Appendix I
Request for Continuing Review
Checklist
FOR IRB USE ONLY

Type of Review:  □ Full Board  □ Expedited

REQUEST FOR CONTINUING REVIEW

Instructions: Please complete this form no later than 45 days prior to the study expiration date and submit with current approved consent documents (if applicable) bearing the IRB approval stamp. Also, include a clean version of consent documents that can be stamped and returned upon approval of the continuing review. Identify any requested changes and provide the IRB with all the necessary information to conduct a thorough and substantive continuing review. Check here if this includes a modification □ and complete sections 5 and 6 below.

1. GENERAL INFORMATION
   Protocol Title:       Faculty:  □  Staff:  □  Student:  □
   E-mail Address:      Date:

2. PRINCIPAL INVESTIGATOR
   Name:                CITI Certified: Yes  □  Date:
   School/Department:
   Campus Mailing Address:
   E-mail Address:      Telephone Number: (   )

3. CO-INVESTIGATOR
   Name:                CITI Certified: Yes  □  Date:
   School/Department:
   Campus Mailing Address:
   Telephone Number: (   )

4. CONTINUING REVIEW TYPE
   □ Continuing Review Only
   □ Continuing Review with a Modification (must complete sections 5 & 6)
   □ Continuing Review for Data Analysis Only

5. MODIFICATION INFORMATION (if Applicable)
   Please provide a detailed description of the requested change(s) including rationale for why change is necessary:

   In your opinion does the change alter the risk/benefit ratio of the research study?
   If yes, how?  □ Yes  □ No

   Will the change affect the safety and/or welfare of research subjects?
   If yes, how?  □ Yes  □ No

   Will the change affect the informed consent process or documents?
   If yes, how?  □ Yes  □ No

6. ATTACHMENTS If change involves the modification of any study materials make sure to include a tracked changed version, a clean version without track changes and new version dates.
   □ Protocol Summary (Version Date:   )
   □ Advertisements (printed, audio, or video)
   □ Study Instruments (surveys, questionnaires, etc.)
   □ Scripts
   □ External Approvals (IRB, Schools, or Centers)
   □ Grant Application
   □ Flyers, Posters and Brochures
   □ Informed Consent Forms/Assent Forms
   □ CITI Certificates
### 7. PARTICIPANT INFORMATION

Maximum Number of Subjects Approved by the IRB for Enrollment Based on Initial Application or Subsequent Modification:

<table>
<thead>
<tr>
<th>Number of Participants Screened to Date:</th>
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<table>
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<tr>
<th>Number of Participants Enrolled to Date:</th>
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</table>

<table>
<thead>
<tr>
<th>Participant Demographics (Enrolled):</th>
<th>Number of males:</th>
<th>Number of females:</th>
<th>Number of minorities</th>
</tr>
</thead>
</table>

### 8. WITHDRAWALS

Have any participants withdrawn from the study since its start or since the last continuing review? If yes, list the reason for each participant (only list those not previously reported) Yes ☐ No ☐

### 9. DROPS

Have any participants been dropped from the study by the investigator since the last continuing review? If yes, list the reason for each participant (only list those not previously reported) Yes ☐ No ☐

### 10. ADVERSE EVENTS OR UNANTICIPATED PROBLEMS

Have there been any unanticipated problems or adverse events from the last 12 months? If yes, please report them below. Yes ☐ No ☐

### 11. RECENT RELEVANT LITERATURE

Has there been any publication of recent literature that may be relevant to this study? If yes, please identify below. Yes ☐ No ☐

### 12. PREVIOUS PROTOCOL MODIFICATIONS:

Have there been any protocol modifications made to the protocol and approved by the IRB in the last 12 months? If yes, please list dates of modifications approved below. Yes ☐ No ☐

### 13. PARTICIPANT COMPLAINTS

Have there been any complaints made about the protocol in the last 12 months? If yes, please describe the nature of the complaint and remedy below. Yes ☐ No ☐

### 14. CONFLICTS OF INTEREST

Have you previously disclosed any conflicts of interest related to this study? Yes ☐ No ☐

Do you presently have a conflict of interest, financial or otherwise, related to this study? If yes, describe the nature of the conflict of interest and complete and attach an approved COI Management Plan. Yes ☐ No ☐

### 15. OTHER RELEVANT INFORMATION

Please list any other relevant information of which the IRB should be made aware (such as change in study personnel or change in sponsor).

### 16. SUMMARY OR PROGRESS/PRELIMINARY FINDINGS

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*E-SIGNATURES ARE REQUIRED PRIOR TO SUBMISSION from the following:

Department Chair or Dean
Principle Investigator
Co-Investigator(s)
Faculty Advisor (for students only if different from PI)

Please contact the Office of Research and Sponsored Programs if you need assistance with setting up an account on www.irbnet.org.
Appendix J

Continuing Review Checklist
### §46.109(e) CONTINUING REVIEW CHECKLIST (EXPEDITED)

#### INITIAL PROTOCOL REVIEW
- **Was the research initially reviewed and approved at a convened meeting of the IRB?**
  - **Yes**
  - **No**
  
  **If NO → continue. If YES → STOP continuing review must take place at a convened meeting of the IRB (the only exceptions are for continuing review under categories 8a, 8b, 8c or category 9).**

#### RISK ASSESSMENT AND MONITORING: §46.110 Determination of Risk
- **Does the research present more than minimal risk to subjects as determined by initial review of the protocol by the IRB?**
  - **Yes**
  - **No**
  
  **If NO → continue. If YES → STOP continuing review must take place at a convened meeting of the IRB.**

- **Is new information presented by the investigator, such as new procedures or a modification of procedures that would likely increase risk to subjects?**
  - **Yes**
  - **No**
  
  **If NO → continue. If YES → STOP continuing review must take place at a convened meeting of the IRB.**

#### Adequacy of the Informed Consent Process
- **Does the investigator make adequate provisions in the research plan for monitoring the data collected to ensure the safety of subjects?**
  - **Yes**
  - **No**

- **Are adequate provisions in place to protect the privacy of subjects and to maintain confidentiality of data?**
  - **Yes**
  - **No**

#### Adequacy of the Informed Consent Process—Continued
- **Does the continuing review include a modification to the informed consent process whereby a waiver of informed consent or waiver of documentation of informed consent is requested by the investigator?**
  - **Yes**
  - **No**
  
  **If NO → continue. If YES → STOP continuing review must take place at a convened meeting of the IRB.**

- **Is there any new information that should be considered to represent such a significant new finding that it should be communicated to subjects who have already enrolled in the research?**
  - **Yes**
  - **No**

  **If NO → continue. If YES, indicate in the comments section below, if the investigator included provisions for communicating such findings to research participants.**

#### Adequacy of the Informed Consent Process—Continued
- **Is informed consent sought from each prospective subject or the subject’s legally authorized representative.**
  - **Yes**
  - **No**

