

# Kuali Protocols NEW Form Guide – Reportable EventPublished 07.01.2023 (version 7)

This form guide is meant as a tool for investigators, HRPP staff, and IRB members and provides information about the Kuali Protocols Reportable Event 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** |
| 5001 | Date(s) event occurred. | Free text |  |
| 5002 | Date event was discovered by the study team. | Date picker |  |
| 5074 | Reportable Event Number | Free text | Assign a reportable event number in the form FXXX (e.g. F007) |
| 5003 | At which site(s) did the event occur? | Free text |  |
| 5004 | 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.
 |  |
| 5079 | *If 5004 = Open to Enrollment – Enrollment continues, Closed to Enrollment – Research interventions continue or Clinical Follow-up Only, OR Data Analysis Only* State the total number of subjects enrolled since the beginning of the study. | Free text |  |
| 5005 | *IF 5004 = Open to Enrollment – Enrollment continues OR Closed to Enrollment*State the total number of ACTIVE subjects currently in the study. | Free text |  |
| 5006 | *IF 5004 = Open to Enrollment – Enrollment continues OR Closed to Enrollment*Summarize the status of the active subjects. | Free text |  |
| N/A | Choose the type of event(s) being reported. | * Local or external Adverse Event requiring prompt reporting
* Major protocol deviation requiring prompt reporting
* Study suspension or hold related to risk, safety, or compliance issues
* Unanticipated Adverse Device Effect
* Conduct of human subjects research without IRB approval
* Consent and/or authorization issue
* Subject incorrectly billed for research procedures
* Disclosure or release of identifiable subject data outside the research team
* Audit Report
* Failure to submit an amendment which updates risks, benefits, or procedures within sixty (60) days of receipt
* Failure to submit this reportable event within five (5) business days of the study team becoming aware of the event
* Failure to report required information to the IRB at time of renewal
* VA Adverse Event or Death requiring prompt reporting
* Complaints about the conduct of the research
* This event meets the description of more than one of these event types
* Follow-up information regarding previously reviewed reportable event
* Other
* FOR HRPP PURPOSES ONLY
 | For more information, visit the IU HRPP Policy on [Reportable Events](https://research.iu.edu/policies/human-subjects-irb/reportable-events.html). |
| 5007 | *IF event type = This event meets the description of more than one event*Choose the type of event(s) being reported. Select all that apply. | * Local or external Adverse Event requiring prompt reporting
* Major protocol deviation requiring prompt reporting
* Study suspension or hold related to risk, safety, or compliance issues
* Unanticipated Adverse Device Effect
* Conduct of human subjects research without IRB approval
* Consent and/or authorization issue
* Subject incorrectly billed for research procedures
* Disclosure or release of identifiable subject data outside the research team
* Audit Report
* Failure to submit an amendment which updates risks, benefits, or procedures within sixty (60) days of receipt
* Failure to submit this reportable event within five (5) business days of the study team becoming aware of the event
* Failure to report required information to the IRB at time of renewal
* VA Adverse Event or Death requiring prompt reporting
* Complaints about the conduct of the research
* This event meets the description of more than one of these event types
* Follow-up information regarding previously reviewed reportable event
* Other
* FOR HRPP PURPOSES ONLY
 | For more information, visit the IU HRPP Policy on [Reportable Events](https://research.iu.edu/policies/human-subjects-irb/reportable-events.html).  |
| 5008 | *IF event type OR 5007 = Local or external Adverse Event* Confirm the event meets ALL three (3) of the required prompt reporting criteria by selecting the options below. | * Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the study-related documents, and (b) the characteristics of the subject population being studied
* Related or possibly related to participation in the research
* Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized
 |  |
| 5009 | *IF event type OR 5007 = VA Adverse Event*Confirm the event is a local research death or serious adverse event which meets both of the following required prompt reporting criteria by selecting the options below. | * Unanticipated
* Related to the research
 |  |
| 5010 | *IF event type OR 5007 = Local or external Adverse Event, VA Adverse Event, or Unanticipated Adverse Device Effect*Describe the event, including whether the adverse event has resolved. | Free text |  |
| 5011 | *IF event type OR 5007 = Local or external Adverse Event, VA Adverse Event, or Unanticipated Adverse Device Effect*Did the event occur with a local or external subjects? | * Local
* External, i.e., subject was not enrolled at any site covered by the IU IRB approval
 |  |
| 5012 | *IF 5011 = Local*Will the subject remain enrolled in the study? | * Yes, study procedures will continue with the subject
* Yes, but no additional interventions will be done with the subject. The subject will remain on clinical follow up
* No, subject has been/will be withdrawn and no further data will be collected from the subject
 |  |
| 5013 | *IF event type OR 5007 = Local or external Adverse Event, VA Adverse Event, or Unanticipated Adverse Device Effect*Will the risk information in the study documents be updated as a result of this event? | * Yes
* No
 |  |
| 5014 | *IF 5013 = Yes*Has an Amendment been submitted revising study documents? | * Yes
* No
 |  |
| 5015 | *IF 5014 = No*Explain the plan for updating study documents. | Free text |  |
| 5016 | *IF 5014 = No*Select to confirm. | * Enrollment will be held until the IRB has approved revised study documents.
