IRB+

User Manual for Online Submissions

Updated April 15 2007

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2.Introduction

This document describes how to use the Online Submissions Module of IRB+. The Online Submissions Module allows investigators to:

- Submit initial applications, continuing reviews, amendments, adverse events, unanticipated problems and project completion applications online.
- Upload supporting documents like the consent form, full protocol description, advertising material, etc.
- View their activity letters online and respond online.
- Check which IRB meeting their studies are scheduled for.

The Online Submissions Module integrates seamlessly with the IRB Administrator Module of IRB+, allowing IRB Administrator to:

- Accept submissions online or return submissions to the PI for changes.
- View all information entered by the PI online and download the supporting documents for the submission.

This document is divided into two sections.

<u>Investigators</u> - This section explains how the researcher community should use the Online Submissions Module in IRB+.

IRB Administrators - This section explains how the IRB Administrators should use the Online Submissions Module in IRB+.

All screen shots and examples in this user manual are of test information only and utilize the demo system. The actual online forms, supporting documents and printable forms in your Online Submissions Module will be customized for you organization.

3. Investigators

3.1 Login Screen

IRB+ is located at the following website: <u>http://www.irbplus.com/</u>. To use IRB+ you must have Internet Explorer 6 or 7. Click the "Customer Login" button and enter your email address and password in the following login page:

🖉 IRB+ - Microso	oft Internet Explorer pro	wided by Verizon Online					- 7 🛛
GO - 🔊	https://www.irbplus.com/Login	.asp			✓ I	Google	₽
😭 🏟 🔡 🗸	€IRB+	€ IRB+	ØIRB+ X	🏉 IRB+		🟠 🔹 🗟 👘 🖶 🖬 Page	🔹 🍈 Tools 🔹 🎽
IRB-	+						<u>~</u>
		Welcome to	IRB+				
		Click here if y	ou have forgotton your pas	sword.			
		Email Addres	s:				
		Password:					
			Login				
							~
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If you have forgotten your password click the "Click here if you have forgotten your password" link. You will be asked to enter your email address. IRB+ will email the current password on your account to this email address.

<u>If you do not have a login</u> contact your IRB office. They will add you as an investigator to IRB+ and give you a temporary password.

3.1.1 Terms of Use

It is important that you read and agree with the Terms of Use before using IRB+. The Terms of Use are located in the left menu of the Login screen.

3.2 My Studies Screen

After logging in you will see the "My Studies" screen that will be similar to the following screen shot.

🖉 IRB+ - Microsoft Internet Explorer provided by Verizon Online										
💽 🗸 🖉 https:/	//www.irbplus.com/MySt	udies.asp				✓ 🔒	₩ ₩	Google	P	•
🚖 🍄 🔠 🕶 🏈 IRI	в+	🖉 IRB+	🏉 IRB +	x	🔏 IRB+		- 🖒	S - 🖶	🔹 🔂 Page 👻 🏠 Tools 🔹	, »
IRB+	Planned Submis	sions								^
	Study Number	Su	bmission Type		P.I.	P	rotocol Title	e	Delete	
New Protocol Application	(not assigned)	Co	ntinuing Review		Lo, Reg	j te	st 2		×	-
New Continuing Review	IRB Action Pend	ling								
New Amendment,	Study Number	P.I. Stu	dy Title	Online Da	te Submitted	IRB	Meeting	Last	Correspondence	
Change or Update	(not assigned)	Lo, Reg tes	1							-
New Adverse Event										
New Unanticipated Problem	Active Protocols	;								
	Study	P.I.	Study 1	Title		Status			Expiration	
Project Completion	Number	Lo, Reg	test 2			ACTIVE		4/9/2008	Date	-
										_
	Exempt Protoco	ls								
	None.									
	Closed/Expired	Protocols								
	None.									
										\sim
							i 🚺 🍕	Internet	🔍 100% 🔹	•:

The screen contains the following sections:

- <u>Planned Submissions</u>: Displays all submissions that need to be sent to the IRB office. This includes submissions that have been returned by the IRB office for changes.
- **IRB Action Pending**: Submissions that are awaiting review by the IRB office or by the IRB.
- Active Protocols: Displays all Protocols that are active.
- **Exempt Protocols**: Displays all Protocols that are exempt from IRB review.
- **<u>Closed/Expired Protocols</u>**: Displays all Protocols that have been closed or have expired.

In the left menu, you can select from a number of actions.

New Protocol Application	Click this link to start a new online protocol application.
New Continuing Review	Click this link to start a new continuing review application for one of your existing protocols.
New Amendment, Change or Update	Click this link to start a new amendment, change or update application for one of your existing protocols.
New Adverse Event	Click this link to start a new adverse event application for one of your existing protocols.
New Unanticipated Problem	Click this link to start a new unanticipated problem application for one of your existing protocols.
Project Completion	Click this link to start a new project completion application for one of your existing protocols.

3.3 Managing Protocols & Submissions

This sections describes all activities related to creating and submitting submissions e.g. completing online forms, uploading documents, granting access to protocols.

