Appendix I

Request for Continuing Review

Checklist

Suffolk University
Office of Research and
Sponsored Programs

INSTITUTIONAL REVIEW BOARD
73 Tremont St.
Boston, MA 02108
Phone: (617) 725-4169
Fax: (617) 725-4166
Email:irb@suffolk.edu

Protocol Number:_____

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:	
E-mail Address:	Faculty: ☐ Staff: ☐ Student: ☐
Date:	
2. PRINCIPAL INVESTIGATOR	
Name:	CITI Certified: Yes ☐ Date:
School/Department:	
Campus Mailing Address:	Telephone Number: ( ) -
E-mail Address:	Faculty: ☐ Staff: ☐
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:		
Number of Participants Screened to Date:		
Number of Participants Enrolled to Date:		
Participant Demographics (Enrolled): Number of males: Number of females: Number of minorities:		

8. WITHRAWALS		
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

* 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

Suffolk University
Office of Research and Sponsored Programs

Institutional Review Board (IRB)
Reviewer Worksheet

§46.109(e) CONTINUING REVIEW CHECKLIST *(EXPEDITED)*

Protocol Number:	
Protocol Title:	
PI:	Co-PI:

INITIAL PROTOCOL REVIEW

☐ Yes ☐ No	Was the research initially reviewed and approved at a convened meeting of the IRB? *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

☐ Yes ☐ No	Does the research present more than minimal risk to subjects as determined by initial review of the protocol by the IRB? *If NO→ continue. If YES→ STOP continuing review must take place at a convened meeting of the IRB.*
☐ Yes ☐ No	Is new information presented by the investigator, such as new procedures or a modification of procedures that would likely increase risk to subjects? *If NO→ continue. If YES→ STOP continuing review must take place at a convened meeting of the IRB.*
Comments:	

☐ Yes ☐ No	Are risks to subjects minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purposes? - 45CFR46.111(a)(1).
Comments:	

☐ Yes ☐ No	Are risks to subjects reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be reasonably expected to result? – 45CFR46.111(a)(2)
Comments:	

☐ Yes ☐ No	Does the investigator make adequate provisions in the research plan for monitoring the data collected to ensure the safety of subjects?
Comments:	

☐ Yes ☐ No	Are adequate provisions in place to protect the privacy of subjects and to maintain confidentiality of data?
Comments:	

ADEQUACY OF THE INFORMED CONSENT PROCESS

☐ Yes ☐ No	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? *If NO→ continue. If YES→ STOP continuing review must take place at a convened meeting of the IRB.*
☐ Yes ☐ No	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? *If NO→ continue. If YES, indicate in the comments section below, if the investigator included provisions for communicating such findings to research participants.*
Comments:	

☐ Yes ☐ No	Is informed consent sought from each prospective subject or the subject's legally authorized representative.
☐ Yes ☐ No	Is informed consent is 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?
Comments:	

☐ Yes ☐ No ☐ NA	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?
Comments:	

Review Worksheet Version 7/1/2013

☐ Yes ☐ No	Does the informed consent document or process provide an accurate and up-to-date description of the reasonably forseeable risks and discomforts.
Comments:	

☐ Yes ☐ No ☐ NA	If applicable, does the informed consent document or process disclose alternative procedures or courses of treatment that might be advantageous to the subject?
Comments:	

☐ Yes ☐ No	Is any ew 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)?
Comments:	

EVALUATING THE INVESTIGATOR AND INSTITUTIONAL ISSUES

☐ Yes ☐ No	Have there been any changes in the investigator's situation or qualifications?
☐ Yes ☐ No	Have there been any complaints by research subjects or others related to the investigator's conduct of the research?
☐ Yes ☐ No	Have there been any changes in the acceptability of the proposed research in terms of institutional commitments and applicable regulations (State & local law or standards of professional conduct)?
☐ Yes ☐ No	Have there been any reports received from any third party observations of the research?
Comments:	

EVALUATING RESEARCH PROGRESS

☐ Yes ☐ No	Is the information provided by the investigator consistent with the research protocol previously approved by the IRB?
☐ Yes ☐ No	Is enrollment consistent with the planned number of subjects described in the IRB-approved protocol and are enrollment targets being met?
☐ Yes ☐ No	Is enrollment occurring at a rate expected with the ability to provide sufficient data to answer the scientific question being addressed?
☐ Yes ☐ No ☐ N/A	Is the rate of subject withdrawal and the reasons for withdrawal reasonable?
Comments:	

OTHER CONSIDERATIONS

☐ Yes ☐ No	Selection of subjects is equitable – 45CFR46.111(a)(3)
☐ Yes ☐ No	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, an D respectively.
Comments:	

Provide Protocol Specific Comments

☐ **Approved**
☐ **Referred to Full Board**
☐ **Requires Information or Modifications**

Reviewer: **Date:**

Appendix K

Protocol Modification Request

Suffolk University
Office of Research and
Sponsored Programs

INSTITUTIONAL REVIEW BOARD
73 Tremont St.
Boston, MA 02108
Phone: (617) 725-4169
Fax: (617) 725-4166
Email:irb@suffolk.edu

Protocol Number:_____

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:	CITI Certified: Yes ☐	Date:
School/Department:		
Campus Mailing Address:	Telephone Number: ( ) -	
E-mail Address:	Faculty: ☐ Staff: ☐	
3. CO-INVESTIGATOR		
Name:	CITI Certified: Yes ☐	Date:
School/Department:		
Campus Mailing Address:	Telephone Number: ( ) -	

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? 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 be 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
☐ Other

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 L

Modification Reviewer Checklist

MODIFICATION REVIEW WORKSHEET

Protocol Number:	
Protocol Title:	
Principal Investigator:	**Co-Investigator:**

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

Is this a <u>minor</u> 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:**

Appendix M

Report of Unanticipated Problems Involving Risks to Subjects or Others

Suffolk University
Office of Research and
Sponsored Programs

INSTITUTIONAL REVIEW BOARD
73 Tremont St.
Boston, MA 02108
Phone: (617) 725-4169
Fax: (617) 725-4166
Email:irb@suffolk.edu

UPIRTSO Report
Number:_____

FOR IRB USE ONLY Type of Event: ☐ Protocol Deviation ☐ Adverse Event ☐ Unanticipated Problem

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 (UPIRTSO)" 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 UPIRTSO and should be reported in summary form only at the time of continuing review or in the final report.

1. GENERAL INFORMATION				
Protocol Title:				
Protocol Number:		Date of Report:	Initial Report: ☐	Follow-up Report: ☐
Name of Person Reporting:		Email Address of Individual Reporting:		
Date of Event:		Location of Event: On site: ☐ Off site: ☐		
2. PRINCIPAL INVESTIGATOR				
Name:			Faculty: ☐ Staff: ☐	
School/Department:				
E-mail Address:			Telephone Number: ( ) -	
3. CO-INVESTIGATOR				
Name:			Faculty: ☐ Staff: ☐ Student: ☐	
School/Department:				
Campus Mailing Address:				
E-mail Address:			Telephone Number: ( ) -	
4. TYPE OF EVENT				

The event is believed to be related to the research ☐   The event is *not* believed to be related to the research ☐

☐ **Protocol Deviation** *(Please describe deviation below and risk to subject that was eliminated as a result)*
- *Any deviation from the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research subject*
- *Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur*

☐ **Unanticipated Problem** *(Please describe the nature of unanticipated problem below and the change in the risk-benefit ratio if applicable)*
- *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*
- *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*

☐ **Adverse Event** *(Please describe the event and the nature of the risk to subjects below)*
- *Any breach in confidentiality that may involve risk to subject or others*
- *Any complaint of a subject that indicates an unanticipated risk that cannot be resolved by the research staff*
- *Any serious and possibly related event which in the opinion of the investigator constitutes an unanticipated risk*

5. INFORMED CONSENT PROCESS		
Does this problem/event alter risk to past, present or future subjects?		Yes ☐ No ☐ Don't Know ☐
Based on your judgment, should this problem/event be added to the consent form as a potential risk? Explain rationale.		Yes ☐ No ☐

Based on your analysis of this problem/event, should currently enrolled subjects be notified? Explain rationale.	Yes ☐ No ☐

* 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

Suffolk University
Office of Research and
Sponsored Programs

INSTITUTIONAL REVIEW BOARD
73 Tremont St.
Boston, MA 02108
Phone: (617) 725-4169
Fax: (617) 725-4166
Email:irb@suffolk.edu

Protocol Deviation
Report Number:_____

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.