- **Is informed consent appropriately documented or did the investigator receive IRB approval for a waiver of documentation of informed consent or waiver of some or all of the elements of informed consent?**
  - **Yes**
  - **No**

**Comments:**

- **Is the investigator using the most recently approved version of the informed consent document and does the document contain the most accurate and up-to-date information about the research?**
  - **Yes**
  - **No**
  - **NA**

**Comments:**
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>Does the informed consent document or process provide an accurate and up-to-date description of the reasonably foreseeable risks and discomforts.</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>If applicable, does the informed consent document or process disclose alternative procedures or courses of treatment that might be advantageous to the subject?</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Is any new information presented by the investigator (or others) that raises concerns about the circumstances under which informed consent is being obtained (e.g., conflicts of interest)?</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>EVALUATING THE INVESTIGATOR AND INSTITUTIONAL ISSUES</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Have there been any changes in the investigator's situation or qualifications?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Have there been any complaints by research subjects or others related to the investigator's conduct of the research?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Have there been any changes in the acceptability of the proposed research in terms of institutional commitments and applicable regulations (State &amp; local law or standards of professional conduct)?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Have there been any reports received from any third party observations of the research?</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>EVALUATING RESEARCH PROGRESS</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Is the information provided by the investigator consistent with the research protocol previously approved by the IRB?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Is enrollment consistent with the planned number of subjects described in the IRB-approved protocol and are enrollment targets being met?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Is enrollment occurring at a rate expected with the ability to provide sufficient data to answer the scientific question being addressed?</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Is the rate of subject withdrawal and the reasons for withdrawal reasonable?</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>OTHER CONSIDERATIONS</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Selection of subjects is equitable – 45CFR46.111(a)(3)</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
<td>Appropriate safeguards are in place to protect subjects that are likely to be vulnerable to coercion or undue influence and when the research involves pregnant women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval 45CFR46.111(b) and subparts B, C, and D respectively.</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide Protocol Specific Comments</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Review Worksheet Version 7/1/2013
<table>
<thead>
<tr>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referred to Full Board</td>
</tr>
<tr>
<td>Requires Information or Modifications</td>
</tr>
</tbody>
</table>

Reviewer: ___________________________  Date: __________
Appendix K

Protocol Modification Request
**FOR IRB USE ONLY**  
Type of Review: □ Full Board □ Expedited

**PROTOCOL MODIFICATION REQUEST**

**Instructions:** All changes to previously IRB-approved research must be IRB reviewed and approved prior to implementation. Please complete this form to identify the requested changes and provide the IRB with all the necessary information to conduct a thorough and substantive review.

### 1. GENERAL INFORMATION
- **Protocol Title:**
- **Date:**

### 2. PRINCIPAL INVESTIGATOR
- **Name:**
- **School/Department:**
- **Campus Mailing Address:**
- **E-mail Address:**
- **CITI Certified:** Yes □ No □ **Date:**
- **Telephone Number:** (____) —
- **Faculty:** □ **Staff:** □

### 3. CO-INVESTIGATOR
- **Name:**
- **School/Department:**
- **Campus Mailing Address:**
- **Telephone Number:** (____) —
- **CITI Certified:** Yes □ No □ **Date:**

### 4. MODIFICATION TYPE
- □ Minor (e.g. administrative edits to recruitment materials or informed consent document(s), minor changes in study procedures, addition of research staff)
- □ Major (e.g. significant changes to research study which may alter the risk and/or benefit ratio)

### 5. AMENDMENT INFORMATION
Please provide a detailed description of the requested change(s) including rationale for why change is necessary:

- **In your opinion does the change alter the risk/benefit ratio of the research study?** Yes □ No □
- **If yes, how?**
- **Will the change affect the safety and/or welfare of research subjects?** Yes □ No □
- **If yes, how?**
- **Will the change affect the informed consent process or documents?** Yes □ No □
- **If yes, how?**

### 6. ATTACHMENTS
- If change involves the modification of any study materials be sure to include a tracked changed version, a clean version without tracked changes and new version dates.
- □ Protocol Summary (Version Date: ___)
- □ Advertisements (printed, audio, or video)
- □ Study Instruments (surveys, questionnaires, etc.)
- □ Scripts
- □ External Approvals (IRB, Schools, or Centers)
- □ Grant Application
- □ Flyers, Posters and Brochures
- □ Informed Consent Forms/Assent Forms
- □ CITI Certificates
- □ Other
* E-SIGNATURES ARE **REQUIRED PRIOR TO SUBMISSION** from the following:

* Department Chair or Dean
* Principle Investigator
* Co-Investigator(s)
* Faculty Advisor (for students only if different from PI)

Please contact the Office of Research and Sponsored Programs if you need assistance with setting up an account on [www.irbnet.org](http://www.irbnet.org).
Appendix L

Modification Reviewer Checklist
MODIFICATION REVIEW WORKSHEET

<table>
<thead>
<tr>
<th>Protocol Number:</th>
</tr>
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<tbody>
<tr>
<td>Protocol Title:</td>
</tr>
<tr>
<td>Principal Investigator:</td>
</tr>
</tbody>
</table>

§46.110(b) (2) An IRB may use the expedited review procedure to review minor modifications of already approved research:

| Is this a minor change to previously approved research? If YES → continue. If NO → STOP the amendment cannot be reviewed via expedited review. |  □ Yes □ No |
| Does the change alter the risks/benefit ratio? If NO → continue; If YES → STOP change is not minor and amendment cannot be reviewed via expedited review. | □ Yes □ No |
| Will the modification likely impact the subjects' willingness to participate? If NO → continue; If YES → STOP change is not minor and amendment cannot be reviewed via expedited review. | □ Yes □ No |

Please describe the requested changes and any protocol specific comments below:

☐ Approve

☐ Recommended for Full Committee; please provide rationale in space provided below.

Comments:  

Reviewer:  | Date:

Review Worksheet Version 7/2/2003
Appendix M

Report of Unanticipated Problems

Involving Risks to Subjects or Others
REPORT OF UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS

Instructions: Federal regulations [45 CFR 46.103(b)(5) and 21 CFR 56.108(b)(1)] require the prompt reporting by investigators "any adverse events or unanticipated problems involving risk to subjects or others (UIRITO)." The IRB defines unanticipated problems or risks to others as any problem or event which in the opinion of the local investigator was unanticipated, serious and at least possibly related to the research procedures. Report to the IRB within 5 working days, all protocol deviations, adverse events, serious adverse events, and unanticipated problems. Non-serious problems/events do not meet the IRB's definition of UIRITO and should be reported in summary form only at the time of continuing review or in the final report.

