Appendix L

Full Committee Review □
Expedited Review □

BACONE COLLEGE

Institutional Review Board Application for Review

(11/15/2019)

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

Application Number: Approval Date:
Disapproved: IRB Chair's Signature:

****

Date:

I. Investigators and Associates (list all investigators involved; application will be filed under name of first person listed)

NAME: TITLE:
DEPT: PHONE #:
Complete Department and/or Home Address (where you want the approval letter sent):
E-MAIL ADDRESS:
DATE TRAINING COMPLETED: _____ *[Suggested training: CITI Training; see website for link]*

SIGNATURE (PI or ADVISOR): _____

NAME: TITLE:
DEPT: PHONE #:
COMPLETE ADDRESS:
E-MAIL ADDRESS:
DATE TRAINING COMPLETED: _____ *[Required training: CITI Training; see website for link]*

(repeat for additional investigators if needed; or delete extra if not necessary)

Do you as PI, any family member or any of the involved researchers or their family members have consulting agreements, management responsibilities or substantial equity (greater than $10,000 in value or greater than 5% total equity) in the sponsor, subcontractor or in the technology, or serve on the Board of the Sponsor? _____ YES _____ NO

If you answered Yes, you will need to contact Kellie Peterson, Legal Counsel-JD at

406-994-3480.

II. Title of Proposal: *[please try to keep title on front page; use smaller font and delete excess lines if necessary]*

III. Beginning Date for Use of Human Subjects:

IV. Type of Grant and/or Project (if applicable)

Research Grant:
Contract:
Training Grant:
Classroom Experiments/Projects:
Thesis Project:
Other (Specify):

V. Name of Funding Agency to which Proposal is Being Submitted (if applicable):

VI. Signatures

Submitted by Investigator
Typed Name:
Signature:
Date:

Faculty sponsor (for student)
Typed Name:
Signature:
Date:

VII. Summary of Activity. Provide answers to each section and add space as needed. Do not refer to an accompanying grant or contract proposal.

A. RATIONALE AND PURPOSE OF RESEARCH. (What question is being asked?)

B. RESEARCH PROCEDURES INVOLVED. Provide a short description of sequence and methods of procedures that will be performed with human subjects. Include details of painful or uncomfortable procedures, frequency of procedures, time involved, names of psychological tests, questionnaires, restrictions on usual life patterns, and follow up procedures. **If you are planning on posting flyers, posters, etc. anywhere on Campus, you must check with the building managers and/or departments located in BACONE COLLEGE buildings and obtain their approval prior to the posting.**

C. DECEPTION - If any deception (withholding of complete information) is required for the validity of this activity, explain why this is necessary and attach a debriefing statement.

D. SUBJECTS

1. Approximate number and ages
How Many Subjects:
Age Range of Subjects:

How Many Normal/Control:
Age Range of Normal/Control:

2.Criteria for selection:

3.Criteria for exclusion:

4.Source of Subjects (including patients):

5.Who will approach subjects and how? Explain steps taken to avoid coercion.

6. Will subjects receive payments, service without charge, or extra course credit? Yes or No
(If yes, what amount and how? Are there other ways to receive similar benefits?)

7.Location(s) where procedures will be carried out.

E.RISKS AND BENEFITS (ADVERSE EFFECTS)

1.Describe nature and amount of risk and/or adverse effects (including side effects), substantial stress, discomfort, or invasion of privacy involved.

2.Will this study preclude standard procedures (e.g., medical or psychological care, school attendance, etc.)? If yes, explain.

3.Describe the expected benefits for individual subjects and/or society.

F.ADVERSE EFFECTS

1.How will possible adverse effects be handled?

By investigator(s):
Referred by investigator(s) to appropriate care:
Other (explain):

2.Are facilities/equipment adequate to handle possible adverse effects? Yes or No
(If no, explain.)

3.Describe arrangements for financial responsibility for any possible adverse effects.

Bacone College compensation (explain):
Sponsoring agency insurance:
Subject is responsible:
Other (explain):

G.CONFIDENTIALITY OF RESEARCH DATA

1.Will data be coded? Yes or No

2.Will master code be kept separate from data? Yes or No

3.Will any other agency have access to identifiable data? Yes or No
(If yes, explain.)

4.How will documents, data be stored and protected?
Locked file:
Computer with restricted password:
Other (explain):

VIII.Checklist to be completed by Investigator(s)

A.Will any group, agency, or organization be involved? Yes or No
(If yes, please confirm that appropriate permissions have been obtained.)

B.Will materials with potential radiation risk be used (e.g. x-rays, radioisotopes)? Yes or No

1.Status of annual review by BACONE COLLEGE Radiation Sources Committee (RSC). Pending or Approved
(If approved, attach one copy of approval notice.)

2.Title of application submitted to BACONE COLLEGE RSC (if different).

C.Will human blood be utilized in your proposal? Yes or No
(If yes, please answer the following)

1. Will blood be drawn? Yes or No
(If yes, who will draw the blood and how is the individual qualified to draw blood? What procedure will be utilized?)

2.Will the blood be tested for HIV? Yes or No

3.What disposition will be made of unused blood?

4.Has the Bacone College designated Occupational Health Officer been contacted? Yes or No

D.Will non-investigational drugs or other substances be used for purposes of the research? Yes or No

Name:
Dose:
Source:
How Administered:
Side effects:

E.Will any investigational new drug or other investigational substance be used? Yes or No
[*If yes, provide information requested below and one copy of: 1) available toxicity data; 2) reports of animal studies; 3) description of studies done in humans; 4) concise review of the literature prepared by the investigator(s); and 5) the drug protocol.]*