If this trial does not involve a CASE employee accessing electronic medical records, this section 13.2.3 should be marked "N/A" and all instructions as well as the text below deleted.

This study will access electronic medical records systems to obtain medical information for the subjects enrolled to this study.

Explain why electronic systems must be used. The following text is to be modified for the specific protocol:

In order to insure patient safety, investigators and study personnel must have up-to-the-minute health information for subjects enrolled to this study. Therefore, electronic medical records must be utilized to obtain medical information in a timely manner.

Explain which electronic systems will be accessed and for what purpose. The following text is to be modified for the specific protocol:

The following electronic systems will be used: IDX program to access scheduling information; UH Physician Portal to access lab results and physician notes; PCOSS LITE as necessary to locate archived medical records; COPATH to locate archived pathology records; PACS to access radiological imaging results; and MySecureCare (Sunrise Clinical Manager) to access some or all of the above information when this application is fully functional.

Explain how long electronic access is needed. The following text is to be modified for the specific protocol:

Access to these systems is required for the life of this research study.

Explain how data will be obtained and what will be done with the data. The following text is to be modified for the specific protocol:

Information obtained from electronic systems will be copied into the Seidman Cancer Center Clinical Trials Unit research chart and/or printed (lab results, physician notes, etc.) and stored in the research chart. Research charts are kept secure and destroyed according to UH policy.

Explain who will be accessing data. You must specifically name CASE employees and their role on the study. The following text is to be modified for the specific protocol:

Study data will be obtained by the PI, co-investigators, study coordinator, and/or data manager for this study via password-protected login. _____ is a Case Western Reserve University employee with a University Hospitals email address and IT&S log on ID and Password. _____ will be assessing EMR to **[Explain what data the person will obtain and what that person will do with the data]**. All

study personnel involved in this research will adhere to the UH policies regarding confidentiality and Protected Health Information.