

# Kuali Protocols NEW Form Guide – Renewal Requestv07.01.2022

This form guide is meant as a tool for investigators, HRPP staff, and IRB members and provides information about the Kuali Protocols Renewal Request form. This information is meant as a tool only and should be considered guidance. Please contact the HRPP if you are unsure how to answer a specific question.

| **Question ID** | **Question** | **Options** | **Guidance** |
| --- | --- | --- | --- |
| **Renewal Request** |
| 3001 | Select the current status of the study. | * Open to Enrollment – No subjects consented to date
* Open to Enrollment – Enrollment continues
* Closed to Enrollment – Research interventions continue
* Closed to Enrollment - Clinical Follow-up Only (Remaining research activities are limited to accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care)
* Data Analysis Only (Remaining research activities are limited to analysis of identifiable information or biospecimens)
 |  |
| 3002 | *IF 3001 = Data Analysis Only*At last renewal, was the study in Data Analysis Only OR Closed to Enrollment – Clinical Follow-up Only? | * Yes
* No
 |  |
|  | ***IF 3002 = No OR 3001 = Open to Enrollment – Enrollment continues OR Closed to Enrollment*** |
|  | ***Since the beginning of the study…*** |
| 3003 | Number of subjects who have consented | Number |  |
| 3004 | Number of subjects who have failed screening after consent | Number |  |
| 3005 | Number of subjects who have withdrawn | Number |  |
| 3006 | Number of completed subjects | Number |  |
| 3007 | *IF 3005 is greater than 0*List the reasons for subject withdrawals since the beginning of the study.  | Free text  |  |
| 3008 | If necessary, provide further explanation regarding the number of subjects.  | Free text | Enter N/A if none. |
| 3009 | Have any subjects consented using a non-English short form consent document? | * Yes
* No
 |  |
| 3010 | *IF 3009 = Yes*Have you translated your IRB approved consent document(s) into the subject’s language and re-consented using the full translated consent form? | * Yes
* No
 |  |
| 3011 | *IF 3010 = No*Explain why the subject has not been re-consented. | Free text | Appropriate justifications may include minimal risk research or active study participation is limited to a short time frame. |
| 3012 | Since the last renewal, have any of the following occurred at an IU IRB-approved site:* Minor protocol deviations
* Minor noncompliance
 | * Yes
* No
 |  |
| 3013 | *IF 3012 = Yes*Provide a summary of the events or indicate a summary has been attached. | Free text |  |
|  | ***IF 3002 = No OR 3001 = Open to Enrollment OR Closed to Enrollment*** |
| 3014 | Is there a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) for this study? | * Yes
* No
 |  |
| 3015 | *IF 3014 = Yes*Confirm the most recent report has been attached. | * Yes
* No
 |  |
| 3016 | *IF 3015 = No*Explain why a report or findings are not available. | Free text |  |
| 3017 | *IF 3014 = No*Summarize the findings from the ongoing review of studywide data to ensure the safety of subjects or attach a summary or report. | Free text |  |
| 3018 | *IF 3014 = No*Did any adverse events occur studywide at a greater frequency and/or severity than was previously expected based on the current protocol, informed consent document, and/or investigator’s brochure? | * Yes, and a Reportable Event has been submitted or is in the submission process.
* No
 |  |
|  | ***IF 3002 = No OR 3001 = Open to Enrollment – Enrollment continues OR Closed to Enrollment*** |
| 3020 | Summarize any subject complaints about the conduct of the research, including those that have been resolved by the study team.  | Free text | If no complaints have been received, enter N/A. |
| ***3001 = Open to Enrollment, Closed to Enrollment, or Data Analysis Only*** |
| 3019 | Summarize any new information that may be relevant in assessing the risks and/or benefits of the study. | Free text | Relevant information may include literature publications, audit/monitoring findings, results from this or similar studies, and/or interim findings.  |
| N/A | Renewal AttachmentsUpload Renewal documents, if applicableSelect +Add Line to list each attachmentFile AttachmentDocument NameDocument Version | ListDrag & Drop a FileFree textFree text | Be sure any documents uploaded have been redacted to remove all PHI. |
| **End of Renewal form. No changes can be made to the main protocol.**  |