African Research Group for Oncology

Ile – Ife

REDCap Manual

Table of Contents

A1: Introduction

This document provides information regarding the procedures for the use of REDCap within the African Research Group for Oncology (ARGO) network. It is designed to guide us with a process and set of rules that establish effective communication between ARGO staff and external researchers for exchange of information and other electronic data capturing services that foster REDCap database maintenance. This document outlines an effective and efficient method for ARGO to build and maintain internal REDCap studies while also defining a concrete plan for external researchers to make use of this powerful tool. The protocol also spells out the roles and functions of personnel dedicated to and supporting REDCap use as explained below for studies employing REDCap.

A2: REDCap Description

REDCap (Research Electronic Data Capture) is a web-based electronic data capture tool that was developed at Vanderbilt University. It does not require additional installations and has few compatibility issues. It is fast and flexible for survey setup and design; with features including data validation; ability to import data from external sources; automated exports to the most common statistical packages (SPSS, SAS, R, and Stata); audit trails for tracking data changes and exports; branching logic, calculations, and piping to increase functionality and personalization. It is a sophisticated data entry tool for building and managing online surveys and licensed for use at Obafemi Awolowo University (OAU) to which the National Headquarters of ARGO is affiliated. Using the REDCap platform, ARGO hopes to provide support in the realm of oncology studies in Nigeria to researchers that have affiliated themselves with ARGO. Furthermore, ARGO hopes to work towards strengthening the REDCap community at OAU through participation at community meetings and the offering of office hours to help OAU researchers outside the ARGO network in their understanding and increased use of REDCap.

A3: REDCap Personnel

- Core ARGO Personnel:
    - National Principal Investigator: the co-founder and director of ARGO
    - ARGO Management Team: higher level management personnel within ARGO that oversee the operations of the group

    - ARGO REDCap Administrator: a dedicated position within ARGO that is responsible for the building, maintenance, and administration of REDCap databases
    - Core ARGO Research Assistants: ARGO personnel that collects data and input it into REDCap for its core studies
- ARGO Network Personnel:
    - ARGO Principal Investigators: lead researcher for a study that is responsible for leading a study
    - ARGO Network Research Assistants: ARGO personnel that collects data and input it into REDCap for studies in its network
    - External REDCap Support: ARGO researchers and administrators at institutions outside of OAU that have expertise with REDCap functionalities and volunteer their time to assist with REDCap building and administration
- Personnel External to ARGO Network:
    - OAU REDCap Community Management Team: maintainers and administrators of the OAU REDCap

B: Steps for developing a REDCap Database

Below is a general outline of the steps required to receive ARGO support to build an online database on REDCap:

1. The PI of such a study must make his/her intention known to the ARGO REDCap Administrator through the National Principal Investigator. The National Principal Investigator will decide whether to approve the study and/or request a fee for the mobilization of ARGO REDCap resources towards the project.
2. The ARGO REDCap Administrator will request the PI to complete a Study Initiation Form and attach necessary documents. [See *Study Initiation Request* section below]
3. Upon receiving the Form and necessary documents the ARGO REDCap Administrator will proceed to build a REDCap database to host the study. [See the *Building REDCap Database* section below]
4. The ARGO REDCap Administrator will meet with External REDCap Support. [See the *Technical Review Meeting* section below]
5. A REDCap desk review meeting between stakeholders will occur. [See the *Desk Review Meeting* section below]
6. The project will be moved to production. [See the *Moving Projects to Production* section below]
7. The PI will be contacted and will ensure that data collection begins.
8. In the case that necessary modifications or additions need to be made, the PI will contact the ARGO REDCap Administrator and initiate the process of database update–this will require express approval of the National Principal Investigator [See the *Modifying REDCap Database* section below]

B1: Study Initiation Request

A Study Initiation Form [See *Appendix A*] will be completed by the Study PI to ensure that the ARGO REDCap Administrator can efficiently and accurately build a REDCap database for the study, and that the study has the sufficient regulatory clearance such that data can be collected in the database. Note that completing the Study Initiation Form is to standardize and facilitate initiation for the ARGO REDCap Administrator. The Study PI must also attach documents that are referenced in this form.