 |  |
| 5017 | *IF 5013 = No*Provide justification for not revising any study documents. | Free text |  |
| 5018 | *IF event type OR 5007 = Major protocol deviation* Describe the deviation, including what should have occurred per protocol, how the deviation was discovered, and if applicable, the current status of the subject(s) affected. | Free text |  |
| 5019 | *IF event type OR 5007 = Major protocol deviation*Explain how the deviation, * Placed subjects at greater risk of harm (including physical, psychological, economic, or social harm),
* Caused actual harm to subjects or others, OR
* For greater than minimal risk research, compromised the integrity of study data such that the subject’s data can no longer be used in analysis of study outcomes.
 | Free text |  |
| 5020 | *IF event type OR 5007 = Study suspension*Describe the event/circumstances that led to the suspension of the study, including who imposed the suspension, what activities were suspended, and why. | Free text |  |
| 5021 | *IF event type OR 5007 = Study suspension*Explain how subjects were impacted by the suspension and if they have been notified. | Free text |  |
| 5022 | *IF event type OR 5007 = Conduct of human subjects research without IRB approval*Choose the type of event(s) being reported. Select all that apply. | * Conduct of research without submitting study for IRB review
* Conduct of research prior to receiving IRB notification of final approval
* Initiation of substantive changes without prior IRB approval, including changes necessary to eliminate apparent immediate hazards to the subject
* Inclusion of vulnerable population without specific IRB approval
* Conduct of research when IRB approval has expired or been closed, suspended or terminated
* Subject interactions or review of identifiable research data by individual(s) who had not completed appropriate investigator requirements
 | For more information, visit the IU HRPP Policy on [Reportable Events](https://research.iu.edu/policies/human-subjects-irb/reportable-events.html).  |
| 5023 | *IF 5022 = Conduct of research without submitting study for IRB review OR Conduct of research prior to receiving IRB notification of final approval OR Conduct of research when IRB approval has expired*What study procedures were conducted prior to IRB review or approval or during expiration? | Free text |  |
| 5024 | *IF 5022 = Conduct of research without submitting study for IRB review OR Conduct of research prior to receiving IRB notification of final approval OR Conduct of research when IRB approval has expired* Has a Renewal or an Initial (New Study) submission been submitted to request approval to conduct the research? | * Yes
* No
 |  |
| 5025 | *IF 5024 = No*Explain why a Renewal or Initial submission has not been submitted. | Free text |  |
| 5026 | *IF 5022 = Initiation of substantive changes without prior IRB approval*Were the changes made to eliminate apparent immediate hazard to subjects? | * Yes
* No
 |  |
| 5027 | *IF 5022 = Initiation of substantive changes without prior IRB approval*What changes were made without prior IRB approval? | Free text |  |
| 5028  | *IF 5022 = Inclusion of vulnerable population*Which vulnerable population was included in the study without IRB approval? Select all that apply. | * Children
* Individuals lacking consent capacity (ILCC)
* Pregnant women and/or fetuses
* Nonviable neonates or neonates of uncertain viability
* Prisoners
 |  |
| 5029 | *IF 5022 = Inclusion of vulnerable population*Explain why the vulnerable population was included. | Free text |  |
| 5030 | *IF 5022 = Conduct of research without submitting study for IRB review OR Conduct of research prior to receiving IRB notification of final approval OR Conduct of research when IRB approval has expired OR 5026 = No*Are you requesting to use research data collected during the period you did not have valid IRB approval? | * Yes
* No
* Not applicable – no data collection occurred
 |  |
| 5031 | *IF 5022 = Inclusion of vulnerable population*Are you requesting to use research data collected from the subject(s)? | * Yes
* No
 |  |
| 5032 | *IF 5030 = Yes OR 5031 = Yes*Provide justification for the use of the data collected. | Free text |  |
| 5033 | *IF 5030 = No OR 5031 = No*Select to confirm | * Data will be stored securely in accordance with applicable data management policies and not used for any other purpose.