1. GENERAL INFORMATION				
Protocol Title:				
Protocol Number:	Date of Report:		Initial Report: ☐	Follow-up Report: ☐
Name of Person Reporting:		Email Address of Individual Reporting:		
Date(s) of Event:		Location of Event: On site: ☐ Off site: ☐		
2. PRINCIPAL INVESTIGATOR				
Name:			Faculty: ☐ Staff: ☐	
School/Department:				
E-mail Address:			Telephone Number: ( ) --	
3. CO-INVESTIGATOR				
Name:			Faculty: ☐ Staff: ☐ Student: ☐	
School/Department:				
Campus Mailing Address:				
E-mail Address:			Telephone Number: ( ) --	

4. TYPE OF DEVIATION (Check appropriate (box and describe in detail below)
☐ Research conducted without IRB approved protocol *(includes continuing research after lapse in IRB approval)*
☐ 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)*

5. PLAN FOR CORRECTIVE ACTION
Describe below the plan for corrective action

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

Principle Investigator
Co-Investigator(s)

Appendix O

Human Subjects Research Final Report

Suffolk University
Office of Research and
Sponsored Programs

INSTITUTIONAL REVIEW BOARD
73 Tremont St.
Boston, MA 02108
Phone: (617) 725-4169
Fax: (617) 725-4166
Email:irb@suffolk.edu

Protocol Number:_____

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.

1. General Information			
Protocol Title:		Protocol Number:	
Date of Report:			
2. Principal Investigator			
Name:			
Email Address:	Telephone Number:	Faculty: ☐	Staff: ☐
3. Co-Investigator			
Name:			
Email Address:	Telephone Number:	Faculty: ☐ Staff: ☐	Student: ☐

4. Reason For Closure

☐ The only remaining activity involves the analysis of aggregate data sets without individual subject identifiers
☐ All research related activities, including data analysis, has been completed
☐ Study closed at this site by sponsor. Please Explain:
☐ Other. Please Explain:

5. Subject Enrollment: Enter "0" Where there are no numbers to report. Please do not leave any spaces blank.

Maximum number of subjects/records approved for enrollment:

	Since Last IRB Approval[1]	Since Initial IRB Approval[2]
Number of subjects screened		
Number of subjects enrolled		
Number of subjects who were dropped		
Number of subjects who voluntarily withdrew		
Number of female participants enrolled		
Number of male participants enrolled		
Number of minors enrolled		

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

a. In the past year have there been any of the following?

• Any expected/unexpected and/or serious/non-serious associated adverse events:	☐ Yes*	☐ No
• Unanticipated problems or adverse events involving risks to subjects or others: :	☐ Yes*	☐ No
• Withdrawal of Subject(s) from the research, including reasons: :	☐ Yes*	☐ No
• Complaints about this research study:	☐ Yes*	☐ No

*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:

All monitoring reports, Sponsor's reports, preliminary results, abstracts of recent scientific literature with full citation
☐ 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.

Appendix P

IRBNet User Information

National
Research
Network ®

New User Energizer
Training Energizer

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.

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

New User Registration

IRBNet

To begin the registration process, go to **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

IRBNet

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.

Registration

Account Information

must be REGISTERED to access IRBNet. Registration is free.

ep is to enter your basic account information and create your IRBNet User Name and Password.

First Name *	
Last Name *	
User Name *	
Password *	
Confirm Password *	
Password Hint	

Continue   Cancel

* required fields

3

Individual Terms of Use

IRBNet

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

IRBNet

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 Dataware, 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 cordance with this Agreement. Nothing in this Agreement shall be deemed to confer any third party or benefits.

   [Accept] [Reject]

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

Select Your Organization

IRBNet

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

IRBNet

Registration

Add Affiliation

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

...zation with which you are affiliated. If you are affiliated with more than one organization, you may add ...ns after you complete the registration process by logging in to IRBNet and accessing your User Profile.

...or an organization [metro] [Search] [Clear]

...on types to display ☑ Research Institutions ☐ Boards ☐ Sponsors [Display]

Metropolitan University, Frederick, MD

✓ Highlight your institution, and click continue.

...our Organization *

If you do not see your organization listed you may **add a new organization.**

[Continue] [Cancel]

* required fields

Contact Information

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.

IRBNet

Registration

Your Contact Information

Specify your contact information at Metropolitan University, Frederick, MD. The email address that you specify will be used for communications related to Metropolitan University projects.

Telephone Number *	[ ] - [ ] - [ ]	ext. [ ]
Fax Number	[ ] - [ ] - [ ]	ext. [ ]
Email *	[ ]	

[Continue] [Cancel]

* required fields

✓ 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.

6

Finalize Registration

IRBNet

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.

IRBNet

Registration

Confirm Registration Information

Please review your information and click "Register" to complete the reg... may update your account information, and add or update affiliations at... User Profile.

[Register] [Cancel]

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

User Account Information and Password (Edit)
User Name jrresearcher
First Name John
Last Name Researcher

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

ffiliations

searcher at Metropolitan University, Frederick MD (Edit)
Telephone Number (555) 555-5555
Email jrresearcher@mailinator.com

7

Registration Complete

IRBNet

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.

IRBNet.

Registration

Registration is Complete

An activation email has been sent to your contact email address. You must click on the activation link within the email to activate your account.

Having trouble receiving your activation email from IRBNet? Try the following:

1. Check your spam box to make sure important IRBNet emails aren't getting accidentally filtered.
2. Make sure to whitelist all emails coming from irbnet.org to assure you receive them properly.
3. Generate a new activation email by logging in to IRBNet and clicking on your User Profile. Make a simple update (such as adding a fax number) and a new activation email will automatically be generated for you.
4. Contact the IRBNet Coordinator at your local Research Office who can provide more helpful information and can assist you in registering your account.

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

Continue

Complete Activation

IRBNet

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.

IRBNet Activation Required

activation@irbnet.org to me

Welcome to IRBNet!

Please confirm your affiliation with Metropolitan IRB by clicking on the following link:
https://www.irbnet.org:443/release/public/act.jsp?i=866946&a=se6pZUXLwz

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

✓ Click the link to complete your activation.

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

Manage Affiliations

IRBNet

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

User Profile

✓ 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.

Your User Profile

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

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

count Information and Password (Edit)
- **User Name** jrresearcher
- **First Name** John
- **Last Name** Researcher

Affiliations
- **Add an Additional Affiliation**

| Send me an activation email |

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

Training & Credentials

IRBNet allows you to track and share your training records, certifications, resumes and oth added to your profile, your training and credentials can be easily linked to your projects fro by your project teams and can be quickly accessed and tracked by the boards that review permit you to directly submit your training and credentials without requiring you to link thes

There are currently no documents in your profile.

✓ Click the "Send me an activation email" link to trigger an additional activation email to your registered email address.