B2: Building REDCap Database

1. The ARGO REDCap Administrator will build a REDCap database based on the completed Study Initiation Form and attached documents ensuring that the following elements are incorporated:
    i. The study name (corresponds with approved IRB), the study PI (noted along with email, phone number), and the IRB expiration date (*Main project settings*)
    ii. The questionnaire is built into a REDCap. The questionnaire will match with the REDCap build that is done, including appropriate headers and matching questions. If aspects of the soft copy questionnaire are omitted or unclear, the ARGO REDCap Administrator can make edits and track changes for further discussion with PI (*Design your data collection instruments*)
        - Any studies that include biobanking samples should follow the standardized protocol for biobanking [See *ARGO Biobanking Data Protocol* section below]
        - Any longitudinal database studies that collect patient treatment and investigation history should follow the standardized protocol for entering histology data. [See *ARGO Histology Data Protocol* section below]
    iii. Hospital number is enabled as a secondary unique field if the study involves patients in a hospital system (*Enable optional modules and customizations*)
    iv. To ensure the security of data housed within the REDCap server, users at different levels shall be granted the minimal amount of user rights as appropriate to their level so as to be able to complete their job duties within REDCap [See *Appendix B* for standardized user rights]. All research assistants, study PIs, and statistical analysis support will be added to the REDCap study, with roles according to their status in the project. If it is a multiple site study, data access groups should be created. If any of the involved individuals are not in the OAU REDCap system, the ARGO REDCap Administrator will follow the protocol for adding them [See *Adding Users to the OAU REDCap* section below] (*User rights and permissions, DAGs*)

2. To facilitate RAs in reporting weekly accrual statistics, the ARGO REDCap Administrator will create one or more necessary weekly reports based on details provided in the completed Study Initiation Form *(Data Exports, Reports, and Stats (My Reports & Exports))*
3. To ensure that all study personnel can access the study documents through a centralized platform, the ARGO REDCap Administrator will upload all documents attached to the Study Initiation Form into the file repository of the REDCap study. All questionnaires/proformas that are being used should be marked "(in use)", e.g., "Study questionnaire 01/01/2021 (in use).docx". In the case of confusion regarding which documents are being used to accrue patients or what regulatory documents are attached to the study, they can be accessed easily through this system by all parties *(File Repository)*

B3: Adding Users to the OAU REDCap

This is one of two tasks that will require support from the OAU REDCap Community Management Team. If a user that needs access to a database on the OAU REDCap system does not have an account on it, the ARGO REDCap Administrator will need to add them to the OAU REDCap system. To do this, he/she will contact the National Principal Investigator, who will liaise with the OAU REDCap Community Management Team and provide the user's name, surname, and email to ensure that they can be added to the OAU REDCap system. The same process will occur if a user is to be deleted from the OAU REDCap system.

B4: Technical Review Meeting

The ARGO REDCap Administrator will interface with the External REDCap Support throughout the building of the REDCap database, and will meet once the process is complete. This will provide a second look by another pair of eyes to minimize any errors and ensure a quality control in the form of a Technical Review Meeting. In addition, this technical meeting will serve to ensure that new databases are interlinked with already created databases, which is an overarching responsibility of external REDCap support.