3.3.1 Submitting a new protocol application

To create a new protocol application, click the "New Protocol Application" link on the top left of your screen. You will see the following screen:

New Protocol Application Screen

Sew Protocol Application - Microsoft Internet Explorer provided	
https://www.irbplus.com/NewApp.asp	~ ₽
What is the title for this new study?	
New Test Study	~
OK Cancel	
Done 📑 🚱 Internet 🌚	100% 🔹 💡

Enter the protocol title and click the OK button to continue and you will then see the Protocol Edit screen.

Note: You new protocol will appear in the "Planned Submissions" section of the My Studies screen until you submit it to the IRB office.

3.3.2 Protocol Edit Screen

The Protocol Edit screen allows you to manage all submissions for a protocol. The Protocol Header, which is above the tabbed panel, displays general information about the protocol such as the study title and Pl. If you need to change the title of the protocol, you can enter the new title at the top of the screen and click the "Save" button. All other fields in the Protocol Header are read-only.

You can quickly email the PI by clicking the PI's email address in the Protocol Header. Similarly, you can email the Study Coordinator by click the Study Coordinator's email address in the Protocol Header.

Each of the tabs in the Protocol Edit screen will be described in more detail in the sections below:

- **Online Forms tab**: All online forms that must be completed for this submission.
- **Documents tab**: Supporting documents associated with the submission.
- **Printable Forms tab**: A printable version of the submission and other printable documents e.g. fax sheets, PI's Assurance Sign-off Sheet.
- Submit tab: Allows you to electronically submit the submission to the IRB office for review.
- Security tab: Allows you to grant and remove access to personnel on the protocol.

The following tabs will be displayed once the initial submission has been submitted to the IRB office:

- <u>Meetings tab</u>: All IRB Meetings this study has been scheduled for.
- Correspondence tab: View activity letters for this study and respond online.
- **Init. Application**: Initial application online forms, supporting documents and printable forms for this study.
- **Cont. Reviews**: Continuing review submissions and associated online forms, supporting documents and printable forms for this study.
- <u>Amendments</u>: Amendment submissions and associated online forms, supporting documents and printable forms for this study.
- <u>AEs</u>: Adverse event submissions and associated online forms, supporting documents and printable forms for this study.
- <u>Unanticipated Problems</u>: Unanticipated problem submissions and associated online forms, supporting documents and printable forms for this study.
- **<u>Project Completion</u>**: Project completion submissions and associated online forms, supporting documents and printable forms for this study.



The screenshot below displays a newly created initial application.

🖉 IRB+ New Test Study -	Microsoft Internet Explorer provided	by Verizon Online		_ 7 🛛
GO - 🖉 https://www	w.irbplus.com/eSubmission.asp?nStudyId=3719	5	oracle forms 6 pre-block	P -
😭 🏟 🌈 IRB+ New Test	Study		🟠 🔹 🗟 👻 🖶 🖬 Page 🗸	💮 Tools 🔹 🂙
Co to My Studies	otocol Title: New Test Study ncipal Inv.: udy Coord.: nline Forms Documents Printable Fo	Phone: Phone: ms Submit Security	Save Email: Email:	~
V	Veb Form	Status Instructions		~
P	Principal Investigator and Co- Researchers	Incomplete		
P	Protocol Summary	Incomplete		
S	Subjects and Recruitment Methods	Incomplete		
R	Research Procedures	Incomplete		
R	Risks and Discomfort	Incomplete		
0	Other Requirements	Incomplete		
				~

In the left menu, you can select the following action.

Go to My Studies	Click this to return to the My Studies screen to view all your
	protocols and submissions.

3.3.3 Online Forms Tab

The Online Forms tab lists all the online forms that you will need to complete before you can submit the protocol to the IRB office. These forms should be familiar to you as they contain questions similar to the paper-based forms you have used previously. As you complete each form, the status of the form will change from "Incomplete" to "Complete". Partially completed forms may be saved as "In Process". All incomplete forms will have a status in **red** and all in process forms will have a status in **beige** to indicate that they require further action. Instructions may be displayed next to each form to give further information on what the form contains and how it must be completed.



3.3.3.1 Completing Online Forms

To open a online form, click on the name of the form and it will be displayed in a new window. For example, when the "Protocol Summary" online form is clicked for an initial application, the following new window will be displayed.

Project Summary Online Form, Initial Application

Service Summary - Microsoft Internet Explorer provided by Verizon Online	
https://www.irbplus.com/WebForm.asp?nInstanceId=936	✓
What type of review are you applying for?* © Exempt Review © Expedited Review © Full Review	^
Department:*	
College/School/Graduate School of:*	
Date Research is scheduled to begin:*	
Are you applying for funding through the Office of Research Administration, and/or whether expected source of funds, if any?	nat is your
Date proposal must be submitted to funding agency (if applicable):	
Abstract or summarize your proposed research.*	
Done 🕢 🚺 🚺 Internet	🔍 100% 🔹 .:



Entering data

- In the online forms the required fields are marked with a red * and must be entered before saving. Some fields become required depending on the answers given to prior questions.
- Dates should be entered in the format mm/dd/yyyy.
- Numeric fields should only contain numbers, commas and decimal points.