Add New Record

10

Add Training & Credential Records **IRBNet**

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

User Profile

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 (Edit)

User Name	jrresearcher
First Name	John
Last Name	Researcher

Affiliations

- **Add an Additional Affiliation**

Researcher at Metropolitan University, Frederick, MD (Edit) (Deactivate)

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 ___ ur training and credentials can be easily linked to your projects from the Designer, are accessible ___ d can be quickly accessed and tracked by the boards that review your projects. Some boards also ___ bmit your training and credentials without requiring you to link these records to specific projects.
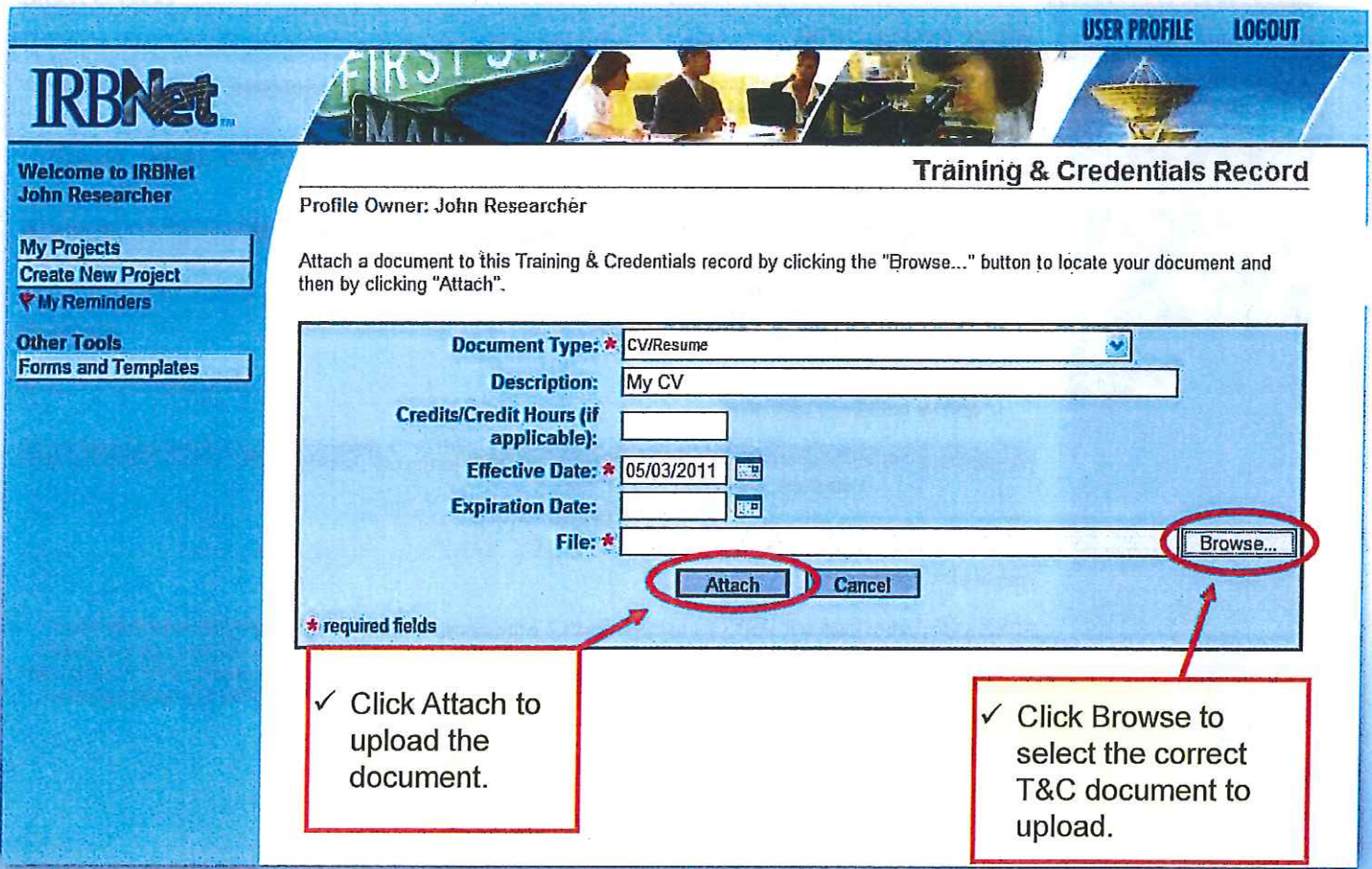
✓ **Click here to upload T&C documents.**

There are currently no documents in your profile.

Add New Record

Enter Record Information

IRBNet

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

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
♥ **My Reminders**

Other Tools
Forms and Templates

Training & Credentials Record

Profile Owner: John Researcher

Attach a document to this Training & Credentials record by clicking the "Browse..." button to locate your document and then by clicking "Attach".

Document Type: *	CV/Resume
Description:	My CV
Credits/Credit Hours (if applicable):	
Effective Date: *	05/03/2011
Expiration Date:	
File: *	Browse...

Attach   Cancel

* required fields

✓ Click Attach to upload the document.

✓ Click Browse to select the correct T&C document to upload.

12

Submit T&C Documents

IRBNet

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

Create New Project
My Reminders

Other Tools
Forms and Templates

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 (Edit)

User Name	jrresearcher
First Name	John
Last Name	Researcher

Affiliations

- **Add an Additional Affiliation**

Researcher at Metropolitan University, Frederick, MD (Edit) (Deactivate)

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

Training & Credentials

IRBNet allows you to track and share your training records, certifications, resume added to your profile, your training and credentials can be easily linked to your p by your project teams and can be quickly accessed and tracked by the boards th permit you to directly submit your training and credentials without requiring you t

✓ Click to **submit** the document to your committee.

| Show all Versions |

Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	Status		
38.1	▼ CV/Resume	My CV		05/03/2011		05/16/2011 01:44 PM	Not Submitted		✏ ✕
									Submit

Add New Record

Manage your User Profile

IRBNet

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

Other Tools
Forms and Templates

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 (Edit)

User Name	jrresearcher
First Name	John
Last Name	Researcher

Affiliations

- **Add an Additional Affiliation**

Researcher at Metropolitan University, Frederick, MD (Edit) (Deactivate)

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

Training & Credentials

IRBNet allow[...]added to you[...]by your proje[...]permit you to[...]

✓ Highlighted Expiration Date indicates this document will expire within the next 60 days.

[...]sumes and other pers[...]our projects from the D[...]rds that review your pr[...]you to link these recor[...]

✓ Manage eac T&C document using these icons.

✓ To update a document, use the Pencil icon.

| Show all Versions |

Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	Status		
48.1	CITI 3. Principal or Asso. Investigators Biomedical Research - Basic Course	My CITI Training	15	06/16/2010	06/15/2011	05/18/2011 02:27 PM	Accepted		✏
								Submit	🔔 ✉
47.1	CV/Resume	My CV			05/03/2011	05/18/2011 02:26 PM	Accepted		✏
								Submit	🔔 ✉

Add New Record

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.

National Research Network ®

Committee Member
Training Energizer

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

IRBNet

IRBNet Innovative Solutions for
Compliance and Research Management

Login: Username   Password   Login

new User Registration   Forgot Your Password?

Home | The IRBNet Difference | Demo | Contact Us | FAQ |

Comprehensive Solutions

Test Drive IRBNet
See for yourself...

Demo

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."

- *Bruce Day*
Director, Office of Research Integrity
Marshall University

Next ►

2010 Events - Join Us

2

Access your Submission Manager

IRBNet

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.

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
Lisa Franklin

Submission Manager
Agendas and Minutes
My Reminders (1)

Forms and Templates

Submission Manager

✓ 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.

ick on the project title to view more information about the

Search All: [   ] Search All

Agenda: [04/16/2010 07:00 AM ▾]

☐ Only show submissions awaiting Board Action.
☑ Only show submissions not marked Review Completed.

Search: [   ]
Search By Tag: [▾]

[Search]   [Clear]

✓ Access reviewer templates, checklists, and committee guidance documents here.

| Show Agenda Item Numbers |

I◀ ◀ 1 - 1 of 1 ▶ ▶I [10 ▾]

	IRBNet ID	Project Title	Principal Investigator	Submission Type	Review Type	Action	Ref #	Submission Date	🔒
⚑	163073-2	⭐ Motivations of Research Subjects: A Mixed Met...	Researcher	Revision	EXP	Pending Review	10-15	03/30/2010	🔒
		Special Pop.							

I◀ ◀ 1 - 1 of 1 ▶ ▶I [10 ▾]

Agenda, Minutes and other Administrative Documents for this Mee

Agenda   Educational

✓ Agenda documents and Minutes can be found here.

3

Manage your work queue

IRBNet

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.

USER PROFILE   LOGOUT

IRBNet™

Submission Manager

**Welcome to IRBNet
Lisa Franklin**

Submission Manager
Agendas and Minutes
☿ My Reminders (1)

Other Tools
Forms and Templates

Submissions for: Metropolitan IRB

The following submissions are available for your review. Click on the project title to view more information about the submission and to access project documents.