B5: Desk Review Meeting

A meeting will occur between the ARGO REDCap Administrator, Research Assistants for the study, study Principal Investigator(s) and all other relevant stakeholders. It is highly recommended that an in-person meeting be undertaken and a desk review be conducted to check for possible errors. The meeting will be organized surrounding the following tasks:

i. Research Assistants confirm access to the REDCap
ii. Necessary changes to the soft-copy of the questionnaire will be explained to the Principal Investigator by the ARGO REDCap Administrator
iii. The final version of the questionnaire will be tested by each Research Assistant to ensure entry into the REDCap is working properly. Any changes needed to be made will be communicated to the ARGO REDCap Administrator to effect the corrections

B6: Moving Projects to Production

This is one of two tasks that will require support from the OAU REDCap Community Management Team. Having verified with the study PI whether they would like the test data deleted or not, the ARGO REDCap Administrator will proceed to move the project to production. To do this, he/she will contact the National Principal Investigator, who will liaise with the OAU REDCap Community Management Team to ensure that the project is accepted into production in a timely fashion.

B7: Modifying REDCap Database

Modifications to questionnaires may arise but should be approached with caution as not to render analysis of the study (data collected through more than one questionnaire) difficult for subsequent publication. It is strongly suggested that PIs discuss proposed changes between themselves and with biostatisticians that will do the analysis of the data. Furthermore, it is suggested that changes are made all in one go such that complications do not arise with changes in document versions and coordination between all parties.

1. The PI must present the proposed changes at an ARGO joint meeting for review and approval. (If PI is unable to present at a joint meeting due to timing, the PI will forward

the request and detailed explanation to Dr. Peter Kingham (kinghamp@mskcc.org) and Professor Isaac Alatise (segunalatishe@gmail.com) for review.

2. Once approval is received from Dr. Kingham and Professor Alatise, PI will send modification request with documented approval attached to the REDCap ARGO administrators: Taiwo and Matteo.
3. To make study changes that are incorporated on REDCap, a finalized (approved by all PIs) updated questionnaire with tracked changes should be provided to the ARGO REDCap Administrator, and if the study is to be expanded to other sites, the final section (Study Individuals) of the Study Initiation Form will be recompleted. [See *Study Initiation Request* section]
4. Once the study changes are submitted through the updated questionnaire, it will be reviewed and require express approval of the National Principal Investigator before modifications are to be made by the ARGO REDCap Administrator
5. The ARGO REDCap Administrator will make changes in REDCap draft mode:
    i. The questionnaire is built into a REDCap. The questionnaire will match with the REDCap build that is done, including appropriate headers and matching questions. If aspects of the soft copy questionnaire are omitted or unclear, the ARGO REDCap Administrator can make edits and track changes for further discussion with PI (*Design your data collection instruments*)
    ii. To ensure the security of data housed within the REDCap server, users at different levels shall be granted the minimal amount of user rights as appropriate to their level so as to be able to complete their job duties within REDCap [See *Appendix B* for standardized user rights]. All research assistants, study PIs, and statistical analysis support will be added to the REDCap study, with roles according to their status in the project. If it is a multiple site study, data access groups should be created. If any of the involved individuals are not in the OAU REDCap system, the ARGO REDCap Administrator will follow the protocol for adding them [See *Adding Users to the OAU REDCap* section] (*User rights and permissions*, *DAGs*)
6. The ARGO REDCap Administrator will objectively check the changes with the assistance of External REDCap Support. [See the *Technical Review Meeting* section]

7. The updated study documents will be saved in the REDCap. All questionnaires/proformas that are being used should be marked "(in use)", e.g., "Study questionnaire 01/01/2021 (in use).docx".
8. Once complete, the ARGO Management Team will ensure that the Research Assistants will stop using the "old" version of study questionnaire and that all previously administered questionnaires are entered into the REDCap.
9. Once the above is confirmed, the ARGO REDCap Administrator will push the study into production. [See the *Moving Projects to Production* section]
10. The PI will be contacted and will ensure that data collection resumes with the updated questionnaire.