 | For more information, see HRPP Policy on [Research Data Management](https://research.iu.edu/policies/human-subjects-irb/research-data-management.html). |
| 5034 | *IF 5022 = Initiation of substantive changes without prior IRB approval*Has an Amendment seeking IRB approval for the substantive change(s) been submitted? | * Yes
* No
 |  |
| 5035 | *IF 5034 = No*Explain why an amendment has not been submitted. | Free text |  |
| 5036 | *IF 5022 = Inclusion of vulnerable population*Has an Amendment seeking IRB approval for inclusion of this population been submitted? | * Yes
* No
 |  |
| 5037 | *IF 5036 = No*Select to confirm the following: | * No additional subjects from this population will be included in the study.
 |  |
| 5038 | *IF 5022 = Subject interactions or review of identifiable research data by individual(s)*List name(s) of individuals who interacted with subjects or reviewed identifiable subject data without having completed appropriate investigator requirements. | Free text |  |
| 5039 | *IF 5022 = Subject interactions or review of identifiable research data by individual(s)*Describe the study procedures that were conducted by these individuals. | Free text |  |
| 5040 | *IF 5022 = Subject interactions or review of identifiable research data by individual(s)*Explain why the lack of training and/or COI disclosure did not adversely affect the rights of subjects. | Free text |  |
| 5041 | *IF 5022 = Subject interactions or review of identifiable research data by individual(s)*Choose all that apply. | * Individuals will complete/have completed all investigator requirements and if not already listed as Personnel, an Amendment will be submitted adding this individual as study personnel.
* The individuals who have not completed requirements will not engage in study procedures going forward.
 |  |
| 5042 | *IF 5041 = Individuals will complete/have completed all investigator requirements AND The individuals who have not completed requirements*List individuals who will engage in study procedures going forward. | Free text |  |
| 5043 | *IF 5041 = Individuals will complete/have completed all investigator requirements AND The individuals who have not completed requirements*List individuals who will NOT engage in study procedures going forward. | Free text |  |
| 5044 | *IF event type OR 5007 = Consent and/or authorization* Select the type of consent/authorization issue you are reporting. Select all that apply.  | * Failure to obtain consent, assent, and/or authorization
* Failure to obtain the subject’s signature on the informed consent document
* Enrolling subjects or continuation of subject participation using an inaccurate consent that could affect the subject’s willingness to participate (such as omission of study procedures, risks, and/or benefits)
* Failure to document the involvement of a witness
* Conduct of research after subject decides not to participate, dissents, or withdraws from the research
* Failure to obtain consent prior to direct interaction after a subject turns eighteen years of age
* Failure to obtain consent prior to direct interaction after a subject gains consent capacity
* Following use of a short form consent, failure to re-consent the subject on a translated consent form unless an exception applies
 |  |
| 5045 | *IF event type OR 5007 = Consent and/or authorization* Describe the issue, how many subjects were affected, and any information subjects should have received but did not. | Free text |  |
| 5082 | *If 5044 = Enrolling subjects or continuation of subjects participation*Describe the differences between the informed consent documents. | Free text |  |
| 5081 | *If 5080 = Yes*Select to confirm: | * IU Health Revenue Cycle Services (RCS) has been notified to adjust billing.
 |  |
| 5046 | *IF event type OR 5007 = Consent and/or authorization* Explain whether affected subjects will be re-consented/re-authorized, and if so, the process and/or timing for re-consent/re-authorization. | Free text |  |
| 5047 | *IF event type OR 5007 = Consent and/or authorization*Explain whether you intend to use data collected from affected subjects. Include a plan for subjects that are unavailable or unwilling to provide re-consent/re-authorization, if applicable. | Free text |  |
| 5083 | *IF event type or 5007 = Subject incorrectly billed* Describe the error that resulted in the subject being incorrectly billed, including how many subjects were affected and whether the error occurred due to failure to record subject consent and/or visit in OnCore. | Free text |  |
| 5084 | *IF event type or 5007 = Subject incorrectly billed* Describe how the error was discovered. | Free text |  |
| 5085 | *IF event type or 5007 = Subject incorrectly billed* Select to *confirm*. | * IU Health Revenue Cycle Services (RCS), or applicable non-IU Health billing office, has been notified to adjust billing.