Is this study related to ecoli?* ◯Yes ◯No	111
Is this a pet food study* ◯Yes ◯No	
Save Save as 'In Process' Cancel	~
Done 📑 🚱 Internet 🔍 100% 🗸	

Saving the Form

At the end of each online form, you will see a "Save" button, a "Save as 'In Process" button and a "Cancel" button. If you click the "Save" button and a required field is unanswered, IRB+ will remind you to specify an answer. If you would like to save the online form without completing all the required fields, click the "Save as 'In Process" button. *Note: the status of the online form then remains at "In Process" until you go back and complete the form.* Click the "Cancel" button if you <u>do not</u> wish to save any of your changes.

Optionally Required Fields

Some fields in the online forms are optionally required depending on the value of other fields in the form. For example, in the "Risks & Discomfort" form for initial applications, if you answer "Yes" to the question "*When you have completed your contact with the research participant, will there be a debriefing session*?", then you will be required to explain the procedures for the debriefing session.

🤗 Risks and Discomfort - Microsoft Internet Explorer provided by Verizon Online 🛛 📗	
https://www.irbplus.com/WebForm.asp?nInstanceId=939	× 🔒
When you have completed your contact with the research participant, will there be a debriefine session?*	ng
If your answer is YES, please describe the procedure that you will utilize:	
	^
	~

Optionally Required Forms & Supporting Documents

In the online forms, specifying certain information will require you to fill out additional forms or attach additional supporting documents. For example, in the "Description of Change" online form in the amendment submission, if you check that the there is an "Consent Change" IRB+ will add a

"Clean Consent Form" and "Consent Form with Changes Highlighted " to the Documents tab. For this reason it is important to check the Online Forms and Document tabs regularly to ensure the submission has been completed.

000	cription of Change - Microsoft Internet Explorer provided by Verizon Online	
🦲 http	s://www.irbplus.com/WebForm.asp?nInstanceId=547	4
Identif	y the type of change requested (check all that apply):	^
Pr	otocol Amendment/Change	
	Version/Date:	
Co 🗹	nsent Change Version/Date:	
Co	nsent Change Version/Date: Version 2.1 dated 4/14/2007	
Co	nsent Change Version/Date: Version 2.1 dated 4/14/2007 How will currently enrolled subjects be informed of this revision (i.e. verbally with documentation of notification in the medical record or by re-consenting with a written consent)?	_



Most of the online forms are self-explanatory. However, the following more complex online forms are described in the sections below.

3.3.3.2 Study Staff Online Form

Study Staff - Microsoft Internet Explorer provided by Verizor	n Online	
https://www.irbplus.com/eSubmissionStaff.asp?nInstanceId=935	¥	
Lookup Person		<u>^</u>
Principal Investigator:		
Address 1:	Phone:	
Address 2:	Fax:	
City:	Email:	
State: Zip:	Date of Training:	
Save Add Co-Investigator Add Study Coordinator		Cancel

The "Study Staff" online form contains all research personnel associated with this study and will be required for all initial applications. You can replace a person or lookup a person by clicking the "Lookup Person" button. Co-investigators and study coordinators may be added to the study by clicking the "Add Co-Investigator" and "Add Study Coordinator" buttons. If you need to edit the contact details of an existing person, click the "Edit Person" button.

Remember to click the "Save" button after you have finished editing the research personnel.

Editing a Person

🖉 Study Staff - Microsoft Internet Explorer provided by Verizon Online									
🖉 https://www.irbplus	.com/eSubmissior	nStaff.asp							× 🔒
Principal	Salutation:	First Name:*			Last N	Name:*		Degrees:	~
Investigator:	Dr	John			Doe			D.Div.	
Address 1:*	222 Main Stre	222 Main Street				*Phone:	111 222 33	3	
Address 2:						Fax:			
City:	Anytown					*Email:	jdoe@goog	le.com	
State:	CA		Zip:	12345		Date of Training:	5/1/2005		
Save Cance	əl								

Once you click the "Edit Person" button, the person's contact and other details will be editable as shown above. Most fields in the Edit Person view are self-explanatory. The more complex fields are explained in more detail below.

The **<u>Email</u>** address is used by that person to logon on to IRB+ so it is important to enter this correctly.

The **Date of Training** of IRB training. All personnel are required to have up-to-date training.

Find Person Screen

🖉 Find Person - Microsoft Internet Explorer provided by Verizon 🔳 🔲 🔀						
https://www.irbplus.com	n/PersonFind.asp		▼			
Last Name: will		First Name:				
Find Cancel Click on the person's n	ame to select the	person.				
Name	Phone	Email				
Williams, Dennis Williams, Dennis	641-4492	immed@sitwin.com				
Williams, Margaret Williams, Thomas	804-555-1212 569-5227	mwilliams@stmaryscro	iss.org			
Cancel						
		😌 Internet	🔍 100% 🔻 💡			

Click the "Add Co-Investigator" or "Add Study Coordinator" button to add personnel to the "Study Staff" form with the specified role. The Find Person screen will be displayed.

Enter the first few letters of the person's first name or last name and click the "Find" button. All matching people in the system will be displayed. Click the person's name to add the person to the "Study Staff" form.

If you cannot find the person you are looking for, check the spelling of the person's name or contact the IRB office and ask them to create this person's record.