Search All: [   ]   [Search All]

Agenda: [04/16/2010 07:00 AM ▾]   Search: [   ]
☐ Only show submissions awaiting Board Action.   Search By Tag: [▾]
☑ Only show submissions not marked Review Completed.

[Search]   [Clear]

✓ One Star indicates you are the primary reviewer.

✓ The flag indicates an active reminder, which may be read in the My Reminders page.

| Show Agenda Item Numbers |

◄◄ ◄ 1 - 1 of 1 ► ►◄ 10 ▾

☿	IRBNet ID	Project Title	Principal Investigator	Submission Type	Review Type	Action	Ref #	Submission Date	🔒
☿	153073-2	⭐ Motivations of Research Subjects: A Mixed Met... [Special Pop.]	Researcher	Revision	EXP	Pending Review	10-15	03/30/2010	🔒

✓ Coordinator-defined Tags allow custom organization of submissions. Clicking the Tag will display all submissions with that Tag.

Agenda, Minutes and other Admi...

📄
Agenda

4

View My Reminders

IRBNet

Notifications sent to you across all of your submissions will appear here. An email will be sent to your registered email address.

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
Lisa Franklin

Submission Manager
Agendas and Minutes
⚑ My Reminders (1)

Other Tools
Forms and Templates

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.

|◀ ◀ 1 - 1 of 1 ▶ ▶| 10 ▾

| Show Silenced Reminders | Silence All Reminders |

	IRBNet ID	Project Title	Message Type	Date
⚑	163073-2	Motivations of Research Subjects: A Mixe...	🔔 Reviewer Access Granted	03/30/2010 08:10 AM

|◀ ◀ 1 - 1 of 1 ▶ ▶| 10 ▾

✓ Indicates an active Reminder.

✓ Click the Project Title to go to the Submission Detail page.

✓ Click here to view the message.

View Submission Details

IRBNet

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

Welcome to IRBNet
Lisa Franklin

✓ **Project Status**

✓ **Package Information**

Project Administration
Project Overview
Send Project Mail
Reviews
Project History
⚠ Messages & Alerts

Other Tools
Forms and Templates

✓ **Package Documents**

Submission Detail

Metropolitan IRB
[163073-2] Motivations of Research Subjects: A Mixed Methods Study
Project Status as of: 08/23/2012 ▼   Reviewing Board: Metropolitan IRB, Frederick, MD

| Project Status: Deferred - Modifications Required | Project Expiration Date: |
| Project Risk Level: Minimal Risk | Initial Approval Date: |

Package Details

IRBNet ID 163073-2
Title Motivations of Research Subjects: A Mixed Methods Study
Special Pop....
Principal Investigator Researcher, Trent, PhD
Lock Status 🔒 Locked | View History |

Submission Details

Submission Date 03/30/2010
Submitted by John Researcher
Submission Type Revision
Local Board Reference Number 10-15

Review Details:

Agenda		Review Type		Action	Effective Date	Expiration Date
04/16/2010 07:00 AM		EXP	📝	Pending Review		

New and Revised Documents in this Package:

Document Type	Description		Last Modified	
Amendment/Modification	Research Team Member Addition		03/30/2010 08:04 AM	
Consent Form	Consent Form v2		03/30/2010 08:26 AM	
Training/Certification	Training Certification - Murray Rogers		03/30/2010 08:02 AM	

There is **1 Training & Credentials record** linked to this package. | View Linked Records | Show Project Team Tracking |
There is **1 COI Disclosure record** linked to this package. | View Linked COI Disclosures |

Scroll down to see additional information.

* Browse the complete list of project documents, and access historical documents, on the **Designer**.

This Package has been Signed By:

Date	Signed By	Role
03/30/2010 08:06 AM	Murray Rogers	Team Me
03/30/2010 08:05 AM	Enrico Palazzo	Advisor
03/30/2010 08:04 AM	John Researcher	Principal

✓ Electronic Signatures

This submission is currently shared with the following Committee Me...

✓ Click here to send a message to any member with whom the submission has been shared.

IRBNet User	Special Designation	Share Date	Shared By
Franklin, Lisa	Primary Reviewer	03/30/2010 08:10 AM	Halway, Ann
Halway, Ann		Not Applicable	Not Applicable
Lang, Ji	Secondary Reviewer	03/30/2010 08:10 AM	Halway, Ann

Committee / Admin access list

🔔 **Committee Messages** (1)   ✉ **Send Committee Mail** to Members and Administrators.

Add comments and reviewer documents to this submission.

✓ Reviewer comments. The check indicates the user has completed their review.

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

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

Welcome to IRBNet
Lisa Franklin

Submission Manager
Agendas and Minutes
⚑ My Reminders **(1)**

Project Administration
Project Overview
Designer
Package Signatures
Send Project Mail
Reviews
Project History
⚠ Messages & Alerts

Other Tools
Forms and Templates

Submission Detail

Metropolitan IRB
[163073-2] Motivations of Research Subjects: A Mixed Methods Study
Project Status as of: 08/23/2012 ▼   Reviewing Board: Metropolitan IRB, Frederick, MD

Project Status: Deferred - Modifications Required	Project Expiration Date:
Project Risk Level: Minimal Risk	Initial Approval Date:

Package Details

IRBNet ID 163073-2
Title Motivations of Research Subjects: A Mixed Methods Study
Special Pop....

Principal Investigator Researcher, Trent, PhD
Lock Status 🔒 Locked | View History |

Submission Details

Submission Date 03/30/2010
Submitted by John Researcher
Submission Type Revision
Local Board Reference Number 10-15

Review Details:

Agenda		Review Type		Action	Effective Date	Expiration Date
04/16/2010 07:00 AM		EXP	📝	**Pending Review**		

New and Revised Documents in this Package:

⚑	⬧ Document Type	⬧ Description	⬧	Last Modified
⚑	**Amendment/Modification**	Research Team Member Addition		03/30/2010 08:04 AM
⚑	**Consent Form**	Consent Form v2		03/30/2010 08:26 AM
	Training/Certification	Training Certification - Murray Rogers		03/30/2010 08:02 AM

There is **1 Training & Credentials record** linked to this package. | View Linked Records | Show Project Team Tracking |
There is **1 COI Disclosure record** linked to this package. | View Linked COI Disclosures |

✓ Open any submitted document by clicking the blue link.

8

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

Welcome to IRBNet
Lisa Franklin

Submission Manager
Agendas and Minutes
⚑ My Reminders (1)

Project Administration
Project Overview
Designer
Package Signatures
Send Project Mail
Reviews
Project History
⚠ Messages & Alerts

Metropolitan IRB
[163073-2] Motivations of
Project Status as of: 08/

Project Status
Project Risk Level

Package Details

Principi

Designer

[163073-2] Motivations of Research Subjects: A Mixed Methods Study

This package is: 🔒 Locked | View History |

Get stamped documents, approval letters and other board documents, and track reviews for this package: **Review details.**

New and Revised Documents in this Package:

Document Type	Description	Last Modified	
Amendment/Modification	Research Team Member Addition	03/30/2010 08:04 AM	
Consent Form	Consent Form v2	03/30/2010 08:26 AM	
Training/Certification	Training Certification – Murray Rogers	03/30/2010 08:02 AM	

There is **1 Training & Credentials record** linked to this package. | View All Links |
There is **1 COI Disclosure record** linked to this package. | View All Links |

Documents from Previous Packages:

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	
1	IRB Basic Application Part 1	IRB Basic Application Part 1	03/24/2010 03:03 PM	03/24/2010	Approved	
1	Protocol	ASM981 C2439 Protocol.pdf	03/24/2010 03:03 PM	03/24/2010	Approved	

✓ 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.

Type	Description	Modified	
Modification	Research Team Member Addition	03/30/2010 08:04 AM	
	Consent Form v2	03/30/2010 08:26 AM	
fication	Training Certification – Murray Rogers	03/30/2010 08:02 AM	

There is **1 Training & Credentials record** linked to this package. | View Linked Records | Show Project Team Tracking |
There is **1 COI Disclosure record** linked to this package. | View Linked COI Disclosures |

Add reviewer comments and documents

IRBNet

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

---

* Browse the complete list of project documents, and access historical documents, on the **Designer**.

