Research Ethics Annual Renewal Form

Project Info

File No:
PI:
Project Title:
Submitted:
Submitted by:

Event Info

Event No:
Notes:

Common Questions

1. Annual Renewal

#	Question	Answer
1.1	Expected date of research completion:	
1.2	Are you actively enrolling research participants?	
1.3	Number of enrolled participants (i.e. number of persons who provided consent):	
1.4	Current number of active participants:	
1.5	Number of participants who have completed the study to date:	
1.6	Local enrollment goal:	
1.7	Number of participants who withdrew consent:	
1.8	Number of screen failures:	
1.9	Number of participants that were withdrawn because they moved:	
1.10	Number of medically related withdrawals (described below or summary attached):	
1.11	Number of other withdrawals (described below or summary attached):	
1.12	Please describe withdrawals due to 'medically related' or 'other' reasons:	
1.13	Number of participant deaths (total) since initial Research Ethics Board approval:	
1.14	Number of participant deaths in the past year:	
1.15	For Chart Review research projects: How many participant records have been reviewed or are in the process of being reviewed?	
1.16	Current version identifier (version number/date) of Research Ethics Board approved MAIN consent form in use at your site:	

1.17	Date of Research Ethics Board approved main consent form in use at your site:	
1.18	NEW CHANGES TO RESEARCH: Have there been any changes to the research that have NOT previously been reported to the Research Ethics Board?	
1.19	NEW SITE CHANGES: Have there been any changes at your site that have NOT previously been reported to the Research Ethics Board?	
1.20	NEW UNANTICIPATED PROBLEMS: Have there been any unanticipated problems involving increased risk to participants or others that have NOT previously been reported to the Research Ethics Board?	
1.21	NEW SAEs: Have there been any serious, unexpected, and related adverse events that have NOT previously been reported to the Research Ethics Board?	
1.22	NEW DEVIATIONS: Have there been any significant deviations from protocol, applicable regulatory requirement or Research Ethics Board recommendations that have NOT previously been reported to the Research Ethics Board?	
1.23	NEW COMPLAINTS: Have there been any complaints about the research at your site that have NOT previously been reported to the Research Ethics Board?	
1.24	NEW SAFETY REPORTS: Has there been a recent Data Safety Monitoring Board Report or sponsor-generated safety report that supports continuation of the study that has NOT previously been submitted to the Research Ethics Board?	
1.25	NEW FUNDING: Have there been any changes in the funding status that have NOT previously been submitted to the Research Ethics Board?	
1.26	NEW CONFLICTS OF INTEREST: Have there been any changes in the conflict of interest status of the Principal Investigator or Co-Investigator that have NOT previously been submitted to the Research Ethics Board?	

1.27	Please describe any other changes or describe those indicated above.	
1.28	Please look in the Project Team Info tab of your study application to verify that your list of study team members (including contact information) is up-to-date. Please indicate any changes that need to be made:	
1.29	Please indicate to whom the invoice should be directed and how the fee will be paid (e.g. wire transfer):	
1.30	Please indicate when the fee will be sent:	