



INVESTIGATOR'S ASSURANCES

- ✓ I certify that the information provided is true and correct to the best of my knowledge.
- ✓ I understand as the Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and adherence to any stipulations imposed by the IRB.
- ✓ Before actual commencement of this research activity, I will make sure all necessary arrangements have been completed with appropriate Piedmont Administration and Medical Staff Committees to coordinate the use of hospital personnel or facilities that may be required in connection with this research study and confirm that all investigators and research personnel have appropriate clinical privileges to carry out the study.
- ✓ I understand that I may not implement the proposal described above or any changes to the protocol until I have received written approval from the Piedmont Healthcare IRB. (Except in an emergency, if necessary, to safeguard the wellbeing of human subjects).
- ✓ Legally effective informed consent will be obtained from human subjects or their legally responsible representative.
- ✓ I will promptly report significant or untoward adverse effects or unanticipated problems to the IRB in writing within 10 working days of occurrence.
- ✓ I agree that if approval is granted, I will abide by the protocol submitted and will comply with all policies, procedures, and requirements of Piedmont Healthcare and each of its entities as well as with all federal, state and local laws regarding the protection of human subjects in research.
- ✓ I agree to maintain sufficient expertise to carry out the functions of the protocol. This will be done by ensuring that all required medical qualifications or licensures are utilized for the life of the research study.
- ✓ I certify that all study team members will maintain valid required training certifications for the duration of their involvement in the study. Study team members with expired certifications will be immediately dismissed from study participation until such time they are in compliance with the education and training requirements.
- ✓ I certify that, minimally, all study team members will be properly trained to all non-administrative protocol amendments.