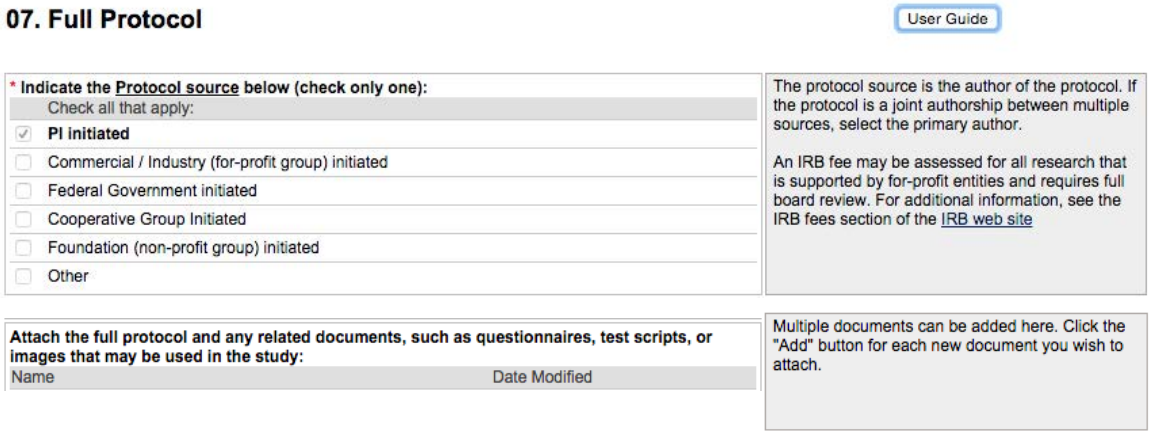
Section 07: Full Protocol

In this section, you should upload all supplemental study-related documents: **questionnaires, surveys, telephone scripts**, etc. It is not necessary to re-upload the same Research Summary from Section 06.



07. Full Protocol

User Guide

* **Indicate the Protocol source below (check only one):**

Check all that apply:

- [x] **PI initiated**
- [ ] Commercial / Industry (for-profit group) initiated
- [ ] Federal Government initiated
- [ ] Cooperative Group Initiated
- [ ] Foundation (non-profit group) initiated
- [ ] Other

The protocol source is the author of the protocol. If the protocol is a joint authorship between multiple sources, select the primary author.

An IRB fee may be assessed for all research that is supported by for-profit entities and requires full board review. For additional information, see the IRB fees section of the IRB web site

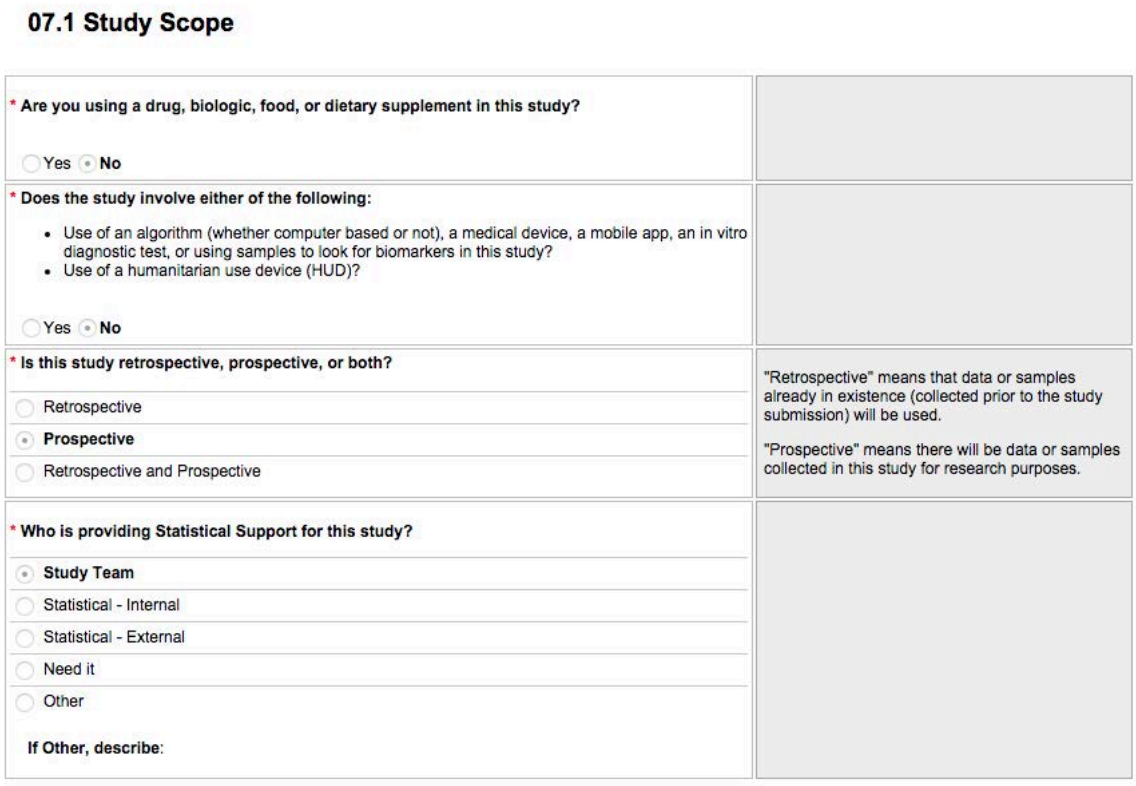
Attach the full protocol and any related documents, such as questionnaires, test scripts, or images that may be used in the study:

Name	Date Modified

Multiple documents can be added here. Click the "Add" button for each new document you wish to attach.

Section 07.1: Study Scope

This section will determine whether your application requires Sections 08 (Drugs, Biologics, and Other Substances) and 09 (Devices) of the application. It also includes questions about study design and statistical support.



07.1 Study Scope

* **Are you using a drug, biologic, food, or dietary supplement in this study?**

○ Yes ◉ **No**

* **Does the study involve either of the following:**

- Use of an algorithm (whether computer based or not), a medical device, a mobile app, an in vitro diagnostic test, or using samples to look for biomarkers in this study?
- Use of a humanitarian use device (HUD)?

○ Yes ◉ **No**

* **Is this study retrospective, prospective, or both?**

- ○ Retrospective
- ◉ **Prospective**
- ○ Retrospective and Prospective

"Retrospective" means that data or samples already in existence (collected prior to the study submission) will be used.

"Prospective" means there will be data or samples collected in this study for research purposes.

* **Who is providing Statistical Support for this study?**

- ◉ **Study Team**
- ○ Statistical - Internal
- ○ Statistical - External
- ○ Need it
- ○ Other

If Other, describe: