INSTITUTIONAL REVIEW BOARD FOR PROTECTION OF HUMAN PARTICIPANTS (IRBPHP)

MODIFICATION APPLICATION

APPENDIX E
IRBPHP MODIFICATION APPLICATION

DOMINICAN UNIVERSITY OF CALIFORNIA

INSTITUTIONAL REVIEW BOARD FOR
THE PROTECTION OF HUMAN PARTICIPANTS

MODIFICATION APPLICATION

All information must be typed and submitted electronically to irbphp@dominican.edu. Handwritten applications will be returned to researcher.
A signature page must accompany all applications.

IRBPHP Number on Initial Application:

APPLICANT INFORMATION:

Name:

Date:

School:

Department:

Campus or Local Address:

Home Address (only if different than above):
Note: This will be used for contact during periods when you may not be living on campus/locally.

Local Phone:

Work Phone:

E-mail Address:
Note: All communication regarding your application will be sent by email so be sure you include a functioning email address.

Name(s) of Co- Investigator(s):

FACULTY ADVISOR INFORMATION:

Name:

Campus Phone:

E-mail Address:
Note: All communication regarding a student's application will be sent by email. Advisors will be copied on all correspondence so be sure to provide a functioningl email address.

RESEARCH PROJECT INFORMATION (from Initial Application):

Exact Title of Project:
Duration of Project: (cannot exceed 1 year)

Note: All requested information must be typed directly into the application form. Refer to page 22 in the IRBPHP Handbook for aid in providing required information.

Background and Rationale (no more then 300 words): Describe nature of research problem and purpose of current study. Include References at the end for any works cited.

Description of Sample (check all boxes that pertain to your sample.)

- ☐ Patients as participants
- ☐ Non-patient volunteers
- ☐ Students as participants
- ☐ Minor subjects (less than 18 years)
- ☐ Participants whose major language is not English (include copies of translated documents)
- ☐ Mentally disabled participants
- ☐ Prisoners, parolees, or incarcerated subjects
- ☐ Other vulnerable or sensitive populations (e.g.,children, persons with alcoholism or drug addiction, LGBT individuals, etc.) Please identify:

- ☐ Participants studied at non-Dominican locations.
- ☐ Filming, video, or voice-recording of participants
- ☐ Data banks, data archives and/or registration records
- ☐ There is a dual relationship between researcher and participant (explain):

Recruitment Procedure: Indicate how applicant will solicit participation (face-to-face, phone contact, mail, email, etc) along with copies of materials used to recruit participants and permission letters if applicable.

Participant Consent Process: Attach Informed Consent Forms to be used. If consent forms are not to be used, explain why and provide copy of the Consent Cover Letter.

Procedures: Describe in detail what your participants will experience and include copies of all written materials participants will see including surveys, questionnaires, interview questions, etc.

Potential Risks to Participants: Describe all potential risks.
Note: All research projects involve some potential risks to participants. Applications that do not address risks will be returned.

Minimization of Potential Risks: Describe ways the Potential Risks to Participants (detailed in section above) will be minimized by researcher.

Potential Benefits to Participants: Describe in detail all potential benefits to the individual (focus is individual not society). There is always some benefit – why else do the study.

Costs to the Participants: Describe any costs to participants (transportation, time, effort, etc.).

Reimbursement of Compensation to Participants: Describe and provide rationale for any reimbursement or compensation in response to participation in the research.

Confidentiality of Records:

☐ Data will be anonymous

How will anonymity be ensured?

☐ Data will not be anonymous

How will data be kept confidential? Who will see it?

How will raw data and computerized data be stored?

How will participant identity be kept separate from participant data?

(Note: all tapes and records should be destroyed after a period of one year following completion of the research project).

MODIFICATION(S) REQUESTED

Briefly describe the modification(s) for which you are seeking approval:

Research Project Information:

(All requested information must be typed directly on the application form. Refer to page 20 in the IRBPHP Handbook for aid in providing required information.)

Participants:

Number of participants used last year in project:

Number of participants who completed the study:

Number of participants needed to complete the research study:

Summary of Results to Date (limit to 300 words or less):

Changes in Anticipated Risks. List any changes in potential risk to human participants due to changes in protocol.

Changes in Anticipated Benefits. List any changes due to impact of changes in research protocol.

Discussion of Problems: Summarize any problems experienced or encounted by human participants during past year.

Explanation of Modification in Protocol: Summarize any modifications in research protocol made during the past year.

Discussion of any changes in risks or benefits related to the modification and how risks will be managed.