|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Protocol Number:** | Pro | **PI Name (Last):** |  | **Meeting Date:** |  |
| **Risk Level:** | **Greater than Minimal Risk (use chart 1)**  ☐  **Minimal Risk (use chart 2)** | **Admin Pre-Reviewer:** |  | **Pre-Review Date:** |  |
|  | | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Router Continuing Review Pre-Review** | | | | | |
| **Question** | | **Yes** | **No** | **N/A** | **Comments** |
| **IRB Researcher Training Records** | | | | | |
| 1 | The PI, Co-I, and all Other Study Personnel completed CITI within the past 3 years. (not applicable to Non-Human/QA/QI projects) |  |  |  | If NO, list names below and send email via eIRB to study coordinator/personnel informing them they will need to complete CITI for final approval. If YES, but expiring within 30 days, list names below. • Name • Name |
| 2 | If this is a clinical trial funded by NIH, please check if the PI, Co-I, and Other Study Personnel completed the GCP module within the past 3 years. |  |  |  | If NO, list names below. If YES, but expiring within 30 days, list names below. • Name • Name |
| **Conflict of Interest (COI)** | | | | | |
| 1 | The PI, CI, and OSP completed, eCOI within the past year OR Non-Rutgers Financial disclosure for Non-Rutgers research personnel (not applicable to Non-Human/QA/QI projects) |  |  |  | If NO, describe what is missing below. • Name |
| 2 | eCOI is under ‘Monitor Review’ |  |  |  | If eCOI is under ‘Monitor Review’,  email sent to COI Admin and upload in eIRB • Name |
| 3 | eCOI under Mitigation/Management Plan |  |  |  | If COI under Mitigation/Management Plan, note added in eIRB system for the Analyst • Name |
| If this is a GMR study, go to chart 1 | | | | | |
| If this is a MR study, go to chart 2 | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Continuing Review Decision Chart 1 (Greater than Minimal Risk Study)** | | | | | |
| **Question** | | **Yes** | **No** | **N/A** | **Comments** |
| A.1. | Is the study considered Greater than Minimal Risk? |  |  |  |  |
| **Answered NO to A.1., STOP - move to chart 2** | | | | | |
| **Answered YES to A.1., move to section B.** | | | | | |
| B.1. | Have any subjects been enrolled? |  |  |  |  |
| B.2. | Does the CR indicate change to the previously reviewed risks? |  |  |  |  |
| **Answered NO to B.1. AND B.2. STOP - Expedited Review 8b** | | | | | |
| **Answered NO to B.1. AND YES to B.2. STOP - FULL BOARD** | | | | | |
| **Answered YES to B.1. AND B.2. STOP - FULL BOARD** | | | | | |
| **Answered YES to B.1. AND NO to B.2. - Go to section C** | | | | | |
| C.1. | Does the study remain open to enrollment? |  |  |  |  |
| **Answered YES to C.1. STOP - FULL BOARD** | | | | | |
| **Answered NO to C.1. - Go to section D** | | | | | |
| D.1. | Do participants continue to receive study interventions? |  |  |  |  |
| **Answered YES to D.1. STOP - FULL BOARD** | | | | | |
| **Answered NO to D.1. - Go to section E** | | | | | |
| E.1. | Are participants are only active for long-term follow-up? |  |  |  |  |
| E.2. | During last year's approval was it determined to be Expedited 8a? |  |  |  |  |
| **Answered YES to E.1. AND E.2. STOP - Expedited 8a** | | | | | |
| **Answered YES to E.1. and NO to E.2. STOP - Full Board with recommendation for Expedited 8a** | | | | | |
| **Answered NO to E.1. - Go to section G** | | | | | |
| G.1. | Is the study open to Data Analysis Only? |  |  |  |  |
| G.2. | During last year's approval was it determined to be Expedited 8c? |  |  |  |  |
| **Answered YES to G.1. AND G.2. STOP - Expedited 8c** | | | | | |
| **Answered YES to G.1. AND NO to G.2. STOP - Full Board with recommendation for Expedited 8c** | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Continuing Review Decision Chart 2 (Minimal Risk Study)** | | | | | |
| **Question** | | **Yes** | **No** | **N/A** | **Comments** |
| A.1. | Is the study considered Minimal Risk? |  |  |  |  |
| **Answered NO to A.1., STOP - move to chart 1** | | | | | |
| **Answered YES to A.1., move to section B.** | | | | | |
