

Application for Initial Review

EI Centro College Institutional Review Board
U.S. Dept. of Health and Human Services (DHHS) IRB00006364

For IRB Use Only	
File Number	
Approval Date	

Please save this Application as a Word document on your computer, answer all questions completely, and submit it along with all supplemental documents to the EI Centro College Institutional Effectiveness & Research Office as described on the Signature Page. Handwritten forms will not be accepted.

1. Principal Investigator Information

Must be the same Principal Investigator named in any proposal for external or internal funding.

First Name	Last Name	E-mail

If EI Centro College faculty or staff:

ECC Department	ECC Division/Building/Office room number	Division Dean/Director
Office Phone Number	Fax Number	

If External Researcher or student:

Home address		
City, State, and Zip Code		
Home Phone Number	Fax Number	Institution Affiliated With
Faculty Advisor's Name (For Students)		Faculty Advisor's E-mail (For Students)
Faculty Advisor's Department		Faculty Advisor's Office Phone Number
Is this study for your master's thesis or doctoral dissertation?		
<input type="checkbox"/> Yes		<input type="checkbox"/> No
Is this study for your other course work?		
<input type="checkbox"/> Yes		<input type="checkbox"/> No

2. Co-Investigator Information

If applicable; students should include their Faculty Advisor as Co-Investigator only if he/she will be actively involved in conducting the study.

First Name	Last Name	E-mail
Office Phone Number	University or Other Entity	
The Co-Investigator's classification is:		
<input type="checkbox"/> Faculty/Staff		<input type="checkbox"/> Graduate Student

3. Key Personnel

List the names, titles and roles, and emails of all other Key Personnel who are responsible for the design, conduct, or reporting of the study.

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4. Purpose of Study

A. Study Purpose Category (check all that apply, assuming that each category includes online as well as regular environments and publications):

- 1. Improved pedagogy
- 2. Presentation to a general public
- 3. Presentation to a professional / academic setting.
- 4. Publication in a popular medium.
- 5. Publication in a professional / academic medium.
- 6. Institutional or instructional evaluation and / or planning.
- 7. Pure academic, pedagogical, or professional research.
- 8. Other. Specify. _____

B. Study Purpose Statement

Briefly state the purpose of your study, the hypotheses or research question(s) you intend to answer; and previous research (your own or others') upon which the study is based.

4A. Publication of Results

Please identify all methods in which you plan to publicly disseminate the results of your study (academic journal, academic conference, thesis or dissertation, etc.).

5. Project Information

Project Title (Must be the same as any proposal for external or internal funding.)

Start Date (mm/dd/year)

End Date (mm/dd/year)

Project Sponsors (Identify the source(s) of any external and/or internal funding and attach a complete copy of the funding proposal.) Faculty Research Grant – ROP. Proposal is attached.

* Has this project already been reviewed by another IRB? Y N

* If so, which? Attach documentation, which must include a description of the methodology to be used.

* If not, attach a complete description of the methodology to be used.

* In either case, please answer the following methodological questions.

5A. Data Collection

Describe all procedures you will use to collect data (interviews, surveys, focus groups, observation, review of existing records, etc.). Attach a copy of all data collection instruments and interview scripts to be used.

5B. Location of Study

Identify all locations where the study will be conducted. For each data collection site other than ECC, attach a signed and dated original of a letter on the cooperating institution's letterhead giving approval for collection of data at that site. This letter should reflect a general understanding of the nature of the study and how it will be conducted.

5C. Recruitment Population

Describe the population from which the subjects (including controls, if applicable) will be recruited.

5D. Subject Recruitment

Describe how you will recruit subjects to participate in the study; attach a copy of all recruitment materials (newspaper advertisements, posters, telephone scripts, etc.).

5E. Subject Population Composition

Describe the anticipated gender, racial/ethnic composition, age range and health status of the study population and the criteria for inclusion or exclusion of any subpopulation.

5F. Vulnerable Populations

Please identify any vulnerable populations who will specifically be targeted for participation in this study:

Children (under 18 years of age)

Pregnant women

Prisoners, including juveniles

Mentally impaired or mentally retarded

If any boxes are checked, describe any special precautions to be taken in your study due to the inclusion of these populations:

5G. Number of Participants

Total number of subjects (including controls):

Number of controls (if applicable):

5H. Time

Estimate the total time each subject will be involved in the study (include time per session, total number of sessions, etc.).

5J. Compensation

Describe any payment or other compensation subjects will receive for participating in the study, including the timing for payment and any conditions for receipt of such compensation:

5K. Risks and Precautions

Describe any foreseeable risks to subjects presented by the procedures described above in the Data Collection section, including any physical, psychological, social, economic, legal, or confidentiality risks (see the ECC IRB Guidelines for more information about these risks). Include your assessment of the degree of each risk presented and all precautions you will take to minimize such risks or to respond to any adverse events, should they occur:

5L. Medications

Will any subjects be under the influence of any medication, drugs or stressful condition which could diminish their ability to give effective informed consent?

Yes

No

If "Yes," please explain and describe what steps you will take to verify that potential subjects possess the mental capacity to give meaningful informed consent to participation in the study.

5M. Benefits

Describe the benefits to the subjects or others (explain how the subjects will benefit from participating in the study, other than any compensation described in the Compensation section above; if the subjects will not directly benefit from the research, explain how the study will benefit others or contribute to your field of research):

6. Significant Financial Conflict of Interest

If any external funding is proposed, have you and all Key Personnel submitted a Significant Financial Interest Disclosure form in compliance with the DCCCD Conflict of Interest Policy for Sponsored Projects? (For more information, see Dallas County Community College District 057501: EMPLOYMENT REQUIREMENTS AND RESTRICTIONS DBD CONFLICT OF INTEREST

([http://www.tasb.org/policy/pol/private/057501/pol.cfm?DisplayPage=DBD\(LOCAL\).pdf&QueryText=CONFLICT%20OF%20INTEREST](http://www.tasb.org/policy/pol/private/057501/pol.cfm?DisplayPage=DBD(LOCAL).pdf&QueryText=CONFLICT%20OF%20INTEREST))

Yes

No

No External Funding

7. NIH Training

Have you and all key personnel completed the required NIH training course ("Human Participant Protections Education for Research Teams") and submitted a copy of the completion certificate to the Office of Institutional Effectiveness & Research?

Yes

No

If "No," this training is required for all key personnel before your study can be approved. This free on-line course may be accessed at <http://phrp.nihtraining.com/users/login.php>

8. Previous Research

Summarize previous research leading to the formulation of this study, including any past or current research conducted by the Principal Investigator or key personnel.

9. Informed Consent Forms

Written Informed Consent Forms signed by the subject or the subject's legally authorized representative are required for most IRB projects (exceptions include telephone surveys and internet surveys for which an Informed Consent notice is substituted). If any subjects will be children (under 18 years of age in Texas), the parent/guardian Informed Consent Form must include a section for obtaining assent by children ages 7-17. Submit a copy of all consent/assent forms to be used.

Templates for creating informed consent forms are located on the Office of Research Services website at the address shown for each type of study:

- Faculty/staff investigators:
 - adult consent (ages 18 and older): <http://www.unt.edu/ospa/docs/IRB.Consent.FSAS.doc>
 - parent/guardian consent with minor assent (ages 7-17): <http://www.unt.edu/ospa/docs/IRB.Consent.FSMA.doc>
- Student investigators:
 - adult consent (ages 18 or older): <http://www.unt.edu/ospa/docs/IRB.Consent.GRAS.doc>
 - parent/guardian consent with minor assent (ages 7-17): <http://www.unt.edu/ospa/docs/IRB.Consent.GRMA.doc>

10. Informed Consent

Describe the steps for obtaining the subjects' informed consent/assent (by whom, where, when, etc.).

11. Languages

Will your study involve the use of Informed Consent Forms, data collection instruments, or recruitment materials in any language other than English?

Yes

No

If "Yes", identify all languages below and submit English translations of any documents appearing only in a non-English language.

12. HIPAA

Will your study involve obtaining individually identifiable health information from health care plans, health care clearinghouses, or health care providers?

Yes

No

If "Yes," describe the procedures you will use to comply with the HIPAA Privacy Rule. (For more information about HIPAA, see the HIPAA Guidance page on the ECC Institutional Effectiveness & Research website at <http://www.unt.edu/ospa/news/hipaa.htm>.)

13. Confidentiality of Research Records

Describe the procedures you will use to maintain the confidentiality of any personally identifiable data (including any videotapes and/or audiotapes of the participants).

Describe where your research records will be maintained, any coding or other steps you will take to separate participants' names from research data, and how long you will retain personally identifiable data in your research records.

Identify the categories of all persons other than the research team to whom personally identifiable data will be disclosed and the purpose of each such disclosure (presentations at academic conferences, dissertation committee, etc.).

IRB Application Signature Page

Principal Investigator

I certify that the information in this application is complete and accurate. I agree to conduct this study in accordance with the ECC IRB Guidelines and the study procedures and forms approved by the ECC IRB. I agree that I will not make any changes to the approved procedures or forms without prior written approval from the ECC IRB. I understand that I can not initiate any contact with human subjects until I have received written ECC IRB approval.

Signature of Principal Investigator

Date

Faculty Advisor (if applicable)

I have examined this completed application and I am satisfied with the adequacy of the proposed research design and the precautions to be taken for the protection of human subjects. My oversight of this study will include verification that it is being conducted in accordance with the ECC IRB Guidelines and the study procedures and forms approved by the ECC IRB. I agree that no changes will be made to the approved procedures or forms without prior written approval from the ECC IRB.

Signature of Faculty Advisor

Date

Submission of Your Application and Supplementary Documents

1. Print the entire application and sign this page. If you are a student, ask your Faculty Advisor to also sign this page.
2. Attach all supplementary documents, including:
 - A. Copies of all NIH Training completion certificates not previously submitted to the Planning, Assessment, and Research Office;
 - B. A copy of any proposal for internal or external funding for this study;
 - C. The original of the approval letters from all cooperating institutions (other than ECC) where you will collect data;
 - D. A copy of all recruitment materials;
 - E. A copy of all informed consent forms;
 - F. A copy of all data collection instruments; and
 - G. A current curriculum vita or resume of the principal investigator and the co-investigator (if applicable).
3. Send or deliver the entire application (including this Signature Page) and all supplementary documents to:
 - A. Physical Address:
Planning, Assessment, and Research Office
Room A218
 - B. Mailing Address:
El Centro College
Planning, Assessment, and Research Office
801 Main Street
Dallas, TX 75202-3604

Thank you for submitting your application to the ECC IRB. For questions about your application, please contact Karen Mongo at (214) 860-2016 or kmongo@dccc.edu.