RUTGERS UNIVERSITY Office for Research

WORKSHEET – Router and IRBA Continuing Review Submission Pre-Review

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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 and JIT 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 and JIT 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 IRBA • 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 that need to be reported to the IRB.	☐	☐	☐	
2	If the PI has indicated events occurred 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.