 |  |
| 5048 | *IF event type OR 5007 = Disclosure or release of identifiable subject data*Describe the disclosure or release, including what information may have been released outside the research team. | Free text |  |
| 5049 | *IF event type OR 5007 = Disclosure or release of identifiable subject data*If the disclosure or release involved protected health information (PHI), have you notified the appropriate HIPAA Privacy Officer? | * Yes
* Not applicable. The disclosure or release did not involve PHI.
 |  |
| 5050 | *IF event type OR 5007 = Local or external Adverse Event, VA Adverse Event, or Unanticipated Adverse Device Effect*Will any previously enrolled subjects be notified of this event? | * Yes
* No
 |  |
| 5051 | *IF 5050 = Yes*Explain which subjects will be notified and which subjects will not. | Free text |  |
| 5052 | *IF event type OR 5007 = Major protocol deviation, Subject incorrectly billed OR 5022 = Initiation of substantive changes OR Inclusion of vulnerable population OR 5049 = Not applicable*Have affected subjects already been notified? | * Yes
* No
 |  |
| 5054 | *IF 5052 = Yes*Explain what information was provided to the subjects and how they were notified (including timing and form of notification). | Free text |  |
| 5053 | *IF 5052 = No OR 5022 = Conduct of research*Will affected subjects be notified? | * Yes
* No
 |  |
| 5073 | *IF 5053 = Yes OR 5050 = Yes*Explain what information will be provided to the subjects and how they will be notified (including timing and form of notification). | Free text |  |
| 5055 | *IF 5053 = No OR 5050 = No*Explain why subjects will not be notified of this event. | Free text |  |
| 5056 | *IF event type OR 5007 = Failure to submit amendment* Describe the circumstances that led to the failure to submit the amendment within sixty (60) days of receipt. | Free text |  |
| 5057 | *IF event type OR 5007 = Failure to submit amendment* Has the amendment been submitted for IRB review? | * Yes
* No
 |  |
| 5058 | *IF 5057 = Yes*Provide the amendment number and the date the amendment was submitted. | Free text |  |
| 5059 | *IF 5057 = No*Explain why an amendment has not been submitted. | Free text |  |
| 5060 | *IF event type OR 5007 = Failure to submit amendment* Describe the changes to risks, benefits, or procedures. | Free text |  |
| 5061 | *IF event type OR 5007 = Failure to submit this reportable event*Explain why this reportable event was not submitted within five (5) business days of the study team becoming aware of the event. | Free text |  |
| 5076 | *IF event type OR 5007 = Failure to report required information to the IRB*Explain what information should have been reported to the IRB at the time of renewal. | Free text |  |
| 5062 | *IF event type OR 5007 = Major protocol deviation* Explain any corrective actions taken to mitigate the impact on affected subjects. | Free text |  |
| 5063 | *IF event type or 5007 = Local or external Adverse Event OR Major protocol deviation OR Unanticipated Adverse Device Effect OR Conduct of human subjects research OR Consent and/or authorization OR Subject incorrectly billed OR Disclosure or release of identifiable subject data OR Failure to submit an amendment OR Failure to submit this reportable event OR VA Adverse Event OR Failure to report required information*Describe the preventive actions that have been or will be taken to prevent the events from occurring again. | Free text |  |
| 5064 | *IF event type OR 5007 = Complaints*Describe the complaint. | Free text |  |
| 5065 | *IF event type OR 5007 = Complaints*Describe any actions taken to address the complaint. | Free text |  |
| 5066 | *IF event type OR 5007 = Complaints*Provide any additional information for the IRB to consider as it relates to the complaint, if applicable. | Free text |  |
| 5067 | *IF event type OR 5007 = Follow-up*Provide the previous reportable event item number. | Free text |  |
| 5068 | *IF event type OR 5007 = Follow-up*Describe additional information related to the event. | Free text |  |
|  | *IF event type OR 5007 = Audit Report* |  | Upload the audit report in the Attachments section below. |
| 5070 | *IF event type OR 5007 = Other or FOR HRPP PURPOSES ONLY*Describe the issue you are reporting, including why this issue is being reported promptly to the IRB and any corrective or preventive actions. | Free text |  |
| 5071 | AttachmentsUpload Reportable Event documents*Select +Add Line to list each attachment* | List | Be sure any documents uploaded have been redacted to remove all PHI. |
| 5072 | File Attachment | Drag & Drop a File |  |
| 5075 | Comments | Free text |  |
| 5076 | Reviewer Attachments | List | This section is reserved for use by HRPP staff. |
| 5077 | File Attachment | Drag & Drop a File |  |
| 5078 | Comments | Free text |  |