Continuing Review or Study Closure Form

Abbreviated Study Title: Sample Project

Principal Investigator: Nick Getzendanner

Study Coordinator:

1.0 * Project Status: please check the appropriate box:

- [ ] Currently enrolling subjects
- [ ] Subjects have not been enrolled and additional risks have not been identified
- [ ] Subjects have not been enrolled and additional risks have been identified
- [ ] CLOSED TO ACCRUAL: Subjects are still receiving treatment/intervention/procedures.
- [ ] CLOSED TO ACCRUAL: Subjects have completed study treatment/intervention/procedures, but continue in follow-up observation or long-term follow-up.
- [ ] CLOSED TO ACCRUAL: Subject involvement is complete, but data analysis is ongoing. (If all data are de-identified and the PI no longer plans to access identifiable information, the PI can terminate the project and analyze data without IRB approval.)
- [ ] The NU IRB has placed this study on clinical hold.
- [ ] The sponsor has placed this study on clinical hold.
- [ ] The PI has placed this study on clinical hold.
- [ ] The FDA has placed this study on clinical hold.
- [ ] This Project is now completed/terminated.

Abstract Summary (This section maps over from the approved eIRB application and cannot be modified unless a Revision form is submitted):

...

Protocol Procedural Summary (This section maps over from the approved eIRB application and cannot be modified unless a Revision form is submitted):

2.0 Please provide a summary of any relevant recent literature and interim findings from the last year.

Relevant documents:

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
</tr>
</tbody>
</table>

Relevant Literature Link:

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
</tr>
</tbody>
</table>

3.0 Upload relevant multicenter trial reports from the last year.

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
</tr>
</tbody>
</table>
4.0 Any other relevant information, especially information about risks associated with the research in the last year? This includes Data Safety Monitoring Board reports that have not already been submitted to the IRB.

Related documents:
Name | Version
--- | ---
There are no items to display

5.0 In your opinion based on the study results to date, do the risks continue to be reasonable in light of the potential benefits?
- Yes
- No

If no, please explain:

Submission ID: CR1_STU00048289
Study Title: Sample Project
PI: Nick Getzendanner
Expiration Date: 5/14/2012

Protocol Completion/Termination

1.0 Please indicate why you are closing this study:
Study was terminated by the investigator.

*Terminated means that the research was stopped before meeting the approved goals and objectives.

2.0 Please summarize the reason(s) for closing the study:
- If the study was never started, explain why.
- If the study objectives were met, summarize your research findings in lay language.
- If it is due to the identification of new risks, submit a Safety/Other form to report these new risks.

This study is being terminated because...

Attach relevant documentation (including documentation from the sponsor) about the study closure, including:
- Findings or publications resulting from this study
- Any documents to be shared with the subjects about this study
- Sponsor closure letters and sponsor documentation of datalock at Northwestern

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Number of Research Subjects

Total number of subjects/cases/records that have been approved by the IRB to be consented or studied:
48

1.0 Total number of subjects who have been consented to date. This includes all individuals who gave consent, even if they did not complete the study (such as screen failures who did not proceed to enrollment)

and/or

Total number of records, cases, samples that have been collected to date with a waiver of consent:
Note: If your answer is zero, explain why there has been no progress to date. If the study involves various groups of subjects, (such as healthy controls and patients, children and adults, etc.), provide a breakdown by subject group.

2.0 Enter the total number of subjects who were consented in the last year. This includes all individuals who gave consent, even if they did not complete the study (such as screen failures who did not proceed to enrollment), and/or

Total number of records, cases, samples that have been collected this year with a waiver of consent:

48

Note: If your answer is zero, explain why there has been no progress in the last year. If the study involves various groups of subjects, (such as healthy controls and patients, children and adults, etc.), provide a breakdown by subject group.

