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| The purpose of this worksheet is to provide support for the IRB reviewing information items. Section 1 is completed by the HRPP staff. All other sections are used by the convened IRB. This worksheet is to be used. This worksheet does not need to be completed or retained. See figure on the reverse side. | | | | |
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| 1. Preliminary Determinations Made by the HRPP Staff, IRB Chair and/or IRB Director Before the IRB Meeting (Consider actions in Section 3 when any are checked. No individual may reverse determinations made before the IRB meeting.) | | | | |
| Yes  No | | Serious Non-Compliance | | |
| Yes  No | | Continuing Non-Compliance | | |
| Yes  No | | Unanticipated Problem Involving Risks to Subjects or Others | | |
| Yes  No | | Suspension of IRB Approval | | |
| Yes  No | | Termination of IRB Approval | | |
| Yes  No | | Undetermined | | |
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| 1. Final Determinations Made By Convened IRB (Do not reverse determinations made before the IRB meeting.) See figure on the reverse side. | | | | |
| * 1. Is there any Allegations of Non-Compliance where a determination has not been made about whether it has a basis in fact?   If yes, determine whether each Allegation of Non-Compliance has a basis in fact, i.e., is a Finding of Non-Compliance. Take no action on Allegations of Non-Compliance that has no basis in fact. Follow 2.2 for all that are Findings of Non-Compliance.   * 1. Is there any Findings of Non-Compliance where a determination has not been made whether the Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance?   If yes, determine whether each Finding of Non-Compliance is Serious Non-Compliance or Continuing Non-Compliance. Refer Non-Compliance that is neither Serious Non-Compliance nor Continuing Non-Compliance to IRB staff for management. Consider actions in Section 3 for all Serious Non-Compliance and Continuing Non-Compliance.   * 1. Is there any information for which a determination has not been made whether it represents an Unanticipated Problem Involving Risks to Subjects or Others?   If yes, determine whether each information item is an Unanticipated Problem Involving Risks to Subjects or Others. Take no action on information that is not an Unanticipated Problem Involving Risks to Subjects or Others. Consider actions in Section 3 for all information items that are an Unanticipated Problem Involving Risks to Subjects or Others.   * 1. If the convened IRB determines that the New Information does not meet Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problem Involving Risks to Subjects or Others, Suspension of IRB Approval or Termination of IRB Approval then the IRB can acknowledge the New Information Form and investigator’s recommendations, if any.   2. If the convened IRB determines Serious Non-Compliance; Continuing Non-compliance; Suspension of IRB Approval; Termination of IRB Approval; Unanticipated Problem Involving Risks to Subjects or Others then follow 5.7.4.3 in SOP HRP-024. | | | | |
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| 1. Actions | | | | |
|  | Modify the protocol. | |  | Terminate IRB approval. |
|  | Modify the information disclosed during the consent process. | |  | Suspend IRB approval. |
|  | Provide additional information to current subjects (Whenever the information may relate to the subject’s willingness to continue.) | |  | Transfer subjects to another investigator |
|  | Provide additional information to past subjects. | |  | Make arrangements for clinical care outside the research |
|  | Have current subjects to re-consent. | |  | Allow continuation of some research activities under the supervision of an independent monitor. |
|  | Increase the frequency of continuing review. | |  | Require follow-up of subjects for safety reasons. |
|  | Observe the research. | |  | Require adverse events or outcomes to be reported to the IRB and the sponsor |
|  | Observe the consent process. | |  | Obtain additional information. |
|  | Require additional training of the investigator. | |  | Consider whether changes without prior IRB review and approval were consistent with ensuring the subject’s continued welfare. |
|  | Notify investigators at other sites. | |  | Other: |



Undetermined