3.3.3.3 Demographic Information Online Form

The "Demographics Information" online form is used to record the breakdown of participants by ethnicity and gender. The total fields are ready only and will be automatically calculated as you enter the participant figures.

🖉 Demog	🖉 Demographic Information - Microsoft Internet Explorer provided by Verizon Online								
🖉 https://	🖉 https://www.irbplus.com/eSubmissionDemographicInfo.asp?nInstanceId=877 🛛 👻 🔒								1
4. DEMO	GRAPHIC INF	ORMATION:							
	American Indian or Alaskan	Asian	Black, not of Hispanic- American Origin	Hispanic- American	White, not of Hispanic- American Origin	Hawaiian or Pacific Islander	Other or Unknown	Total	
Female]
Male]
Total]
NOTE: To	Total								

3.3.4 Documents Tab

The Documents tab indicates which documents must accompany this submission. As you complete the various online forms the list of documents may change depending on your answers. Hence, frequently return to the Documents tab to check what documents you need to submit.



3.3.4.1 Uploading Supporting Documents

Documents that are required for submission should be uploaded on the Documents tab in electronic format (e.g. Microsoft Word, PDF, Excel etc.). To upload a document, use the "Click here to upload the document" link. The "Upload Document" screen will be displayed.

Upload Document screen



Click the "Browse..." button to select the file to upload. You can upload any file on your computer. Click the "Upload" button to save this document to your submission.



Once the file is uploaded, the name of the document becomes a link and the status changes to "Uploaded". To see what you uploaded, click on the name of the document. At any time before you electronically submit the application to the IRB office, you can re-upload the document if the document changes by clicking the "Click here to upload a new document" link. To delete the document, click the "Click here to remove the document" link.

If you do not submit the appropriate documents, either electronically or by mail, your protocol may not be reviewed and you will not be able to perform your study.

3.3.5 Printable Forms

A printable version of each submission may be found under the "Printable Forms" tab e.g. "Printable Single Project Approval Form". Clicking on this link will open a new window containing

a printable version of all the online forms for this submission. This document may be printed for your files by clicking the "Print" button at the bottom of the window.

The "Printable Forms" tab also contains fax sheets such as the "Project Approval Sign-off Sheet" that may be printed and faxed for sign-off.

🖉 IRB+ New Test Stud	y - Microsoft Ir	nternet Explorer prov	ided by V	erizon Online					- 7 🛛
💽 🗸 🖉 https://	/www.irbplus.com/	eSubmission.asp?nStudyId	=37196&nSu	ubmissionId=152	[✓ ↓	oracle forms 6 pre-blo	ick	•
😭 🏟 🌈 IRB + New T	Fest Study						• 🔊 - 🖶 • 🗄	Page 🔹 🌾	🕽 Tools 🔹 🎽
IRB+	Protocol Title: Principal Inv.:	New Test Study Doe, John	Pł	none: 111 222 333	Email: jdoe(@google.com	S	ave	~
Go to My Studies	Study Coord.: Online Forms	Documents Printab	Pr le Forms	one: Submit Security	Email:				
	PDF File			Instructions				~	J
	Printable Sing	le Project Approval Fo	rm	If you would lik press the Prin	e a hard-copy of your o er icon in the toobar.	online forms, clic	k on this document	and	
	Project Appro	val Sign-off Sheet		Please print a this document	Id make sure the approvement	opriate people si	gn this document. M	ail in	

Printable Submission

🖉 Printable Form - I	Microsoft Internet Explorer prov	vided by Verizon Online	
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😭 🏟 🌈 Printable	Form	🚹 🔹 🗟 🔹 🖶 Page -	Tools - »
	Initial A	Application	^
Study Number: (not	t vet assigned)		
Study Title: Nev	w Test Study		_
Principal Investigator:	Dr John Doe D.Div.		
Area of research:			
Address 1:	222 Main Street	Phone: 111 222 333	
Address 2:		Fax:	
City:	Anytown	Email: jdoe@google.com	
State:	CA Zip: 12345	Date of Training: 5/1/2005	
Co-Investigator:	Dr. Douglas Gorman M.D.		
Address 1:	288 Sutter Street	Phone: 966-3991	
Address 2:	Suite 4B	Fax: 966-3887	
City:	Anytown	Email: bbb@hotmail.com	
State:	CA Zip: 95007	Date of Training: 4/1/2003	
What type of review ar Exempt Review Expedited Review Full Review	e you applying for?		~
Done		🏹 😌 Internet	🔍 100% 🔹 🛒

Sign-off Fax Sheet

C Fax Cover Sheet - Microsoft Internet Explorer provid	ded by Verizon Online	×				
COO - E https://www.irbplus.com/FaxSheet.asp?nSubmis	s 🖌 🔒 🔄 🗶 Google	•				
🚖 🎄 🏉 Fax Cover Sheet	📄 🕴 🔹 📾 🔹 🔂 Zage 🔹 🎯 Tools 🔹	»				
Fax Signat	ture Sheet	^				
То:	From: John Doe	_				
Fax:	Pages:	=				
Phone:	Date:					
Re: Signature Page for Study	CC:					
It is understood that I will keep on file (for at least three yea on request by the IRB, copies of signed Informed Consent It is understood that any medical procedures or medical tre present research will be performed by, or under the supervi that particular procedure.	ars from the project completion date) and make available, Forms of all subjects participating in this research. Natments of human subjects for the purposes of the sion of, a person who is licensed or certified to perform					
It is understood that students at should be initially recruited by personal solicitation.	d as research subjects by public announcement and not					
It is understood that, if there are any changes, modifications, or revisions either in the research protocol, title, or names of Researchers, the IRB must be immediately notified and prior permission must be received before proceeding.						
Graduate Students are advised that it is the policy of the U	niversity that all IRB requirements and stipulations must	*				
Done	🏹 😜 Internet 🔍 100% 🔻					

