



## CONTINUING REVIEW OF RESEARCH INSTITUTIONAL REVIEW BOARD

OFFICE OF SPONSORED PROGRAMS (OSP)  
Northeastern Illinois University  
5500 N. St. Louis Avenue, Chicago, IL 60625-4699  
Phone: 773-442-4670 / Fax: 773-442-4673  
<http://www.neiu.edu/~sprogram/>

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### DIRECTIONS FOR COMPLETING THE CONTINUING REVIEW FORM

Please detach pages (i) and (ii) before copying and submission to OSP.

1. **Investigator Education:**

All investigators (Deans, Directors, Department Heads, faculty, research staff, and student researchers) must complete initial and continuing education requirements in human subject protections. Otherwise, the submission will not be accepted.

2. **Submission Procedure:**

Submit the collated documents as outlined below to ensure scheduling for IRB review prior to the expiration of IRB approval. Incomplete submissions (e.g. those lacking original signatures, those missing documents, those that have documents that are missing information, those that are missing documentation of investigator training) will not be accepted.

3. **Review Process:**

Please read each of the following three (3) choices to determine which review process is appropriate for your research protocol and how to submit your research protocol for continuing review. You may use this checklist to ensure your submission is complete.

a. **Continuing Review by the Convened IRB:**

For research protocols that were reviewed and approved by the convened IRB, submit **8 collated copies** of the following documents:

- The original completed and signed Continuing Review form.
- The currently approved informed consent document(s) (with the IRB's approval stamp) being used to obtain informed consent, including any parental permission document(s) and assent document(s).
- All recruiting materials currently being used.
- Any reports to the sponsors since the last initial or continuing review.
- Any new amendments (include the "Amendment to Previously Approved Research" form).
- If the amendment includes revised informed consent document, include copies with revision highlighted, underlined, shaded etc.

**2 copies** of the following documents:

- The research protocol that is currently being used with amendments incorporated.

**2 copies** of the following documents:

- Unmarked copies of the informed consent document(s), including any parental permission document(s) and assent document(s).
- Unmarked copies of all recruiting materials.

**(The unmarked copies will be stamped with the date of approval and returned for your use when enrolling subjects)**

**b. Continuing Review under Expedited Review Procedures:**

For research protocols that were previously reviewed under expedited review procedures, **2 collated copies** of the following documents:

- The original completed and signed Continuing Review form.
- The currently approved informed consent document(s) (with the IRB's approval stamp) being used to obtain informed consent, including any parental permission document(s) and assent document(s).
- All recruiting materials currently being used.
- Any reports to the sponsors since the last initial or continuing review.
- The research protocol that is currently being used with amendments incorporated.
- Any new amendments (include the "Amendment to Previously Approved Research" form).
- If the amendment includes revised informed consent document, include copies with revision highlighted, underlined, shaded etc.

**2 copies** of the following documents:

- Unmarked copies of the informed consent document(s), including any parental permission document(s) and assent document(s).
- Unmarked copies of all recruiting materials.

**(Unmarked copies will be stamped with the date of approval and returned for use when enrolling subjects)**

**c. Continuing Review Now Eligible for Expedited Review Procedures:**

If your research was previously approved by the convened IRB but now may meet one of the following three categories, your research may be eligible for review under expedited review procedures [45 CFR 46.110(b)(1)].

- All of the following accurately describe your research:
    - (a) the research is permanently closed to the enrollment of new subjects; **AND**
    - (b) all subjects have completed all research-related interventions; **AND**
    - (c) the research remains active only for long-term follow-up of subjects.
- OR**
- No subjects have been enrolled and no additional risks have been identified since the last approval.
- OR**
- The remaining research activities are limited to data analysis only.

Submit the following documents in **2 collated packets**:

- The original completed and signed Continuing review form.
- The currently approved informed consent document(s) (with the IRB's approval stamp) being used to obtain informed consent, including any parental permission document(s) and assent document(s).
- All recruiting materials currently being used.
- Any reports to the sponsors since the last initial or continuing review.
- The research protocol that is currently being used, with amendments incorporated.
- Any new amendments (include the "Amendment to Previously Approved Research" form).
- If the amendment includes revised informed consent document, include copies with revision highlighted, underlined, shaded etc.

**2 copies** of the following documents: **This applies only if new subjects will be enrolled.**

- Unmarked copies of the informed consent document(s), including any parental permission document(s) and assent document(s).
- Unmarked copies of all recruiting materials.

