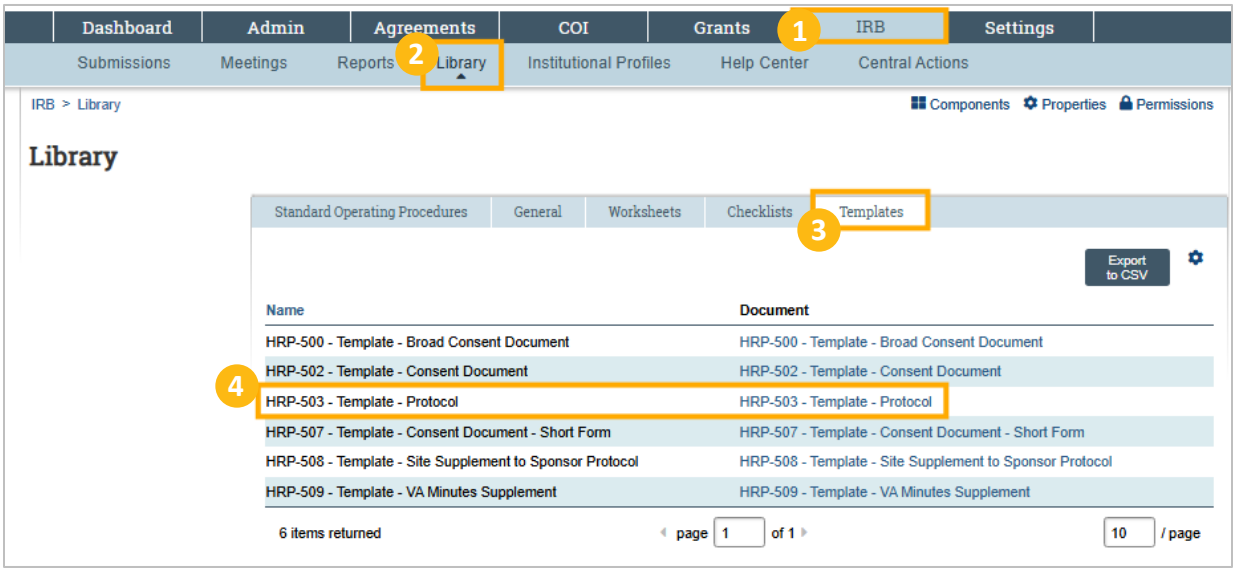
Protocol Documents Overview

A protocol acts as the work plan for the study and will serve as a resource for those involved in the study. The HRPP recommends using a protocol as a best practice.

This guide will cover:

- **Where to find the protocol template on myUABResearch**
- **How to fill out the template**
- **How to upload it when creating a study**

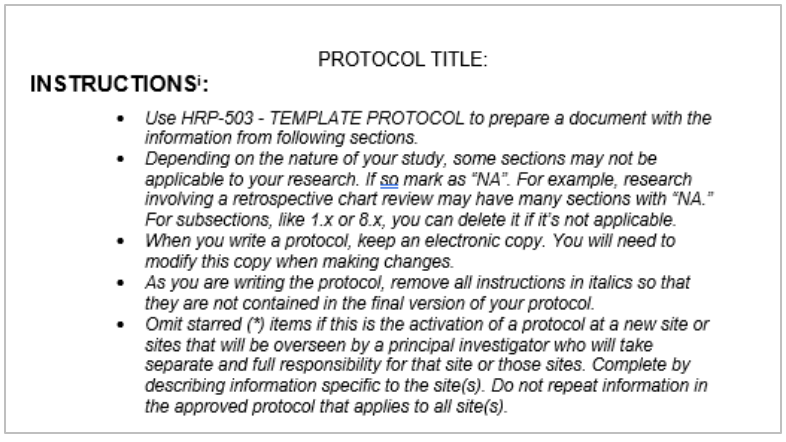
1. **To locate the protocol template, click on the IRB tab, then the Library tab, then the Templates tab, click on the name of the template you want to use. The templates you see in MyUABResearch may differ from what is shown below. The template will automatically download to your computer. Note: make sure you download the template directly from the library to ensure you are using the most up to date version.**



To choose the correct protocol template:

HRP-503A – TEMPLATE SBS PROTOCOL	Use when developing standard protocol that fully describes your study from objectives through procedures and subject protections.
HRP-508 – TEMPLATE SITE SUPPLEMENT TO SPONSOR PROTOCOL	Use when your site is participating in a multi-site or sponsor-led study and you need to provide site-specific details that supplement an existing sponsor protocol.
HRP-503B – TEMPLATE NHSR PROTOCOL	Use when you need the IRB to determine whether an activity does not meet the definition of human subject research (NHSR) prior to starting the activity.
HRP-503 – TEMPLATE PROTOCOL	Use as the general starting point for drafting a full investigator protocol for IRB submission.

