Continuing Reviews

Medical University of South Carolina

What is a Continuing Review?

- A Continuing Review (CR) is a renewal of the study protocol required by federal mandate.
- The IRB will conduct a CR of research at intervals appropriate to the degree of risk, but not less than once per year.
- The evaluation includes:
  - Subject accrual and current status of all study participants
  - Any study revisions since the last review
  - Any unanticipated problems
  - Any subject complaints
  - Any conflicts of interest
  - Any new information or findings relating to the risk/benefit ratio

Continuing Review Deadlines

eIRB CR Deadline Notifications

- Eight weeks prior to expiration
- Six weeks prior to expiration
- Four weeks prior to expiration
- Day before expiration

Deadline to IRB

- No later than one month prior to the expiration of the study

Getting Started

- In your inbox, select the study that needs a Continuing Review.
- Under “My Activities” select “New Continuing Review”

Continuing Review Statuses Explained

- **Enrolling Subjects and/or Collecting Data**: use this status if actively enrolling subjects and/or collecting data on enrolled subjects
- **Enrolling Subjects – No accrual/enrollment to date**: use this status if trying to enroll subjects, but at the time of continuing review, there are no subjects enrolled
- **Enrollment Closed – Subjects continue to receive study treatment/intervention**: use this status once enrollment has been reached or closed, but are still actively treating the subjects
- **Enrollment closed – Follow-up and collecting data only**: use this status when enrollment is closed but no active treatment is occurring. Subjects are just in follow-up.
- **Data Analysis Only – Identifiable**: use this status when enrollment is closed and only completing data analysis with identifiable data.
- **Data Analysis Only – De-identified**: use this status when enrollment is closed and only completing data analysis with de-identified data.
- **Enrollment Temporarily Suspended**: use this status when enrollment has been suspended by the sponsor/PI
- **Permanently Closed – All study activities are completed**: use this status when closing out/terminating the study with the IRB

Number of Subjects Chart

- Report the number and status of subjects.

NOTE: if 4.0 is reported higher than 2.0, a protocol deviation must be submitted.

1.0 Number of Subjects

Note: *"last review" is the study's initial review or continuing review, whichever is most recent. For the first continuing review, the numbers will be the same in both columns.*

1.0	Number of study wide subjects approved for enrollment		
2.0	Number of local subjects approved for enrollment		
		Number since LAST Review	**Cumulative** Number since INITIAL Review
3.0	Number of subjects enrolled study wide, or for a chart review number of records reviewed ?		
4.0	Number of subjects enrolled locally, or for a chart review number of records reviewed ?	*	*
5.0	Number of subjects who screen failed ? *("0" if no screen failures or the study has no screening procedures)*	*	*
6.0	Number of local subjects who have completed the study ? *(Including death(s) expected as an endpoint)*	*	*
7.0	Number of local subjects who have withdrawn ?	*	*
8.0	Number of local subjects who died unexpectedly	*	*
9.0	Number of local subjects currently receiving treatment/intervention ? * 0		
10.0	Number of local subjects currently in follow-up only ? * 0		

Number of Subjects Chart Helpful Hints!