**(Unmarked copies will be stamped with the date of approval and returned for use when enrolling subjects)**



**CONTINUING REVIEW OF RESEARCH  
INSTITUTIONAL REVIEW BOARD**

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**DATE REPORT COMPLETED:**

<b>RESEARCH PROTOCOL NUMBER:</b>	<b>PROJECT TITLE</b>		
<b>PRINCIPAL INVESTIGATOR</b>			
Name (Last, First)	Degree(s)	University Status	Campus Phone/Fax Number
Department	College	Campus Mailing Address	E-mail Address
<b>INVESTIGATOR EDUCATION</b>		<b>IRB APPROVALS</b>	
Date of most recent (initial or continuing) human subject protection education		Date of original IRB approval :	Date of most recent IRB continuing review approval:
<b>NEW AMENDMENTS</b>			
Are there any <b>new</b> amendments to the research protocol and/or informed consent documents <b>included</b> with this continuing review? <input type="checkbox"/> <b>Yes</b> <input type="checkbox"/> <b>No</b> If <b>yes</b> , you must include a separate "Amendment to Previously Approved Research" form.			

## REVIEW PROCESS

Is this research being submitted for Continuing Review under expedited review procedures?

Yes No

If **yes**, (1) check the criteria, which are being claimed, and (2) provide the rationale for choosing that category.

*Research originally reviewed under expedited procedure [45CFR46.110(b)(1-7)]*

OR

*Expedited review procedures [45CFR46.110(b)(8)]:*

*All of the following accurately describe your research:*

*(a) the research is permanently closed to the enrollment of new subjects; AND*

*(b) all subjects have completed all research-related interventions; AND*

*(c) the research remains active only for long-term follow-up of subjects.*

OR

*No subjects have been enrolled and no additional **risks** have been identified since the last approval.*

OR

*The remaining research activities are limited to data analysis only.*

Provide the rationale for choosing that category:



2. **PRELIMINARY RESULTS OR FINDINGS FROM THIS RESEARCH:**

a. Describe any preliminary results or findings from this research at NEIU and other sites, if appropriate.

b. Do these results or findings, including any early indications that one of the interventions under investigation may be significantly better or worse than others, affect the:

- Risks associated with the research.
- Risk-benefit analysis.
- Alternatives to participation. – or -
- Subject's willingness to continue participating in the research?

**Yes      No**

If **yes**, provide a summary of those results or findings and an evaluation of how this information is relevant, addressing the following items (as applicable): [if necessary, attach a separate page(s)]

- Whether any changes to the research protocol and informed consent process and/or documents were or may be necessary, or any changes have occurred as a result of the findings;
- If the significant new finding(s) or information have been shared with currently enrolled subjects and how it was shared; and
- If the significant new finding(s) or information have been shared with subjects who have completed their participation in the research and how it was shared.

If **no**, explain.

3. **SUMMARY OF RECENT LITERATURE, OTHERS' FINDINGS, OR RELEVANT INFORMATION:**

a. In your own words, provide a summary of recent literature, findings, or relevant information.

b. Does the recent literature, findings, or other relevant information affect the:

- Risks associated with the research.
- Risk-benefit analysis.
- Alternatives to participation. -or-
- Subject's willingness to continue participation?

**Yes      No**

If **yes**, provide a summary evaluating how this information is relevant. Be specific. [if necessary, attach a separate page(s)]

4. **INFORMED CONSENT IN OTHER LANGUAGES:**

a. Have any subjects whose primary language for communication and understanding is not English been approached to participate and/or enrolled in the research?  **Yes**       **No**

If **yes**, summarize:

- The number of subjects enrolled;
- The language(s) in which the informed consent process was conducted; and
- The language(s) in which the informed consent document was provided to those subjects.

b. Have subjects been excluded based on this?  **Yes**  **No**  
If **yes**, explain.

5. **INFORMED CONSENT PROCESS:**

Are you still enrolling new subjects using the selection method, recruitment procedures and informed consent process that the IRB approved?

**Yes**  **No**

If **no**, please explain.

⇒ Attach the informed consent documents (including any parental permission and assent forms) and all recruitment materials (flyers, pamphlets, ads, etc.) (with the IRB approval stamp) currently being used to enroll subjects.

6. **SUBJECT COMPLAINTS:**

Have any subjects made complaints about the research?  **Yes**  **No**

If **yes**, summarize the following for each complaint:

- Provide a description of the complaint;

- The number of times it occurred;
- A determination as to whether it was related to the research; and
- Any actions taken by the investigator in response to the complaints.

7. **SUBJECTS AND/OR PARENTS/GAURDIANS/LEGALLY AUTHORIZED REPRESENTATIVES DECLINING TO PARTICIPATE:**

Have any subjects and/or parents, guardians, or legally authorized representatives declined to participate in the research after being approached?

**Yes**     **No**

If **yes**, indicate:

- The number of subjects and/or parents, guardians, or legally authorized representatives;
- The reason(s) they declined to participate; and
- If any changes in the recruitment process might be necessary.

If **no**, explain.