This package has been signed by:

Date	Message
03/30/2010 08:06:15	Signed by Murray Rogers as Team Member
03/30/2010 08:05:38	Signed by Enrico Palazzo as Advisor
03/30/2010 08:04:49	Signed by Trent Researcher as Principal Investigator

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

IRBNet User	Special Designation	Share Date
Franklin, Lisa	Primary Reviewer	03/30/2010 08:10 AM
Halway, Ann		Not Applicable
Lang, Ji	Secondary Reviewer	03/30/2010 08:10 AM

🔔 **Committee Messages** (1)   ✉ **Send Committee Mail** to

✓ View comments by administrators and other members.

Add comments and reviewer documents to this submission.

✓ Click "Add" to record reviewer comments

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

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

10

Add comments

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

Agendas and Minutes

✓ Record your comments in the rich text editor.

Sign this Package
Send Project Mail
Reviews
Project History
🔔 **Messages & Alerts**

Other Tools
Forms and Templates

Reviewer Comments:

B *I* U ABC | ☰ ☰ ☰ ☰ || -- Format -- ⌄ -- Font family -- ⌄ -- Font size -- ⌄

✂ 🗐 🗐 🗐 🗐 | 🔍 🔍 | ☰ ☰ | ☰ ☰ | ↺ ↻ | HTML 📷

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.

Recommendation: Approve ⌄
Last Updated: 03/30/2010 10:37 AM

☐ Mark my personal review as complete.
Completed Date:

✓ Be sure to save your comments first before doing anything else.

| Save & Exit | Save | Cancel |

Reviewer Documents:

✓ You may attach completed reviewer worksheets, edited consent forms and other documents here.

There are no reviewer documents attached.

Add New Document

Return to **Submission Detail**.

Attach worksheets and more...

IRBNet

Agendas and Minutes
My Reminders (1)

Back to Submission Detail

Project Administration
Project Overview
Designer
Sign this Package
Send Project Mail
Reviews
Project History
Messages
Other Tools
Forms and T

Welcome to IRBNet
Lisa Franklin

Submission Manager
Agendas and Minutes
My Reminders (1)

Back to Submission Detail

Project History
Messages & Alerts

Reviewer Comments:

B I U ABC | ≡ ≡ ≡ ≡ | – Format – ✔ – Font family – ✔ – Font size – ✔

✄ 🔲 🔳 🔲 🔲 | 🔍 🔍 | ≔ ≔ | ⁝ ⁝ | ↺ ↻ | HTML 🔲

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.

Reviewer Documents

[163073-2] Motivations of Research Subjects: A Mixed Methods Study

You may attach documents to this comment by clicking the "Browse..." button to locate a document and then by clicking "Attach".

Document Type *	✔
Description	
File *		Browse...

Attach   Cancel

* required fields

You may also use the IRBNet Document Wizards to create documents on-line. Documents that you create on-line are automatically attached in PDF format.

On-Line Document   Reviewer Checklist ✔

Add   Cancel

✓ Attach completed reviewer worksheets, edited consent forms and other documents here.

✓ If your institution uses a reviewer checklist wizard, it will be located here.

There are no reviewer documents attached.

Add New Document

Return to **Submission Detail**.

"Electronically Sign" your review

IRBNet

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.

Project Administration
Project Overview
Designer
Sign this Package
Send Project Mail

I have reviewed the study and support approval as well. Se reviewer worksheet.

The consent form is very clear. Only a few grammatical edi

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

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

Recommendation: Approve
Last Updated: 03/30/2010 10:37 AM

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

☑ Mark my personal review as complete.
Completed Date:

Save & Exit   Save   Cancel

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

eviewer Documents:

ocument Type	Description	Last Modified	View	Update	Delete
▼ Other	ICF – Minor edits	03/30/2010 10:38 AM	🗋	Update	Delete
▼ Reviewer Worksheet	Reviewer Checklist	03/30/2010 10:38 AM	🗋	Update	Delete

Add New Document

Return to **Submission Detail.**

Complete your review

IRBNet

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

This package has been signed by:

Date	Message
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).

currently shared with the following Committee Members and Administrators:

	Special Designation	Share Date	Shared By
Franklin, Lisa	Primary Reviewer	03/30/2010 08:10 AM	Halway, Ann
Halway, Ann		Not Applicable	Not Applicable
Lang, Ji	Secondary Reviewer	03/30/2010 08:10 AM	Halway, Ann

🔔 **Committee Messages** (1)   ✉ **Send Committee Mail** to Members and Administrators.

Update your comments and reviewer documents.

✓ Your comments are recorded.

Reviewer	Comment	Recommend		Last Updated	Completed Date	
☑ Franklin, Lisa	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.	Approve		03/30/2010 10:37 AM	03/30/2010 10:39 AM	View
☑ Lang, Ji	I support approval of this amendment. See attached reviewer worksheet.	Approve		03/30/2010 08:12 AM	03/30/2010 08:12 AM	View
☑ Halway, Ann	All proper documentation has been submitted. Please complete and attach the appropriate reviewer worksheet.			03/30/2010 08:10 AM	03/30/2010 08:10 AM	View

Committee Messages & Alerts

IRBNet

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

IRBNet ID: 163073-2

USER PROFILE   LOGOUT

IRBNet.

Welcome to IRBNet
Lisa Franklin

Committee Messages & Alerts

Submission Manager
Agendas and Minutes
🚩 My Reminders (1)
Back to Submission Detail

Project Administration
Project Overview
Designer
Sign this Package
Send Project Mail
Reviews
Project History
🔔 Messages & Alerts

[163073-2] Motivations of Research Subjects: A Mixed Methods Study

The following ... n posted for this submission. You can set an IRBNet personal reminder on ... will automatically appear in your My Reminders list. Other IRBNet users ... turn on or silence a personal reminder without affecting other IRBNet users ... communications between the project team and the board can be viewed in the ...

> ✓ The red number will decrease every time a message is "silenced."

| ◄ ◄ 1-1 of 1 ► ►| 10 ▾

| Silence All Reminders |

	IRBNet ID	**Project Title**	**Message Type**	**Date**
🚩	163073-2	Motivations of Research Subjects: A Mixe...	🔔 Reviewer Access Granted	03/30/2010 08:10 AM

| ◄ ◄ 1-1 of 1 ► ►| 10 ▾

> ✓ Click the red flag and "silence" the message as an easy way to keep track of completed reviews.

Track your progress

IRBNet

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
IRBNet as well as advice on how
to comply with important policies
and standards as you use IRBNet.

National Research Network ®

Researcher 1: New Project Submission
Training Energizer

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.

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

IRBNet

Enter your User Name and Password at: <u>www.irbnet.org</u>

IRBNet Innovative Solutions for
Compliance and Research Management

Login: | Username | Password | | Login |

New User Registration | Forgot Your Password?

Home | The IRBNet Difference | Demo | Contact Us | FAQ

Comprehensive Solutions

Test Drive IRBNet
See for yourself...

Demo

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.

Satisfied Members

"IRBNet makes our entire operation more efficient, saving time and money. It is amazing how much more we get done, in less time and with the same staff. It's fantastic."

- Ken Grissett
IRB Manager
Sacred Heart Health System

Next ▶

2008 Events - Join Us

2

Access My Projects

IRBNet

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

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders

Other Tools
Forms and Templates

My Projects

Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (**Learn More**)

Search: _____   **Search By Tag:** [_____]

[**Search**]   [**Clear**]

◄◄ ◄ 1–2 of 2 ► ►◄ 10 ▼

Create and Manage Tags | Show Archived Projects (4) |

IRBNet ID ▼	Project Title	Principal Investigator	Submission Type	Status	Effective Date	🔒
108459-3	Double-Blind, Multicenter Phase 3 Study ... 🔲 Oncology Dept	Researcher	Adverse Event	Acknowledged	02/16/2010	🔒
107645-2	A Phase 3, Randomized, Placebo-Controlle... Need Signatur...	Bird		Work in progress		

◄◄ ◄ 1–2 of 2 ► ►◄ 10 ▼

✓ 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

IRBNet

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

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders

Other Tools
Forms and Templates

My Projects

Your "My Projects" workspace shows projects that you have created and projects that have been shared with you by other users on the National Research Network. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)

Search: Search By Tag:

Search   Clear

Add and Remove Tags

Personal tags 🔒 can only be seen by you. Shared tags 🔓 can also be seen by others. (Learn More)

Off 🔒 🔓
○ ◉ ○   **Need Signatur...**
◉ ○ ○   **Oncology Dept**

| Create and Manage Tags | Show Archived Projects (4) |

Create and Manage Tags

	IRBNet ID ▾	Project Title	Principal Investigator
	108459-3	Double-Blind, Multicenter Phase 3 Study ... 🔓 Oncology Dept	Researcher
	107645-2	A Phase 3, Randomized, Placebo-Controlle... Need Signatur...	Bird Work in progress

✓ 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

IRBNet

Provide basic information about your project.