3.3.6 Security Tab

You can give personnel on this protocol permission to see and edit the protocol in IRB+. To grant access to a protocol, go to the Security tab, select the person from the drop down and click the

"Grant Access" button. To disable access, click the button next to the person's name, under the "Click button to disable access" title.

🖉 IRB+ New Test Stu	dy - Microsoft II	nternet Explorer provid	led by Verizon Or	nline				- 7 🛛
💽 🗸 🖉 https:/	//www.irbplus.com/	eSubmission.asp?nStudyId=3	7196&nSubmissionId=	=152	✓ 🔒	47 🗙	oracle forms 6 pre-block	P -
😭 🏟 🌈 IRB + New	Test Study						🔹 🔝 🔹 🖶 👻 🔂 Page	• 💮 Tools • »
IRB+	Protocol Title:	New Test Study					Save	~
Cata My Studios	Principal Inv.: Study Coord :	Doe, John	Phone: 111 Phone:	222 333	Email: jdoe@goog Email:	le.com		
Go to My Studies	Online Forms	Documents Printable	Forms Submit	Security	Linai.			
	Name			Click button to disable access	;			~
	Dakhil, Shake	r						
	To grant anoth	er user access to this p	rotocol, select the	user from the list				
	and click the "	'Grant Access" button.						
		Grant Access						
								~
	<u></u>							

3.3.7 Submit Tab

The "Submit" tab summarizes all items that must be completed before your protocol can be electronically submitted and reviewed.

🖉 IRB+ New Test Study - Microsoft Internet Explorer provided by Verizon Online		
🚱 🕤 👻 🖻 https://www.irbplus.com/eSubmission.asp?nStudyId=37196&nSubmissionId=152 🔍 🔒 🚱 🗙 triple j		P -
TRR+ Protocol Title: New Test Study Save		~
Principal Inv.: Doe, John Phone: 111 222 333 Email: jdoe@google.com		
Go to My Studies Study Coord.: Pickerel, Margaret Phone: 301-295-0819 Email: mpickerel@usuhs.mil		
Online Forms Documents Printable Forms Submit Security The following items have not been completed and are required for submission. Risks and Discomfort Research Procedures The following documents, if applicable, must be mailed to the IRB. Complete research proposal or project description (2 copies for exempt, 3 copies for expedited, 11 copies for full review.) Advertising Materials (flyers, newspaper ads, etc) (2 copies for exempt, 3 copies for expedited, 11 copies for full review.) Consent Form (2 copies for exempt, 3 copies for expedited, 11 copies for full review.) Consent Form for Non-English Speakers (2 copies for exempt, 3 copies for expedited, 11 copies for full review.) Consent Form for Non-English Speakers (2 copies for exempt, 3 copies for expedited, 11 copies for full review.) Your submission cannot be reviewed until all applicable documents are received by the IRB.		
	~	

Once you have completed each of the items listed on the Submit tab, a "Submit" button will be displayed.

Click on the "Submit" button to electronically submit the protocol application to the IRB office. Please note, this is analogous to handing a paper copy of your protocol to the IRB office. *Hence, once you have submitted your protocol, you will <u>not</u> be able to make any changes to the protocol. If you need to make a change after submission, contact the IRB office and they can return your submission. Your returned submission will appear in the "Planned Submissions" section of the "My Studies" screen.*



Once you submit, your submission will appear in the "Pending IRB Action" section of the "My Studies" screen. If the IRB office returns the submission, you will receive email notification and the submission will be moved to the "Planned Submissions" section of the "My Studies" screen to allow you to make changes. The email will outline the changes that are required to the submission before you can resubmit to the IRB office.

You will receive email notification when the IRB office accepts your protocol. The IRB office will schedule the submission for IRB review and you may view the meetings the submission is scheduled for and the activity letters for the submission on the "Meetings" and "Correspondence" tabs.

3.3.8 Creating Non-Initial Submissions

Non-initial submissions, such as continuing reviews, amendments, adverse events, unanticipated problems and project closures, can be created on protocols in IRB+.