<table>
<thead>
<tr>
<th>1. GENERAL INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Title:</td>
</tr>
<tr>
<td>Protocol Number:</td>
</tr>
<tr>
<td>Name of Person Reporting:</td>
</tr>
<tr>
<td>Date of Event:</td>
</tr>
<tr>
<td>On site:</td>
</tr>
<tr>
<td>Off site:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. PRINCIPAL INVESTIGATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>School/Department:</td>
</tr>
<tr>
<td>E-mail Address:</td>
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</tbody>
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<table>
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<tr>
<th>3. CO-INVESTIGATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>School/Department:</td>
</tr>
<tr>
<td>Campus Mailing Address:</td>
</tr>
<tr>
<td>E-mail Address:</td>
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</tbody>
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<table>
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<tr>
<th>4. TYPE OF EVENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>The event is believed to be related to the research</td>
</tr>
<tr>
<td>The event is not believed to be related to the research</td>
</tr>
<tr>
<td>Protocol Deviation (Please describe deviation below and risk to subject that was eliminated as a result)</td>
</tr>
<tr>
<td>Any deviation from the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research subject</td>
</tr>
<tr>
<td>Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur</td>
</tr>
<tr>
<td>Unanticipated Problem (Please describe the nature of unanticipated problem below and the change in the risk-benefit ratio if applicable)</td>
</tr>
<tr>
<td>Any serious event, including on-site and off-site adverse events, injuries, side effects, deaths or other problems which in the opinion of the local investigator was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures</td>
</tr>
<tr>
<td>Any publication in the literature, safety monitoring report, interim result or other finding that indicates an unexpected change to the risk-benefit ratio of the research</td>
</tr>
<tr>
<td>Adverse Event (Please describe the event and the nature of the risk to subjects below)</td>
</tr>
<tr>
<td>Any breach in confidentiality that may involve risk to subject or others</td>
</tr>
<tr>
<td>Any complaint of a subject that indicates an unanticipated risk that cannot be resolved by the research staff</td>
</tr>
<tr>
<td>Any serious and possibly related event which in the opinion of the investigator constitutes an unanticipated risk</td>
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</tbody>
</table>

<table>
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<tr>
<th>5. INFORMED CONSENT PROCESS</th>
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</thead>
<tbody>
<tr>
<td>Does this problem/event alter risk to past, present or future subjects?</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Based on your judgment, should this problem/event be added to the consent form as a potential risk? Explain rationale.</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>
Based on your analysis of this problem/event, should currently enrolled subjects be notified? Yes [ ] No [ ]

Explain rationale.

* E-SIGNATURES ARE REQUIRED PRIOR TO SUBMISSION from the following:

Principle Investigator
Co-Investigator(s)
Appendix N

Report of Protocol Deviation Not Involving Risk to Subjects
**REPORT OF PROTOCOL DEVIATION NOT INVOLVING RISK TO SUBJECTS**

Instructions: Federal Regulations require that human subject research be conducted only with prior IRB approval and in accordance with IRB approved procedures. Any modification made to a study which has not received IRB approval prior to implementation is considered a protocol deviation and is not in compliance with regulations or IRB policy. Reports to the IRB should be submitted via IRBNet within 5 working days of the deviation being discovered or made known. Once discovered, no additional work that deviates from the approved protocol is to be carried out. Deviations should also be summarized in the next continuing review of the study or final report.

<table>
<thead>
<tr>
<th>1. GENERAL INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Title:</td>
</tr>
<tr>
<td>Protocol Number:</td>
</tr>
<tr>
<td>Initial Report:</td>
</tr>
<tr>
<td>Name of Person Reporting:</td>
</tr>
<tr>
<td>Date(s) of Event:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. PRINCIPAL INVESTIGATOR</th>
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<tbody>
<tr>
<td>Name:</td>
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<tr>
<td>E-mail Address:</td>
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<tr>
<th>3. CO-INVESTIGATOR</th>
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<tbody>
<tr>
<td>Name:</td>
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<tr>
<td>E-mail Address:</td>
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<table>
<thead>
<tr>
<th>4. TYPE OF DEVIATION (Check appropriate box and describe in detail below)</th>
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</thead>
<tbody>
<tr>
<td>Research conducted without IRB approved protocol (includes continuing research after lapse in IRB approval)</td>
</tr>
<tr>
<td>Research modified without prior IRB approval (includes use of consent document not stamped by the IRB, over-enrollment of subjects, extension of study dates, addition of study procedures, etc)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. PLAN FOR CORRECTIVE ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe below the plan for corrective action</td>
</tr>
</tbody>
</table>

**E-SIGNATURES ARE REQUIRED PRIOR TO SUBMISSION** from the following:

Principle Investigator
Co-Investigator(s)
Appendix O

Human Subjects Research Final Report
HUMAN SUBJECTS RESEARCH FINAL REPORT

Instructions: Principal investigators have the responsibility of informing the IRB when a study has been completed. A study is considered to be open and active until either it is closed administratively by the IRB or the investigator has submitted a Human Subject Research Final Report to the IRB for the applicable study. Complete this form when an approved human participant research project is CONCLUDED. Attach a copy of all relevant materials to this form to be reviewed by the IRB.

<table>
<thead>
<tr>
<th>1. General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Title:</td>
</tr>
<tr>
<td>Date of Report:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Principal Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Email Address:</td>
</tr>
<tr>
<td>Faculty:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Co-Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
</tr>
<tr>
<td>Email Address:</td>
</tr>
<tr>
<td>Faculty:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Reason For Closure</th>
</tr>
</thead>
<tbody>
<tr>
<td>The only remaining activity involves the analysis of aggregate data sets without individual subject identifiers</td>
</tr>
<tr>
<td>All research related activities, including data analysis, has been completed</td>
</tr>
<tr>
<td>Study closed at this site by sponsor. Please Explain:</td>
</tr>
<tr>
<td>Other. Please Explain:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Subject Enrollment: Enter &quot;0&quot; Where there are no numbers to report. Please do not leave any spaces blank.  Maximum number of subjects/records approved for enrollment:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Since Last IRB Approval¹</td>
</tr>
<tr>
<td>Number of subjects screened</td>
</tr>
<tr>
<td>Number of subjects enrolled</td>
</tr>
<tr>
<td>Number of subjects who were dropped</td>
</tr>
<tr>
<td>Number of subjects who voluntarily withdrew</td>
</tr>
<tr>
<td>Number of female participants enrolled</td>
</tr>
<tr>
<td>Number of male participants enrolled</td>
</tr>
<tr>
<td>Number of minors enrolled</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Criteria For IRB Closure of Research: Please make sure to answer all questions (please respond with N/A or NONE if question is not pertinent to study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. In the past year have there been any of the following?</td>
</tr>
<tr>
<td>- Any expected/unexpected and/or serious/non-serious associated adverse events:</td>
</tr>
<tr>
<td>- Unanticipated problems or adverse events involving risks to subjects or others:</td>
</tr>
<tr>
<td>- Withdrawal of Subject(s) from the research, including reasons:</td>
</tr>
<tr>
<td>- Complaints about this research study:</td>
</tr>
<tr>
<td>&quot;If the answer is &quot;YES&quot; to any items in 6a, explain each:&quot;</td>
</tr>
<tr>
<td>b. Were all events, problems, withdrawals, or complaints reported promptly to the IRB?</td>
</tr>
<tr>
<td>&quot;If &quot;NO&quot; to Question 6b, explain:&quot;</td>
</tr>
<tr>
<td>c. Provide copies of and/or summarize* below:</td>
</tr>
<tr>
<td>All monitoring reports, Sponsor's reports, preliminary results, abstracts of recent scientific literature with full citation</td>
</tr>
</tbody>
</table>

