

## Researcher Guidance:

Institutional Review Boards are responsible for ensuring appropriate safeguards are in place when investigators recruit vulnerable individuals for participation in research studies. These individuals may be minors, pregnant women or fetuses, prisoners, economically disadvantaged, racial or ethnic minorities, those who have a stigmatized health condition or mental illness, those with mental disabilities or cognitive impairments, institutionalized persons, etc.

The USA IRB office has determined PASSAGE USA students to be a vulnerable population. In order to gain IRB approval for the inclusion of PASSAGE students in a research study, the below process must be followed:

1. PI (or other study personnel) completes IRB Application Part A Expedited and Full Board
2. PI emails completed Part B to the program director, Dr. Abigail Baxter ([abaxter@southalabama.edu](mailto:abaxter@southalabama.edu)) and requests support for the project
3. If deemed acceptable, Dr. Baxter will provide an official letter of support
4. PI/study personnel submits all required documentation\* for IRB approval via IRBNet
5. Once approved, PI/study team works with PASSAGE faculty to facilitate recruitment and obtaining consent from students and their parents

\*To recruit from this population, required documentation for IRBNet submission is as follows:

- Application Part A
- Application Part B Expedited and Full Board
- Letter of Support
- Student consent form- with signature lines- written at a 2<sup>nd</sup> to 3<sup>rd</sup> grade reading level
- Parent permission form\*\* - with signature lines- written at an 8<sup>th</sup> grade reading level
- Supplemental documents, e.g. survey/questionnaire, interview questions, recruitment scripts

\*\*The parent permission must be a separate document and may not be combined with the student consent form.

All PASSAGE projects receiving IRB approval are required to comply with all other USA IRB policies and procedures such as submitting Amendments and gaining approval before amended activities are implemented, notifying the IRB office with any updates to study personnel, and providing annual status updates to signal continuation of research.

For any questions, please contact the USA IRB administration office by calling 402-53108 or emailing [irb@southalabama.edu](mailto:irb@southalabama.edu).