



Cape Cod Community College IRB Continuing Research Form

INSTRUCTIONS:

- This form should be submitted **30 days** prior to the anniversary of the last approval date for projects exceeding one year in duration. If your project is complete you must submit a final report.
- This form is for projects that occurred over the past year with only minor or no changes to an approved protocol. Changes that are more than minor require filling a new IRB Application Research Form.
- Training certifications must be current before approval is renewed.
- Exempt status research projects do not require Continuing Review.
- Send the completed form to the IRB Chair at IRB@capecod.edu

Continuing Research Project Information

Title of Research Project:		File Number:	
Principal Investigator/Project Director	Department	Phone Ext.	Email Address
Co-Investigator/Student Investigator	Department	Phone Ext.	Email Address
Funding Sources:	Project Starting Date:	Other organizations and/or agencies, if any, involved in the study:	
Initial CCCC IRB Approval Date:		Last Annual Review Date:	

Co-Investigator and/or Research Staff Information:

Name:	Role:	Email:
Training Provider:	Training Completion Date:	Date Training Certificate Filed in IRB :
Name:	Role:	Email:
Training Provider:	Training Completion Date:	Date Training Certificate Filed in IRB :

Project Status (check all that apply):

- Project is on schedule
- No subjects are enrolled to date
- Subject recruitment is ongoing with a projected end date of recruitment of:
- Subject recruitment is completed as of (date):
- Subject recruitment needs to be expanded. Request increase from original approval of:
- Intervention and data collection completed as of (date):
- Data analysis is ongoing with a projected end date of:
- Data analysis is complete as of (date):

Study Abstract:

Summary of activities during past approval period:

Were any manuscripts, publications, or conference presentations related to this study completed during the past approval period?

Yes

No

If yes, list here:

Research Procedures:

Protocol has not been altered since original approval or last continuing review.

Protocol has been modified and a summary of the changes are provided. *(Provide a brief description of the research procedures, incorporating elements of all approved amendments to date for the research.)*

Subject Numbers (Enter N/A for questions that are not applicable)

Number of subjects proposed and approved by the IRB:

Number of subjects screened:

Number of subjects enrolled/consented to participate:

Number of subjects who voluntarily withdrew:

Number of subjects excluded by the PI:

Reason for Exclusion:

Subject Safety (Check at least one)

Not applicable – there is nothing to report.

Describe any problems encountered that involved risk or harm to subjects or other since last annual review:

Describe any unexpected benefits to subjects or others since the last annual review:

Are you aware of new information from other sources that affect risks/benefits from participating in this study?

Yes

No

If yes, please explain and/or provide copies of literature that provides new information on this study's risk/benefit ratio.

Amendments:

None requested at this time.

Minor changes requested (e.g., personnel changes, elimination of a tool, etc.) If checked, please provide a summary of changes.

Study Materials:

If informed consent forms were used, are they on file and available upon request for the IRB to review?

Yes

No

If no, please explain:

Have any changes been made or need to be made to the informed consent form?

Yes

No

If yes, what changes have been made?

Please submit any project materials that have changed since initial review. This may include recruitment materials such as letters, brochures or flyers that have been updated; survey or interview tools and other documents.

PI Assurances:

I certify the accuracy of the information provided, and I agree to abide by Cape Cod Community College policies and procedures governing research with human subjects. This form has been submitted electronically.

Signature

Date