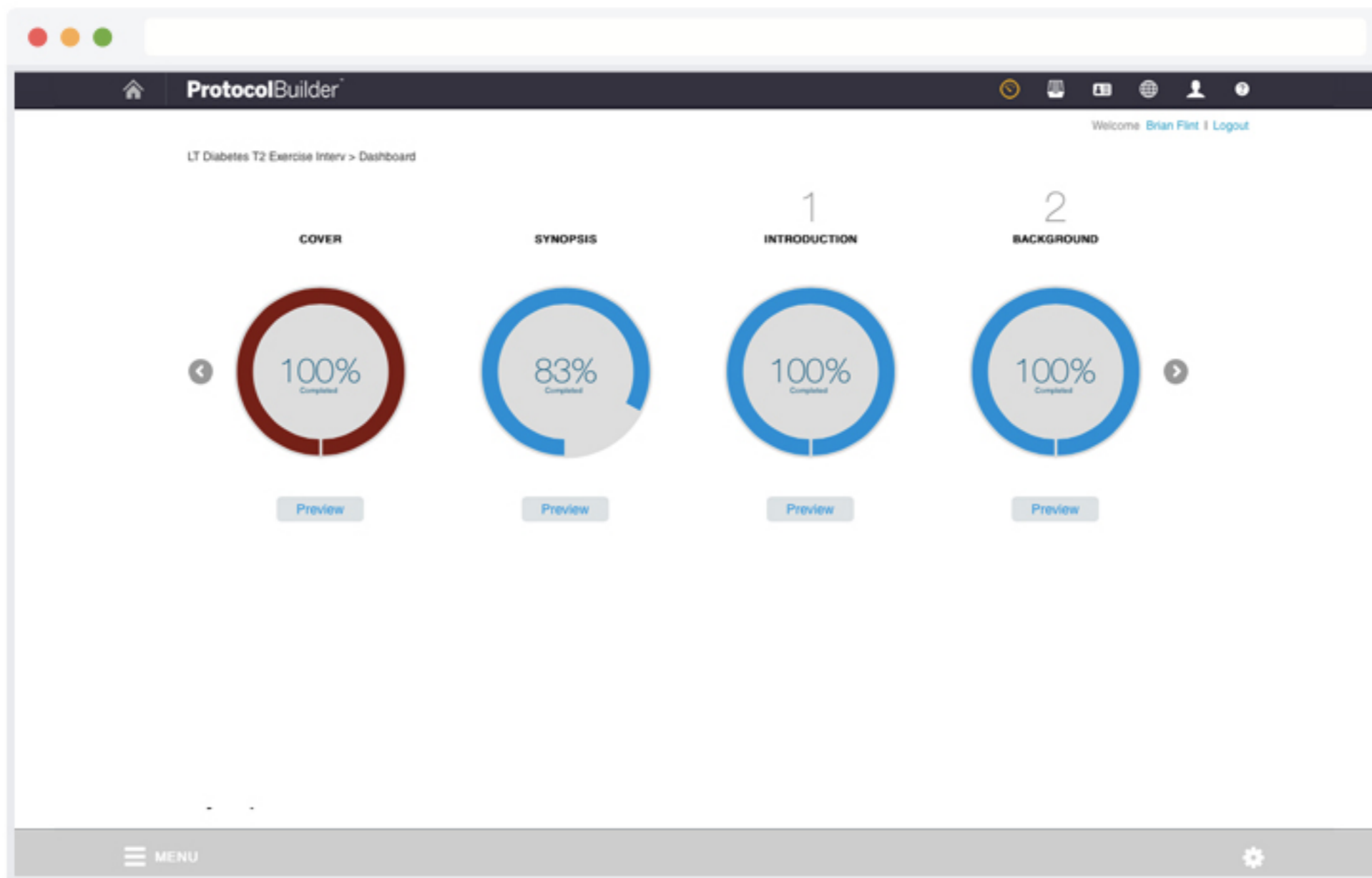
The Needs Review List shows all sections that need to be reviewed before being completed - all in one place. Whenever a new section needs review, the Needs Review alert is added to the bottom of the left navigation/table of contents bar.

