IRB Application Instructions for Distribution of **Identified** Data from the UNC Metastatic Breast Cancer Clinical Database

*Principle investigators and research coordinators wishing to use the UNC Metastatic Breast Cancer Clinical Database for research purposes may copy this language for their IRB applications*

**2. Project Personnel**

Add the following database managers to your study as research assistants:

* Julia Benbow
* Amy Garrett
* Juanita Ramirez

**A.1. Background and Rationale**

A.1.1 Provide a summary of the background and rationale for this study.

UNC Lineberger Comprehensive Cancer Center has established a UNC Metastatic Breast Cancer Clinical Database in an effort to track patient demographics, pathology, evolution to metastatic disease, metastatic treatments, and clinical trial enrollment since 2012. In this clinical database, all metastatic patients seen by the UNC Breast Center are abstracted and updated at 6 month intervals. The clinical database is maintained on REDCap which is a free, secure, web-based application designed to support data capture for clinical research; the REDCap database is supported at UNC by NC TraCS and grant support from Dr. Claire Dees (Susan G. Komen Foundation) and Dr. Carey Anders (Damon Runyon Foundation). The primary purpose of the database is to help the UNC breast team make clinical decisions for treatment of breast cancer patients at UNC. The database itself does not inform research at UNC. However, use of the clinical database, a rich data source, for research is permissible with an IRB approval and appropriate sign off from the Office of Clinical/Translational Research.

There will be no direct contact with patients from the UNC Metastatic Breast Cancer Clinical Database.

**A.4. Study Design, methods and procedures**

A.4.2 Describe the study Design.

Patients diagnosed and treated for metastatic breast cancer at UNC Chapel Hill will be identified through the UNC Metastatic Breast Cancer Clinical Database, a database managed by the Office of Clinical/Translational Research at UNC. The clinical database will be queried by the database managers.

**A.6. Risks and measures to minimize risks**

A.6.1 Psychological

X – Consequences of breach of confidentiality (Check and describe only once on this page)

A.6.2 Describe any items checked above and what will be done to minimize these risks

The risks of breach of confidentiality is rare. Only necessary research personnel listed in this protocol will have access to the identifiable dataset provided by the database managers of the clinical database. Only SOM approved computers protected by ONYEN usernames and password will be used for the collection and processing of the data provided by the database managers. Study data available over a network connection will only be accessed from within a secure network. Computers storing or accessing study data will have appropriate antivirus/antispyware installed and regularly updated.

Confidential research information will not be released to anyone who is not a member of this research team.

**A.9. Identifiers**

A.9.2. For any identifiers checked, how will these identifiers be stored in relationship to the research data?

X – Separate from the research data

Provide details about the option you selected above

Only the database managers for the UNC Metastatic Breast Cancer Clinical Database will have access to the entire clinical database which contains patient information abstracted from medical records. At the request of the investigators of this study, the database managers will pull identifiable data from the clinical database for distribution to the study team. The identifiable dataset will only by analyzed for the stated purposes of this study and will only be viewed by IRB-approved study personnel identified in this application.

**A.10. Confidentiality of the data**

A.10.1 Describe procedures for maintaining confidentiality of the data you will collect or will receive.

Only necessary research personnel listed in this protocol will have access to the dataset provided by the database managers of the clinical database. Only SOM approved computers protected by ONYEN usernames and password will be used for the collection and processing of the data provided by the database managers. Study data available over a network connection will only be accessed from within a secure network. Computers storing or accessing study data will have appropriate antivirus/antispyware installed and regularly updated.

A.10.2 Describe how data will be transmitted among research team.

Identifiable data provided by the clinical database database managers will be transmitted between study personnel in meetings, via encrypted hard drives or via secure UNC email accessed through a secure network.

Data will be released to investigators of this study by the database managers; the personnel listed in this IRB application will have access to the identifiable data.

**A.12. Post-study disposition of identifiable data or human biological materials**

A.12.1 Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. If you plan to destroy linkage codes or identifiers, describe how and when this will be done.

The database used for this study, the UNC Metastatic Breast Cancer Clinical Database, is not specifically for this project and so will not be destroyed after the project is finished. We will not make any separate lists or repositories of identifying information.

**C.1 Existing Data, Records, Specimens**

C.1.1. What existing records, data or human biological specimens will you be used?

X – Data already collected for administrative purposes

For each data source check above, provide a description of the data, proposed use, how data were collected and where data currently reside.

The UNC Metastatic Breast Cancer Clinical Database is a clinical database that tracks patient demographics, pathology, evolution to metastatic disease, metastatic treatments, and clinical trial enrollment; all metastatic patients seen by the UNC Breast Center are abstracted and updated at 6 month intervals. The UNC Metastatic Breast Cancer Clinical Database is controlled by the Office of Clinical/Translation Research.

C.1.2. Describe your plans for obtaining permission from the custodians of the data, records or specimens

The database managers of the UNC Metastatic Breast Cancer Clinical Database will provide the Investigators of this study with an identifiable data set for only those patients meeting all of the eligibility criteria for this study. The data set provided by the database managers of the UNC Metastatic Breast Cancer Clinical Database will include data from only the variable identified in advance by the Investigators and deemed pertinent to the analysis of this study. The dataset will only by analyzed for the stated purposes of this study and will only be viewed by IRB-approved study personnel identified in this application.

The database managers will have the Investigator complete an OCTR Data Use Agreement that will outline how the Investigator can use the identifiable data set that will be provided. The OCTR Data Use Agreement has been added to this IRB application in the Attachments section. The database managers have been added to this application as study personnel.

C.1.3. Do the custodians of the data, records or specimens require a data use agreement?

Yes

**C.2. Coding and Data Use Agreements**

C.2.1 When you receive these data, records or human biological specimens will they be codes?

No

**Attachments**

Upload the completed OCTR Data Use Agreement.

**Coversheet**

The database managers will have the Investigator complete an OCTR Data Use Agreement that will outline how the Investigator can use the identifiable data set that will be provided. The OCTR Data Use Agreement has been added to this IRB application in the Attachments section. The database managers have been added to this application as study personnel.