# APPENDIX J:
# REQUEST FOR EXEMPT STATUS

**Ashford University Institutional Review Board**

If you are requesting to use Ashford University data, you must secure approval from the Office of Research and Creative Scholarship (ORCS@ashford.edu) before applying to the IRB. Please contact your College Research Fellow to obtain the appropriate application.

If you are requesting ASHFORD UNIVERSITY data, have you obtained approval from ORCS?

___ Yes ___ No

Completion and approval of this form required **prior** to collection of ANY data.

Title of Proposed Research: _____

Principal Investigator: _____

Co-Investigator(s): _____

Committee Chair acting as PI (for student research): _____

Program or Department: _____

If student, ID #: _____ Email address: _____

Preferred Telephone Number: _____

Type of research proposed (Check all that apply): ___ Student ___ Faculty ___ Staff

Does the proposed research include data taken from any person or entity affiliated with Ashford University?

___ Yes ___ No

*If yes, include the completed, required form granting permission to collect data from Ashford University.*

Has the proposed research received approval from another IRB or entity responsible for data collection in the planned study (for example, a school district or corporate IRB)?

___ Yes ___ No

*If yes, include copies of any communications authorizing data collection for the planned study.*

Do the proposed participants include minors?

___ Yes ___ No

*If yes, include copies of consent forms for the appropriate parents or guardians, and age appropriate assent forms for the minors involved in the proposed study.*

Please attach or enter a description of the proposed research design, including variables, planned steps in measurement, and any steps planned to ensure the protection and confidentiality of study participants (should be approximately 200 words). Also, be sure to complete and submit the required research summary form.

Is this project currently sponsored?

___ Yes ___ No

*If yes, describe the source:*

Will you be collecting or sharing Protected Health Information?

___ Yes ___ No

Have you completed the Human Participants online training?

___ Yes ___ No

(http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp)

*If yes, please attach your Completion Certificate.*

Conflicts of Interest include:

- Stock (holdings or options) in a sponsoring organization
- Director, advisor, or consultant to a sponsoring organization
- Other vested interests such as the inventor and/or patent holder of the drug, procedure, technique, device, or software being tested.

Does the PI or any Co-PI have an actual, potential, or perceived conflict of interest as included above?

___ Yes ___ No

*If yes, please list*:

Please check the anticipated level of risk below to human participants in proposed research (Levels 3 & 4 must be reviewed by the full IRB Committee):

___ **1-NO RISK**

*No risk* means that the study has no social, psychological, or physical danger to participants.

___ **2-MINIMAL RISK**

*Minimal risk* means that the probability of harm or discomfort anticipated in the research are not greater than those ordinarily encountered during daily life or the performance of routine physical or psychological examinations or tests.

___ **3-MODERATE RISK**

*Moderate risk* means that the risk to participants is beyond what would normally be experienced in a typical day. Study may involve intrusive questions or procedures, or use protected populations. (e.g., infants, prisoners, etc.).

___ **4-HIGH RISK**

*High* risk means that participants may be exposed to risk that may have lasting psychological or physical consequences.

The principal investigator, student supervisor, or chair must affirm the following and sign below.

**Scientific misconduct shall be considered to include:**

- Data collection prior to obtaining IRB approval
- Fabrication, falsification, plagiarism, or other unacceptable practices in proposing, carrying out, or reporting results from research.
- Material failure to comply with federal requirements for the protection of human participants, researchers, and/or the public.
- Failure to meet other material legal requirements governing research.
- Failure to comply with established standards regarding author names on publications.
- Failure to adhere to issues of patient confidentiality as provided in the participant. consent form, the study protocol, and as outlined in the Code of Federal Regulations (45 CFR 46).

**Investigator's Continuing Responsibility to IRB**

Once the protocol has been approved, it is the principal investigator's (PI) responsibility to

- Report changes in research activity related to the project.
- Provide the IRB with all protocol and consent form amendments and revisions. IRB must approve these changes prior to their implementation. All advertisements recruiting study participants must also receive prior approval by the IRB.
- Promptly report all adverse and serious adverse events (including death, hospitalization or prolongation of hospitalization, and unanticipated adverse side effects).
- Renew protocols with the IRB prior to expiration. All projects must have a continuing review at least annually to renew the approval for the protocol. Some projects will have the continuing review more frequently as determined in the initial review and approval.
- Notify the IRB if the protocol is complete.

***Failure to comply with these federally mandated responsibilities may result in suspension or termination of the project.***

**Investigator Acknowledgment**

I have read the definitions of Scientific Misconduct and listed all potential Conflicts of Interest. I have read the Investigator's Continuing Responsibilities to the IRB. I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB. My signature below attests to my agreement to conduct this research study in such a manner that acts of scientific misconduct and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the Ashford University IRB. I will conduct my study in compliance with the Ashford University *IRB Handbook*.

Signature of Principal Investigator: _____ Date: _____

**If the research is part of a student project or thesis**,

Printed Name of Chairperson or Supervisor: _____

Signature: _____

**********

**ADMINISTRATOR USE ONLY**:

Date Received _____ No. _____ IRB Reviewer: _____

Due Date: _____Risk Level: _____

_____ Research proposal approved on (date) _____ until _____ **(*approval expires in one year)***.

[Researcher is responsible for renewal procedures if project extends past this date.]

_____ Research proposal requires modifications before approval, to be given final verification by _____ (Reviewer, IRB Chair, Research Office). Describe modifications below or attach a separate sheet.

_____ Research proposal disapproved, the potential benefits of the research do not outweigh the risks to the participants.

Signature of IRB Reviewer: _____ Risk: _____

Assessment Date: _____

(Do not sign if significant modifications are required.)

## PART 2 - Exemption Category Self-Assessment

While the IRB is ultimately responsible for deciding if research qualifies for exemption, investigators are asked to make an initial determination of the appropriate exemption category.

Please check the category you feel applies to your work.

☐ **Observation of public behavior**

*For minors/children*: Observation of public behavior of minors is eligible for exemption only if the researcher does not participate in the activities being observed and participants cannot be identified directly or indirectly.

*For non-minors*: Generally considered exempt from IRB review as follows:

a. If the information is recorded in a manner that individuals cannot be identified (directly or through identifiers linked to the individual), OR

b. If the information may be recorded in a manner that individuals can be identified (directly or through identifiers linked to the individual), but disclosure of the information could NOT reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation[1].

☐ **Research involving the collection or study of existing data, documents, records, and information** (i.e., existing before the request for exemption is submitted to the IRB to determine whether the research is exempt)

Sources must be listed as publicly available[2].

***Finally, in addition to this request form, PI's must also submit a list of research questions being examined by their project along with a complete methodology if they wish to be considered for exempt status.***

[1] Risks of criminal or civil liability, or of damage to financial standing, employability, or reputation can be dependent on the context of the research and are determined by the IRB Committee based on experience, past precedent, and bench marked best practices. The IRB welcomes the input of investigators in determining the possibility of such risks, but if there is reasonable doubt about whether or not criteria b. applies, the research is not exempt.

[2] Example: A PI who receives access to historical information, may be eligible for exemption under this category if s/he is not recording identifiable private information into her/his own research records and is not merging datasets that may lead to identification of individuals or their families that may cause those identified to be at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation. However, PIs should be advised that the owner of the information or funding agency may have their own policies requiring IRB review.