



DOES THE PROPOSAL'S SCOPE OF WORK CONTAIN CLINICAL PROCEDURES?

IF YES, DO THE CLINICAL PROCEDURES INVOLVE AN INVESTIGATIONAL DRUG, DEVICE OR TREATMENT?

IF NO, STOP DO NOT COMPLETE SECTION B

IF NO, CHECK THIRD BOX IN SECTION B ON SIGN OFF FORM

IF YES, HAS THE SPONSOR AGREED TO PAY FOR ALL COSTS INCLUDING THE CLINICAL PROCEDURES?

IF NO, CHECK FIRST BOX IN SECTION B ON SIGN OFF FORM

IF YES, CHECK SECOND BOX IN SECTION B ON SIGN OFF FORM

COMPLETE THE PRA TEMPLATE (IN THE UR'S BUDGETING WORKBOOK FOR CLINICAL TRIALS)

COMPLETE THE PARTICIPANT GRID/ BILLING PLAN AND TOTAL BUDGET COMPARISON WORKSHEETS (IN THE UR'S BUDGETING WORKBOOK FOR CLINICAL TRIALS)

HAVE PRINCIPAL INVESTIGATOR SIGN THE FORMS (AND ATTACH COPIES TO THE PROPOSAL SIGN OFF FORM) AND THE CERTIFICATION REGARDING COMPLETION OF TRAINING

STOP