

National

Researcher 2: Post-Submission Advanced Topics

Research Network ® Training Energizer



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

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

RESEARCH DATAWARE

Innovation in Research Management

- Review Project Messages & Alerts
- Create a Subsequent Package
- Add and Revise Documents
- Complete and Submit Subsequent Package



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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</u> <u>COORDINATOR</u>.

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. <u>CONTACT YOUR LOCAL BOARD COORDINATOR</u> if you have questions.



# Advanced My Projects Management IRBNet

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

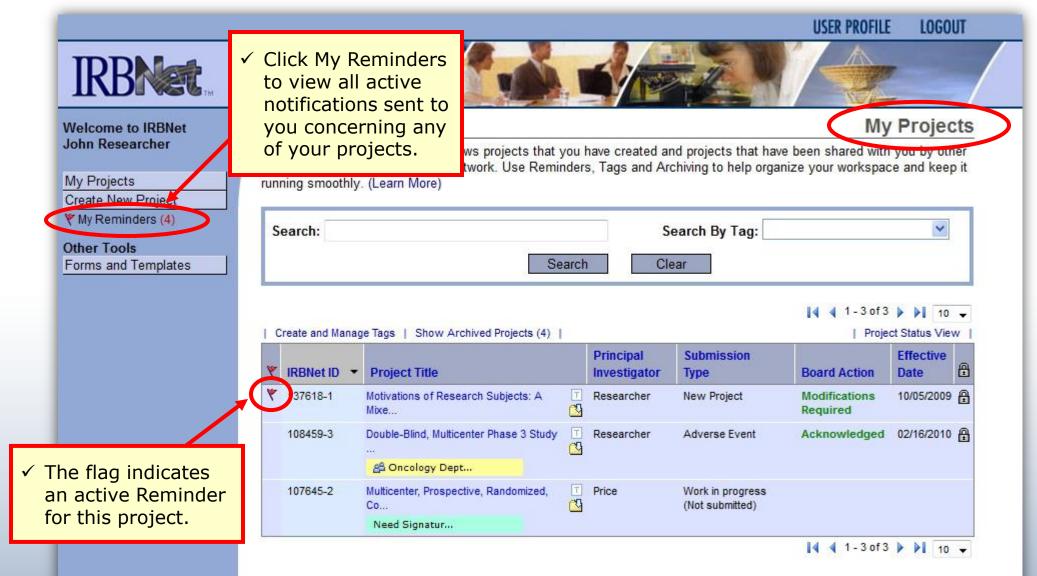
Welcome to IRBNe John Researcher My Projects Create New Project	et	Departi	Example: Find all One ment projects with Dr. n "Smith" + "Oncology	Smith		hat hav	USER PROFILE My be been shared with nize your workspace	Project	ner
My Reminders (4) ther Tools orms and Templat		Search:	Se	arch	Search Clear	n By Tag:		~	
							🚺 🖣 1-3 of 3	10	•
		Create and Manag	ge Tags   Show Archived Projects (4)   Project Title	Princi	692/C	omission e		I0     Ct Status View     Effective     Date	
				5000.00	igator Typ		Projec	ct Status Viev Effective	w I
		🔻 IRBNet ID 👻	Project Title Motivations of Research Subjects: A	Invest	igator Typ cher Nev	e	Project	Effective Date 10/05/2009	e B
		♥ IRBNet ID ▼ ♥ 137618-1	Project Title Motivations of Research Subjects: A Mixe Double-Blind, Multicenter Phase 3 Study 	Resear	rcher New rcher Adv	e v Project	Project Board Action Modifications Required	Effective Date 10/05/2009	e B



