Expedited Research Status Report

IRB#:

Protocol Title:

Investigator/s:

Please complete the Expedited Research Status Report for the above referenced protocol. All questions must be answered.

1. Current research status:

[ ]  Open to enrollment – no participants have been enrolled (consented to participate) to date. This is a

 request for my study to remain open.

[ ]  Open to enrollment – participants have been enrolled (consented to participate). This is a request for my

 study to remain open.

[ ]  Closed to enrollment – currently enrolled participants remain “active” and are still involved in research

 activities. This is a request for my study to remain open.

[ ]  Closed to enrollment – follow-up with currently enrolled participants (or data collection) continues. This is

 a request for my study to remain open.

[ ]  Closed to enrollment – participant engagement has ended and only analysis of identifiable or coded data

 continues. This is a request for my study to remain open.

[ ]  Closed to enrollment – participant engagement has ended and only data analysis on de-identified data

 continues. This is a request to close my study.

 [ ]  All research activities are completed-This is request to close my study.

[ ]  Other (please describe-e.g.-secondary data analysis, etc.):

1. Has the number of currently enrolled participants increased above 20% of the number of participants currently approved for the study to date?

[ ]  No

[ ]  Yes Describe the changes. Include in your description how the changes deviate from your currently

 approved protocol and the rational/justification for the change.

If the IRB is not aware of this change and an amendment for this change is not included with your annual report, it is required at this time. Link to form: [Amendment Form](https://researchintegrity.syr.edu/wp-content/uploads/2021/09/IRB-Amendment-Request-Form-2021.docx)

1. Have there been any changes to the research team (e.g.-change in P.I., addition/removal of research staff, etc.) that have not been submitted to the IRB?

[ ]  No

[ ]  Yes Describe the changes. Include in your description how the changes deviate from your currently

 approved protocol and the rational/justification for the change.

If the IRB is not aware of this change and an amendment for this change is not included with your annual report, it is required at this time.

Link to form: [Amendment Form](https://researchintegrity.syr.edu/wp-content/uploads/2021/09/IRB-Amendment-Request-Form-2021.docx)

1. Please list all currently active members of the research team below:

Please ensure the CITI training certificate is current and has not expired. If the CITI training has expired, the CITI refresher course training modules are required and must be completed to avoid any delays and/or lapse in your research.

Please consult our website for complete guidance regarding CITI training requirements: [Link - Human Research - Education and Required Training](https://researchintegrity.syr.edu/human-research/education-and-required-training/) or to access the CITI training website: [Link - CITI Website](http://www.citiprogram.org/).

1. Have there been any changes to the research methods and/or materials that have not been submitted to the IRB (e.g.-addition/removal of research sites, addition/removal of research instruments, changes to currently approved research instruments, etc.)?

[ ]  No

[ ]  Yes Describe the changes. Include in your description how the changes deviate from your currently

 approved protocol and the rational/justification for the change.

If the IRB is not aware of this change and an amendment for this change is not included with your annual report, it is required at this time. This amendment request must Include the submission of new and/or revised research instruments/materials that have not yet been approved by the IRB. Link to form: [Amendment Form](https://researchintegrity.syr.edu/wp-content/uploads/2021/09/IRB-Amendment-Request-Form-2021.docx)

1. Have there been any changes to the most recently approved consent/assent forms at this time?

[ ]  No

[ ]  Yes Describe the changes. Include in your description how the changes deviate from your currently

 approved protocol and the rational/justification for the change.

If the IRB is not aware of this change and an amendment for this change is not included with your annual report, it is required at this time. This amendment request must Include the submission of new and/or revised consent/assent forms that have not yet been approved by the IRB. Link to form: [Amendment Form](https://researchintegrity.syr.edu/wp-content/uploads/2021/09/IRB-Amendment-Request-Form-2021.docx)

1. Have there been any changes to the most recently approved method for recruitment and/or recruitment instrument/s at this time?

[ ]  No

[ ]  Yes Describe the changes. Include in your description how the changes deviate from your currently

 approved protocol and the rational/justification for the change.

If the IRB is not aware of this change and an amendment for this change is not included with your annual report, it is required at this time. This amendment request must Include the submission of new and/or revised recruitment materials that have not yet been approved by the IRB. Link to form: [Amendment Form](https://researchintegrity.syr.edu/wp-content/uploads/2021/09/IRB-Amendment-Request-Form-2021.docx)

1. Is there any new information or literature that suggests a change in what was previously submitted about the research approved by the IRB that might impact the rights, welfare, or willingness of participants to continue in the research that has not yet been submitted to the IRB?

[ ]  No

[ ]  Yes Describe the changes. Include in your description how the changes deviate from your currently

 approved protocol and the rational/justification for the change.

If the IRB is not aware of this change and an amendment for this change is not included with your annual report, it is required at this time. Link to form: [Amendment Form](http://researchintegrity.syr.edu/wp-content/uploads/2018/09/IRB-Amendment-Request-Form.doc)

1. Have there been any problems or complaints associated with the research that have not been reported to the IRB?

[ ]  No

[ ]  Yes A Report of Unanticipated Problems is required at this time. Link to form: [Report-of-Unanticipated- Problems](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Report-of-Unanticipated-Problems.doc) (Additional action may be required)

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Printed Name (Principal Investigator)

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Signature (Principal Investigator)

The completed form can be submitted either electronically as an email attachment or via hard copy.

Forms should be submitted electronically and must be sent directly from the email of the currently approved P.I. or include an official digital signature. (Computer font is not acceptable.)

Electronic submissions should be returned directly to: orip@syr.edu