

# Kuali Protocols NEW Form Guide – Renewal Request v07.01.2022

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| 3005 | | Number of subjects who have withdrawn | | Number | |  |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 Attachments  Upload Renewal documents, if applicable  Select +Add Line to list each attachment  File Attachment  Document Name  Document Version | | List  Drag & Drop a File  Free text  Free 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.** | | | | | | |