Study Summary for Basic Science Group Exempt IRB Applications

A. For the overall study, please:

1. Identify who will be the overall PI for the group application (only one PI may be named on the IRB application; all others will be named as Co-Investigators). **Please note: all investigators must have current HIPAA and CITI training.**

2. Suggest an overall, broad title for the study (e.g., "Study of Markers in Human Breast Tissue")

3. From the list below, check the disease site(s) the protocol is studying.

Please Note: If the protocol is studying multiple disease sites, check each one that is being studied. If the protocol is studying ANY disease site or non-specified disease sites, check "Any Site". If the site being studied is not listed, check "Other". If the subjects being studied do not have disease, check "No Disease", and if some of the subjects have disease and some do not, check "No Disease" as one of the Disease Sites.

- ☐ Anus
- ☐ Bladder
- ☐ Bones and Joints
- ☐ Brain and Nervous System
- ☐ Breast - Female
- ☐ Breast - Male
- ☐ Cervix Uteri
- ☐ Colon
- ☐ Corpus Uteri
- ☐ Esophagus
- ☐ Eye and Orbit
- ☐ Hodgkin's Lymphoma
- ☐ Kaposi's sarcoma
- ☐ Kidney
- ☐ Larynx
- ☐ Leukemia, Other
- ☐ Lip, Oral Cavity and Pharynx
- ☐ Liver
- ☐ Lung
- ☐ Lymphoid Leukemia
- ☐ Melanoma, skin
- ☐ Multiple Myeloma
- ☐ Mycosis Fungoides
- ☐ Myeloid and Monocytic Leukemia
- ☐ Non-Hodgkin's Lymphoma
- ☐ Other Digestive Organ
- ☐ Other Endocrine System
- ☐ Other Female Genital
- ☐ Other Hematopoietic
- ☐ Other Male Genital
- ☐ Other Respiratory and Intrathoracic Organs
- ☐ Other Skin
- ☐ Other Urinary
- ☐ Ovary
- ☐ Pancreas
- ☐ Prostate
- ☐ Rectum
- ☐ Small Intestine
- ☐ Soft Tissue
- ☐ Stomach
- ☐ Thyroid
- ☐ Any Site
- ☐ No Disease
- ☐ Other (Specify)

4. Check the multidisciplinary departments or shared services that will be collaborating with you on your study:

- ☐ 3P Lab
- ☐ PRC
- ☐ Radiology
- ☐ CRU
- ☐ Pathologist
- ☐ Biostatistician
- ☐ TSB BioBank
- ☐ Radiotherapy
- ☐ Radiopharmaceuticals
- ☐ N/A

B. For <u>each project</u> within the overall study, please answer the following questions for details to be included in the IRB application and PRMC required protocol. Be expansive / general enough, particularly with explanation / rationale and with requests for materials, such that you will cover potential future experimental goals without having to submit amendments. Be brief in project purpose, aims, background and description.

1. Provide the name of the project PI and a project title.

2. Provide names of other key personnel to be listed on the study team. (Note: All study team members need to complete HIPAA and CITI Human Subjects training)

3. What is the overall purpose of this project? (Emphasize cancer-relatedness, and general goal - e.g. to provide a biomarker, or a mechanistic insight, into primary disease)

4. What are the specific aims of this project or study? (Scope of a grant)

5. Background: what prior information or knowledge exists to support the conduct of this research? (Include a few references)

6. Briefly describe the procedures and interventions that will be performed for this research. (This piece will include details of the samples and clinical data set you wish to obtain, and any specific patient set(s) your research needs)

7. What are the prospective benefits of the proposed research?

8. Will there be funding to support the research? Please provide fund account numbers. (This is just to answer questions on the IRB application and PRMC protocol number request form.)

9. Is there any Conflict of Interest, as defined in Attachment 1 below? If yes, please describe.

10. Is there any association with the VA Hospital, as defined below?

☐ There are key personnel engaged in human subjects research for this project or study under their Madison VA (Wm. S. Middleton VA Hospital) appointment.
☐ The study or project enrolls, uses specimens obtained from, or involves the use of medical records of Madison VA (Wm. S. Middleton VA Hospital) patients.
☐ The study or project uses Madison VA (Wm. S. Middleton VA Hospital) facilities (i.e., space that is not rented by the University).
☐ The project or study is supported by VA funds.

11. Where will the research be performed?

12. Please indicate which of the following categories of exemption your project falls under:
☐ **Category 1: Research in educational settings.**
Research conducted in established or commonly accepted educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2: Research involving the use of educational tests, surveys, interviews.**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is

recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ **Category 3: Research involving the use of educational tests, surveys, interviews with public officials, or required by federal statute.**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category 2 above, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ **Category 4: Research involving existing data or specimens.**
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ **Category 5: Demonstration projects.**
Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6: Taste and food quality evaluation and consumer acceptance studies.**
(i) If wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ **Not Research. (e.g., quality improvement/quality assurance, program evaluation)**
IRB oversight of the project is not required because it does not meet the definition of research in 45 CFR 46.102(d) which defines 'research' as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Examples of projects that may not be research include quality improvement programs or required program evaluations that will not be published or disseminated formally.

☐ **Not Human Subjects.**
IRB oversight of the project is not required because it does not involve human subjects as recognized by 45 CFR 46.102(f) which defines a 'human subject' as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Attachment 1

Conflict of Interest (COI)

1. Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a financial interest in an entity that (a) sponsors the study or (b) owns or licenses technology tested or evaluated in the study (including any agent, device, or software) that meets or exceeds one of the thresholds below:

(a) Compensation of $20,000 or more in a calendar year from a publicly traded or privately held business entity
(b) An ownership interest in a publicly traded business entity valued at $20,000 or more or a 5% or greater equity interest
(c) Any ownership interest in a privately held business entity whatever the value
(d) A combination of compensation and ownership interest in a publicly traded business entity valued at $20,000 or more
(e) A leadership position in a business entity (Leadership positions are positions with fiduciary responsibility, including senior managers (e.g., presidents, vice presidents, etc.) and members of boards of directors). Scientific advisory board membership is not a leadership position

☐ **Yes** ☐ **No**

1.1 If yes, identify the personnel who have this interest, and upload the COI management plan(s).

2. Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a proprietary interest in the research, such as royalties, patents, trademarks, copyright, or licensing agreement, that is relevant to this research study (including any agent, device, or software being evaluated as part of the research study)? NOTE: If this proprietary interest is managed through WARF, select Not Applicable.

☐ **Yes** ☐ **No** ☐ **Not applicable**

2.1 If yes, identify the personnel who have this interest, and upload the COI management plan(s).

3. Do ANY of the study team involved in the design or conduct of the research study have a financial interest that requires disclosure to the sponsor or funding source?

☐ **Yes** ☐ **No**

3.1 If yes, identify the personnel who have this interest.

4. In addition to the sponsor(s) of this study or project, are other companies or business entities involved or potentially affected in a significant way by this study or project?

☐ **Yes** ☐ **No**

4.1 If yes, list those companies/business entities, and describe the nature of each company/business entity's involvement.

5. Do ANY of the study team involved in the design or conduct of the study or project have any other financial interest that the investigator believes may interfere with his or her ability to protect subjects?

☐ **Yes** ☐ **No**

5.1 If yes, identify the personnel who have this interest.

6. Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

☐ **Yes** ☐ **No**

6.1 If yes, describe the nature of the incentive.