3.0 Enter the number of subjects who have withdrawn since the last review:

2

Please explain the reasons for withdrawal in the table below:

<table>
<thead>
<tr>
<th>Date Enrolled</th>
<th>Reason for Withdrawal</th>
<th>Other Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>8/25/2011</td>
<td>Subject has moved out of the country</td>
<td></td>
</tr>
<tr>
<td>10/1/2011</td>
<td>Subject did not have the time</td>
<td></td>
</tr>
</tbody>
</table>

4.0 Have there been any subject complaints that were not already reported to the IRB?

☐ Yes ☐ No If Yes, explain the nature of the complaint and how the matter was resolved.

5.0 * Is there a consent form available for each subject reported in 1.0?

☐ Yes ☐ No

If no, please explain:

6.0 If NU is the lead site and the study is a multi-institutional study, please provide the total number of subjects/cases/records that have been consented or studied to date across all study sites:

7.0 You must complete this section if this study utilizes the Jesse Brown VA Medical Center as a recruitment or performance site.

The Principal Investigator must sign the checklist that is uploaded. This is a VA requirement and the submission cannot be approved unless this is provided.

a. VA Submission Checklist: Please upload the VA Submission Checklist, signed by the PI. (This document is available here.)

b. Special Populations Form: Please complete the Special Populations form. (This document is available here.)

c. Appendix JBVAMC-A: Please complete the appendix and upload it to the application. (This document is available here.)

d. NU Data Security Form: Please complete the Data Security form and upload it to the application. (This document is available here.)
Revisions

1.0 Revisions - list of recent revisions created by the study team. Revisions that have been 'withdrawn' are not shown in this list:

<table>
<thead>
<tr>
<th>ID</th>
<th>Date</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9/1/2011</td>
<td></td>
<td>1) The subjects will now be compensated $10 for their participation instead of $5. 2) Noninvasive standard laboratory/clinical sensors applied to the skin has been added to check physiological arousal during experiment. 3) The possible length of the experiment was increased by ten minutes. A recruitment flyer was added. Revised documents with tracking changes: Consent.doc (Revised 9/1/2011) Recruit_E-mail.doc (Revised 9/1/2011) Protocol.doc (Revised 9/1/2011) New documents: Flyer.doc</td>
</tr>
</tbody>
</table>

*NOTE: list shows all revisions entered into the system between Mon May 16 09:46:21 CDT 2011 (date the study was approved or last reviewed) and Wed Apr 25 11:57:14 CDT 2012 (date this Periodic Review was approved or, if not approved, today)*

2.0 * Does the list above include all of the revisions since either the last periodic review or new project submission?
   - Yes ☐ No

3.0 If no, please explain:

Reportable Events

1.0 Safety-Other Events - list of recent Safety/Other Events created by the study team. Items that have been 'withdrawn' are not shown in this list:

<table>
<thead>
<tr>
<th>Description</th>
<th>Date Event Created</th>
<th>Status</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Safety Submission</td>
<td>3/22/2012 3:10 PM</td>
<td>Pre Submission</td>
<td>Enter a summary of the event here</td>
</tr>
</tbody>
</table>

*NOTE: list shows all events entered into the system between Mon May 16 09:46:21 CDT 2011 (date the study was approved or last reviewed) and Wed Apr 25 11:57:14 CDT 2012 (date this Periodic Review was approved or, if not approved, today)*

2.0 * Does the list above include all promptly reportable events that have occurred since the last periodic review or new project submission (whichever is later)? (Promptly reportable events include Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOS), Promptly Reportable Noncompliance (PRNC) and unanticipated and related or possibly related deaths.)
   - Yes ☐ No

3.0 If no, please explain, and complete a Safety/Other form at this time for any deaths, UPIRSOs, or Promptly Reportable Non-compliance matters that should have been reported previously to the IRB.
4.0 Please describe all deaths that occurred at NU or affiliate sites which did not require prompt reporting. This would include anticipated deaths that occurred in NU/Affiliate subjects.