*If the answer is "YES" to any items in 6a, explain each:

b. Were all events, problems, withdrawals, or complaints reported promptly to the IRB?  Yes  No  NA

"If "NO" to Question 6b, explain:

c. Provide copies of and/or summarize* below:

Attached  N/A
Any other information that has become available since the last IRB review related to the risks and benefits associated with this study. □ Attached □ N/A

*Summary: (if applicable)

d. Please provide a brief summary*, report or abstract of the study findings (if available)
□ Findings attached □ N/A

*Summary: (if applicable)

e. Did the research consent form include a statement that subjects would be provided with additional information (preliminary and/or study findings, randomization arm, etc.)?
□ YES □ NO □ N/A

*If “YES” to Question 6e, have subjects been provided with this information?
□ YES (Please include a copy of what was sent to subjects)
□ NO (Please explain):

f. Are identifiable data still being stored for this study? Identifiable data include:
   - Paper or electronic records that are connected to name, address, email address, phone number, medical record number, student record number or any code that could make it possible to link the data to an individual
   - Voice or video recordings
□ N/A (protocol did not include the collection of identifiable data)
□ YES*
□ NO - Data has been de-identified as specified by the IRB-approved protocol

*If “YES” to Question 6f was this approved by the IRB? Explain, in detail, the measures that are being taken to protect the confidentiality of the records/recordings:

7. Publication and Data Collection

a. Were there any publications, presentations, manuscripts derived from this research?
□ YES* □ NO

*If “YES” to Question 7a, please list or attach findings:

**E-SIGNATURES ARE REQUIRED PRIOR TO SUBMISSION** from the following:

Principle Investigator
Co-Investigator(s) (if applicable)
Faculty Advisor (for students only if different from PI)

Please contact the Office of Research and Sponsored Programs if you need assistance with setting up an account on [www.irbnet.org](http://www.irbnet.org).
Appendix P

IRBNet User Information
This Energizer covers how to register an account in IRBNet and manage your User Profile. It will illustrate how to:

- Create and activate your account in IRBNet
- Manage your affiliations from your User Profile
- Add and submit necessary Training & Credential records
- Maintain your T&C records on an on-going basis
To begin the registration process, go to [www.irbnet.org](http://www.irbnet.org) and click the New User Registration link.

- Users that are not registered on IRBNet may click here to self-register.
- If you have forgotten your password, click here.
Basic Account Information

Fill out your first and last name, and choose a username and password.

- Always use your proper name, with standard capitalization as this information is used throughout the system.
- Passwords must contain 8 (eight) characters.
Individual Terms of Use

All IRBNet users must agree to the Individual Terms of Use in order to register on the system.

IRBNet: Individual User Terms of Use

To register on IRBNet, you must read and agree to these Terms of Use, including any future amendments (collectively, the "Agreement").

1. Acceptance of Terms.

This Agreement governs your participation as an individual user of IRBNet. IRBNet is a service provided by Research Datware, LLC and both the company and service name are used interchangeably in this Agreement. In addition, when using particular IRBNet owned or operated services, you shall be subject to any posted guidelines or rules applicable to such services which may be posted from time to time. All such guidelines or rules are hereby incorporated by reference into this Agreement. IRBNet may also offer other services that are governed by different Terms of Use.

If this Agreement or any future changes are unacceptable to you, your sole remedy is to terminate your use of the Service. If you do not accept and abide by this Agreement, you may not use the services offered by IRBNet. By accessing or using the Service, you confirm your acceptance of, and agree to be bound by, this Agreement and any future changes to this Agreement. You agree to use the Service only in accordance with this Agreement. Nothing in this Agreement shall be deemed to confer any third party or benefits.

✓ Click "Accept" to accept the terms of use and continue.
Select Your Organization

Search to find your local institution. Contact your local coordinator if you are unclear where you should register.

- **Search to find your local institution.** You may search for your institution using any terms, such as "metro".

- **Highlight your institution, and click continue.**

If you do not see your organization listed, you may add a new organization.
Fill in your contact information. Be sure to use a valid email address. You will need to be able to receive emails from IRBNet in order to activate your account.

Use your institution-approved email to ensure that you receive your activation email and all automatic notifications from the system. Failure to use an appropriate email address may result in your account not being activated.
Finalize Registration

Verify that the information you have entered is correct. If any of the fields need to be edited, you may do so using the yellow "Edit" links.

Take a moment to confirm that the correct email is listed. It can be corrected by clicking "Edit" and re-entering the address.

Click "Register" and continue. An automated activation email will be sent to your email address.
Registration Complete

Once you finalize your registration, an activation email will be sent to your registered email address. You will need to click the link within that email to activate your account.

✓ Click "Continue" to finalize your registration and send the activation email.
Complete Activation

Visit the inbox of your registered email address and click the link within the "IRBNet Activation Required" email to activate your account.

☑ From your email inbox, open the "IRBNet Activation Required" message.

☑ Click the link to complete your activation.

IRBNet Activation Required

activation@irbnet.org to me

Welcome to IRBNet!

Please confirm your affiliation with Metropolitan IRB by clicking on the following link:

If you cannot click on the above link, you may copy and paste the link into your browser to confirm your affiliation.

Thank you,
The IRBNet Support Team

www.irbnet.org

Congratulations, you are now a member of the National Research Network!
Manage Affiliations

From the User Profile page you can add additional affiliations and trigger additional activation emails, if needed.

- Use the Add an Additional Affiliation link to add research affiliations.
- This is helpful if you are affiliated with multiple institutions, or if you are both a researcher and a board member.

- Click the “Send me an activation email” link to trigger an additional activation email to your registered email address.
Add Training & Credential Records

Upload appropriate Training & Credential (T&C) documents to your User Profile, as required by your local institution.

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders

Other Tools
Forms and Templates

Manage Your User Profile

You may access this page at any time to update your account information, change your password, manage your affiliations and manage your Training & Credentials records.

Note that if you add or update an affiliation you will be sent an activation email to your contact email address. You must click on the link in the activation email to confirm your changes.