C: Other REDCap Tasks

Beyond building and modifying REDCap databases, a number of other tasks will arise as part of REDCap maintenance. While this section provides a list of how these tasks are handled by various ARGO REDCap personnel, it is understandable that some tasks will fall outside of the previously outlined structure. To ensure communication and tracking of these tasks, they should be documented in the following Google Document when they come up: https://docs.google.com/document/d/1D9SMvnSZWXTtIh6BDx3Ys-2iN21a1EwG0qFSa_BLkR0/edit?usp=sharing

C1: Data retrieval

- Exports of full datasets or subspecific inquires will be executed solely by the ARGO REDCap Administrator to ensure high quality of data exports. The ARGO REDCap Administrator and other study builders are the only individuals with privileges to export data with patient identifiers
- The following specific details should be provided by an individual who has the appropriate credentials to view and access study data to the ARGO REDCap Administrator:

    - Export format (e.g., labeled/raw data csv, SPSS, Stata, R)
    - Filtering (e.g., patients younger than 40 years, post-menopausal patients)
    - Output (e.g., entire treatment instrument, patient phone number)
- All filtering and output will be done through the REDCap user interface to ensure that no modifications to the data are made in Excel or downstream by the ARGO REDCap Administrator, who will send the data to the requesting individual

C2: Data Quality Assurance:

To ensure quality data on all our REDCap databases, quality assurance (QA) will be done weekly and monthly. This will ensure that the consent document is in line with the consent section on the REDCap and that collected data is completely and accurately entered. For a weekly QA, the ARGO REDCap Administrator will review all newly created records, verifying that all consents are properly done and that the data is entered completely. The appropriate RA to rectify any issues discovered will be notified. On a monthly basis, the ARGO REDCap Administrator will export the data into an Excel file to be able to easily QA all of the datapoints that were entered into the REDCap database. The ARGO REDCap Administrator will highlight any records with issues and also notify the appropriate RA for necessary correction.

C2: Data Interlinking

Seeing that ARGO studies have often involved collecting data from the same patients as part of different studies, a system of interlinking patient records across studies has been built that interface through patient's unique hospital numbers. Given that datasets may remain in different REDCap systems (beyond OAU REDCap), data interlinking will be entirely the responsibility of external REDCap support, who will work closely with the ARGO REDCap Administrator to ensure that this is continued and regularly checked.

C3: Addition/Deletion of Users in a Study

The addition or deletion of users within a study (once they are added to the OAU REDCap system). This is the responsibility of the ARGO REDCap Administrator. The ARGO Management Team will keep the ARGO REDCap Administrator updated with which users are working on various studies in the system. Users in a study should be monitored regularly to ensure data safety.

C4: Importing a Study with Collected Data Outside of REDCap

Given that REDCap is a high-quality system for collecting, storing, and backing up data, keeping studies on REDCap is suggested over collecting data on other systems like Excel or SPSS. Therefore, the need may exist to move studies from these other data collection instruments to the OAU REDCap. This will be done by the ARGO REDCap Administrator and External REDCap Support. This involves a lot of data cleaning and restructuring and should be done with caution.

C5: Importing a REDCap Study Collected in Another REDCap System

Given that some ARGO data has been collected in other REDCap systems and could be moved to the OAU REDCap system, there could be the need to move REDCap databases from those systems to the OAU one. This will be done by the ARGO REDCap Administrator and External REDCap Support.

D: ARGO Data Protocols

Given the importance of properly collected biobanking and histology data, we provide protocols to collect these data types.

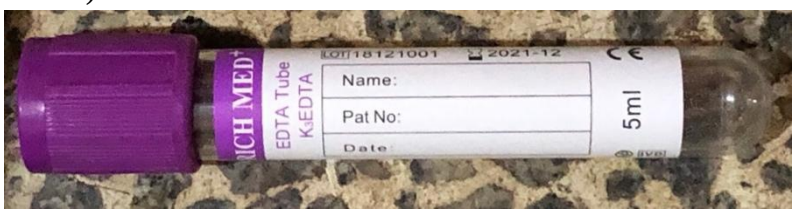
D1: ARGO Biobanking Data Protocol

This is applicable for all sites.