To create a submission, click appropriate "New" link in the "My Studies" screen e.g. the New Continuing Review link. The New Submission screen will be displayed:

🟉 IRB+ - Microsoft In	ternet Explorer	provided by Verizon O	nline					_ 7	×
💽 🗸 🖉 https:	//www.irbplus.com/	MyStudies.asp			✓ ▲	🛉 🗙 triple j		P	•
IRB+	Planned Sub	missions							^
	Study Number	Submission Type	P.I.	Protocol Title				Delete	í.
New Protocol	(not assigned)	Initial Application		My new study.				×	
Application	(not assigned)	Initial Application		asdf				×	
New Continuing	(not assigned)	Initial Application		humans				×	
Review	(not assigned)	Initial Application		Test Study				×	
	(not assigned)	Initial Application		Test Study				×	
New Amendment,	(not assigned)	Initial Application		survey				×	
Change or Update	(not assigned)	Initial Application		Karri				×	
New Adverse Event	(not accigned)	Initial Application	Doo John	Now Test Study				×	
How Marchoo Liton	C New Continu	uing Review - Microsoft	Internet Explorer	provided by Verizon	Online	🛛		×	
New Unanticipated	https://www.ir	bplus.com/NewOther.asp?sSu	ubmissionType=Continu	ing+Review		✓		×	
Problem	Create a new C	ontinuing Review for: (on	ly first 100 characte	ars of the protocol title i	is shown)			×	
Draiget Completion	Create a new C	ontinuing review for. (on	ly mat foo characte	ara or the protocor title i			h AML.	×	
Project Completion							h AML.	×	-
		anaal					h AML.	×	
		ancer					h AML.	×	
							h AML.	×	
							h AML.	×	
							h AML.	×	
	Done				🌆 😌 Internet	100% 🔹 👬	h AML.	×	
	HSR 06-001	Unanticipated Problem	Dakhil, Shaker	SWOG 9999 A Double	e-Blind Randomized S	Study of XYZ in Patients wit	th AML.	×	
	SBR-06-001	Adverse Event	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Adverse Event	Whiteley, George	SBR Study 001				×	-
	SBR-06-001	Amendment	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Continuing Review	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Continuing Review	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Project Completion	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Project Completion	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Project Completion	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Project Completion	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Unanticipated Problem	Whiteley, George	SBR Study 001				×	
	SBR-06-001	Unanticipated Problem	Whiteley, George	SBR Study 001				×	
	SBB1061009	Advarea Evant	Sanford Therees	How fructrated do neo	nle net in long airline	01101100		×	2

Select the protocol for which you wish to create the Continuing Review and click the OK button. The drop down list will be populated with protocols in a valid status for continuing reviews.

🖉 IRB+ HSR 06-001 SV	WOG 9999 A Double-Blind Randomized Study of XYZ in Patients with AML Microsoft Internet Explorer provided b 📃 🖻	×
💽 🗸 🖉 https://	//www.irbplus.com/eSubmission.asp?nStudyId=24726&nSubmissionId=154	•
IRB+	Study #: HSR 06-001 Expedited: Protocol Title: SWOG 9999 A Double-Blind Randomized Study of XYZ in Patients with AML.	~
Go to My Studies	Principal Inv: Dakhil, Shaker Phone: 123 123 1234 Email: dshaker@swog.org Study Coord.: Marge Good, WCCOP Phone: Email: Status: ACTIVF Exprimes: 4/17/2008	
New Continuing Review	Meetings Correspondence Init. Application Cont. Reviews Amendments AEs Unanticipated Problems Project Completion Security	
New Amendment, Change or Update	All Continuing Reviews Online Forms Documents Printable Forms Submit Expiration Date Associated with Continuing Review: 4/17/2008	
New Adverse Event	Web Form Status Instructions	
New Unanticipated Problem	Registry and Database Renewal Form Incomplete Please complete this form.	
Project Completion		



The new continuing review submission will be displayed in the "Protocol Edit" screen. You must complete the online forms, upload the documents and submit as per an initial application process.

3.3.9 Meetings tab

The "Meetings" tab display all meeting this study is scheduled for.

🖉 IRB+ HSR 06-001 S	WOG 9999 A D	ouble-Blind Randomized Stud	ly of XYZ in Patients with AML.	- Microsoft Internet Explorer provided b	- 7 🛛
💽 🗸 🖉 https:/	/www.irbplus.com/	eSubmission.asp?nStudyId=24726&n	SubmissionId=105	🗙 🔒 🔶 🗙 triple j	
IRB+	Study #: Protocol Title:	HSR 06-001 SWOG 9999 A Double-Blind	d Randomized Study of XYZ in F	Expedited: Patients with AML.	
Go to My Studies	Principal Inv.: Study Coord.:	Dakhil, Shaker Marge Good, WCCOP	Phone: 123 123 1234 Phone:	Email: dshaker@swog.org Email:	
New Continuing Review	Status: Meetings Co	ACTIVE prrespondence Init. Application	Expires: 4/17/2008	AEs Unanticipated Problems Project Co	ompletion Security
New Amendment,	Date	Reason			
Change or Update	3/31/2006	New Protocols			
New Adverse Event	4/14/2007	Continuing Reviews			
New Unanticipated Problem					
Project Completion					

3.3.10 Correspondence tab

The "Correspondence" tab displays all correspondence activity letters from the IRB office. You may view these activity letters by clicking the "View Letter" button. Some activity letters may require a response, and for these activity letters you may respond online by clicking the "Click here to respond online" link.