User Account Information and Password [EXIT]

- User Name: jresearcher
- First Name: John
- Last Name: Researcher

Affiliations

- Add an Additional Affiliation

Researcher at Metropolitan University, Frederick, MD (Exit [Bronxville])

- Telephone Number: (123) 456-7890
- Email: irbdefault@mailinator.com

Training & Credentials

IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once your training and credentials can be easily linked to your projects from the Designer, are accessible and can be quickly accessed and tracked by the boards that review your projects. Some boards also limit your training and credentials without requiring you to link these records to specific projects.

There are currently no documents in your profile.

Click here to upload T&C documents.

Add New Record
Enter Record Information

Enter the appropriate information and select the correct T&C document. Be sure to enter accurate Credit Hours and Expiration Date if applicable.

- Click Attach to upload the document.
- Click Browse to select the correct T&C document to upload.
Submit T&C Documents

Submit uploaded T&C documents to the correct committee, according to local committee SOPs.

Note that if you add or update an affiliation you will be sent an activation email to your contact email address. You must click on the link in the activation email to confirm your changes.

User Account Information and Password

User Name: jresearcher
First Name: John
Last Name: Researcher

Affiliations

- Add an Additional Affiliation

Researcher at Metropolitan University, Frederick, MD
Telephone Number: (123) 456-7890
Email: jresearcher@university.edu

Training & Credentials

IRBNet allows you to track and share your training records, certifications, resumes, etc., added to your profile; your training and certifications can be easily linked to your project by your project teams and can be quickly accessed and tracked by the IRBDB. This feature permit you to directly submit your training and credentials without requiring you to enter them again.

Click to submit the document to your committee.
Manage your User Profile

Upload additional T&C documents as needed and keep your existing documents up to date as credentials change.

Note that if you add or update an affiliation you will be sent an activation email to your contact email address. You must click on the link in the activation email to confirm your changes.

User Account Information and Password

User Name: jresearcher
First Name: John
Last Name: Researcher

Affiliations

Add an Additional Affiliation

Researcher at Metropolitan University, Frederick, MD
Telephone Number: (123) 456-7890
Email: irbdefault@mailinator.com

Training & Credentials

- Highlighted Expiration Date indicates this document will expire within the next 60 days.
- Manage each T&C document using these icons.
- To update a document, use the Pencil icon.

<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Document Type</th>
<th>Description</th>
<th>Cre</th>
<th>Effective Date</th>
<th>Expiration Date</th>
<th>Last Modified</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>48.1</td>
<td>CII13 Principal Investigator's Biomedical Research - Basic Course</td>
<td>My CII13 Training</td>
<td>15</td>
<td>02/15/2011</td>
<td></td>
<td></td>
<td>Accepted</td>
</tr>
<tr>
<td>47.1</td>
<td>CV/Resume</td>
<td>My CV</td>
<td></td>
<td>05/03/2011</td>
<td>05/16/2011</td>
<td></td>
<td>Accepted</td>
</tr>
</tbody>
</table>

Add New Record
Where to Get Help...

Your Committee Office can offer you assistance and training on IRBNet as well as advice on how to comply with important policies and standards as you use IRBNet.
IRBNet provides the research community with an unmatched set of secure, web-based collaboration tools to support the design, management, review and oversight of research involving human subjects, animal models, recombinant DNA, and more.

- Manage your Submission Manager workspace
- Review project submission details, including documents, Training & Credentials, and COI Disclosures
- Communicate with committee administrators and members
- Add comments and reviewer documents to a submission
- Manage your review work queue
Log into IRBNet at: www.irbnet.org

Comprehensive Solutions

The Industry's Most Complete Solution
IRBNet's unmatched suite of electronic solutions drives compliance and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC, COI and other Boards with a unified solution.

Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. Powerful reporting and performance metrics. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.

Secure, Reliable and Cost-Effective
IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is cost-effective and designed to accommodate institutions of any size.

Satisfied Members
"Our first electronic meeting went so smoothly! It was over so fast the members didn't know what to do. They just sat there for a few minutes in disbelief."

- Bane Day
Director, Office of Research Integrity
Marshall University

2010 Events - Join Us
Access your Submission Manager

The Submission Manager provides you with quick access to all submissions that have been shared with you, as well as administrative meeting documents such as agendas and minutes.

- Advanced search tools allow you to search within agenda dates by keywords and Tags. You may also search all agenda dates at once using the "Search All" tool.
- Access reviewer templates, checklists, and committee guidance documents here.
- Agenda documents and Minutes can be found here.
Manage your work queue

Your default view is the next upcoming agenda date. Use the Submission Manager to manage the reviews you have been assigned for the next meeting.

- The flag indicates an active reminder, which may be read in the My Reminders page.
- One Star indicates you are the primary reviewer.
- Coordinator-defined Tags allow custom organization of submissions. Clicking the Tag will display all submissions with that Tag.
Notifications sent to you across all of your submissions will appear here. An email will be sent to your registered email address.

### My Reminders

An IRBNet personal reminder is automatically activated for you each time you receive a new message or alert. You can also set additional reminders for yourself on the Messages & Alerts page. Other IRBNet users do not see your personal reminders. You can turn on or silence a personal reminder without affecting other IRBNet users. You can also choose to view recently silenced reminders (within the past 30 days) in addition to your active reminders.

<table>
<thead>
<tr>
<th>IRBNet ID</th>
<th>Project Title</th>
<th>Message Type</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>163073-2</td>
<td>Motivations of Research Subjects: A Noce...</td>
<td>Reviewer Access Granted</td>
<td>03/30/2010 06:16 AM</td>
</tr>
</tbody>
</table>

- ✓ Indicates an active Reminder.
- ✓ Click the Project Title to go to the Submission Detail page.
- ✓ Click here to view the message.
View Submission Details

Click on the title of a submission to access the Submission Detail page and associated information about the project.
View Submission Detail (continued)

Scroll down to see additional information.

<table>
<thead>
<tr>
<th>Date</th>
<th>Signed By</th>
<th>Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/30/2010 08:06 AM</td>
<td>Murray Rogers</td>
<td>Team Member</td>
</tr>
<tr>
<td>03/30/2010 08:05 AM</td>
<td>Enrico Pelazzo</td>
<td>Advisor</td>
</tr>
<tr>
<td>03/30/2010 08:04 AM</td>
<td>John Researcher</td>
<td>Principal</td>
</tr>
</tbody>
</table>

* This Package has been Signed By:

This submission is currently shared with the following Committee Members:

<table>
<thead>
<tr>
<th>IRBNet User</th>
<th>Special Designation</th>
<th>Share Date</th>
<th>Shared By</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franklin, Lisa</td>
<td>Primary Reviewer</td>
<td>03/30/2010 08:10 AM</td>
<td>Halway, Ann</td>
</tr>
<tr>
<td>Halway, Ann</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Long, Ji</td>
<td>Secondary Reviewer</td>
<td>03/30/2010 08:10 AM</td>
<td>Halway, Ann</td>
</tr>
</tbody>
</table>

Committee Messages (1)

- [Send Committee Mail to Members and Administrators]

Add comments and reviewer documents to this submission.

