

# Appendix K

## BACONE COLLEGE

### Request for Designation of Research as Exempt from the Requirement of Institutional Review Board Review

(11/14/2019)

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THIS AREA IS FOR INSTITUTIONAL REVIEW BOARD USE ONLY. DO NOT WRITE IN THIS AREA.

Confirmation Date:

Application Number:

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DATE: \_\_\_\_\_

#### I. PRINCIPAL INVESTIGATOR(s):

Name:

Complete Department and/or Home Address (where you want the approval letter sent):

Telephone:

E-Mail Address:

DATE TRAINING COMPLETED: \_\_\_\_\_ [Suggested training: CITI training; see website for link]

Name of Faculty Sponsor (if above is a student; this is suggested complete CITI training):

SIGNATURE (INVESTIGATOR or ADVISOR): \_\_\_\_\_

(If more than one investigator, repeat information for all investigators or team members.)

#### II. TITLE OF RESEARCH PROJECT: (Try to keep title on first page.)

III. BRIEF DESCRIPTION OF RESEARCH METHODS (also see section VII). If using a survey/questionnaire, provide a copy with this application.

#### IV. RISKS AND INCONVENIENCES TO SUBJECTS (also see section VII; **do not answer 'None'**):

#### V. SUBJECTS:

A. Expected numbers of subjects: \_\_\_\_\_

B. Will research involve minors (age <18 years)? Yes No  
(If 'Yes', please specify and justify.)

C. Will research involve prisoners? Yes No

D. Will research involve any specific ethnic, racial, religious, etc. groups of people?  
(If 'Yes', please specify and justify.) Yes No

- E. Will a consent form be used? (Please use the accepted format from our website. Be sure to indicate that participation is voluntary. Provide a stand-alone copy. Do not include the form here.)

VI.FOR RESEARCH INVOLVING SURVEYS OR QUESTIONNAIRES:

(Be sure to indicate on each instrument, survey or questionnaire that participation is voluntary.)

A.Is information being collected about:

Sexual behavior?Yes No

Criminal behavior?Yes No

Alcohol or substance abuse?Yes No

Matters affecting employment?YesNo

Matters relating to civil litigation? YesNo

- B. Will the information obtained be completely anonymous, with no identifying information linked to the responding subjects? YesNo

- C. If identifying information will be linked to the responding subjects, how will the subjects be identified? (Please circle or bold your answers)

By nameYesNo

By codeYesNo

By other identifying informationYesNo

- D. Does this survey utilize a standardized and/or validated survey tool/questionnaire? YesNo

VII.FOR RESEARCH BEING CONDUCTED IN A CLASSROOM SETTING:

- A. Will research involve blood draws? (If Yes, please follow protocol listed in the "Guidelines for Describing Risks: blood, etc.", section I-VI.)

VIII. FOR RESEARCH INVOLVING PATIENT INFORMATION, MATERIALS, BLOOD OR TISSUE SPECIMENS RECEIVED FROM OTHER INSTITUTIONS:

A.Are these materials linked in any way to the patient (code, identifier, or other link to patient identity)?Yes No

B.Are you involved in the design of the study for which the materials are being collected?  
Yes No

C.Will your name appear on publications resulting from this research?  
Yes No

D. Where are the subjects from whom this material is being collected?

E.Has an IRB at the institution releasing this material reviewed the proposed project?  
(If "Yes", please provide documentation.)Yes No

F.Regarding the above materials or data, will you be:

Collecting themYes No

Receiving themYes No

Sending themYes No

G.Do the materials/instrument already exist?Yes No

H. Are the materials/instrument being collected for the purpose of this study? Yes No

I. Do the materials come from subjects who are:

Minors Yes No

Prisoners Yes No

Pregnant women Yes No

J. Does this materials/instrument originate from a patient population that, for religious or other reasons, would prohibit its use in biomedical research?

Yes No Unknown source

#### IX. FOR RESEARCH INVOLVING MEDICAL AND/OR INSURANCE RECORDS

A. Does this research involve the use of:

Medical, psychiatric and/or psychological records Yes No

Health insurance records Yes No

Any other records containing information regarding personal health and illness Yes No

If you answered "Yes" to any of the items in this section, you must complete the HIPAA Worksheet.