### **Receive Notifications**



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

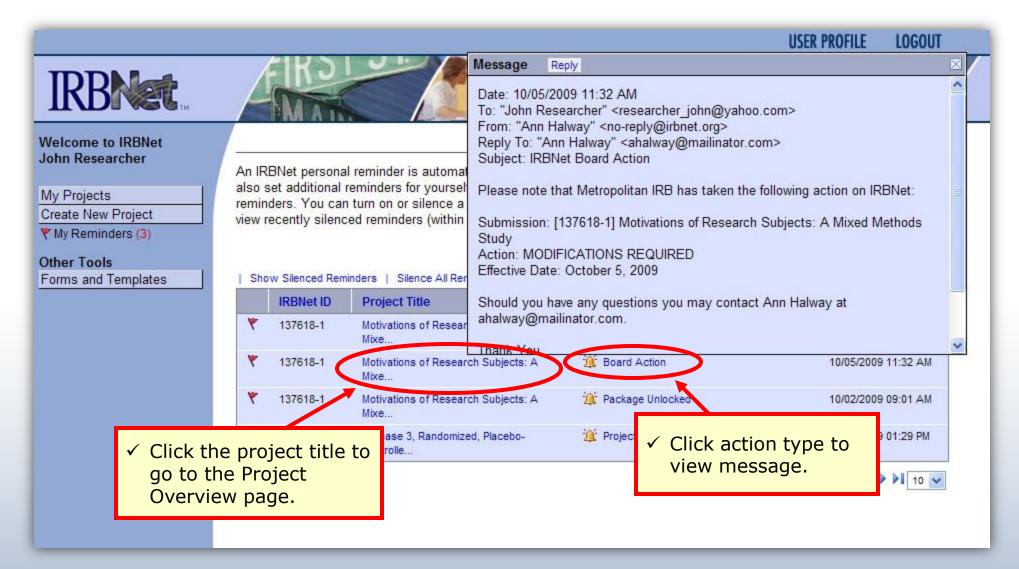




### **Review My Reminders**



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





### Silence Reminders



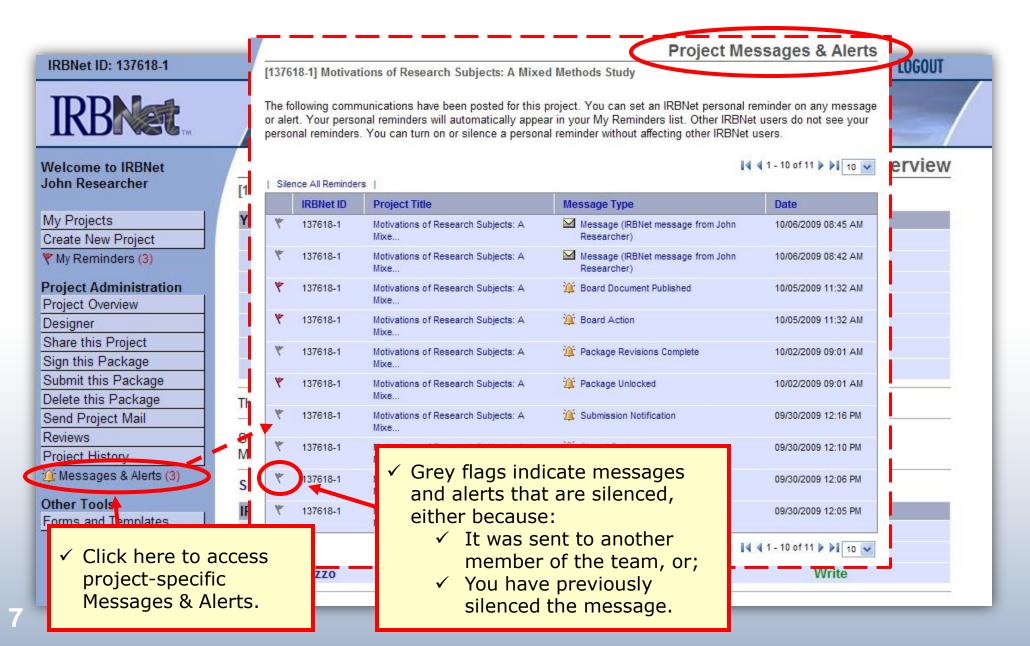
Reminders are indicated with red flags. Silencing the Reminders will remove them from this page in the future.

					USER PROFILE LOGOUT
IRBNet	4	RO			
elcome to IRBNet					My Reminders
My Projects Create New Project My Reminders (3) Other Tools	remino view re	ders. You car ecently silenc	reminders for yourself on the Messag n turn on or silence a personal remind ced reminders (within the past 30 day	ler without affecting other IRBNet use	ers. You can also choose to
orms and Templates	1 310	IRBNet ID	Project Title	Message Type	Date
	٣	137618-1	Motivations of Research Subjects: A Mixe	🎉 Board Document Published	10/05/2009 11:32 AM
	٣	137618-1	Motivations of Research Subjects: A Mixe	Board Action	10/05/2009 11:32 AM
	( v	137618-1	Motivations of Research Subjects: A Mixe	🎉 Package Unlocked	10/02/2009 09:01 AM
	٣	107045-1	A Phase 3, Randomized, Placebo-	Yroject Access Granted	10/01/2009 01:29 PM
			✓ Indicates an active Reminder. Clicking red flag will "siler the Reminder.	ng the	I I I I I I I I I I I I I I I I I I I