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Comment</th>
<th>Recommend</th>
<th>Last Updated</th>
<th>Completed Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long, Ji</td>
<td>I support approval of this amendment. See attached Approve reviewer worksheet.</td>
<td>03/30/2010 08:12 AM</td>
<td>08:12 AM</td>
<td>View</td>
</tr>
<tr>
<td>Halway, Ann</td>
<td>All proper documentation has been submitted. Please complete and attach the appropriate reviewer worksheet.</td>
<td>03/30/2010 08:10 AM</td>
<td>08:10 AM</td>
<td>View</td>
</tr>
</tbody>
</table>

✓ Electronic Signatures
✓ Committee/Admin access list
✓ Reviewer comments. The check indicates the user has completed their review.
✓ Click here to send a message to any member with whom the submission has been shared.
Start your review process

Click on a document to open the document for viewing, downloading, or printing.

Open any submitted document by clicking the blue link.
View project details

Project Administration buttons (on left) allow complete read-only access to historical project information as seen by the investigator.

- Designer: review all documents submitted in previous packages.
- Reviews: view historical review details for all packages, decision letters, and other board documents.
- Project History: view the complete submission history.
Add reviewer comments and documents

You may record your review comments and attach documentation such as reviewer worksheets.

This package has been signed by:

<table>
<thead>
<tr>
<th>Date</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/30/2010 08:06:15</td>
<td>Signed by Murray Rogers as Team Member</td>
</tr>
<tr>
<td>03/30/2010 08:06:38</td>
<td>Signed by Enrico Palazzo as Advisor</td>
</tr>
<tr>
<td>03/30/2010 08:04:49</td>
<td>Signed by Trent Researcher as Principal Investigator</td>
</tr>
</tbody>
</table>

This submission is currently shared with the following Committee Members and Administrators:

<table>
<thead>
<tr>
<th>IRBNet User</th>
<th>Special Designation</th>
<th>Share Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franklin, Lisa</td>
<td>Primary Reviewer</td>
<td>03/30/2010 08:10 AM</td>
</tr>
<tr>
<td>Hulvey, Ann</td>
<td>Secondary Reviewer</td>
<td>03/30/2010 08:10 AM</td>
</tr>
<tr>
<td>Ling, Ji</td>
<td>Not Applicable</td>
<td></td>
</tr>
</tbody>
</table>

Select [Committee Messages (1)] to view comments by administrators and other members.

Click “Add” to record reviewer comments.

Add comments and reviewer documents to this submission.

- Ling, Ji: I support approval of this amendment. See attached approval reviewer worksheet.
- Hulvey, Ann: All proper documentation has been submitted. Please complete and attach the appropriate reviewer worksheet.

Note: Administrator / reviewer comments are private and may not be accessed by researchers.
Add comments

Use this page to record any comments you have regarding this submission.

- Record your comments in the rich text editor.
- Be sure to save your comments first before doing anything else.
- You may attach completed reviewer worksheets, edited consent forms and other documents here.
Attach completed reviewer worksheets, edited consent forms and other documents here.

If your institution uses a reviewer checklist wizard, it will be located here.
"Electronically Sign" your review

Checking the "Mark my personal review as complete" box will indicate a completed review on the Submission Detail page. It will also help you track your work on your Submission Manager.

**Step 1:** Record your recommendation for this submission here.

**Step 2:** When your review is complete, be sure to check this box.

**Step 3:** Save and exit when finished.

Note: Accomplishing steps 1, 2, and 3 verifies you have completed your review.
Complete your review

Once you have completed your review, use Committee Messages as a checklist.

This package has been signed by:

15  Signed by Murray Rogers as Team Member
38  Signed by Enrico Palazzo as Advisor
49  Signed by Trent Researcher as Principal Investigator

Committee Messages will display all notifications for this submission (including important messages from your Coordinator).

Your comments are recorded.

Update your comments and reviewer documents.

<table>
<thead>
<tr>
<th>Reviewer</th>
<th>Comment</th>
<th>Recommend</th>
<th>Last Updated</th>
<th>Completed Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Franklin, Lisa</td>
<td>I have reviewed the study and support approval as well. See the attached reviewer worksheet. The consent form is very clear. Only a few grammatical edits. See attached.</td>
<td>Approve</td>
<td>03/30/2010 10:37 AM</td>
<td>03/30/2010 10:39 AM</td>
</tr>
<tr>
<td>Lang, Ji</td>
<td>I support approval of this amendment. See attached reviewer worksheet.</td>
<td>Approve</td>
<td>03/30/2010 08:12 AM</td>
<td>03/30/2010 08:12 AM</td>
</tr>
<tr>
<td>Halway, Ann</td>
<td>All proper documentation has been submitted. Please complete and attach the appropriate reviewer worksheet.</td>
<td></td>
<td>03/30/2010 08:10 AM</td>
<td>03/30/2010 08:10 AM</td>
</tr>
</tbody>
</table>
Committee Messages & Alerts

All messages from your administrator relating to this submission are filed in the Messages & Alerts page as a permanent part of the audit trail.

- The red number will decrease every time a message is “silenced.”
- Click the red flag and “silence” the message as an easy way to keep track of completed reviews.
Track your progress

Your Submission Manager will show you which submissions you have completed your review on.

- The filter tool hides your completed reviews.
- "Check mark" indicates you have completed your review.
Your Committee Office can offer you assistance and training on IRBNNet as well as advice on how to comply with important policies and standards as you use IRBNNet.
Researcher 1: New Project Submission

Training Energizer

IRBNet provides the research community with an unmatched set of secure, web-based collaboration tools to support the design, management, review and oversight of research involving human subjects, animal models, recombinant DNA, and more.

As a Researcher, Research Manager, or Research Coordinator you should know how to:

- Log In to IRBNet
- Manage projects in your My Projects page
- Build Your First Electronic Project Package
- Share with Your Research Team
- Communicate with Your Team
- Sign Your Project Package
- Submit Your Project Package for Review
- Revise Incomplete Submissions
- Access Review Decisions and Board Documentation
Log In to IRBNet

Enter your User Name and Password at: www.irbnet.org

Comprehensive Solutions

The Industry’s Most Complete Solution
IRBNet's unmatched suite of electronic solutions drives effectiveness and productivity for your Administrators, Committee Members, Researchers and Sponsors. These powerful research design, management and oversight tools support your IRB, IACUC, IBC and other Boards with a unified solution.

