PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:
Name:
Institution Name:
Phone Number:
Email Address:

VERSION NUMBER/DATE:

Table of Contents

1.0 Study Summary

Study Title	
Study Design	
Primary Objective	
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	This study is observational only.
IND/IDE #	
Study Population	
Sample Size	
Study Duration for individual participants	
Study Specific Abbreviations/ Definitions	

2.0 Objectives

3.0 Background

4.0 Study Endpoints

5.0 Study Intervention/Investigational Agent

6.0 Procedures Involved

7.0 Data and Specimen Banking

7.1 The PHI data obtained for this study will always remain within the institution infrastructure that is encrypted and password protected.

7.2 A fully de-identified subset of the full dataset, limited to the XXX images and to their XXX data element outcomes obtained from the XXX, will be hosted by the University of Chicago on a cloud compute infrastructure for non-commercial, academic research. Before accessing any data, researchers are required to submit human subjects training certificate and sign a user agreement stating their commitment to use the data for only non-commercial purposes. Downloading the data is strictly forbidden, and there are technical safeguards in place within the cloud platform to prevent any download.

8.0 Sharing of Results with Subjects

9.0 Study Timelines

10.0 Inclusion and Exclusion Criteria

11.0 Vulnerable Populations

12.0 Local Number of Subjects

13.0 Recruitment Methods

14.0 Withdrawal of Subjects

14.1 We will not have direct patient interaction.

15.0 Risks to Subjects

15.1 This study contains no direct patient interaction or intervention. The major risk is data security, which is addressed by ensuring only study staff have access to these PHI data. Removing all PHI as

defined by HIPAA for the de-identified data will protect patient confidentiality.

16.0 Potential Benefits to Subjects

17.0 Data Management and Confidentiality

17.1 We will keep all PHI data within the secure environment provided by the health system information technology. The compute environment will be encrypted and password protected. Any data shared among the study staff will be done using a secure file transfer protocol. Shared results will be deidentified and aggregated to maintain patient confidentiality. All de-identified datasets will comply with HIPAA standards.

The de-identified data on the cloud compute infrastructure, *described above in Section 7.2,* will be available for future research by investigators who commit – via a signed Terms of Use agreement – to use the data for non-commercial research purposes only.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

18.1 We will not have direct patient interaction.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 To protect subjects' privacy interests, all PHI data will remain on a secure compute environment. The de-identified data will be limited through terms of service agreements to protect patient privacy.

20.0 Consent Process

21.0 Setting

22.0 Resources Available

23.0 References