The screenshot displays the ProtocolBuilder interface. On the left, a navigation bar lists various sections, with 'Needs Review' highlighted in dark blue and marked with a yellow warning triangle. The main content area shows the 'Needs Review' page for 'LT Diabetes T2 Exercise Interv'. It features a search bar, a filter button, and a table of review items.

Topic Title	Revised by	Last updated	Actions
2.1 Background/prevalence of research topic	Brian Flint, PhD	1 month 2 weeks ago	Compare Edit
4.2 Primary Objective	Brian Flint, PhD	2 months 1 week ago	Compare Edit
3.1 Problem Statement	Brian Flint, PhD	2 months 1 week ago	Compare Edit
7.14 Study Discontinuation	Mr. Neal ALEN	2 years 2 weeks ago	Compare Edit
6.4.2 Sample Size Considerations	Brian Flint, PhD	2 years 1 month ago	Compare Edit
7.1 Ethical Considerations	Mr. Neal ALEN	2 years 4 months ago	Compare Edit

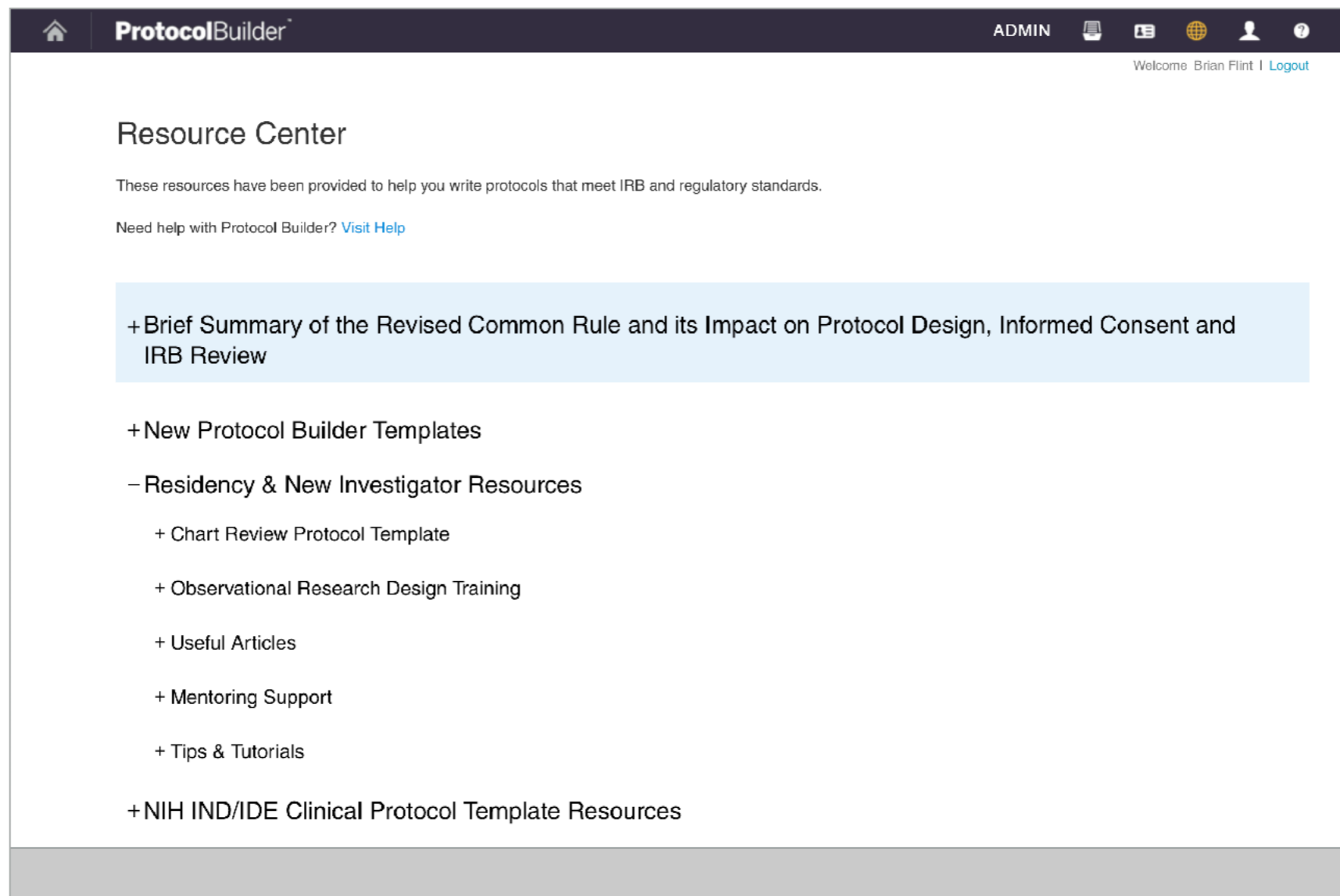
PROTOCOL DASHBOARD

The Dashboard gives you a quick snapshot of your protocol and how much has been completed. Click the Preview button under any section to navigate and see it in Preview mode.



RESOURCE CENTER

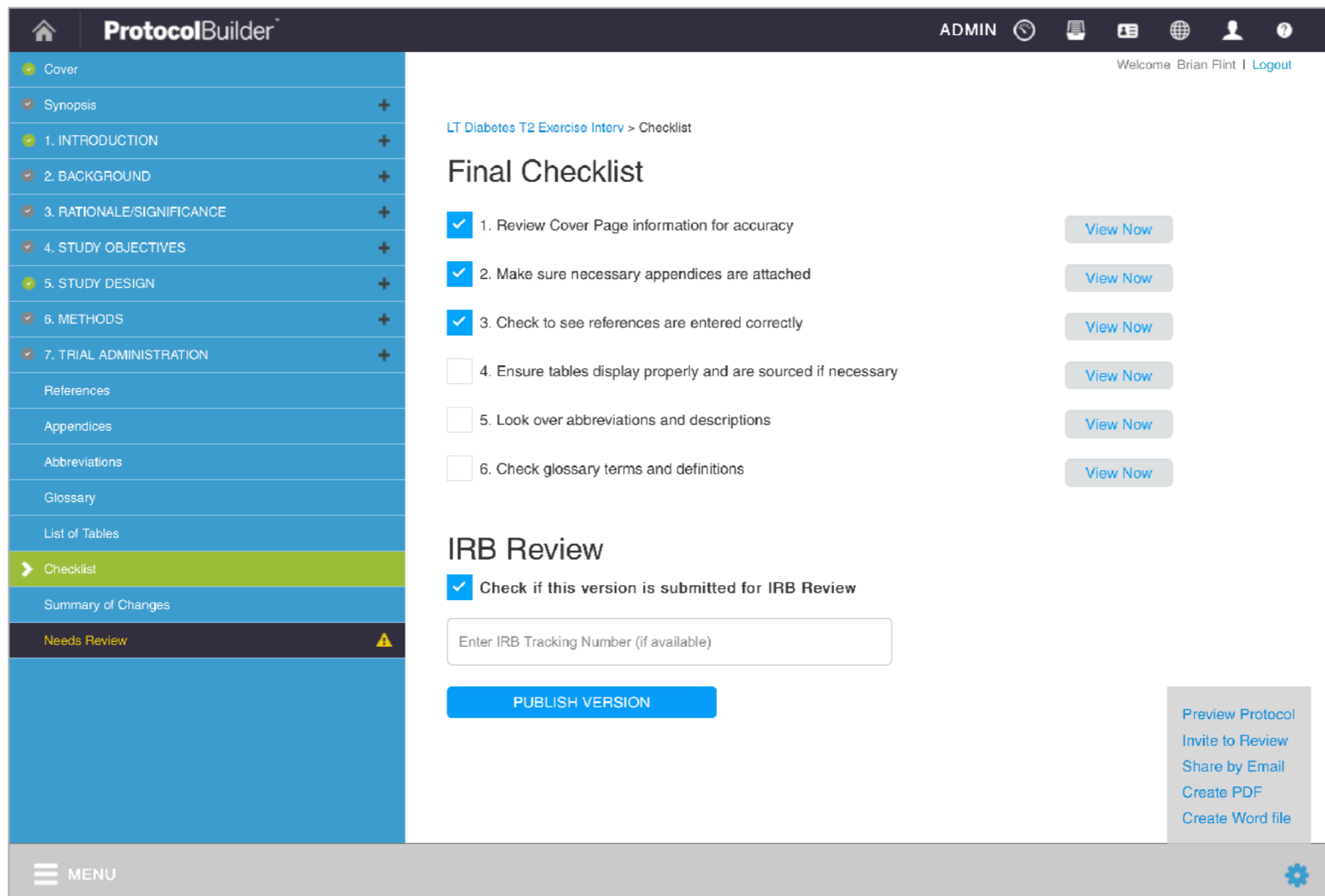
The Resource Center provides additional tools and information to help investigators complete and improve the quality of their protocols. You will find a helpful content such as a summary of the Revised Common Rule, Residency and New Investigator Resources, and NIH IND/IDE Template Resources to name a few.



