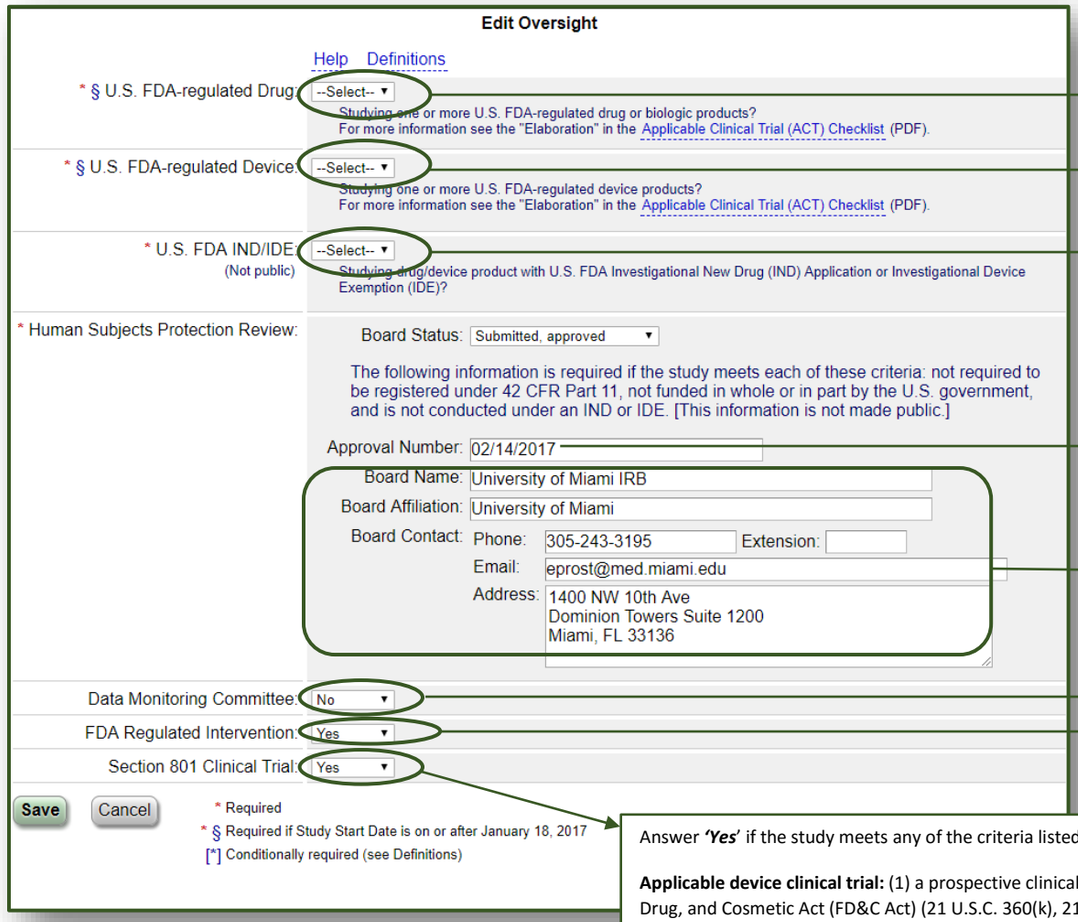
Oversight Cheat Sheet_ClinicalTrials.gov –Protocol Registration and Result Reporting System (PRS)



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.

Answer ***'Yes'*** if the study meets any of the criteria listed below.

Applicable device clinical trial: (1) a prospective clinical study of health outcomes comparing an intervention with a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k), 21 U.S.C. 360e, 21 U.S.C. 360j(m)) against a control in human subjects (other than a small clinical trial to determine the feasibility of a device product, or a clinical trial to test prototype device products where the primary outcome measure relates to feasibility and not to health outcomes); (2) a pediatric postmarket surveillance of a device product as required under section 522 of the FD&C Act (21 U.S.C. 3601); or (3) a clinical trial of a combination product with a device primary mode of action under 21 CFR Part 3, provided that it meets all other criteria of the definition under this part.

Applicable drug clinical trial: a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug product subject to section 505 of the FD&C Act (21 U.S.C. 355) or a biological product subject to section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), where "clinical investigation" has the meaning given in 21 CFR 312.3 and "phase 1" has the meaning given in 21 CFR 312.21. A clinical trial of a combination product with a drug primary mode of action under 21 CFR Part 3 is also an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

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

Version 20170824