

# Kuali Protocols NEW Form Guide – Close 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 Close 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** |
| --- | --- | --- | --- |
| **Close Request** |
| 6000 | Select you Protocol Type | * Expedited/Full Board
* Exempt
* Request to rely on a non-IU IRB
* Not Human Subjects Research
* Humanitarian Use Device (HUD)
 |  |
| 6001 | *IF 6000 = Expedited/Full Board*Select all of the following that apply to your study. This study was IRB-approved as: | * Greater than minimal risk
* FDA-regulated
* VA
* None of the above
 |  |
| 6002 | *IF 6001 = None of the above*Have any of the following occurred at an IU IRB-approved site:* Minor protocol deviations not previously reported
* Minor noncompliance not previously reported
 | * Yes
* No
 |  |
| ***IF 6001 = Greater than minimal risk, FDA-regulated, or VA*** |
| 6003 | Select the current status of the study. | * Study will not be initiated.
* Study closed prior to completion.
* Study completed. No further interaction/intervention with subjects, including follow-up, or access to subjects’ personally identifiable information for the purpose of research data collection AND all data collection and analysis of identifiable data (including specimens) involving the research site(s), under the IU IRB approval, is complete.
 |  |
| 6004 | *IF 6003 = Study will not be initiated or Study closed prior to completion.*Explain why the study will not be initiated or completed. | Free text |  |
| 6005 | *IF 6003 = Study closed prior to completion or Study completed.*At last renewal, was the study in Data Analysis Only or Closed to Enrollment – Clinical Follow-up Only? | * Yes
* No
 |  |
|  | ***IF 6005 = No*** |
|  | ***Since the beginning of the study…*** |
| 6006 | Number of subjects who have consented | Number |  |
| 6007 | Number of subjects who have failed screening after consent | Number |  |
| 6008 | Number of subjects who have withdrawn | Number |  |
| 6009 | Number of completed subjects | Number |  |
| 6011 | If necessary, provide further explanation regarding the number of subjects.  | Free text | Enter N/A if none. |
| 6012 | *IF 6003 = Study closed prior to completion*Since the last renewal, have any of the following occurred at an IU IRB-approved site:* Minor protocol deviations not previously reported
* Minor noncompliance not previously reported
 | * Yes
* No
 |  |
| 6013 | *IF 6002 = Yes OR 6012 = Yes*Provide a summary of the events or indicate a summary has been attached. | Free text |  |
|  | ***IF 6005 = No*** |
| 6014 | Is there a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) for this study? | * Yes
* No
 |  |
| 6015 | *IF 6014 = Yes*Confirm the most recent report has been attached. | * Yes
* No
 |  |
| 6016 | *IF 6015 = No*Explain why a report or findings are not available. | Free text |  |
| 6017 | *IF 6014 = 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 |  |
| 6018 | *IF 6014 = 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
 |  |
| 6019 | *IF 6003 = Study closed prior to completion OR Study completed.*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.  |
| 6020 | *IF 6005 = No*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. |
| N/A | Closeout AttachmentsUpload Closure documents, if applicableSelect +Add Line to list each attachmentFile Attachment | ListDrag & Drop a File |  |
| **End of Closeout Form. No changes can be made to the main protocol.** |