Department of Pathology and Laboratory Medicine Project Proposal Form *(v.1.2)*

Contact information:

General questions: Histology Research: Alexa Buskey, Alexa.Buskey@uvmhealth.org, 847-7973; Allison Ciolino, Allison.ciolino@uvmhealth.org, 802-847-2469.

> ### Instructions
> **1. Complete PARTS 1 & 2(A-C)**
> **2. Meet with Statistician (PART 2D)**
> **3. Complete PARTS 2 (E-G)**
> **4. Submit completed Proposal**

PART 1: Basic Study Information and Projected Impact

1. **Draft / Modification Date**:

2. **Title of study:**

3. **Initiating Investigator(s**) (name, address, phone and fax numbers, e-mail address):

4. **Other Departmental Co-Investigators:**

5. **Project timeline**:

6. **IRB approval (Y/N/NA)**:

7. **Does this effort exceed your current allocation of time for academic activities? (Y/N, if Y please elaborate):**

8. **Does this project require Department funds? (Y/N, if Y complete HRS Budget Form):**

Has this study already been approved by a peer review group for scientific validity (e.g. UVM Cancer Center, multi-institutional collaborative group, competitive intra- or extra mural grant review committee)? Please check box.
No ☐ Continue to Part 2.

Yes ☐ Provide an Abstract (described below) and copy of approval (letter, form, email or grant information, if applicable). DO NOT COMPLETE PART 2.

PART 2: Description of the Proposed Ancillary Study

*Please provide a **brief (maximum 2 pages not including any citations)** description of the proposed study. Include the following:*

A.   Abstract

Summarize background information and literature, and state how they lead to the question(s) of interest. Include a concise justification and explanation of the research question(s) to be addressed. End by stating the general aim of the study and briefly mention the method(s) that will be used to address the question(s) and the impact.

B.   Background and Rationale and Impact

Provide the details of the background information summarized in the Abstract paragraph. Explain what information is missing in the literature, and how the proposed study will address that gap. Finally, explain how the methods and/or information you collect will address the study question(s). Acknowledge any limitations or concerns related to the proposed methods, and explain how they have been or will be dealt with.

C.   Specific Aims

Detail the research question(s) and hypothesis(es) to be addressed by the study.

D.   Statistical Preparation Analysis:

Meet with statistician, Joan Skelly, MS (joan.skelly@uvm.edu) to prepare statistical analysis and data collection plans. This step must be completed before moving onto E, F and G.

Please initial that you have met with Joan Skelly:_____

E.   Methods

1) Study Population
      Describe the samples or people of interest and indicate the number of samples or people being studied. Include the anticipated time frame of participant involvement (if any).

2) Data Collection
      Describe information to be collected and any methods or equipment to be used. Explain how the information you collect will address the question(s) of the study.

3) Statistical Analysis
      Explain how each study hypothesis (from section 3 - Specific Aims) will be addressed with respect to data analyses and statistical approach. Include any current hypotheses or information that might influence the approach to the analysis or the question itself.

F.   Sample Size Calculations

Explain why you've chosen to study the designated number of samples or people.

G.   Literature References

Committee approval sign off:_____