2. **Open the downloaded copy of the template and review the instructions at the beginning.**



PROTOCOL TITLE:

INSTRUCTIONS[i]:

- *Use HRP-503 - TEMPLATE PROTOCOL to prepare a document with the information from following sections.*
- *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as "NA". For example, research involving a retrospective chart review may have many sections with "NA." For subsections, like 1.x or 8.x, you can delete it if it's not applicable.*
- *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
- *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*
- *Omit starred (*) items if this is the activation of a protocol at a new site or sites that will be overseen by a principal investigator who will take separate and full responsibility for that site or those sites. Complete by describing information specific to the site(s). Do not repeat information in the approved protocol that applies to all site(s).*

3. **Fill out each section with information about the study. The text in italics provides instructions for what to add to each section. Delete the instructions in italics from the final version of the study protocol.**

1.0 Study Summary

Protocol Information	Description
Study Title	
Study Design	
Primary Objective	
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	
IND/IDE #	
Study Population	
Sample Size	
Study Duration for individual participants	
Study Specific Abbreviations/ Definitions	

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives.

2.2 State the hypotheses to be tested.

3.0 Background*

3.1 Describe the relevant prior experience and gaps in current knowledge.

3.2 Describe any relevant preliminary data.

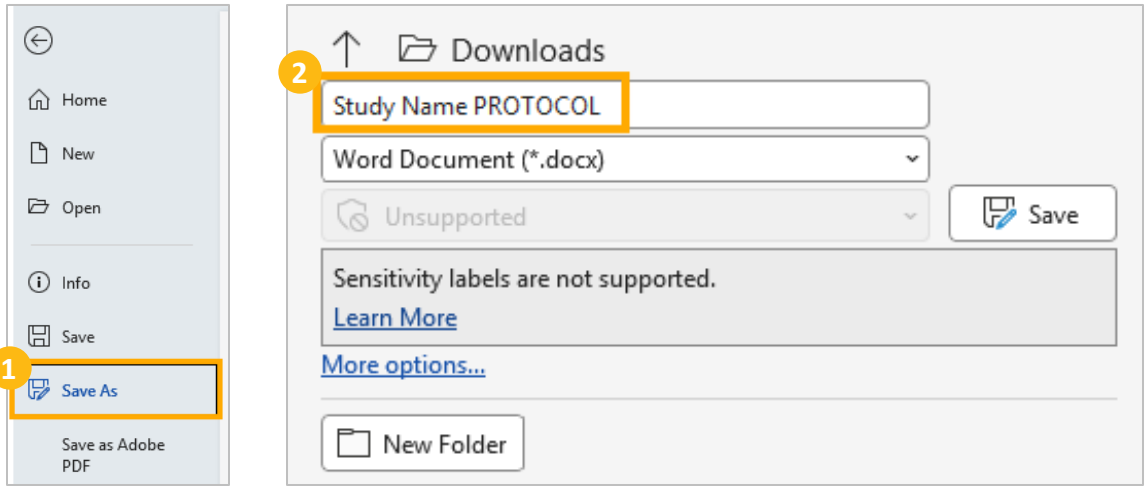
3.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

4.0 Study Endpoints*

4.1 Describe the primary and secondary study endpoints.

4.2 Describe any primary or secondary safety endpoints.

4. **When you are finished, save the final version as <Insert study name> Protocol.**



5. **When you create your study, upload the protocol on the Basic Study Information page, where it says, "Attach the protocol" by clicking Add, then Choose File, then selecting the Protocol you just created. Click OK. To learn how to create a study, see the Create and Submit a Single Site Study job aid.**