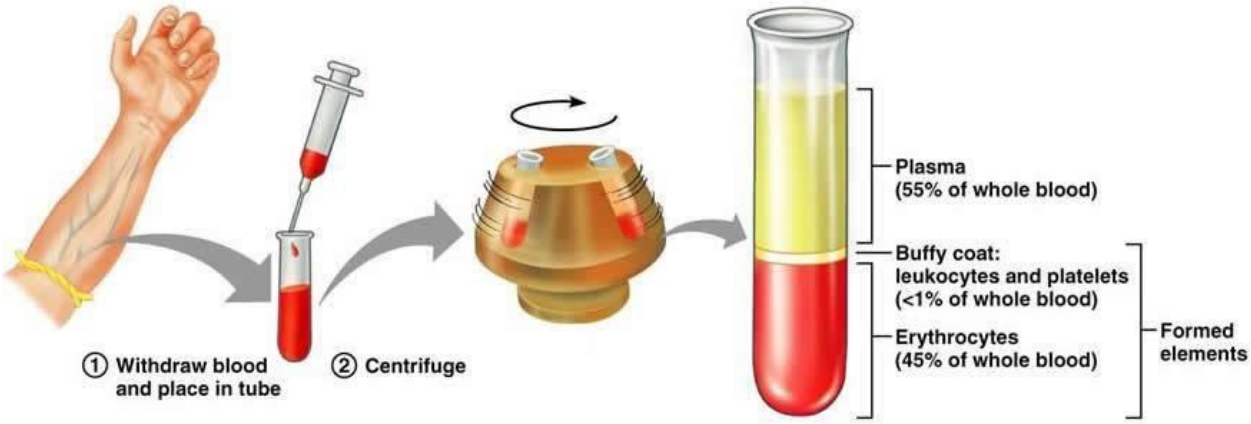
The purpose of this protocol is to standardize the collection of biobanking data for storage and documentation for ARGO databases for breast and colorectal cancer and related sub studies. The need for this emerges from a lack of standardized methodology for labeling sample data and storing data regarding these samples in REDCap databases. We propose a protocol to ensure that samples are labeled and data regarding these are collected for depositing into the ARGO database with ease, efficiency, and to lessen the burden on research assistants. Be reminded that gloves should be worn while collecting all specimen.

Blood collection (plasma / buffy coat):

1. With the help of the treating physician when the patient is first approached for entry into the study, collect 5mls of blood sample into the purple top bottle labelled EDTA bottle (anticoagulant bottle)



2. Transport EDTA bottle from collection point to the laboratory using ice pack or transport freezer
3. Allow to stand for 30 minutes to 1 hour at room temperature
4. Centrifuge for 15 minutes at 1,500 rpm