Flexible, Intuitive and Easy to Use
Your own forms. Your own processes. Your own standards. The data you need. From electronic submissions to form wizards, to agendas, minutes, and more. Our easy to use, web-based tools are rapidly launched and backed by our best practices expertise and the industry's leading support team.

Secure, Reliable and Affordable
IRBNet's secure web-based solution is accessible to your research community anytime, anywhere. Our enterprise-class technology is affordable and designed to accommodate institutions of any size.

Test Drive IRBNet
See for yourself... Demo

Satisfied Members
"IRBNet makes our entire operation more efficient, saving time and money. It is amazing how much more we got done, in less time and with the same staff. It's fantastic."
- Ken Grinett
IRB Manager
Sacred Heart Health System

2008 Events - Join Us
Access My Projects

The My Projects page provides you with quick access to all of your projects.

Access your institution's forms and guidance documents here.

NOTE: The search feature at the top allows you to search by Project Tags, as well as fields such as Internal Reference Number and Sponsor.
Manage your My Projects page

Organize your projects and manage workflow using Project Tags and Archiving.

- Create and edit Project Tags by clicking this link.
- Click here to Archive projects which are no longer active.
- Add any existing Project Tag as a Personal tag (only you can see it) or a Shared tag (everyone with access can see it).
Create your New Project

Provide basic information about your project.

The asterisk indicates a required field.
Build your project package
Attach your electronic project documents.

IRBNet ID: 137618-1

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders

Project Administration
Project Overview

Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts

Other Tools
Forms and Templates

---


Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Metropolitan IRB, Frederick, MD
Select a Document: IRB Submission Checklist

Download

Step 2:
Assemble your document package. In addition to adding project documents to your package, IRBNet will link your project team's Training & Credentials to your package.

Documents in this Package:

There are currently no documents in this package.

Add New Document

Validation:
✓ Drop down menu for institution-specific libraries.
✓ Select appropriate document and download.
✓ Add project documents here.
IRBNet provides two mechanisms for entering documents into the system.

- **Attach Document**

You may attach documents to this package by clicking the "Browse..." button to locate a document and then by clicking "Attach". The "Document Type" and optional "Description" are informational fields to assist you in managing your attached documents.

- **Browse your hard drive for completed documents and attach as required by your institution.**

- **If your institution requires the completion of an online IRBNet Document Wizard, it will be located here.**

Also use the IRBNet Document Wizards to create documents on-line. Documents that you create on-line are typically attached in PDF format.
Complete your project package

Attach as many documents as necessary. Be sure to link any required Training & Credential (T&C) documents.

- View
- Update
- Delete document

**NOTE:** For information on uploading and submitting T&C documents, see the New User Registration energizer.

**Click to Link any necessary T&C documents to this package.**
Share with your Research Team

Give access to any colleague with whom you will be collaborating.

- **Share**: Use this option if you wish to share your project with other Researchers, Committee Members, Administrators or Sponsors at your own institution or any other institution. For example, you may wish to share this project with other members of your research team so that you may collaborate in the design and development of the project, or with a selected Committee Member or Administrator to solicit feedback prior to submitting your project for review. You may provide any individual with Full, Write or Read access.

- **Full-Edit**: Use this option only if your project is a multi-site project and you wish to send a complete and independent copy of this project to a Principal Investigator at another site. The local Principal Investigator will be able to obtain project documents from the lead site and may modify their copy of those documents (such as consent forms) to meet the requirements of their local Board. You will be able to monitor the progress of this project at every local site. The other local Principal Investigators will also be able to monitor the progress of this project at every local site (including your own).

- **Transfer**: Transfer your ownership of this project to another user. In doing so you will relinquish all access to this project and the designated user will be granted Full access.
Select your colleague's institution

You may collaborate both within your Institution and across Institutions in the course of your project.

- Select 'Research Institution' to share with a project collaborator.
- Select the Institution in which your colleagues are members.
- The default institution highlighted is your home institution.
Set the proper level of access

You may grant each member of your team the level of access that they require.

✓ Grant only the level of access required for each collaborator.
Communicate with your Project Team

Use the Send Project Mail tool to quickly communicate with your team.

New Project Message


Use this page to send communications to the Project Team or to the Board Contacts for any submitted package. Your message will also be automatically posted to the Project Messages & Alerts. Messages sent from this page become part of the project record and can be viewed by the Project Team and other users who have been granted access to this project as well as by Committee Members and Administrators that review this project.

Project Team:

<table>
<thead>
<tr>
<th>User</th>
<th>User Organization</th>
<th>Send Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chandy, Francis</td>
<td>Metropolitan University, Frederick, MD</td>
<td></td>
</tr>
<tr>
<td>Nebzda, Enrico</td>
<td>Metropolitan University, Frederick, MD</td>
<td></td>
</tr>
<tr>
<td>Researcher, John</td>
<td>Metropolitan University, Frederick, MD</td>
<td></td>
</tr>
</tbody>
</table>

Board Contacts:

There are no submitted packages.

Subject: IRBNet message from John Researcher


Please login to IRBNet to review this project.

Regards,

John Researcher
Sign your project package

Electronic signatures become a permanent part of your electronic audit trail.

- Choose your project role from the drop down menu.
- Sign according to your institution's requirements.
- Anyone with shared access to the study may sign a study.
Submit your package for review

You may submit your package to one or more boards for review.

[Screen shot of IRBNet interface with highlighted options]

The default board for your institution is highlighted.
Submit to your Board

The system enables you to send a message to your coordinator, and indicate submission type. IRBNet knows the coordinator of your committee.

Note: The package will be locked upon submission.
Did you submit an incomplete package?

If you have forgotten to add a necessary document or need to make a quick change to a recently submitted project package, CONTACT YOUR LOCAL BOARD COORDINATOR.

For advanced topics, such as submitting subsequent packages (for reportable events, continuing reviews, modifications, etc.), please refer to the R2 Training Energizer. CONTACT YOUR LOCAL BOARD COORDINATOR if you have questions.
Managing unlocked packages

If revisions are needed before your submission is reviewed, your coordinator may unlock the package for you to revise. Unlocked projects can easily be managed from the My Projects page.

Indicates your Coordinator has “unlocked” the package for further revisions.
Make necessary revisions

While the package is "unlocked," you may add new documents or revise existing ones as needed.

- View complete audit trail of package locking and unlocking. Instructions from your Coordinator may be found here.

- Indicate to your Coordinator you have completed your revisions. This will "re-lock" the package.
Receive your review decision

Review decisions are available in real time from your Project Overview.

[Image of IRBNet interface]

- [ ] Click “Review Details.”
View Review Details

Details include Agenda Date, Review Type, Status, Effective and Expiration Dates, and Board Documents.