Example Activity Letter

🖉 View Letter - Microsoft Internet Explorer provided by Verizon Online			×
https://www.irbplus.com/eSubmissionViewLetter.asp?nActivityId=181310		~	9
April 17, 2007			~
Shaker Dakhil, M.D. 123			
RE: Your application dated regarding study number HSR 06-001: SWOG 9999 A Double-Blind Randomized Study of Patients with AML. (Southwest Oncology Group)	XYZ	in	
Dear Dakhil:			
Your request for revision of the study listed above was reviewed at the 4/17/2007, meeting of the Thirdsky IRB.			
The requested revision involves changes to the protocol and consent form The following information and/or changes a required:	re		
Please submit the requested information or documents for re-review. You may not implement the proposed changes revised application is approved. Contact Demo (800-123-4567; fax 800-987-6543; email: demo) if you have any quest require further information.	until ions	you or	ır
Sincerely,			
R. Lo IRB Chair			

When you chose to respond online, the Online Response screen will be displayed. In this screen you may enter response to the IRB questions and concerns and upload supporting documents. Click the "Submit" button to submit your response to the IRB office.

IRB+

🙆 IRB+ HSR 06-001 S	WOG 9999 A	Double-Blind Randomized Study of XYZ in Patients with AML	Microsoft Internet Explorer prov	ided b 📃 🖬 🔀
(30) - 🖉 https:/	/www.irbplus.co	m/eSubmission.asp?nStudyId=24726&nSubmissionId=105	💌 🔒 🐓 🗙 triple	ej 🖉 🗸
IRB+ Go to My Studies	Study #: Protocol Tit Principal Inv Study Coor	HSR 06-001 Response - Microsoft Internet Explorer provided by Verizon https://www.irbplus.com/Response.asp?nActivityId=181310	Expedited: Online	og.org
	Status: Meetings Date	Please type enter your response below:		Project Completion Security
Update New Adverse Event New Unanticipated	4/17/200			View Letter Click here to respond online.
	4/17/200			View Letter
			V	
		Click here to attach a file to this response.	Dist	
		🕢 🕡 🚱 Inter	net 🕀 100% 👻 🦷	

4.IRB Administrators

4.1 Logging onto IRB+

Members of the IRB office should logon to the WebKit with their email and IRB+ password.

4.2 eSubmission Inbox

The eSubmission Inbox shows recently submitted protocol applications, continuing reviews, amendments, adverse events, unanticipated problems and project closures that require review.

🖉 IRB+ - Microsoft In	ternet Explorer pro	vided by Verizon Online				Jax
🚱 🗸 🖉 https://www.irbplus.com/eSubmissionInbox.asp						
😭 🍄 🌈 IRB+					🟠 🔹 🔝 🔹 🖶 🔹 🔂 Page 👻 🏠	ools - »
IRB+	eSubmission Inl	oox				~
	Initial Applicatio	n				
Find Study or Activity	P.I.	Study Title	Date Submitted	Outstanding Doc	uments	
eSubmission Inbox New Study	Spitz, Jonathan	Tanning	4/12/2007	 Project Approva 	al Sign-off Sheet	
Goto Last Study My Selected Studies	Adverse Event					
Investigators	Study Number	P.I.	Study Title	Date Submitted	Outstanding Documents	
Coordinators Members	SBR-06-001	Whiteley, George	SBR Study 001	4/10/2007	External AE Report	
Missed Deadlines Meeting Materials	Project Complet	tion				
Create Letters	Study Number	P.I.	Study Title	Date Submitted	Outstanding Documents	
Mailing Labels Reports	SBR-06-001	Whiteley, George	SBR Study 001	4/10/2007		
Housekeeping						
Logout						
References						
Need Help? irbhelp@thirdsky.com						

Submissions remain in the eSubmission Inbox until you either return the submission to the PI to make changes or accept the submission. Generally, you should leave a submission in the inbox until all outstanding documents are received. The outstanding documents are listed on the right side of the screen.

To return or accept a submission, click on the protocol, go to the submission, and click the "Accept/Reject" tab. If the submission meets your approval, click the "Accept" button to accept the submission. The PI will receive email notification that the study is approved.

If you wish to return the submission to the PI, enter the reasons for return and the changes that should be made to the study in the text box. When you click the Reject button, the submission will be returned to the PI and they will be emailed the reasons for return.

🖉 IRB+ SBR-06-040 T	anning - Microsoft Internet Explorer provided by Verizon	Online	- 7 🛛
💽 🗸 🖉 https:/	/www.irbplus.com/eSubmission.asp?nStudyId=37154&nSubmissionId=137	7 🖌 🚽 🖌 Google	P •
🔶 🏟 🌈 IRB + SBR-	06-040 Tanning	👌 • 🔊 •	🖶 🔹 🔂 Page 🔹 🍈 Tools 🔹 🎽
IRB+ Back to Study Info	Study #: SBR-06-040 Protocol Title: Tanning Principal Inv.: Spitz, Jonathan Phone Study Coord.: Phone Status: EXEMPT Expire: Meetings Correspondence Init. Application Cont. Revie Online Forms Documents Printable Forms Accept/Re Date Submitted: 4/12/2007 Click the "Accept" button to upload this Initial Application Accept To reject this Initial Application will be unlocked so the Principal Inv. Study Coordinator can continue to make changes. Reject	Expedited: Expedited: e: 877-999-8887 Email: jspitz@cox.com e: Email: s: ws Amendments AEs Unanticipated Problems Pro eject into IRB+. click the "Reject" button. restigator and/or	ject Completion Security