The screenshot shows the ProtocolBuilder Resource Center interface. At the top, there is a dark navigation bar with the ProtocolBuilder logo on the left, the word "ADMIN" in the center, and several utility icons (print, chat, globe, user, help) on the right. Below the navigation bar, the page title "Resource Center" is displayed. A brief introductory text states: "These resources have been provided to help you write protocols that meet IRB and regulatory standards." Below this, there is a link: "Need help with Protocol Builder? [Visit Help](#)". The main content area features a list of resource categories, with the first item, "+ Brief Summary of the Revised Common Rule and its Impact on Protocol Design, Informed Consent and IRB Review", highlighted in a light blue box. Other categories include "+ New Protocol Builder Templates", "- Residency & New Investigator Resources" (with sub-items: "+ Chart Review Protocol Template", "+ Observational Research Design Training", "+ Useful Articles", "+ Mentoring Support", "+ Tips & Tutorials"), and "+ NIH IND/IDE Clinical Protocol Template Resources".

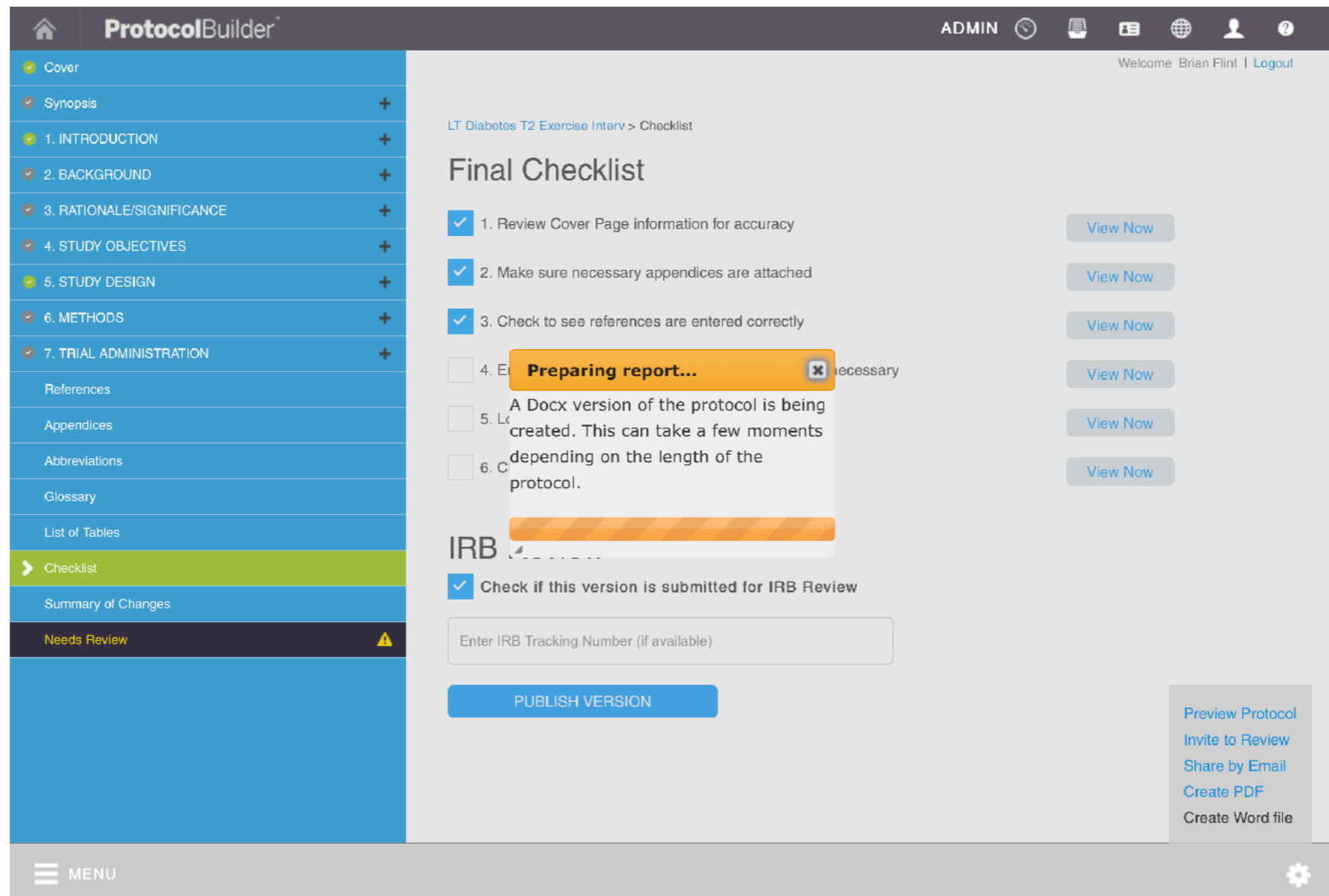
THE GEAR ICON - SHARING & OUTPUT

Use the “gear” icon in the bottom right to go to Preview mode, invite others to review or share a pdf via email.



OUTPUT OPTIONS

Protocol Builder provides the option to output the final protocol document in either PDF or Word format.



FINAL CHECKLIST & IRB TRACKING

Once you've finished writing your protocol (and made sure all sections are complete), you can go through the checklist to make sure you've completed all the necessary step before submitting your protocol. Protocol Builder also provides a way to keep track of the versions submitted for IRB Review and the corresponding tracking number.

