Protocol Title: The WIIA – The Wright Center of Innovation Imaging Archive

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OBJECTIVES

This data bank will serve as a data resource for a multidisciplinary team of clinicians and basic scientists. Specifically, this data bank will allow investigators to generate preliminary data for competitive consideration in intermural and extramural funding while enabling advanced analytical tool development and deep learning methodologies. This effort will enable the use of leading edge innovation in biomedical imaging by using clinical imaging studies that otherwise could not be used for such developments.

We aim to use these data to improve diagnostics and disease management. With this data bank, we hope to improve the quality of imaging and the precision of imaging based analytics to better detect potential health risks, predict treatment response, and monitor disease progression in order to guide management of future patients.

BACKGROUND AND RATIONALE

Imaging technology has widespread medical uses. Ultrasound, PET, CT, and MRI techniques are used to diagnose and monitor diseases, especially in the areas of oncology, neuroscience, cardiovascular, orthopedics, and sports medicine. Therefore, optimizing the use of imaging techniques benefits many patients, and unsurprisingly, this is a primary focus of clinical research. The Wright Center of Innovation and its researchers explore advancements in imaging technologies and techniques to improve patient lives and therapeutic outcomes.

The constant advances in computational capabilities and abilities of deep learning necessitate the availability of large imaging data sets that can be further analyzed. We therefore create the WIIA – The Wright Center of Innovation Imaging Archive – to serve as a repository for advanced data

analytics and simulation. This will provide researchers access to a robust, comprehensive pool of imaging data for impactful research.

DATA COLLECTION, STORAGE, AND RELEASE

Data Collection

Data collected will include imaging scans, coded demographics, abbreviated medical history, current diagnoses, coded medical reports, coded surgical/nonsurgical treatment procedures, and follow up information. These data will be collected from Standard of Care (SOC) or investigational imaging studies. Specifically, data may be collected directly from the imaging device, directly from the imaging network (PACS), or using other electronic data exchange means, such as USB device, CD, DVD, or Blu-Ray. The data will be coded and annotated with limited subject and clinical information.

The imaging data will be coded using the SOP's of the Imaging and Radiation Oncology Core (IROC) service so that only coded protected health information (PHI) will be included within the data sets. The following coding approach will be used:

Patient Name (First, Middle, Last) will be replaced with a WIIA ID code in the form of RP310_XXXXXX using leading zeros. Each participant will receive a unique WIIA ID.

The date of the exam will be coded to the first day of the quarter when the study was performed, except in cases where follow up studies are performed at a shorter time interval. If a shorter time interval exists, the date will be coded in relation to the baseline study that will be coded as the 1st of the quarter. For example, a baseline CT scan was performed on 10/5/2017 with a follow up on 10/7/2017, and the date coding would be 10/1/2017 for the baseline and 10/3/2017, preserving the relative time ratio within the quarter, but changing the date to a coded date.

The birthdate will be coded as 1/1/decade; someone born on September 11, 1984 will have a coded birthdate of 1/1/1980. It will be always January 1 of the decade.

The gender information will be retained as it is also fairly easy to identify physical gender from the medical imaging.

If available, the following information will be coded:

- Weight in pounds in 20 pound increments based on rounding.
- Height in feet (rounded)
- Ethnicity
- Reason for imaging study (screening, diagnostic, response assessment)
- Findings of the imaging study
- Whether participant has been under treatment (Y/N)
    - If yes, whether the participant is currently under treatment or is post-treatment
    - If yes, what kind of treatment (surgery, chemotherapy, immunotherapy, radiation therapy)

Data Storage
Data will be coded and stored in the Wright Center of Innovation Imaging Archive, which is a secure database of imaging studies. Data will be stored indefinitely.

If the study Principal Investigator were to leave the study or university, the data would remain within the Wright Center of Innovation, and management of the repository study would be transferred to one of the designated Co-Investigators in this study. The archive will be encrypted, password protected, will contain only coded data, and will have limited access restricted to study investigators and administrative staff. Administrative staff will construct and maintain the database as well as conduct annual quality assurance assessments of bank data.

The oversight structure of the bank is as follows. The Principal Investigator will oversee that only appropriately authorized data are collected and distributed. Any data requests must be approved by the PI or appropriately delegated authorization person. The Co-Investigators will verify that the appropriate authorization was acquired prior to upload and inclusion of data into the database. Investigators will also review the de-identification and technology functionality of the dataset.

Data Release
To maximize the use of this data bank and to promote collaborative, multi-institutional research, we are not limiting future data use. Data may be shared with Ohio State or non-Ohio State researchers. However, only investigators with sound, hypothesis driven research proposals can request data by completing a Data Request Form. These requests will be reviewed by the Principal Investigator of the repository. Investigators requesting use of the data will provide copies of all study protocols, data acquisition forms, and/or institutional review approval documents prior to release of data. Additionally, any data shared with others will be coded and de-identified. Lastly, annual auditing processes will be conducted internally by administration personnel to ensure proper data release.