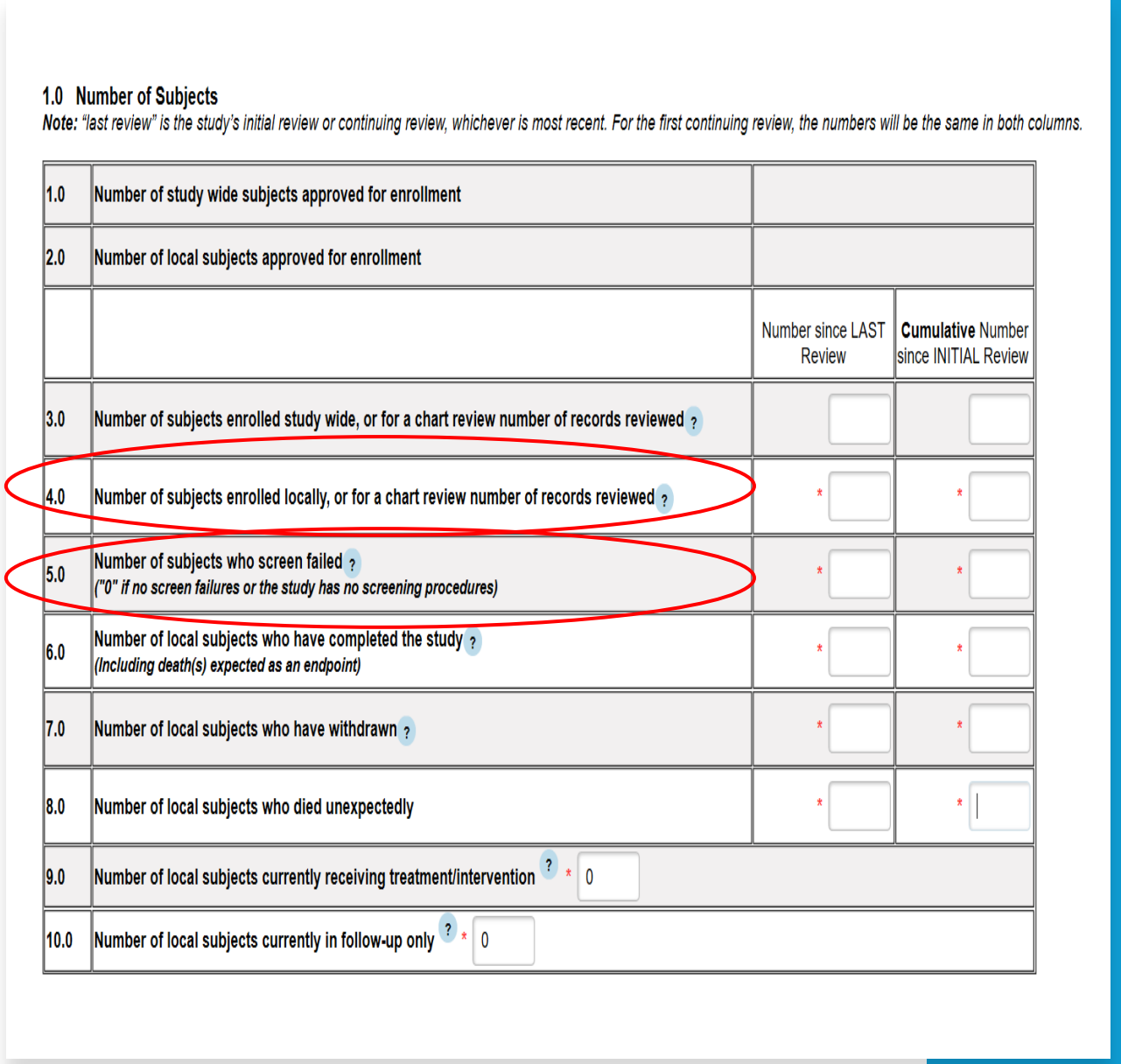
4.0 – Number reported reflects those who are enrolled in the study.

5.0 – Screen fails are reported here.

*Do NOT include screen fails in 4.0.

RULE OF THUMB:

6.0+7.0+8.0+9.0+10.0= 4.0



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3.0	Number of subjects enrolled study wide, or for a chart review number of records reviewed ?		
4.0	Number of subjects enrolled locally, or for a chart review number of records reviewed ?	*	*
5.0	Number of subjects who screen failed ? *("0" if no screen failures or the study has no screening procedures)*	*	*
6.0	Number of local subjects who have completed the study ? *(Including death(s) expected as an endpoint)*	*	*
7.0	Number of local subjects who have withdrawn ?	*	*
8.0	Number of local subjects who died unexpectedly	*	*
9.0	Number of local subjects currently receiving treatment/intervention ? * 0		
10.0	Number of local subjects currently in follow-up only ? * 0		

Number of Subjects Chart Helpful Hints!

- If you have reported incorrect numbers in a previous CR, you can adjust those numbers previously reported!

1.0 – Check the box at the end of the sentence, then give an explanation of the error and correct the numbers in the chart in Column B.

1.0 Adjustment to Number of Subjects Previously Reported

Check this box if adjustments are needed to the enrollment numbers reported in a previous continuing review. ☐

When making adjustments, complete column B in section 2.0 below so that column A + column B reports the total number of accumulated subjects in column C.