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

Project Information

Create a New Project

My Projects
Create New Project
My Reminders

Other Tools
Forms and Templates

To create a new project, first provide the basic project information below. Once your project is created you may attach project documentation and share the project with other users.

Research Institution: Metropolitan University, Frederick, MD

✓ The asterisk indicates a required field.

Title: * Motivations of Research Subjects: A Mixed Methods Study

First Name: * John

Local Principal Investigator:

Last Name: * Researcher   **Degree(s):** PhD

Keywords: Incentive, Extra Credit

Sponsor: National Research Foundation

You may specify an internal account number, billing identifier or reference number for this project.

Internal Reference Number:

Continue   Cancel

* required fields

Build your project package

IRBNet

Attach your electronic project documents.

✓ Drop down menu for institution-specific libraries.

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

Designer

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

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
link your project team's Training & Credentials to your package.

Documents in this Package:

There are currently no documents in this package.

There are no Training & Credentials records linked to this package. | **Link / Un-Link Records** |

Add New Document

✓ Select appropriate document and download.

✓ Add project documents here.

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Attach document

IRBNet

IRBNet provides two mechanisms for entering documents into the system.

IRBNet ID: 137618-1   USER PROFILE   LOGOUT

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

Attach Document

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

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.

Document Type *
Description
File *

Attach   Cancel

* required fields

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

...so use the IRBNet Document Wizards to create documents on-line. Documents that you create on-line are ...lly attached in PDF format.

On-Line Document   DMRN Research Project Cover Sheet

Add   Cancel

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

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Complete your project package

IRBNet

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

IRBNet ID: 137618-1

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

Designer

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

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

① View
③ Update
④ Delete document

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

Documents in this Package:

Document Type	Description	Last Modified	①	③	④
▼ Application Form	IRB Application	09/30/2009 12:04 PM		✎	✗
▼ Consent Form	Consent Form	09/30/2009 12:04 PM		✎	✗
▼ Protocol	ASM981 C2439 Protocol.pdf	09/30/2009 12:04 PM		✎	✗

There are no Training & Credentials records linked to this package | Link / Un-Link Records |

Add New 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

IRBNet

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

IRBNet ID: 137618-1

USER PROFILE **LOGOUT**

IRBNet™

Welcome to IRBNet
John Researcher

Share Project

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

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

You may share this project with other Researchers, Committee Members, Administrators and Sponsors. You may also send a complete copy of this project to a Principal Investigator at another site if this is a multi-site project. You may also transfer ownership of this project to another individual.

- **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.

- **Multi-site:** 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 these 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.

✓ Almost every project requires the "Share" designation.

Select your colleague's institution

IRBNet

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

IRBNet ID: 137618-1   USER PROFILE   LOGOUT

✓ Select 'Research Institution' to share with a project collaborator.

Share Project

[518-1] Motivations of Research Subjects: A Mixed Methods Study

You may share this project with other IRBNet users. Sharing a project consists of three steps:

1. Select an organization to display a list of IRBNet users at that organization.
2. Specify the access that you wish to grant each user at that organization.
3. Save your changes.

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

Search for an Organization [   ] [Search] [Clear]

Organization types to display ☑ Research Institutions ☐ Boards ☐ Sponsors [Display]

Select an Organization *

Metropolitan University, Frederick, MD
Metsch & Metsch, P.A., Miami, FL
Miami Children's Hospital , Miami, FL
Miami Children's Hospital IRB, Miami, FL
Miami Research Associates, Miami, FL
Miami University, Oxford, OH
Michigan CardioVascular Institute, Midland, MI
Michigan State University, East Lansing, MI

✓ Select the Institution in which your colleagues are members.

[Select Organization]

* required fields

✓ The default institution highlighted is your home institution.

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Set the proper level of access

IRBNet

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

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

Share Project

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

Specify the access that you wish to grant to each user at **Metropolitan University**. You should grant each user only the minimum level of access necessary to perform their work on this project.

- **Signature Only (Read):** Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.

- **Read:** Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.

- **Write:** Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.

- **Full:** Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.

Search for a User: | chan | **Search**

IRBNet User	Permission Access			
Chandry, Francis	O Full	O Write	⦿ Read	O No Access
	One User found.			

✓ Grant only the level of access required for each collaborator.

Each user will be automatically notified that they have been granted access to this project. You may also specify additional comments to be included in this notification:

Your Comments

Save   **Cancel**

Communicate with your Project Team

IRBNet

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

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

New Project Message

[137775-1] Motivations of Research Subjects: A Mixed Methods Study

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:

| Select All Project Owners Only | Select All | Un-Select All |

⊖User	⊕User Organization	Send Mail
Chandry, Francis	Metropolitan University, Frederick, MD	☐
Palazzo, Enrico	Metropolitan University, Frederick, MD	☐
Researcher, John	Metropolitan University, Frederick, MD	☐

Board Contacts:

There are no submitted packages.

Subject ✱	IRBNet message from John Researcher
Message ✱	Re: [137775-1] Motivations of Research Subjects: A Mixed Methods Study Please login to IRBNet to review this project. Regards, John Researcher

[Send] [Cancel]

✱ required fields

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

IRBNet ID: 137618-1

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

Sign Package

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

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

I John Researcher, the [_____▼] accept that I have read the documents in th[...] entirety and agree that they are ready for submission. [**Sign**]

OR If you must sign on behalf of someone who is not able to electronically sign for him/herself, ent[...] **mode**.

✓ 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.

13

Submit your package for review

IRBNet

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

IRBNet ID: 137618-1   USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

Submit Package

My Projects
Create New Project
🏳 **My Reminders (2)**

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 (2)**

Other Tools
Forms and Templates

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

IRBNet supports multiple models of review. Using the IRBNet "Submit" feature, you may electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization   [   ]   [Search]   [Clear]

Metropolitan IRB, Frederick, MD
Metsch & Metsch, P.A., Miami, FL
Miami Children's Hospital IRB, Miami, FL
Michigan Technological University, Houghton, MI
Select a Board ✱   Middle Tennessee State University, Murfreesboro, TN
Middlesex Hospital IRB, Middletown, CT
Mission Health Institutional Review Board, Asheville, NC
Mission Health Cancer Institutional Review Board, Asheville, NC

[Continue]   [Cancel]

✱ required fields

✓ The default board for your institution is highlighted.

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Submit to your Board

IRBNet

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

IRBNet ID: 137618-1   USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
⚑ My Reminders (2)

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 (2)

Other Tools

Forms and Templates

Submit Package

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

The following IRBNet users at **Metropolitan IRB** will be automatically notified of your submission:

Halway, Ann

Submission Type: ✱ New Project

You may also specify additional comments to be included in this notification.

Your Comments: Thank you for your help!

[Submit]   [Cancel]

✓ Send a kind word to your committee coordinators!

Note: The package will be locked upon submission.

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

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

Managing unlocked packages

IRBNet

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.

IRBNet ID: 137618-1   USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher   **Designer**

My Projects
Create New Project
My Reminders (3)

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

This package is: 🔓 **Unlocked - Revisions Pending** | **View History** | **Mark Revisions Complete** | (When should I do this?)

Get stamped documents, approval letters and other board documents, and track reviews for this package: **Review details.**

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 (3)

Other Tools
Forms and Templates

✓ 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.