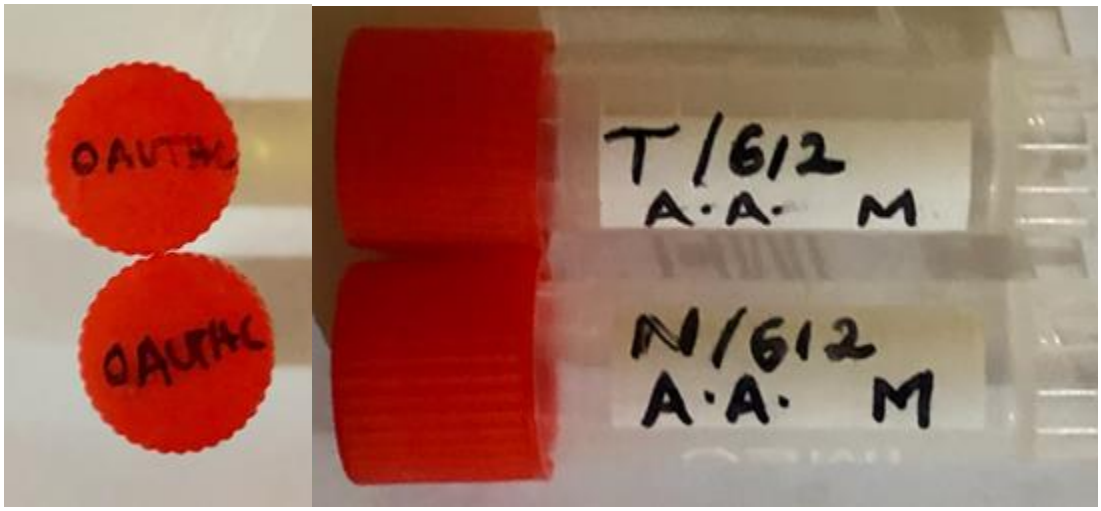
5. RedCap unique number *(including site code if present)*, Initial and Sex should be on the side of the bottles for both plasma and buffy coat. Label using a permanent marker while the vial is dry. Example: B/P (nature of specimen) for both Buffy Coat and Plasma respectively, 612 (RedCap number), AA (initials) M (sex). The top of the vial should contain the site name
6. Pipette aliquots of the first layer plasma supernatant into labelled cryovials / Eppendorf tubes (add P to label for plasma). Example: P/612, A.A., M
7. Then, pipette aliquots of second layer buffy coat supernatant into labelled cryovials / Eppendorf tubes (add a big B to label for buffy coat). Example: B/612, A.A., M

8. Discard remaining red blood cells
9. Arrange each into appropriately labelled PCR rack and store in the appropriately labelled compartment of the -80^{0}C freezer
    a. If a -80^{0}C freezer is not available, place tubes in a -20^{0}C and contact the appropriate ARGO management team.

Tissue collection (tumor / normal tissue):

1. As most patients are recruited prior to surgery, it is advisable to collect tumorous tissue from biopsy or colonoscopy in case the patient does not return for treatment at the study site
2. During surgery, operating physician will take tissue from the gross tumor tissue and from the specimen apparently appearing normal (far from the grossly tumorous tissue), and tumor tissue should be collected at this point even if tumorous tissue is collected during investigation
3. Transport fresh tissue(s) collected into labelled cryovial from respective collection point to the laboratory using ice pack or transport freezer
4. The warm and cold ischemic time (time of transportation) should be less than 30 minutes

5. <u>Label appropriate tube to be used while it is dry using a permanent marker. RedCap unique number *(including site code if present)*, Initial and Sex should be on the side of the bottles for both tumor and normal tissue.</u> Example: T/N (nature of specimen), 612 (RedCap number), AA (initials) M (sex). The top of the vial should contain the site name
6. Tumour tissue should be placed in labelled cryovials / Eppendorf tubes (add a big T to label for tissue). Example: T/612, AA, M
7. Normal tissue should be placed in labelled cryovials / Eppendorf tubes (add a big N to label for normal tissue). Example: N/612, AA, M



8. Arrange each into appropriately labelled PCR rack and store in the appropriately labelled compartment of the -80^{0}C freezer
    a. If a -80^{0}C freezer is not available, place tubes in a -20^{0}C and contact the appropriate ARGO management team contact

<u>Storage of Biobank data in REDCap</u>

- On patient-by-patient basis, research assistant will enter the data regarding biobanked samples numbers into the fields in the *Biobank* instrument for the study appropriate REDCap
- If the data is not collected at OAU, RAs are responsible for marking (for each type of sample collected):
    - Sample label
    - Number of samples collected (total)
    - Date of collection
    - Shipment status (to OAU)—to be changed if samples are shipped to OAU
    - Number samples remaining (at primary site)—to be changed if samples are shipped to OAU
- If the data is collected at OAU, RAs are responsible for marking (for each type of sample collected):
    - Sample label

