

Request for Annual Update for Research Protocol Involving Human Participants

Fitchburg State University
Institutional Review Board (IRB)

Request for Annual Update for Research Protocol Involving Human Participants

Instructions

Complete all fields. If not applicable, please enter N/A. Type your responses on the lines/in the space provided. Attach any updated or new documents referenced.

Section 1: Applicant Information

- Principal Investigator (PI)

Full Name: _____

Phone Number: _____

Email Address: _____

- Faculty Advisor (if PI is a student)

Full Name: _____

Phone Number: _____

Email Address: _____

Section 2: Project Information

Project Title

Project Period

Start Date (MM/DD/YYYY): _____

End Date (MM/DD/YYYY): _____

Fitchburg State IRB#

Project Type (Select one)

Exempt

Expedited

Full Review

Section 3: Annual Update

Summary of Previous Year and Description of Proposed Plan for Renewal Period

Reason for Extension:

Number of participants who completed the study: ____

Number of participants who are currently enrolled in the study: ____

Number of participants expected to enroll in the study in the next 12 months: ____

Number of participants who voluntarily withdrew from the study: ____

Number of participants who experienced adverse reactions, complications, or injuries resulting from participation in the study: ____

Please include a description or explanation for each participant that withdrew or experienced other reactions or complication:

Do you intend to make any changes to the research protocol? (If yes, please complete **Section 4** through **Section 7**. If no, please indicate below and then complete **Section 7**.)

Yes

No

Section 4: Proposed Changes

Description of Proposed Changes (Please attached any revised documents, CITI training certificates, etc.)

Section 5: Justification for Changes

Reason for Proposed Changes

Section 6: Title II/ADA Compliance

Verification

____ By checking here, we verify that all digital content submitted is designed to comply with Title II of the Americans with Disabilities Act.

Section 7: Signatures

Primary Researcher Certification

I certify that the information provided is accurate and complete.

Signature: _____

Printed Name: _____

Date (MM/DD/YYYY): _____

Faculty Advisor Certification (if applicable)

I have reviewed and approve the proposed changes.

Signature: _____

Printed Name: _____

Date (MM/DD/YYYY): _____