PROCEDURES
Sample
The patient population under study includes adults who are 18 years of age and older. Children will be excluded from this study as they are unable to give voluntary consent. A partial waiver of HIPAA authorization will be requested to permit access to and use of PHI for recruitment purposes. However, investigational data will only be collected once consent to participate in the study is acquired.

Participants can include or donate their imaging data independently if it was performed at OSU or outside of OSU. For example, a subject may be willing to donate an imaging study performed previously or for different purposes and provides the WIIA with a CD or other data set.

There will be no upper limit to the number of people who participate in this study. We expect 100-150 participants per year, with plans for the study to continue indefinitely.

Selection Criteria

Inclusion

1. Patient provides consent
2. Patient is receiving or has received a SOC or investigational imaging scan

Exclusion

1. Patient does not wish to or is unable to provide consent
2. Patient is below the age of 18

Recruitment

Patient recruitment will take place during their SOC or investigational imaging scan. The patient will meet with a qualified personnel who will explain the purpose of the bank, requirements for participation, and will provide the combined Informed Consent and HIPAA Authorization Form. If the patient is unsure about participating, they will be given the Informed Consent and HIPAA Authorization Form to keep. The consenter can approach the patient at subsequent visits to answer questions, provide additional information, and seek consent. If the patient consents to have their data made available to our data bank, the patient will sign the Informed Consent and HIPAA Authorization Form. The original, signed, hard copy consent form will be kept indefinitely by the Department of Radiology in a secure location. This clinical trial will also be uploaded to clinicaltrials.gov to recruit individuals interested in donating past imaging information. Recruitment will not involve the use of patient information or PHI.

Informed Consent

The patient will meet with a qualified personnel who will explain the purpose of the bank, the requirements for participation, and will provide the combined Informed Consent and HIPAA Authorization Form. If the patient is unsure about participating, they will be given the Informed Consent and HIPAA Authorization Form to keep. The consenter can approach the patient at subsequent visits to answer questions, provide additional information, and seek consent. If the patient consents to have their data made available to our data bank, the patient will sign the Informed Consent and HIPAA Authorization Form. The original, signed, hard copy consent form will be kept indefinitely by the Department of Radiology in a secure location.

Patients may choose at any time to discontinue participation in the data bank. Patients will be advised in the Informed Consent and HIPAA Authorization Form that if they decide to withdraw consent, they simply need to notify the Principal Investigator in writing. Upon withdrawal, the individual's file will be tagged, and no additional data or specimens will be collected. All samples and study data will be destroyed and not used in any further research.

Confidentiality

Patient confidentiality will be fully maintained within this banking protocol. Only for the purpose of coding and tracking of the completed informed consent will there be access to PHI. This PHI coding list will be kept completely separate from the actual WIIA and the imaging data sets.

Any personal health information (PHI) will be only accessed in the appropriately authorized offices at The Ohio State University Wexner Medical Center. It may be used in a secure email communication with appropriately authorized and identified team members or staff that are part of the healthcare service process. If any PHI is written in a hard copy document, it will be appropriately identified as containing PHI and either securely stored for the temporary purpose in locked spaces or securely shredded. The PHI information will be stored at either of these three locations: 1) 395 W. 12th Ave., 4th Floor, Imaging Core Lab Suite (key access only) 2) 2050 Kenny Road, Room 1233 (keycard access only) 3) 1216 Kinnear Rd., secure and monitored basement storage facility (keycard access only).

The imaging studies will be scrubbed and coded using the specialized software of the WCIBMI ICL, which serves also the National Institutes of Health National Clinical Trial network. This QC process ensures that data adhere to the coding requirements of PHI information while securing that private imaging systems tags remain accessible.

Risk/Benefit

This study will impose minimal medical risk to participants. A data leak is the primary risk, which will be minimized through precautions to protect PHI. Nevertheless, in the event of a data breach, the nature of the collected data ensures minimal financial or professional impact on the patient.
This study does not confer a direct benefit to the patient. However, society may benefit from imaging advancements that arise from future studies using this data.

Incidental Findings

Incidental findings will not be generated from this study. Participants in the data bank will have either already had a standard of care scan accompanied with their research scan, or they would have had a diagnostic review as part of the primary research performed. Therefore, this study will not generate new incidental findings.

Adverse Event Reporting

Adverse event reporting will be reported in compliance with the requirements of the overseeing IRB and all other applicable regulatory agencies. The most likely adverse event of this study would be a privacy breach. However, limited access to and secure storage of PHI will minimize this risk.

Conflict of Interest

The principal investigator and all other study team members will remain informed and compliant with all OSU Conflict of Interest (COI) policies. If a conflict arises that is greater than the minimum allowable by OSU COI, a conflict management plan will be developed and approved by the University COI Committee.