<table>
<thead>
<tr>
<th>IRBNet ID: 137618-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Welcome to IRBNet</td>
</tr>
<tr>
<td>John Researcher</td>
</tr>
<tr>
<td>My Projects</td>
</tr>
<tr>
<td>Create New Project</td>
</tr>
<tr>
<td>My Reminders (3)</td>
</tr>
<tr>
<td>Project Administration</td>
</tr>
<tr>
<td>Project Overview</td>
</tr>
<tr>
<td>Designer</td>
</tr>
<tr>
<td>Share this Project</td>
</tr>
<tr>
<td>Sign this Package</td>
</tr>
<tr>
<td>Submit this Package</td>
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<tr>
<td>Delete this Package</td>
</tr>
<tr>
<td>Send Project Mail</td>
</tr>
<tr>
<td>Reviews</td>
</tr>
<tr>
<td>Project Risks</td>
</tr>
<tr>
<td>Messages &amp; Alerts (2)</td>
</tr>
<tr>
<td>Other Tools</td>
</tr>
</tbody>
</table>


**Metropolitan IRB, Frederick, MD**

<table>
<thead>
<tr>
<th>Submission Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submitted To: Meteoropolitan IRB, Frederick, MD</td>
</tr>
<tr>
<td>Submitted by: John Researcher</td>
</tr>
<tr>
<td>Submission Date: 09/30/2009</td>
</tr>
<tr>
<td>Submission Type: New Project</td>
</tr>
<tr>
<td>Local Board Reference Number: 09-497</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda</td>
</tr>
<tr>
<td>10/16/2009 08:00 AM</td>
</tr>
<tr>
<td>Review Type</td>
</tr>
<tr>
<td>Expedited Review</td>
</tr>
<tr>
<td>Status</td>
</tr>
<tr>
<td>Pending Review</td>
</tr>
<tr>
<td>Effective Date</td>
</tr>
<tr>
<td>Expiration Date</td>
</tr>
</tbody>
</table>

**Board Documents:**
There are currently no documents from Metropolitan IRB.

- Follow the review process here.
- Board documents will appear here.
- Board Documents and review information for all packages can be found here.
Where to Get Help...

Your Committee Office can offer you assistance and training on IRBNet as well as advice on how to comply with important policies and standards as you use IRBNet.
This Energizer covers advanced submission topics for Researchers, Research Managers, and Research Coordinators. This Energizer illustrates how to:

- Advanced My Projects Management
- Manage My Reminders
- Review Project Messages & Alerts
- Create a Subsequent Package
- Add and Revise Documents
- Complete and Submit Subsequent Package
Did you submit an incomplete package?

If you have forgotten to add a necessary document or need to make a quick change to a recently submitted project package, CONTACT YOUR LOCAL BOARD COORDINATOR.

Responses to board requests and normal actions in the project life cycle (reportable events, continuing reviews, adverse events, study team changes, investigator - and sponsor - initiated modifications, etc.) require the creation of subsequent packages in a project. CONTACT YOUR LOCAL BOARD COORDINATOR if you have questions.
Advanced My Projects Management

Using the Search field combined with the Search By Tag menu enables focused searching.

- Search Example: Find all Oncology Department projects with Dr. Smith as the PI (Search "Smith" + "Oncology Dept" tag)

- Click any Project Tag to search for all projects with that Tag.
Receive Notifications

Once the committee has rendered a decision you will receive an automatic e-mail notification. That notification can be found in My Reminders.

- Click My Reminders to view all active notifications sent to you concerning any of your projects.
- The flag indicates an active Reminder for this project.
Review My Reminders

All notifications sent to you across all of your projects will appear here. An e-mail will be sent to your registered e-mail address.

- Click the project title to go to the Project Overview page.
- Click action type to view message.
Silence Reminders

Reminders are indicated with red flags. Silencing the Reminders will remove them from this page in the future.

- Indicates an active Reminder. Clicking the red flag will "silence" the Reminder.
Review Project Messages & Alerts

All project-specific notifications remain filed in the Messages & Alerts page as a permanent part of the project file.

Grey flags indicate messages and alerts that are silenced, either because:
- It was sent to another member of the team, or;
- You have previously silenced the message.

Click here to access project-specific Messages & Alerts.
Revise Your Project

You can easily revise your project by creating a new package. All versions of your project become a permanent part of your electronic project record.

- Note that this is the first package in the sequence.
- To create a new package from an existing package, click on "Project History."
Create a New Package

The Project History page displays all packages in this project. From here you can create a second package.


The following document packages are available in Project History:

<table>
<thead>
<tr>
<th>Pkg #</th>
<th>Package Type</th>
<th>Status</th>
<th>Create Date</th>
<th>Submission Date</th>
<th>Review Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>New Project</td>
<td>Modifications Required</td>
<td>09/30/2009</td>
<td>09/30/2009</td>
<td>10/05/2009</td>
</tr>
</tbody>
</table>

One Package found.

Your current document package has already been submitted and is presently locked by your Board. You may prepare new or modified documents (such as Revision/Amendment materials, Renewal/Continuing Review materials, and Adverse Event Reports) by creating a new document package.

✓ Click "Create New Package."
Access New Package

The new package has a status of Work in Progress and is editable.

- Note that a second package is created.
- The Project History lists all packages in the project lifecycle.
- Now click on the New Document Package to begin building the package.
Add or Revise Documents

Bring forward and revise documents previously submitted, or add a new document as required.

To revise an older document:
1. Download the previous version to your computer, modify as required and save.
2. Click on the pencil icon (see next page for more information).

To add a new document, click "Add New Document".

All documents from previously submitted packages are listed here.
Attach a Document

Browse and locate the revised or new document on your computer, and attach by clicking the Update button.

- This attachment was loaded from the file Consent Form.doc.
- It was attached on 09/30/2009.
- It has a size of 93184 bytes.

- Browse your hard drive for documents, and attach.
- This view is for updating a document from package 1. The view for attaching a new document is similar.
Document Management Tools

IRBNet provides powerful tools to update and review project documents.

![Image of IRBNet interface with highlighted options: View, View revision history, Update, Delete document.]

- **View**
- **View revision history**
- **Update**
- **Delete document**

**Note:** After revising, the document is removed from the visible list of documents from previous packages.
Revision History

The document revision history tool reveals all versions of a document type in the project.


Step 1:
Download blank forms, document templates and reference materials to assist you in assembling your document package.

Select a Library: Metropolitan IRB, Frederick, MD
Select a Document: Application for Continued Approval

Step 2:
Assemble your document package. In addition to adding project documents to your package, you can link your project team's Training & Credential to your package.

New and Revised Documents in this Package:

The Document Revision History lists the most recent document and every previous version submitted by package.
Complete Submission Process

When project documentation is completely assembled, sign and submit according to your institution’s SOPs.

**View T&C documents linked to any package within this project.**

**Attach T&C documents to this package is necessary.**
Your Committee Office can offer you assistance and training on IRBNet as well as advice on how to comply with important policies and standards as you use IRBNet.