8. **SUBJECT/PARENT WITHDRAWAL:**

Have any subjects and/or parents, guardians, or legally authorized representatives withdrawn from the research after initial enrollment and participation?

**Yes**     **No**

If **yes**, include:

- The number of subjects and/or parents, guardians, or legally authorized representatives;
- The reason(s) for their withdrawal;
- When the subjects withdrew, (i.e., during screening, intervention, follow-up); and
- If any changes to the research protocol and informed consent process and/or documents were made or may be necessary to make.

If **no**, explain.

9. **ADVERSE OR UNANTICIPATED EVENTS:**

Summarize all adverse or unanticipated events that have occurred involving this research protocol since the initial review or the most recent continuing review. Include those that:

- Are of significant frequency and severity.
- Were related to the research intervention itself, procedure, drug, device, and/or biologic.
- Resulted in a change in the risk-benefit analysis and change in the research protocol and/or Informed Consent Document.

10. **AMENDMENTS TO THE RESEARCH PROTOCOL AND/OR INFORMED CONSENT DOCUMENT(S):**

Have there been any amendments reviewed and approved by the IRB since the most recent initial or continuing review?  **Yes**  **No**

If **yes**, describe each specific amendment that has been approved by the IRB, such as:

- Amendments to the research protocol itself;
- Amendments to the informed consent document(s);
- Changes (additions/deletions) of investigators; and/or
- Increase number of subjects for enrollment.

Amendment (brief description)

Date

Version #

NEIU IRB Approval Date

**To submit any amendments that have not been approved by the IRB, submit the “Amendment to Previously Approved Research” form separately.**

11. **REVIEW BY OTHER IRBS:**  **Not Applicable**

a. If NEIU is the sponsor/grantee/awardee and there are other performance sites, have the IRBs from those performance sites reviewed and approved this research?

**Yes**  **No**

If **yes**, please provide documentation of the most recent IRB approval.

If **no**, explain.

b. If NEIU is the sponsor/grantee/awardee, have any other IRB's from those performance sites disapproved this research?  **Yes**  **No**

If **yes**, provide documentation.

- c. For any other multi-center research, have any other IRBs disapproved this research?  **Yes**  **No**  
If **yes**, please provide documentation and explain.

**12. SUSPENSION (STOPPING) OF SUBJECT ENROLLMENT:**

Has subject enrollment or any research activities been stopped (for any reason) since the last review, and has not already been reported to the IRB?  **Yes**  **No**

If **yes**, explain. Provide the specific dates and reasons.

**13. PRESENTATION(S) AND/OR PUBLICATION(S):**

Have there been any presentations or publications (including abstracts) from this research since the last review?

**Yes**  **No**

If **yes**, list and attach copies of each.



**INVESTIGATOR'S ASSURANCE FOR CONTINUING REVIEW OF RESEARCH**

I certify that the information provided in this Continuing Review application is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the research and the ethical performance of the project. I agree to comply with all NEIU policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- The research will be performed by qualified personnel according to the approved research protocol,
- No changes will be made in the research protocol or informed consent document until approved by the NEIU IRB,
- Legally effective informed consent will be obtained from human subjects, if applicable and appropriate, and
- Adverse events will be reported to the NEIU IRB as required.

I certify that I and all key research personnel have completed the required initial and/or continuing educational program on the ethical principles and regulatory requirements for human subject protections.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

**FACULTY SPONSOR'S ASSURANCE**

By my signature as faculty sponsor on this Continuing Review application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular research in accord with the approved protocol. In addition,

- I agree to meet with the investigator on a regular basis to monitor research progress,
- Should problems arise during the course of the research, I agree to be available, personally, to supervise the investigator in solving them,
- I will ensure that the Principal Investigator will promptly report significant or untoward adverse effects to the NEIU IRB as required,
- If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence and I will advise the NEIU IRB by letter of such arrangements, and
- I have verified that the investigator completed the required initial and/or continuing educational program on the ethical principles and regulatory requirements for human subject protections.

\_\_\_\_\_  
Signature of Faculty Sponsor\* (if PI is a student or a fellow)

\_\_\_\_\_  
Typed Name

\_\_\_\_\_  
Date

\*The faculty sponsor must be a member of the NEIU faculty. The faculty member is considered the responsible party for the ethical performance and regulatory compliance of the research project.

**DEPARTMENT HEAD SIGNATURE**

As department head, I acknowledge that this research is in keeping with the standards set by our department and I assure that the Principal Investigator has met all departmental requirements for continuing review and approval of this research.

\_\_\_\_\_  
Signature of Department Head/Dean\*

\_\_\_\_\_  
Typed Name of Department Head/Dean

\_\_\_\_\_  
Date

Dept. Name: \_\_\_\_\_

Address: \_\_\_\_\_

\*If the Principal Investigator is also the Department Head, this signature must be that of the College Dean.