    - Number of samples collected (total)
    - Date of collection
    - Shipment status (to MSK)—to be changed if samples are shipped to MSK
    - Number samples remaining (at OAU)—to be changed if samples are shipped to MSK
- For data not collected at OAU with samples shipped to OAU before sending to MSK, RAs are responsible for marking (for each type of sample collected):
    - Shipment status (to MSK)—to be changed if samples are shipped to MSK
    - Number samples remaining (at OAU)—to be changed if samples are shipped to MSK

Working with benign samples

- Complications have arisen with benign samples due to the fact that patients and their data are collected when physicians suspect a tumor to exist, and sometimes these tumors are found to be benign. Furthermore, replacing of samples has been found to be problematic due to two samples from separate patients being biobanked with the same ID number
- For each REDCap, results regarding benign histopathology diagnoses will be indicated in a column named "Is the result benign?" which is calculated based on the histopathology results entered in appropriate fields
    - Each REDCap will have a weekly report that among other things will easily tabulate the number of benign patients such that these can be reported weekly and subtracted from the total number of cases
- **For the purposes of biobanking, no samples will be replaced**

D2: ARGO Histology Data Protocol

This may not be applicable for all sites.

The purpose of this protocol is to standardize the collection of histology data into ARGO databases for breast and colorectal cancer. The need for this emerges from the fact that while research assistants find it easy to interface with patients at the point of treatment for the various aspects of data that they are collecting, getting histology data is difficult as it is accumulated through the pathology department such that records are not easily accessible to the research assistants. However, the (OAUTHC) pathology department is using an online database for the storage of histology reports that contains the valuable data that they collect, making the process for interfacing with this data essential. An issue that remains is that this database is only searchable by histology number, which makes the collection of this data a two-step process as seen below. We propose a protocol to ensure that data is collected for depositing into the ARGO database with ease, efficiency, and to lessen the burden on research assistants.

Retrieval of histology number

1. Patients will undergo a procedure that involves a sample being removed, such as:
    a. Biopsy
    b. Colonoscopy
    c. Surgical resection
2. The sample is given to the patient/patient's relative, who is expected to bring the sample to the pathology department
3. Before the patient/ relative brings the sample over to the pathology department, ARGO research assistants will explain that they should note their histology number and return to the hospital to collect the report of the procedure that was just undertaken. To motivate the patient/relative to return, the research assistants will explain that returning with this histology number will:
    a. Ensure that their patient's data is collected and stored for future requests as needed
    b. Explain that storing the patient data with ARGO can improve subsequent treatment as all records will be easily accessible
    c. Ensure quicker turnaround of pathology results
4. Once the patient arrives at the pathology department, the front office will collect the sample and issue a histology number in the following format: H number/year (e.g., for a sample collected in 2021: H123/21)
5. The patient will return to the department of surgery / ARGO office to receive the report of the procedure, which will be issued by the research assistant who will, in turn, collect the histology number.
6. A research assistant will go to the pathology lab once a week to collect the histology number of any patient that did not return with his histology number (e.g., inpatient that had surgery). The retrieval of histology numbers should be done before the weekly meeting of the organization and the data should be reported at the meeting.

Storage of histology data in REDCap

- On patient-by-patient basis, research assistant will enter the histology numbers into the fields in the *Histology* instrument for the study appropriate REDCap, having received it from the patient/patient relatives
- Two fields will be available for this in each REDCap (given that patients usually give two samples, maximum, for histopathological evaluation). For each sample, the research assistant will mark, in the REDCap, the histology number, and the type of sample that the histology number corresponds to
    - Biopsy
    - Colonoscopy
    - Surgical resection