## Review Project Messages & Alerts

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





### **Revise Your Project**



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

Welcome to IRBNet							Proje	ect Overview
John Researcher	[137618-1] Motivations of R	lesearch Subj	ects: A Mixed	Method	ls Study			
My Projects	You have Full access to th	is project. 🕧	Edit)					
Create New Project	Researc	ch Institution 2	Zanzibar Univer	rsity, Fre	derick, MD			
$\checkmark$ Note that this is the	Title Motivations of Research Subjects: A Mixed Methods Study							
first package in the	Principal	Investigator I	Researcher, Jo	hn, PhD				
sequence.		Keywords Incentive, Extra Credit						
Object this Desired	-	Sponsor	National Resea	rch Four	ndation			
Share this Project Sign this Package Submit this Package	The documents for this proje	ct <mark>can be acce</mark>	ssed from the	Designe	r.			
Delete this Package	Project Status as of: 03/20/20	13						
Send Project Mail Reviews	Particular Provid		Board	1	15.4	Desired Sta		Euripeira Data
Project History	Reviewing Board		Ref #	Initial Aj	oproval Date	Project Star	tus	Expiration Date
Messages & Alens (3)	Metropolitan IRB, Frederick, MD		09-497					04/03/2013
	Package 137618-1 is:	cked	09-497			14 4 1	Package 1 of 2	04/03/2013 ▶ ▶   Jump ▼
Messages & Alerts (3) Other Tools		cked Submission Date	09-497 Submission Type	Board Ref #	Board Actio		Package 1 of 2 Effective Date	
Messages & Alerts (3) Other Tools Forms and Templates To create a new package from an	Package 137618-1 is: 🔒 Lo Submitted To Metropolitan IRB, Frederick, MD	Submission	Submission		Board Actio	n	Effective	
Messages x Alerts (3) Other Tools Forms and Templates To create a new package from an existing package, click	Package 137618-1 is: 🔒 Lo Submitted To Metropolitan IRB, Frederick, MD	Submission Date	Submission Type	Ref #		n	Effective Date	▶ ▶I   Jump ▼
Messages & Alerts (3) Other Tools Forms and Templates To create a new package from an	Package 137618-1 is: 🔒 Lo Submitted To Metropolitan IRB, Frederick, MD	Submission Date 09/30/2009	Submission Type	Ref #		n	Effective Date	▶ ▶I   Jump ▼
Messages x Alerts (3) Other Tools Forms and Templates To create a new package from an existing package, click	Package 137618-1 is: 🔒 Lo Submitted To Metropolitan IRB, Frederick, MD	Submission Date 09/30/2009	Submission Type New Project	Ref #		n	Effective Date	▶ ▶   Jump ▼     Review Details
Messages x Alerts (3) Other Tools Forms and Templates To create a new package from an existing package, click	Package 137618-1 is: 🖹 Lo Submitted To Metropolitan IRB, Frederick, MD hared with the following IRI	Submission Date 09/30/2009 BNet users: Organ	Submission Type New Project	Ref #		n	Effective Date 10/05/2009	▶ ▶   Jump ▼     Review Details
Messages x Alerts (3) Other Tools Forms and Templates To create a new package from an existing package, click	Package 137618-1 is: 🖹 Lo Submitted To Metropolitan IRB, Frederick, MD hared with the following IRI IRBNet User	Submission Date 09/30/2009 BNet users: Organi Zanziba	Submission Type New Project	Ref # 09-497		n	Effective Date 10/05/2009 Access	▶ ▶   Jump ▼     Review Details