2.0 Number of Subjects

Note: *"last review" is the study's initial review or continuing review, whichever is most recent. For the first continuing review, the numbers will be the same in both columns.*

1.0	**Number of study wide subjects approved for enrollment**	314		
2.0	**Number of local subjects approved for enrollment**	10		
		Column A Number since LAST Review	**Column B** **Cumulative** Number at LAST Review	**Column C** **Cumulative** Number since INITIAL Review [1]
3.0	**Number of subjects enrolled study wide, or for a chart review number of records reviewed** ?		0	0
4.0	**Number of subjects enrolled locally, or for a chart review number of records reviewed** ?	5	3	8
5.0	**Number of subjects who screen failed** ? *("0" if no screen failures or the study has no screening procedures)*	2	3	5
6.0	**Number of local subjects who have completed the study** ? *(Including death(s) expected as an endpoint)*	5	1	6
7.0	**Number of local subjects who have withdrawn** ?	1	0	1
8.0	**Number of local subjects who died unexpectedly**	0	1	1
9.0	**Number of local subjects currently receiving treatment/intervention** ? 0			
10.0	**Number of local subjects currently in follow-up only** ? 0			

[1] Cumulative Totals will be recalculated when the Continue button is selected. Otherwise, save this page for immediate recalculation of these totals.

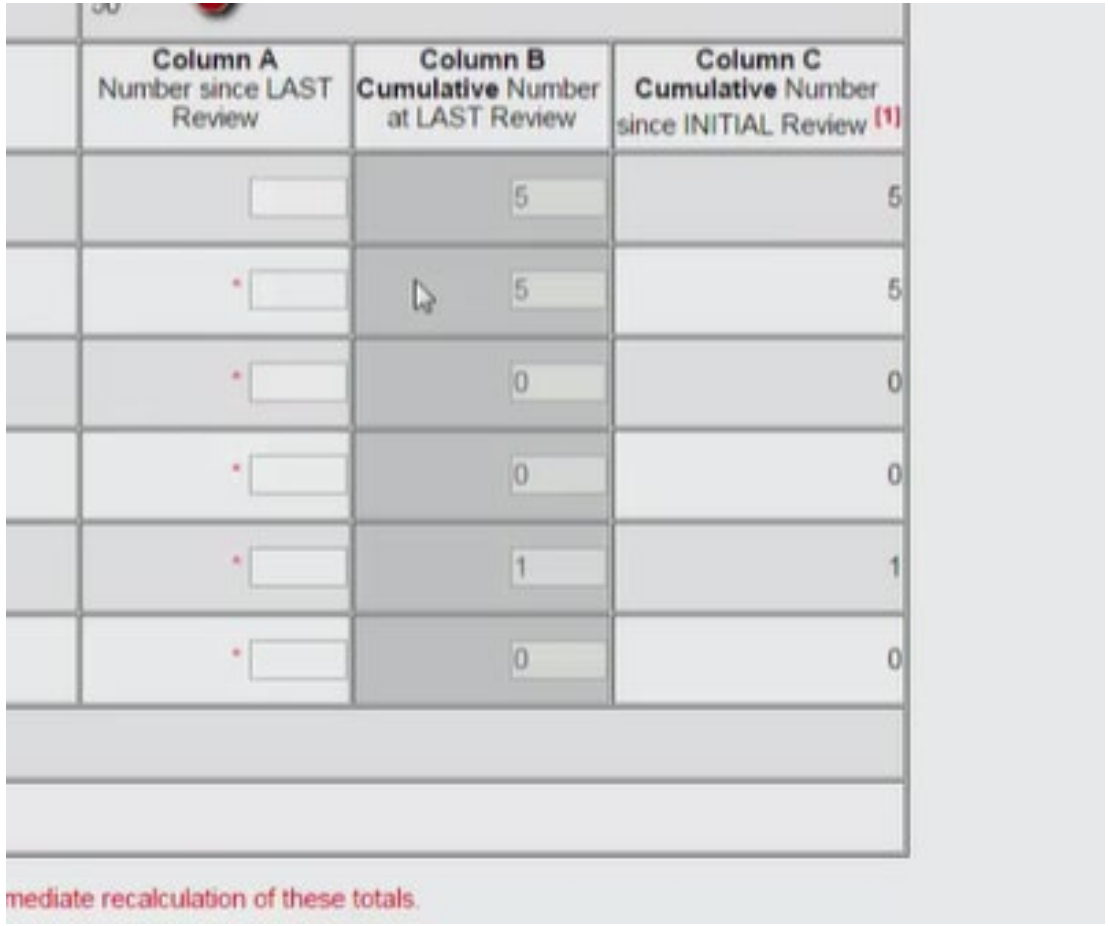
Number of Subjects Chart Explaining the Columns