<table>
<thead>
<tr>
<th>Event Date</th>
<th>Event Type</th>
<th>Event Outcome</th>
<th>Related to Study</th>
<th>Anticipated</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
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</tbody>
</table>

**Submission ID:** CR1_STU00048289  
**View:** SF - Authorized Research Personnel List

**Study Title:** Sample Project  
**PI:** Nick Getzendanner  
**Expiration Date:** 5/14/2012

**Authorized Research Personnel List**

<table>
<thead>
<tr>
<th>Person</th>
<th>Principal Role</th>
<th>Research Experience</th>
<th>Role in Consent Process</th>
<th>Training Certification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nick Getzendanner</td>
<td>Principal Investigator</td>
<td>Over twenty years experience in behavioral research.</td>
<td></td>
<td>Obtaining</td>
</tr>
</tbody>
</table>

**Key Research Personnel**

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Institution</th>
<th>Email Address</th>
<th>Phone Number</th>
<th>Role in Research Project</th>
<th>Human Subjects Training Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

* Is the Information above accurate?  
  ☐ Yes  ☐ No

If personnel are to be added or removed from the study, please submit a new Revision.

**Expiration Status**

You must complete this section if the study’s IRB approval is expired at the time you submit the continuing review form or will expire during the continuing review process.

1.0 Instructions: If, in the Principal Investigator's opinion, it is in the best interests of the research subjects to continue the study procedures (i.e., when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects), please contact IRB staff immediately to seek confirmation that the IRB agrees with this determination. If the investigator or IRB determines that it is not in the best interests of already enrolled subjects to continue participation, the PI must stop all human subjects research activities on this study, including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects.

Select one answer to best reflect the current status of the study:

- ☐ All research activities were stopped after the study expired (including subject recruitment, interaction with subjects, data collection, and analysis of identifiable data).
- ☐ Research continued after the study expired and approval from the IRB to conduct research during the lapse in approval was NOT obtained. (You must submit a Safety/Other submission form to report the conduct of research without IRB approval.)
- ☐ Research continued after the study expired but approval from the IRB to conduct research during the lapse in approval was obtained. (Upload correspondence from the IRB confirming this.)
2.0 Explain why the continuing review was submitted late and provide a plan to submit future continuing review submissions at least 45 days prior to expiration.

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Investigator’s Certification Regarding Conflict of Interest and Fiscal Responsibility

1.0 Below are the current answers regarding Conflict of Interest and Fiscal Responsibility for the Principal Investigator, co-investigators, and any other person listed on the authorized personnel list. Have there been any changes since the last IRB review?

☐ Yes  ☐ No

If yes, please describe these changes and submit a Revision form to make these changes in the Conflict of Interest section of the eIRB form.

1.0 Do you, a spouse, a child, any member of your household or any other person working with you at this site (co-investigators or sub-investigators) responsible for the design, conduct, or reporting of this research have an economic interest in, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? (5% ownership or more or a current value of $10,000).

no

If so, please upload a letter outlining any potential conflicts of interest:

2.0 Do you, a spouse, a child, any member of your household or any person working with you at this site (co-investigators or sub-investigators) responsible for this study have any existing financial holdings or relationships with the sponsor of this study? (This might include salary, royalty, or other payments from the sponsor that are expected to exceed $10,000 per year) Please note that this amount does not include salary from NIH or foundation for the % effort on the grant.

no

If so, please upload a letter outlining any potential conflicts of interest:

3.0 Do you, a spouse, a child, or any member of your household or any person responsible for this study possess a license agreement with the University or an external entity that would entitle you or other in sharing current or future commercial proceeds of the product being evaluated?

no
Summary of Study Status and Next Steps

Click the 'Finish' button to exit this page. The PI must then click on the 'Submit Periodic Review' activity in the project workspace to send to the IRB Office.

INSTRUCTIONS REGARDING REVISIONS SUBMITTED DURING CONTINUING/PERIODIC REVIEW:

- To avoid a delay in the approval of the Periodic Review, do not submit a revision with the continuing review, unless it is necessary to correct inaccuracies, update incomplete sections in the approved study, or the revision is requested by the IRB.
- If a revision is submitted in conjunction with the continuing review, the IRB may choose to process these submissions separately based on various factors, including how soon the project is set to expire and the nature of the revision.