### Create a New Package



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

Welcome to IRBNet John Researcher	[137618-1] Motivations of Research	Subjects: A Mixed Methods Stud	ly	Proj	ject Hist	ory
My Projects					of 1 🕨 🔰 🔟	
Create New Project My Reminders (3)			0	Pr	oject Status Vi	iew
Project Administration	Pkg	Submission Date	Review Type	Board Action	Effective Date	8
Project Overview	Y 1 New Project	09/30/2009	Expedited	Modifications	10/05/2009	
	,		Review	Required		±
Designer						
Designer Share this Project	50.			🚺 🖣 1-1o	of 1 🕨 🔰 🔟	0 🗸
				<b> ∢ 1</b> -1o	of 1 🕨 🔰 1	0 🗸
Share this Project	Your current document package has al			rour Board. You m	nay prepare i	new
Share this Project Sign this Package	or modified documents (such as Revisi	on/Amendment materials, Renewa		rour Board. You m	nay prepare i	new
Share this Project Sign this Package Submit this Package		on/Amendment materials, Renewa		rour Board. You m	nay prepare i	new
Share this Project Sign this Package Submit this Package Delete this Package	or modified documents (such as Revisi	on/Amendment materials, Renewa		rour Board. You m	nay prepare i	new
Share this Project Sign this Package Submit this Package Delete this Package	or modified documents (such as Revisi	on/Amendment materials, Renewa		rour Board. You m	nay prepare i	r



### Access New Package



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

IRBNet ID: 137618-2					USER PRO	FILE LOO	GOUT
<b>IRBNet</b>	FIRST ST.	-		1	1/-		
Welcome to IRBNet John Researcher	[137618-2] Motivations of Research Su	bjects: A N	lixed Methods Study	y	Pro	ject Hist	ory
My Projects Create New Project					🚺 📢 1 - 2 o	of 2 🕨 🔰 🗍	
Y My Reminders (3) Project Administration	Pkg     #     Submission Type		Submission Date	Review Type	Board Action	Effective Date	₿
Project Overview Designer Share this Project	2 Work in progress (Not submitted) 1 New Project		09/30/2009	Expedited Review	Modifications Required	10/05/2009	₿
Sign this Package Submit this Package Delete this Package					<b> 4 4</b> 1-2 o	of 2 🕨 🔰 1	0 🗸
Send Project Mail Reviews Project History Messages & Alerts (3) Other Tools Forms and Templates	<ul> <li>✓ Note that a second package is created.</li> <li>✓ The Project History</li> </ul>		✓ Now click in Progres	s to begir	1		
Tornio and Tompiates	lists all packages in the project lifecycle.		building th	ie packag	e.		



### Add or Revise Documents



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

Welcome to IRBNet	Designer
John Researcher	[137618-2] Motivations of Research Subjects: A Mixed Methods Study
My Projects Create New Project	Step 1: Download blank forms, document templates and reference materials to assist you in assembling your document package.
Wy Reminders (3)	Select a Library: Metropolitan IRB, Frederick, MD -
Project Administration Project Overview	Select a Document: Application for Continued Approval   Download
Designer Share this Project	Step 2: Assemble your document package. In addition to adding project documents and the state of the state of the state
Sign this Package Submit this Package Delete this Package	link your project team's Training & Credentials to your package. New and Revised Documents in this Package: ■ Download the previous
Send Project Mail Reviews Project History	There are currently no documents in version to your computer, modify as required and save.
Messages & Alerts (3) Other Tools Forms and Templates	There are no Training & Credentials records linked to this package. I v IRBNet allows you to revise your existing project documents and mainta
All documents	your package. Learn more. Add New Document OR ✓ To add a new document, click "Add New Document".
from previously submitted packages are listed here.	Documents from Previous Packages that you can Revise:       (When should be a constructed on the should be a constr
	12:04 PM         Required           1 Consent Form         09/30/2009         09/30/2009           12:04 PM         09/30/2009         Modifications           12:04 PM         Dequired         Image: Consent Form



### Attach a Document



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
<b>IRBNet</b>	AKK			1		
Welcome to IRBNet John Researcher         My Projects         Create New Project         ♥ My Reminders (3)         Project Administration         Project Overview         Designer         ✓       Browse your had for documents, a attach.         ✓       This view is for updating a docu from package 1. view for attachin new document i similar.	You are updat This att It was a It has a Ard drive and Iment The ng a	otivations of Research S ing an attachment. To hel tachment was loaded from attached on 09/30/2009. a size of 93184 bytes. Document Type * Description File *	Ip you identify the file t in the file Consent For Consent Form Consent Form v2	hat was attached:		Browse



### Document Management Tools



IRBNet provides powerful tools to update and review project documents.