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

Documents in this Package:

Document Type	Description	Last Modified		
▼ **Application Form**	IRB Application	09/30/2009 12:04 PM	📄	✏️ ✕
▼ **Consent Form**	Consent Form	09/30/2009 12:04 PM	📄	✏️ ✕
▼ **Protocol**	ASM981 C2439 Protocol.pdf	09/30/2009 12:04 PM	📄	✏️ ✕

There are **3 Training & Credentials records** linked to this package. | **View All Links** | **Link / Un-Link Records** |

Add New Document

18

Receive your review decision

IRBNet

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

IRBNet ID: 137618-1

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
♥ **My Reminders (3)**

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 (3)**

Other Tools
Forms and Templates

Project Overview

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

You have Full access to this project. [Edit]

Research Institution Metropolitan University, Frederick, MD
Title Motivations of Research Subjects: A Mixed Methods Study
Principal Investigator Researcher, John, PhD
Status Pending Review
Lock Status 🔒 **Locked - Revisions Complete**
Keywords Incentive, Extra Credit
Sponsor National Research Foundation

The documents for this project can be accessed from the **Designer**.

Submitted to:
Metropolitan IRB 09/30/2009 **Pending Review. Review details.**

✓ Click "Review Details."

Shared with the following IRBNet users

IRBNet User	Organization	Access Type
John Researcher	Metropolitan University, Frederick, MD	Full
Francis Chandry	Metropolitan University, Frederick, MD	Read
Enrico Palazzo	Metropolitan University, Frederick, MD	Write

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View Review Details

IRBNet

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

IRBNet ID: 137618-1

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
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Project History
Messages & Alerts (3)

Other Tools

✓ Board Documents and review information for all packages can be found here.

Review Details

[137618-1] Motivations of Research Subjects: A Mixed Methods Study
Metropolitan IRB, Frederick, MD

Submission Details

Submitted To Metropolitan IRB, Frederick, MD
Submitted by John Researcher
Submission Date 09/30/2009
Submission Type New Project
Local Board Reference Number 09-497

✓ Follow the review process here.

Review Details:

Agenda	Review Type	Status	Effective Date	Expiration Date
10/16/2009 08:00 AM	Expedited Review	Pending Review		

Board Documents:

There are currently no documents from Metropolitan IRB

✓ Board documents will appear here.

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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.

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

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.

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

IRBNet

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

USER PROFILE   LOGOUT

IRBNet

✓ Click My Reminders to view all active notifications sent to you concerning any of your projects.

My Projects

Welcome to IRBNet
John Researcher

...ws projects that you have created and projects that have been shared with you by other ...work. Use Reminders, Tags and Archiving to help organize your workspace and keep it running smoothly. (Learn More)

My Projects
Create New Project
⚑ My Reminders (4)

Other Tools
Forms and Templates

Search: _____   Search By Tag: [_____▼]

[Search]   [Clear]

◄◄ ◄ 1 - 3 of 3 ► ►◄ 10 ▼

| Create and Manage Tags | Show Archived Projects (4) |
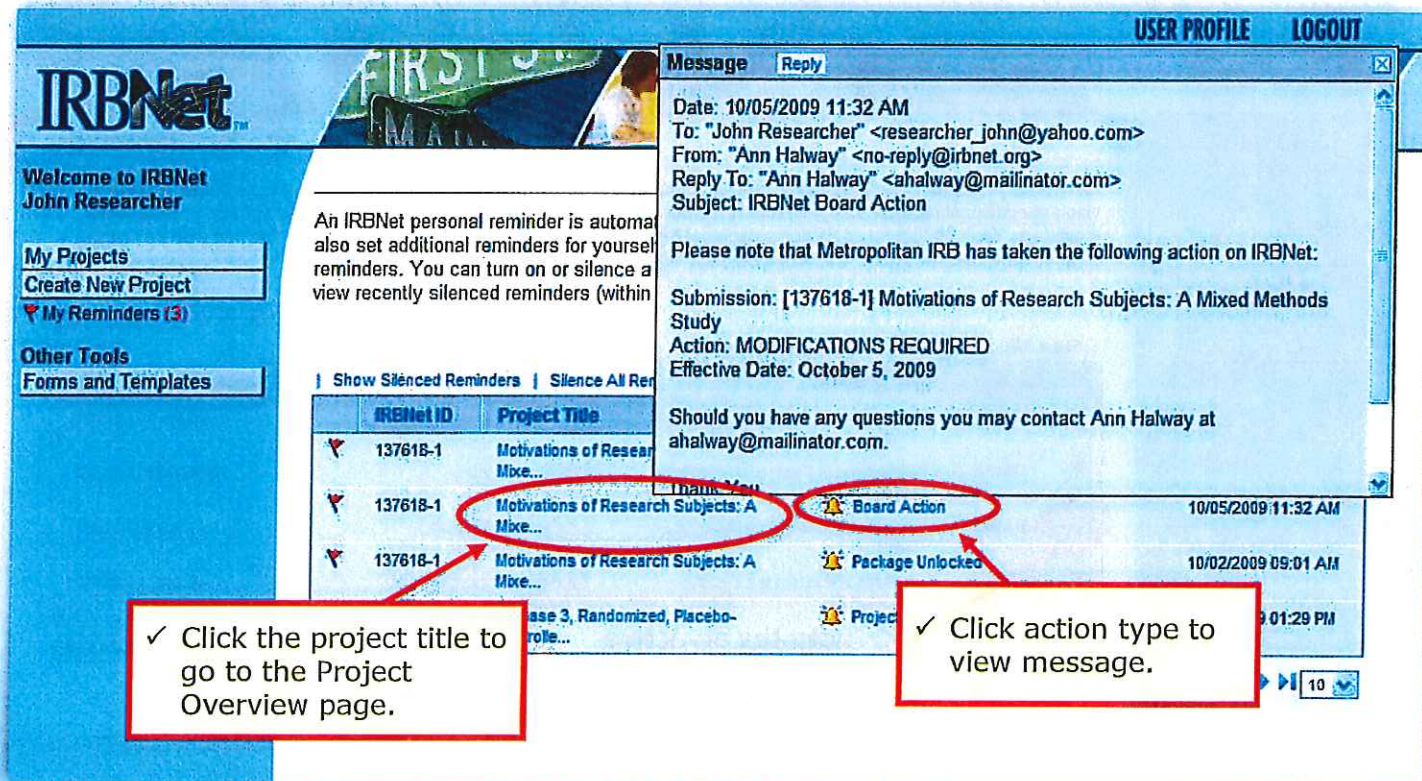
⚑	IRBNet ID ▼	Project Title	Principal Investigator	Submission Type	Status	Effective Date	🔒
⚑	37618-1	Motivations of Research Subjects: A Mixe...	🔲 Researcher	New Project	Modifications Required	10/05/2009	🔒
	108459-3	Double-Blind, Multicenter Phase 3 Study ... 🔲 Oncology Dept	🔲 Researcher	Adverse Event	Acknowledged	09/21/2009	🔒
⚑	107645-2	A Phase 3, Randomized, Placebo-Controlle... Need Signatur...	🔲 Bird		Work in progress		

◄◄ ◄ 1 - 3 of 3 ► ►◄ 10 ▼

✓ The flag indicates an active Reminder for this project.

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

IRBNet

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

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
⚑ My Reminders (3)

Other Tools
Forms and Templates

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.

|◀ ◀ 1 - 4 of 4 ▶ ▶| 10 ▾

| Show Silenced Reminders | Silence All Reminders |

	IRBNet ID	Project Title	Message Type	Date
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Board Document Published	10/05/2009 11:32 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Board Action	10/05/2009 11:32 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Package Unlocked	10/02/2009 09:01 AM
⚑	107645-1	A Phase 3, Randomized, Placebo-	🔔 Project Access Granted	10/01/2009 01:29 PM

|◀ ◀ 1 - 4 of 4 ▶ ▶| 10 ▾

✓ Indicates an active Reminder. Clicking the red flag will "silence" the Reminder.