Retrieval of histology data

On a strictly monthly basis, research assistants will pull out histology numbers for which histopathological data has not been collected, and provide an Excel table with the patient's name, the patient histology number, and, with labeled columns, any fields that need to be filled for that patient. This Excel table will be sent over to the records keeper of the pathology department. *Note: Samples will not be shipped if their histology numbers and associated data has not been gathered and entered into the REDCap*2. Given that the database is easily searchable by histology number, the records keeper of the pathology department will find it easy to enter all the requested data into the excel spreadsheet before sending it over3. The data will be entered into the main study REDCaps (breast and colorectal cancer). They will be linked to the sub-study REDCaps (e.g., WATi, R01) through the interoperability system that is set up. **For the purposes of histology data collection, it is important that samples that are benign are noted as such in appropriate fields.**

Appendix A: Study Initiation Form

Study details:

Study details need to be provided for regulatory purposes on OAUs REDCap servers. The study should have an adjacent institutional review board (IRB) approval.

- Project title _____
- Name of P.I. _____
    - First name _____
    - Middle Initial _____
    - Last name _____
- Email of P.I. _____
- Name of P.I. as cited in publications (e.g., Harris PA) _____
- IRB number _____
- PI phone number _____
- IRB approval expires _____

Attached documents:

Study documents should be provided to ensure that a REDCap can be built for the study. For questionnaire/proforma, all questions will be assumed to be open-ended unless response options are provided. If options are provided, the question will be assumed to be single response unless "(multiple response)" is noted on the question. This questionnaire/proforma should be as specific as possible to ensure that REDCap builders can quickly complete the creation of the REDCap.

- Updated IRB ☐
- Consenting professionals list ☐
- Standardized operating procedure for the study ☐
- Blank study documents that are administered:
    1. Eligibility checklist ☐
    2. Consent sheet ☐
    3. Questionnaire/Proforma ☐

Weekly reports:

All weekly reported statistics should be specified below so that REDCap builders can easily create a report for research assistants to keep track of study progress. This will ensure an easy method of maintaining progress reports towards research goals, assuming that research assistants will have entered all data into REDCap

- Weekly statistic (e.g., number of patients, number of tissue samples, number of patients with disease, etc.)
  - _____
  - _____
  - _____
  - _____
  - _____
- Category to separate by (e.g., data collection site, aim number)
  - _____
  - _____
  - _____
  - _____
  - _____

Study individuals:

All individuals that will work on the study should be noted below, with appropriate role noted as well in the last column. Additional rows can be added if necessary.

First name	Last name	Email	Study role (Data entry/research assistant, Principal investigator, Project manager)

Appendix B: Suggested User Rights

Standardized user rights or privileges are important to ensure the security of data housed within OAU REDCap database. To provide such security to the data on REDCap server, suggested user rights are shown in the table below. Additionally, note that the study PI must be consulted to ensure that privileges are in line with any data sharing agreement(s) that must be completed before granting project rights to external users.

REDCap Project Role	**Data Entry/ Research assistant**	**Principal Investigator**	**Project Manager**	**Study Builder**
Project Design and Setup		✓		✓
User Rights		✓	✓	✓
Data Access Groups		✓	✓	✓
Data Exports	No access	De-Identified*	Full Data Set	Full Data Set
Add/Edit/Organize Reports	✓	✓	✓	✓
Stats & Charts	✓	✓	✓	✓
Calendar	✓	✓	✓	✓
Data Import Tool		✓		✓
Data Comparison Tool		✓		✓
Logging		✓		✓
File Repository	✓	✓	✓	✓
Data Quality (Create & edit rules)		✓	✓	✓
Data Quality (Execute rules)		✓	✓	✓
API (API Export)		✓		✓
API (API Import/Update)		✓		✓
Create Records	✓	✓	✓	✓
Rename Records		✓	✓	✓
Delete Records		✓	✓	✓
Lock/Unlock Records (instrument level)	Disabled	Locking/ Unlocking	Locking/ Unlocking	Locking/ Unlocking
Record Locking Customization		✓		✓

Lock/Unlock *Entire* Records (record level)		✓		✓