Welcome to IRBNet					Designer		
John Researcher	[137618-2] Motivation	s of Research Subjects: A M	ixed Methods Study				
My Projects	Step 1:			u in asse 1 View			
Create New Project	Download blank forms,	document templates and refer	ence materials to assist yo				
Y My Reminders (3)	Select a Library:	Metropolitan IRB, Frederick,	MD 👻	2 View r	evision history	у	
Project Administration	Select a Document:	Application for Continued Ap	proval	3 Update	Ð		
Project Overview	0				document		
Designer	Step 2:			4 Delete	document		
Share this Project		ent package. In addition to add		our package, IRBNet als	allows you to		
Sign this Package	link your project team's	Training & Credentials to your	package.	54 (mag2000)			
Submit this Package	New and Revised Do	cuments in this Package:					
Delete this Package	Document Type	Description	-la	st Modified	234		
Send Project Mail	Consent Form	Consent Form v2	CARE OF	2009 09:28 AM			
Reviews	, concentrent.	Jongon Form 12		-	) 🖞 🖉 🗙 📋		
Project History	There are no Training 8	Credentials records linked to	this package.   View All Lir	ks   Link / Un-Link Records	1		
✓ Note that after		evise your existing project docu	uments and maintain version	history, or add entirely	new documents to		
	your package. Learn r	nore.					
revising, the		A	dd New Document (When	should I do this?)			
document is							
removed from the			OR				
visible list of			UK				
documents from	Documents from Previous Packages that you can Revise: (When should I do this?)						
previous packages.	$\Rightarrow {}^{Pkg}_{\#} \Rightarrow Document$	Type Oescription		Pkg mission ⇔ Pkg Status ∂ate			
	1 Application For	m IRB Application	09/30/2009 09/3 12:04 PM	0/2009 Modifications Required	<u>)</u>		





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

#### Designer Welcome to IRBNet John Researcher [137618-2] Motivations of Research Subjects: A Mixed Methods Study Step 1: My Projects Download blank forms, document templates and reference materials to assist you in assembling your document package. Create New Project Y My Reminders (3) Select a Library: Metropolitan IRB, Frederick, MD ✓ The Document Revision History Project Administration Select a Document: Application for Continued Approval lists the most recent document **Project Overview** Designer and every previous version Step 2: Share this Project Assemble your document package. In addition to adding project documents to you submitted by package. link your project team's Training & Credentials to your package. Sign this Package Submit this Package New and Revised Documents in this Package: Delete this Package Document Type Last Modified Description Send Project Mail Consent Form Consent Form.doc 05/26/2011 04:05 PM X Reviews **Project History** Document Revision History There are Messages & Alerts (3) Pkg Pkg Last **Document Type** Description Submission **Pkg Status** Modified IRBNet all v new documents to Other Tools Date your pac Forms and Templates Consent Form v2 Consent Form 10/06/2009 Work in 09:28 AM progress Consent Form Consent Form 09/30/2009 09/30/2009 Modifications 12:04 PM Required Docume IS 1 D Protocol ASM981 C2439 Protocol.pdf 09/30/2009 09/30/2009 Modifications 1 D 12:04 PM Required



### **Complete Submission Process**



Designer

### 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

Y 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.

Ŧ

Select a Library:

Select a Document: Application for Continued Approval

Metropolitan IRB, Frederick, MD

Download

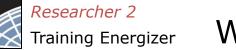
•

#### 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 Mo	dified	
<ul> <li>Consent Form</li> </ul>	Consent Form v2	10/06/2009 0	9:28 AM	🗋 🗘 🖉 🗙
	Credentials records linked to this p			
RBNet allows you to re our package. <mark>Learn n</mark>	vise your existing project document nore.	ts and naintain version hist	ory, or add entill dy	new documents t
Documents from Pre	<ul> <li>✓ View T&amp;C documents linked to any package within this project</li> </ul>	R	✓ Attach T	nts to this is
$ \stackrel{Pkg}{=}                                  $	Type Oescription	← Last Modified → Submissi Date	on 🗢 Pkg Status	5
1 Application For	m IRB Application	09/30/2009 09/30/2009 12:04 PM	Modifications Required	<u>)</u>
1 Protocol	ASM981 C2439 Protocol.pdf	09/30/2009 09/30/2009 12:04 PM	Modifications Required	<u>)</u>





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.

**RESEARCH DATAWARE** *S* Innovation in Research Management

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