FAQ CR

Frequently Asked Questions: Continuing Review Submission Form

NOTE: For the first action you do with an existing protocol (either CR or amendment), you will need to **FIRST** "create a revision" to your study application. **THEN** create the new submission form for your action. Otherwise the CR or amendment form will not carry forward the information correctly.

When a specimen/data analysis protocol is first opened, it is classified as a "no recruitment planned" study (either population known, unknown, or no research performed). Should the study simply stay in that status for its duration? Or, for a study with the population known/unknown, when they are done collecting the samples/data and will acquire no more, but are continuing to analyze the data/specimens, should the study status change to "data analysis only"?

Population known/unknown gets mapped in clinicaltrials.gov to "no longer recruiting/enrolling by invitation". When it enters data analysis, switching the status to completed study is appropriate. So the study status should be changed to "data analysis only" at that time.

I cannot find what the risk/benefit is for my protocol. What should I put in this box?

Look at the original minutes from the initial review of the protocol. The risk/benefit as determined by the IRB should be documented there. Please be sure that if your protocol includes more than one population of subjects (e.g. donors and recipients, children and adults, normal volunteers, etc.) that you note the risk/benefit determination for each group.

There is a question that asks: "have any UPs, deviations and or non-compliance occurred since the IR or last CR?" How do I answer this if I had no events in the last reporting period?

If you have not had any UPs, deviations or non-compliance occur in the past year or time period since the last IRB review, the answer to this question is "no". Only answer "yes" to this question if events have occurred in the time period since the last IRB review of the study.

The next instruction asks you to summarize UPs, reportable adverse events, deviations, and non-compliance as defined in the protocol since the last CR and in **aggregate** since the start of the study. You should prepare a table of all the reportable AEs (which would include the UPs that are also AEs) that have occurred since the last CR and in total since the start of the study. You should also create a table listing of all of the deviations and non-compliance that has occurred since the start of the study. These tables should be put together in a single pdf document before you upload it into iRIS.

FAQs for Routing in iRIS

FAQs for Study Application

FAQs for Amendment Submission Form

FAQs for Planned and Cumulative Enrollment Forms

FAQs for Study Closure Form

These pages will continue to be updated as more information becomes available.

Note: If you have a submission procedure question that isn't answered within these pages, please contact: nciprotocolsupportoffice@mail.nih.gov