CHECKLIST:
OTHER STUDY DOCUMENTS

Upload the following documents under each category:

- Protocol: Current Industry Sponsor Protocol
- Investigator Brochure: For IND studies - current drug brochure
- Device Brochure: For IDE studies – current device brochure
- FDA Document:
  - For IND studies – no FDA letter is required when IND # appears on the industry sponsor protocol.
  - For IDE studies – FDA letter granting the IDE to the industry sponsor
- Recruitment/Advertising:
  - Recruitment scripts
  - Pre-screening forms
  - Newspaper ads
  - If a website, provide the URL and attach screenshots for every page
- Flyer: Recruitment posters or flyers
- Questionnaires to subjects
- Surveys to subjects
- Materials Handed Out to Subjects