Review Project Messages & Alerts

IRBNet

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

IRBNet ID: 137618-1

LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

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 (3)

Other Tools
Forms and Templates

Project Messages & Alerts

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

The following communications have been posted for this project. You can set an IRBNet personal reminder on any message or alert. Your personal reminders will automatically appear in your My Reminders list. Other IRBNet users do not see your personal reminders. You can turn on or silence a personal reminder without affecting other IRBNet users.

erview

| Silence All Reminders | 1 - 10 of 11   10

	IRBNet ID	Project Title	Message Type	Date
⚑	137618-1	Motivations of Research Subjects: A Mixe...	✉ Message (IRBNet message from John Researcher)	10/06/2009 08:45 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	✉ Message (IRBNet message from John Researcher)	10/06/2009 08:42 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Board Document Published	10/05/2009 11:32 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Board Action	10/05/2009 11:32 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Package Revisions Complete	10/02/2009 09:01 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Package Unlocked	10/02/2009 09:01 AM
⚑	137618-1	Motivations of Research Subjects: A Mixe...	🔔 Submission Notification	09/30/2009 12:16 PM
⚑	137618-1			09/30/2009 12:10 PM
⚑	137618-1			09/30/2009 12:06 PM
⚑	137618-1			09/30/2009 12:05 PM

1 - 10 of 11   10

✓ Click here to access project-specific Messages & Alerts.

✓ 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.

Write

7

Revise Your Project

IRBNet

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.

IRBNet ID: 137618-1

USER PROFILE   LOGOUT

✓ Note that this is the first package in the sequence.

Project Overview

[37618-1] Motivations of Research Subjects; A Mixed Methods Study

My Projects
Create New Project
🌱 My Reminders (3)

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 (3)

Other
For...

✓ To create a new package from an existing package, click on "Project History."

You have Full access to this project. (Edit)

Research Institution	Metropolitan University, Frederick, MD
Title	Motivations of Research Subjects; A Mixed Methods Study
Principal Investigator	Researcher, John, PhD
Status	Modifications Required
Lock Status 🔒	Locked
Keywords	Incentive, Extra Credit
Sponsor	National Research Foundation

The documents for this project can be accessed from the **Designer**.

Submitted to:
Metropolitan IRB 09/30/2009 **Modifications Required** 10/05/2009. **Review details.**

Shared with the following IRBNet users

	Organization	**Access Type**
er	Metropolitan University, Frederick, MD	**Full**
y	Metropolitan University, Frederick, MD	**Read**
	Metropolitan University, Frederick, MD	**Write**

8

Create a New Package

IRBNet

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

IRBNet ID: 137618-1

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet John Researcher

My Projects
Create New Project
♥ My Reminders (3)

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 (3)

Other Tools
Forms and Templates

Project History

[137618-1] Motivations of Research Subjects: A Mixed Methods Study

The following document packages are available in Project History:

	Pkg #	Package Type		Status		Create Date	Submission Date	Review Date
▶	1	New Project		Modifications Required		09/30/2009	09/30/2009	10/05/2009
				One Package found.				

▶ You are currently viewing this package.

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.

Create New Package

✓ Click "Create New Package."

9

Access New Package

IRBNet

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

IRBNet ID: 137618-2

USER PROFILE   LOGOUT

IRBNet

Welcome to IRBNet
John Researcher

Project History

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

My Projects
Create New Project
♥ My Reminders (3)

The following document packages are available in Project History:

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 (3)

Pkg #	Package Type		Status	Create Date	Submission Date	Review Date
2	New Document Package		Work in progress	10/06/2009		
1	New Project		Modifications Required	09/30/2009	09/30/2009	10/05/2009
			2 Packages found, displaying all Packages.			

▶ You are currently viewing this package.

Other Tools
Forms and Templates

✓ 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.

10

Add or Revise Documents

IRBNet

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

Designer

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

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 (3)

Other Tools
Forms and Templates

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

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   ▾   **Download**

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

New and Revised Documents in this Package:

There are currently no documents in

There are no Training & Credentials records linked to this package.

IRBNet allows you to revise your existing project documents and maintain your package. **Learn more.**

Add New Document

OR

Documents from Previous Packages that you can Revise: (When shoul

✓ To <u>revise</u> 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.

▲ Pkg #	⊕ Document Type	⊕ Description	⊕ Last Modified	⊕ Pkg Submission Date	⊕ Pkg Status	①	②
1	Application Form	IRB Application	09/30/2009 12:04 PM	09/30/2009	Modifications Required	🗋	✏
1	Consent Form	Consent Form	09/30/2009 12:04 PM	09/30/2009	Modifications Required	🗋	✏

11

Attach a Document

IRBNet

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

IRBNet ID: 137618-2   USER PROFILE   LOGOUT

IRBNet

**Welcome to IRBNet
John Researcher**

My Projects
Create New Project
My Reminders (3)

Project Administration
Project Overview
Designer

Attach Document

[137618-2] Motivations of Research Subjects: A Mixed Methods Study
You are updating an attachment. To help you identify the file that was attached:

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

Document Type ★ [Consent Form   ▼]
Description [Consent Form v2   ]
File ★ [   ] [Browse...]
[Update] [Cancel]
ields

✓ 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.

12

Document Management Tools

IRBNet

IRBNet provides powerful tools to update and review project documents.

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

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 (3)

✓ Note that after revising, the document is removed from the visible list of documents from previous packages.

Designer

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

Step 1:
Download blank forms, document templates and reference materials to assist you in asse

Select a Library: Metropolitan IRB, Frederick, MD ▼

Select a Document: Application for Continued Approval

1 View
2 View revision history
3 Update
4 Delete document

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

New and Revised Documents in this Package:

⬦Document Type	⬦Description	⬦Last Modified	① ② ③ ④
▼ Consent Form	Consent Form v2	10/06/2009 09:28 AM	📄 🗐 ✏ ✕

There are no Training & Credentials records linked to this package. | View All Links | Link / Un-Link Records |

IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. **Learn more.**

Add New Document (When should I do this?)

OR

Documents from Previous Packages that you can Revise: (When should I do this?)

⬦Pkg #	⬦Document Type	⬦Description	⬦Last Modified	⬦Pkg Submission Date	⬦Pkg Status		
1	Application Form	IRB Application	09/30/2009 12:04 PM	09/30/2009	Modifications Required	📄	✏

13

Revision History

IRBNet

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

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

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 (3)

Other Tools
Forms and Templates

Designer

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

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 you link your project team's Training & Credentials to your package.

New and Revised Documents in this Package:

⬍ Document Type	⬍ Description	⬍ Last Modified	
▾ Consent Form	Consent Form.doc	05/26/2011 04:05 PM	🗗 ✎ ✕

There are

IRBNet al
your pac

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

Document Revision History   ☒

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status	
2	Consent Form	Consent Form v2	10/06/2009 09:28 AM		Work in progress	🗋
1	Consent Form	Consent Form	09/30/2009 12:04 PM	09/30/2009	Modifications Required	🗋

new documents to

Docume

▲ Pkg #							s	
1	A							🗋 ✎
1	Protocol	ASM981 C2439 Protocol.pdf	09/30/2009 12:04 PM	09/30/2009	Modifications Required		🗋 ✎

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

Welcome to IRBNet
John Researcher

My Projects
Create New Project
My Reminders (3)

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 (3)

Other Tools
Forms and Templates

Designer

[137618-2] Motivations of Research Subjects: A Mixed Methods Study

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   ▼   **Download**

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

New and Revised Documents in this Package:

Document Type	Description	Last Modified	
Consent Form	Consent Form v2	10/06/2009 09:28 AM	📄 🗐 ✏ ✕

There are no Training & Credentials records linked to this package | **View All Links** | **Link / Un-Link Records** |

IRBNet allows you to revise your existing project documents and maintain version history, or add entirely new documents to your package. **Learn more.**

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

✓ Attach T&C documents to this package is necessary.

Document   (When should I do this?)

Documents from Prev...   (When should I do this?)

Pkg #	Document Type	Description	Last Modified	Pkg Submission Date	Pkg Status		
1	Application Form	IRB Application	09/30/2009 12:04 PM	09/30/2009	Modifications Required	📄	✏
1	Protocol	ASM981 C2439 Protocol.pdf	09/30/2009 12:04 PM	09/30/2009	Modifications Required	📄	✏

15

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.