

This form is for projects using pre-existing data from an approved data source at GWU, GWU-MFA or GWU-Hospital.

PROJECT TITLE:

*(Enter title of protocol-use BOLD type, but not all CAPS-title should match all other applications-grant, IRB, etc.)*

**PROJECT VERSION DATE:**

***(Begin with version 1 and the date. Change the date as you revise the protocol. [Suggestion: do not use the automatic update feature])***

**PRINCIPAL INVESTIGATOR:**

***(Include titles and contact information)***

**CO-INVESTIGATOR(S):**

 ***(Include titles and department)***

**SPONSOR and COLLABORATORS:**

***Please list any company, academic center or other organizations that are involved in the project and a brief description of that role.***

**COORDINATOR:**

***(Include titles)***

# BACKGROUND

***This should be brief but allow a quick understanding of the rationale and relevance of the project. References to literature and data that are relevant to the project, if desired, may be cited at the end of the document.***

# STUDY PURPOSE AND HYPOTHESIS

The primary objective of this project is……

***(Include a brief description of the objectives***)

The secondary objective**(s)** of this project is/are

***(Include a brief description of the secondary objectives)***

#  SELECTION OF SUBJECTS

(**examples provided below** - please use only the appropriate statements below.

Clearly document that the data selected for this study are available or feasibly obtained. This could include confirmation of data availability from the Institution)

This is a request for data stored at ***(GWU, GWU-MFA, GWU Hospital, etc)***

# Inclusion Criteria for participant selection includes the following:

1. ***Please be sufficiently detailed to allow the appropriate identification of tissues for your pilot project.***

(example: ductal breast cancer

* + - * ER/PR and Her2 negative
		- Metastatic site is bone
		- Patient age is 60 or greater
		- Diagnosed between 2010 to 2019

# Exclusion Criteria:

1. (example: ductal CIS or non-invasive)

2.

**RESEARCH PROCEDURES:**

**(Describe what you will do specifically)**

***(Describe briefly the research procedures you will use for this study, such as data coding and statistical analyses that will be used.***

The timeline for this research is ***(give estimated time needed to conduct project)***

**RISKS:**

There are no risks to the patients, as all information linked to the patient will be protected and de-identified. Patients will not be identified in any published articles**.**

***Participant privacy***

***Will any identifiable information about the participants be requested? The investigator should only request the information that is absolutely necessary for this particular study.***

***Select one of the following paragraphs to describe your tissue/data requests and delete the ones that do not fit this study.***

* 1. ***Anonymous:***

The dataset will remain **anonymous** and will be stored without any identifying data such as name, medical record number, initials, or date of birth.

* 1. ***De-identified:***

The Dataset will be **de-identified**, but will retain limited amounts of clinical data (age, sex, race, diagnosis) that can not be linked to the patient.

* 1. ***Linked/Coded:***

The dataset will be stored with individual information, but will be **linked or coded** so as to protect confidentiality

* 1. ***Identifiable:***

The dataset will retain personally **identifiable** information; the participant is identifiable due to the size of the specimen pool or rarity of a trait.

**CONSENT PROCESS**

All patients and data will be already existing and will be obtained through the appropriate GWU, GWU-MFA, GWU-Hospital resource. A waiver of consent/authorization will be requested by the IRB if this project is considered Human Subject Research.

**SHARED INFORMATION –use only when outside data are to be used, or data are sent outside GWU, GWU-MFA, GWU-Hospital.**

***(You must have an agreement in place to send tissue or data to a third party [outside of GWU, GWU-MFA, GWU-Hospital.***

Data will be sent to:

***(Give exact information for destination of the data; address, phone number, who will receive them and what will happen with them). List all outside parties who will receive the data.***

 **Data** will be received from

 ***(List any investigator’s name and address who will send data to GWU, GWU-MFA or GWU-Hospital. What will happen with the data once it arrives at GWU, GWU-MFA, GWU-Hospital? Will the data be de-identified?) List all outside parties who will send data to you.***

**FUNDING for RESEARCH:**

**(Who is paying for this research? Grant, pharmaceutical company, other?)**

**CITED REFERENCES (not necessary, but if preferred):**