The screenshot shows the ProtocolBuilder web interface. On the left is a navigation menu with sections: Cover, Synopsis, 1. INTRODUCTION, 2. BACKGROUND, 3. RATIONALE/SIGNIFICANCE, 4. STUDY OBJECTIVES, 5. STUDY DESIGN, 6. METHODS, 7. TRIAL ADMINISTRATION, References, Appendices, Abbreviations, Glossary, List of Tables, Checklist (highlighted), Summary of Changes, and Needs Review (with a warning icon). The main content area is titled 'LT Diabetes T2 Exercise Interv > Checklist'. It features a 'Final Checklist' section with six items, each with a checkbox and a 'View Now' button. The first three items are checked. Below this is an 'IRB Review' section with a checked checkbox for 'Check if this version is submitted for IRB Review', a text input field for 'Enter IRB Tracking Number (if available)', and a blue 'PUBLISH VERSION' button. The top right of the interface shows 'ADMIN' and user information: 'Welcome Brian Flint | Logout'. A 'MENU' button and a settings gear icon are at the bottom.

Final Checklist

- 1. Review Cover Page information for accuracy [View Now](#)
- 2. Make sure necessary appendices are attached [View Now](#)
- 3. Check to see references are entered correctly [View Now](#)
- 4. Ensure tables display properly and are sourced if necessary [View Now](#)
- 5. Look over abbreviations and descriptions [View Now](#)
- 6. Check glossary terms and definitions [View Now](#)

IRB Review

- Check if this version is submitted for IRB Review

Enter IRB Tracking Number (if available)

PUBLISH VERSION

THANK YOU FOR TAKING THE TOUR!

Protocol Builder helps make it faster and easier to develop research protocols that comply with IRB and regulatory standards.