

## CHANGE OF PROTOCOL (COP)

Researchers may request approval to make modification or amendments in various aspects of a study. **All changes must be approved by the IRB prior to implementation.**

Amendments include the following:

- changes in experimental design
- insertion of new information or correction of errors
- change in principal investigator
- change in number of subjects
- changes in population and/or inclusion/exclusion criteria
- change in study site(s).

CLARKSON COLLEGE - Institutional Review Board (IRB) CHANGE OF PROTOCOL REQUEST	
Instructions: Researchers may request approval to make modification or amendments in various aspects of a study. <b>All changes must be approved by the IRB prior to implementation.</b> Approval of amendment request is not guaranteed.	
<b>SECTION I</b>	
IRB#:	
Title of Study:	
Principal Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: <span style="float: right;">(work)</span>	(cell/home)
Email: <sup>1</sup>	
Co-Investigator:	
Address:	
Clarkson College ID# (if applicable):	
Phone Numbers: <span style="float: right;">(work)</span>	(cell/home)
Email:	

---

<sup>1</sup> Investigators outside the College should provide the email address issued by their institution.

1. Amendment Description (**Check all as appropriate**):

Amendment to currently approved procedures on the application (for example; changes to General information section, data collection methods section, confidentiality section, subject recruitment section, risk and benefits section etc.,)

Amendment to Recruitment materials

Amendment to currently approved consent/Assent/Permission forms

Amendment to Debriefing forms

Amendment to Data collection tools

Other:

2. List and describe the proposed changes to each document or sections on the application:

3. State the reasons for the proposed changes:

4. List and describe potential risks that may occur as a result of the proposed amendment(s):

5. **Did you attach amended material**, as applicable (Note: **highlight/Bold/Underline all changes**)?

Yes

---

(Office Use Only)

**IRB #:** \_\_\_\_\_ **Level of Review:** \_\_\_ Exempt \_\_\_ Expedited \_\_\_ Full-Board

**Approved:** Y or N **Date Approved:** \_\_\_\_\_

**IRB Signature:** \_\_\_\_\_

---

**SECTION IV**

---

**Printed Name of Principal Investigator**

Date

---

**Signature of Principal Investigator**

Submit the Change of Protocol form (and any required attachments) via email at [IRB@clarksoncollege.edu](mailto:IRB@clarksoncollege.edu) or mail it to Clarkson College at the address listed below. A scanned PDF of the executed (signed) signature page(s) can be attached with the submission.

*Note: Changes in protocol must not be implemented prior to IRB approval.*

**Clarkson College Institutional Review Board**  
**101 S. 42<sup>nd</sup> Street**  
**Omaha, NE 68131**  
**Phone: 402.552.3100; Fax: 402.552.6019**