The University of Georgia and Piedmont Athens Regional Hospital (PAR) have executed a Memorandum of Understanding (MOU) for collaborative research where both organizations are engaged in the same human subjects research project. Piedmont Athens Regional Hospital may be considered as an External Site or an External Collaborating Site depending on the project design. When engaged, Piedmont Athens Regional Hospital would be considered an External Collaborating Site. When not engaged, Piedmont Athens Regional Hospital is considered to be an External Site and the research is not collaborative. Different procedures are required depending on whether or not PAR is engaged in the research.

A. Initial Considerations

- **Piedmont engagement** – The final determination of engagement is the responsibility of the institution. Therefore, PAR will be consulted for every project that is conducted at the hospital, targets hospital patients, or utilizes any hospital resources including the electronic medical records. Generally speaking, Piedmont considers that projects including PAR employees (in any capacity) will constitute the engagement of Piedmont in the research.

- **Dual Affiliation** – Researchers who have multiple affiliations (e.g., Medical Partnership or UGA faculty appointments and staff or clinician roles at Piedmont) must carefully consider their role in the research in order to determine if they are engaged on behalf of Piedmont. If a proposed activity is something that someone does regularly as a Piedmont employee, then that same activity as part of a research project would be considered within the scope of the individual’s Piedmont employee capacity. For example, access to medical records is something that someone has due to their affiliation with Piedmont and, therefore, accessing the records for purpose of identifying potential participants would constitute engagement of PAR as an External Collaborating Site.

B. Initial Review - Researcher Procedures

1. List any Piedmont affiliated collaborators as Non-UGA collaborators in Q2 on the Study Team Member page of the online submission.
2. Indicate that External Sites are involved in Q1 on the Study Scope page of the online submission.

3. List Piedmont Hospital Athens as the External Site.

4. List Madeline Peyton as the Piedmont IRB contact. Her contact information is ORS@piedmont.org.

5. If there are Piedmont collaborators, where prompted, indicate that Piedmont IRB will not review and will rely on UGA IRB.

6. If there are no Piedmont collaborators, where prompted, indicate that Piedmont IRB will not review, but do not indicate that PAR will rely on UGA IRB. Instead indicate that authorization is required from the site.

7. If there are Piedmont collaborators, after UGA IRB provides the initial approval letter, send the protocol (Printer Version of the submission), all attachments, and the UGA IRB approval letter to ORS@piedmont.org for administrative review.
   a. If requested by Piedmont, submit modifications to UGA IRB for review.

8. No research activities may be conducted until Piedmont has indicated that they accept the UGA IRB review.

C. Continuing Review or Closure – Researcher Procedures

1. After Continuing Review is approved by the UGA IRB, submit the following to ORS@piedmont.org:
   a. UGA IRB Continuing Review Approval Letter
   b. Piedmont Affiliated Site Renewal & Closure Request Notification form (completed)
   c. Relevant study attachments from form

2. After UGA IRB has processed the study closure request, submit the following to ORS@piedmont.org:
   a. UGA IRB Closure Letter
   b. Sponsor closure/termination letter, if applicable
   c. Piedmont Affiliated Site Renewal & Closure Request Notification form (completed)
   d. Relevant study attachments from form

D. IRB Procedures

1. Review the Study Team page and the External Sites page to make an initial determination pertaining to PAR’s engagement. As needed, request additional information from the study team.

2. If it seems that PAR is not engaged, send an email to ORS@piedmont.org with the protocol and request for an engagement determination and site authorization to be returned.
3. If it seems that PAR is engaged, proceed with the review, informing the study team that Piedmont will review and their agreement to rely on UGA must be received before research activities may begin at PAR.

4. Update the study record with any correspondence from PAR as it is received.

E. Questions

Please contact the Human Subjects Office (706-542-3199 or irb@uga.edu) for any questions or assistance.