Column A – Subjects enrolled in the study SINCE LAST REVIEW

Column B – Subjects enrolled AT LAST REVIEW

*These numbers will automatically populate based on your last review

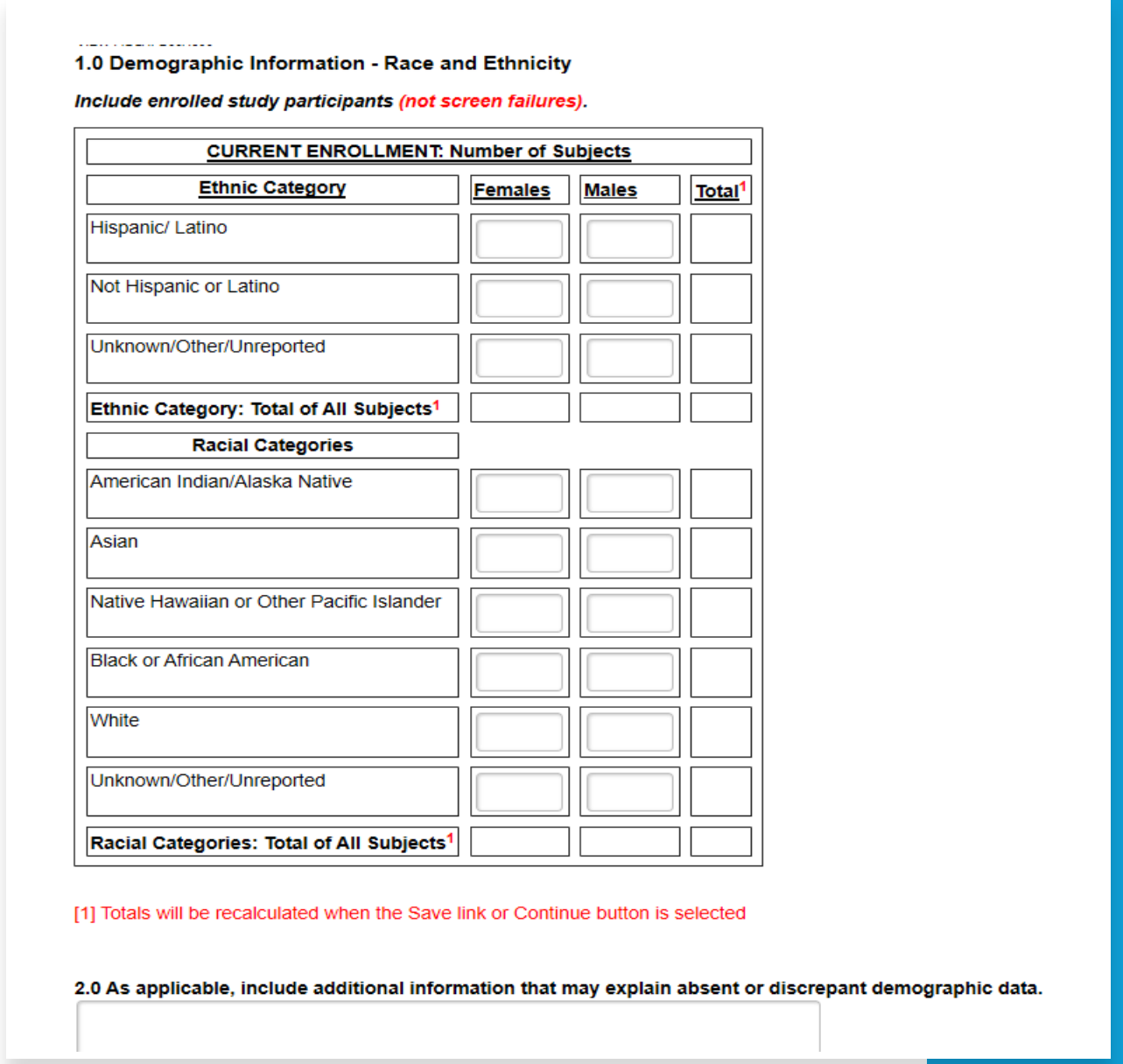
Column C - Cumulative subjects enrolled



Demographic Information

- Record the demographic information in the chart

  Do NOT include screen fails
- The Number reported here must match the total enrolled (4.0 & Column C) in the Number of Subjects Chart.
- If not collecting demographic information, complete 2.0.



