SPECIMEN PROTOCOL TEMPLATE GUIDANCE

1. **TITLE PAGE**
   - Full study title, protocol version number and version date
   - Name, Title(s), and Department of Principal Investigator
   - Collaborators (institutions and departments), if any
   - Sponsor(s), if any

2. **INTRODUCTION AND BACKGROUND**
   A summary of the primary hypothesis, purpose, scholarly rationale, and prior literature, when applicable.

3. **OBJECTIVES**
   The primary and secondary aims and outcome measures.

4. **STUDY DESIGN AND METHODS**
   - Describe inclusion and exclusion criteria.
   - Provide source and ownership details about the specimens to be analyzed.
   - Address whether specimens were collected as part of routine clinical care or as part of a prior research study. If from prior research approved at Piedmont provide the IRBNet ID number. If from prior research approved outside Piedmont provide the exact language in the informed consent document that addresses how the specimens were intended to be used for the research and in the future.
   - If specimens and/or data are to be shared with a collaborating entity and Institutional Authorization Agreement, data sharing, or data use agreement will need to be executed.
   - Address whether there will be any identifiers attached to the specimens and/or data (whether incoming or outgoing).
   - Outline any de-identifying processes and when and where they may occur.
   - Outline any coding procedures that may be used and who will have the identification linking key.
   - Outline how samples collected for this study will be saved/banked/archived for future use, describe plans, who may use the material, and for what purposes.
   - Describe the data and statistical analysis plans

5. **CONFIDENTIALITY**
   - Describe your plans to establish and maintain confidentiality of identifiable data.
     - Description of any linkages from study data to identifiers
     - If you will destroy identifiers indicate when that will occur during the course of the research.

6. **REFERENCES/BIBLIOGRAPHY**