| B.1. | Was the initial approval conducted via Full Board? |  |  |  |  |
| **Answered NO to B.1., STOP - Expedited Review via previously decided category** | | | | | |
| **Answered YES to B.1., move to section C.** | | | | | |
| C.1. | Did the Full Board determine Expedited review? |  |  |  |  |
| **Answered YES to C.1., STOP - Expedited Review via previously decided category or category 9 (look at minutes)** | | | | | |
| **Answered YES to C.1., move to section D.** | | | | | |
| D.1. | Have any subjects been enrolled? |  |  |  |  |
| D.2. | Does the CR indicate change to the previously reviewed risks? |  |  |  |  |
| **Answered NO to D.1. AND D.2. STOP - Expedited Review 8b** | | | | | |
| **Answered NO to D.1. and YES to D.2. STOP - FULL BOARD with recommendation for Expedited 9** | | | | | |
| **Answered YES to D.1. AND D.2. STOP - FULL BOARD with recommendation for Expedited 9** | | | | | |
| **Answered YES to D.1. and NO to D.2. - Go to section E** | | | | | |
| E.1. | Does the study remain open to enrollment? |  |  |  |  |
| **Answered YES to E.1. STOP - FULL BOARD with recommendation for Expedited 9** | | | | | |
| **Answered NO to E.1. - Go to section F** | | | | | |
| F.1. | Do participants continue to receive study interventions? |  |  |  |  |
| **Answered YES to F.1. STOP - FULL BOARD** | | | | | |
| **Answered NO to F.1. - Go to section G** | | | | | |
| G.1. | Are participants are only active for long-term follow-up? |  |  |  |  |
| G.2. | During last year's approval was it determined to be Expedited 8a? |  |  |  |  |
| **Answered YES to G.1. AND G.2. STOP - Expedited 8a** | | | | | |
| **Answered YES to G.1. and NO to G.2. STOP - Full Board with recommendation for Expedited 8a** | | | | | |
| **Answered NO to G.1. - Go to section H** | | | | | |
| H.1. | Is the study open to Data Analysis Only? |  |  |  |  |
| H.2. | During last year's approval was it determined to be Expedited 8c? |  |  |  |  |
| **Answered YES to H.1. AND H.2. STOP - Expedited 8c** | | | | | |
| **Answered YES to H.1. AND NO to H2. STOP - Full Board with recommendation for Expedited 8c** | | | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **IRBA Continuing Review Pre-Review** | | | | | |
| **Question** | | **Yes** | **No** | **N/A** | **Comments** |
| **Confirmation of Review Type** | | | | | |
| 1 | Are the findings of the router correct with regard to the level of review? |  |  |  | If no, please document your findings. If you are not slated as a the reviewer for the level of review selected or if this is for a FB review and it is not your slated deadline, please re-assign to the correct person. |
| **Study status** | | | | | |
| 1 | The study status appears accurate (for example, last year the PI reported Data Analysis Only, and this year they report Open to Enrollment) |  |  |  | If NO, describe what is missing or unclear below. |
| **Enrollment** | | | | | |
| 1 | The enrollment is within the approved limit. |  |  |  | If NO, describe what is missing or unclear below. |
| 2 | If the enrollment is not within the approved limit, a reportable event has been submitted. |  |  |  | If NO, make a note for the reviewer and request via email a reportable event be submitted. |
| 3 | If the enrollment is not within the approved limit, a modification has been submitted requesting to increase the limit. |  |  |  | If NO, make a note for the reviewer and request an amendment be submitted. |
| 4 | If the enrollment is at the approved limit or close to the limit and the study is still open for enrollment, a modification has been submitted requesting to increase the limit. |  |  |  | If NO, make a note for the reviewer and request an amendment be submitted. |
| Reportable Events | | | | | |
| 1 | The PI has indicated events occurred over the past year that need to be reported to the IRB. |  |  |  |  |
| 2 | If the PI has indicated events occurred over the past year that need to be reported to the IRB, those events have been reported. |  |  |  | If NO, make a note for the reviewer and request via email a reportable event be submitted. |