1.0 Demographic Information - Race and Ethnicity

***Include enrolled study participants** (not screen failures).*

CURRENT ENROLLMENT: Number of Subjects			
Ethnic Category	**Females**	**Males**	**Total[1]**
Hispanic/ Latino			
Not Hispanic or Latino			
Unknown/Other/Unreported			
Ethnic Category: Total of All Subjects[1]			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Unknown/Other/Unreported			
Racial Categories: Total of All Subjects[1]			

[1] Totals will be recalculated when the Save link or Continue button is selected

2.0 As applicable, include additional information that may explain absent or discrepant demographic data.

CITI Training

All Study team members listed on the application must have completed:

- **Human Subjects Research:**

Group 1. Biomedical Investigators and Key Personnel **OR**

Group 2. Social/Behavioral Investigators and Key Personnel

- **Good Clinical Practices (GCP):**

GCP for Clinical Trials with Investigational Drugs and Biologics **OR**

GCP-Social and Behavioral Research Best Practices for Clinical Research **OR**

GCP for Clinical Investigators for Devices

A Basic Course must be taken before a Refresher will be accepted!

CITI Training not showing?

Make sure first name, last name, and email addresses are EXACT MATCHES in eIRB and CITI. Keep in mind that completing CITI training doesn't mean that the study team member will show up in eIRB. A separate eIRB registration is required.

DSMP

1.0 – Provide a brief description of the data safety monitoring plan (DSMP).

- Do NOT copy and paste from the protocol. Just briefly describe the DSMP.

2.0 – Respond if any data safety monitoring board (DSMB) met since last IRB review.

- If not, provide an explanation.

3.0 – Respond if all DSMB reports have been submitted to the IRB.

- If not, explain.
- If reports have been received, but need to be submitted, submit as a Reportable Event ASAP!

NOTE: DSMB reports are to be submitted to the IRB via eIRB Reportable Events upon receipt by the PI.

1.0 Provide a general description of the data and safety monitoring plan:

2.0 Did the Data and Safety Monitoring Board/Committee meet since the last IRB review?

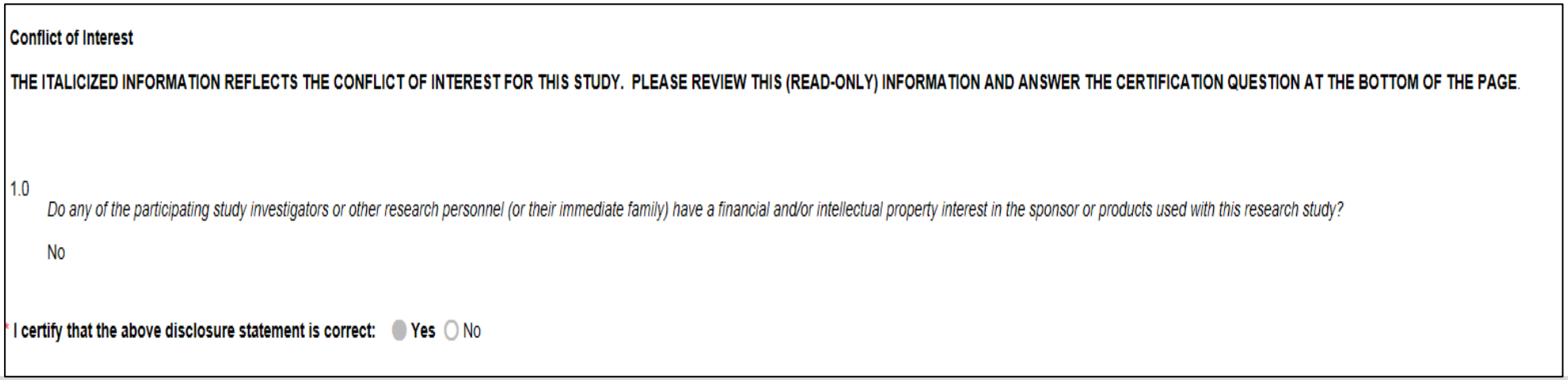
If no, explain:

3.0 Have all DSMB reports been submitted to the IRB?

If no, explain:

Conflict of Interest

- The statement below is a confirmation that the COI Disclosure is correct!
  - Answer YES if the COI has not been changed
  - Answer NO if the COI needs to be updated.
- If the COI needs to be updated, then submit an amendment ASAP!



Conflict of Interest

THE ITALICIZED INFORMATION REFLECTS THE CONFLICT OF INTEREST FOR THIS STUDY. PLEASE REVIEW THIS (READ-ONLY) INFORMATION AND ANSWER THE CERTIFICATION QUESTION AT THE BOTTOM OF THE PAGE.

1.0 *Do any of the participating study investigators or other research personnel (or their immediate family) have a financial and/or intellectual property interest in the sponsor or products used with this research study?*

No

* **I certify that the above disclosure statement is correct:** ◉ **Yes** ○ No

FINISH

The PI will submit the completed Continuing Review!