Answer 'Yes' if a drug / biologic is the intervention being evaluated for a health and/or behavior outcome. Please note that most drugs/biologics are regulated by the FDA.

Answer 'Yes' if the device is subject to section 510(k), 515, or 520(m) of the FD&C Act or a combination product with a device primary mode of action under 21 CFR Part 3.

Answer 'No', if the study is not being conducted under an IND or IDE. NOTE: If you select yes, then choose 'Sponsor-Investigator' for Responsible Party. Be sure to have your IND Information available, including the serial number associated with form FDA 1571 in which the initial submission of the protocol was made.

Enter the date (mm/dd/yyyy) associated with the initial IRB approval date of the study.

Enter the exact information as it appears in this section unless the study was reviewed by an external IRB. NOTE: Record the external IRB number as a secondary ID in the 'Study Identification' section.

Answer 'Yes', if the study will utilize a data monitoring committee or safety monitoring committee.

Answer 'Yes', if you are using an FDA regulated intervention. For example if the intervention evaluated is radiology or tobacco.

If you have any additional questions, you may contact the CTD group at 305-243-4538 or email us at ctdgovum@miami.edu