4.3 Edit Forms & Documents Screen

The Edit Forms & Documents screen can be found under the Housekeeping menu. The Edit Forms & Documents screen lets you customize the "Online Forms", "Documents" and "Printable Forms" tabs. Each form will have a submission type (e.g. initial application, amendment, continuing review) and a form type, which may be:

- Web Form: This form appears on the Online Forms tab for the submission type.
- **Document**: This document appears on the Documents tab for the submission type. The document can be uploaded to IRB+ in an electronic format.
- **Printable Form**: This document appears on the "Printable Forms" tab for the submission type. This is a printable version of all online forms on the submission.
- **Fax Sheet**: This document appears on the "Printable Forms" tab for the submission type. This is a printable fax sheet, often used as sign-off sheets for the submission.

👻 🙋 http:	s://www.irbplus.com/FormList.asp		✓	Google	P
🏉 IRB+			- 🔂 -	• 🗟 • 🖶 • 🕞	Page 👻 🏠 Tools 👻
B+	Edit eSubmission Forms and Documents				New Form
	Form Name	Form Type	Submission Type	Form Order	Click to Edit Fields
	/ System	Web Form			Edit Fields
	Principal Investigator and Co-Researchers	Web Form	Initial Application	100	Edit Fields
	Protocol Summary	Web Form	Initial Application	110	Edit Fields
	Subjects and Recruitment Methods	Web Form	Initial Application	120	Edit Fields
	Research Procedures	Web Form	Initial Application	130	Edit Fields
	Risks and Discomfort	Web Form	Initial Application	140	Edit Fields
	Other Requirements	Web Form	Initial Application	150	Edit Fields
	Complete research proposal or project description	Document	Initial Application	200	
	Grant Application	Document	Initial Application	210	
	Abstract / Summary of Research	Document	Initial Application	220	
	Advertising Materials (flyers, newspaper ads, etc)	Document	Initial Application	230	
	Interview script, questionnaire, tests, etc.	Document	Initial Application	240	
	Consent Form	Document	Initial Application	250	
	Consent Form for Non-English Speakers	Document	Initial Application	260	
	Printable Single Project Approval Form	Printable Form	Initial Application	300	
	Project Approval Sign-off Sheet	Fax Sheet	Initial Application	310	Edit Fax
	Continuing Renewal Application	Web Form	Continuing Review	4000	Edit Fields
	Study Summary	Document	Continuing Review	4100	
	Adverse Event Flow Sheet	Document	Continuing Review	4105	
	Consent Form with changes highlighted	Document	Continuing Review	4110	
	Clean Consent Form	Document	Continuing Review	4120	
	Summary of Protocol Deviations	Document	Continuing Review	4125	
	Personnel Listing for Continuing Review	Document	Continuing Review	4130	
	Printable Continuing Renewal Application	Printable Form	Continuing Review	4200	
@thirdsky.com	Registry and Database Renewal Form	Web Form	Continuing Review	5000	Edit Fields
	Data Collection Form	Document	Continuing Review	5100	
	Sub-Investigator Statement of Assurance	Document	Continuing Review	5110	
	Questionnaires or Surveys	Document	Continuing Review	5120	
	Consent Form with changes highlighted	Document	Continuing Review	5130	

To edit a form or document, click on the name of the form or to create a new form, click the "New Form" button. When you edit or create a form you will see the following screen:

Edit Form Screen – Dynamic Online Form

🖉 Edit Form - Microsoft Internet Explorer provided by Verizon O 🔳 🗖 🔀					
🖉 https://www.irbplus.com/	FormEdit.asp?nFormId=122				
Form Name:	Protocol Summary				
Form Type:	Web Form				
Submission Type:	Initial Application				
Form Order:	110				
Form URL:					
Instructions:					
Document Instructions:					
Auto Create:					
Track Date Received:					
Save Cancel	Delete				

The above screen shot is of an dynamic online form. This is an online form whose fields and instructions can be changed by the IRB office.

Edit Form Screen – Custom Online Form

C Edit Form - Microsof	t Internet Explorer provided by Verizon	0 🔳 🗖 🔀
https://www.irbplus.com/	FormEdit.asp?nFormId=121	▼
Form Name:	Principal Investigator and Co-Researchers	
Form Type:	Web Form	
Submission Type:	Initial Application	
Form Order:	100	
Form URL:	eSubmissionStaff.asp	
Instructions:		
Document Instructions:		
Auto Create:		
Track Date Received:		
Save Cancel		Delete
		A
Done	Lø 😻 Internet	💐 100% 🔻 🚲

The above screen shot is of an custom online form. This is an online form whose fields and instructions <u>cannot</u> be changed by the IRB office and may only be change by Third Sky. Custom forms can be identified by the Form URL. Custom forms will always have a Form URL while dynamic online forms will have no Form URL.

4.3.1 Managing Online Forms & Documents

To create a new or edit an existing online form or document supply the following information.

Specify the name of the form in the **Form Name** text box. This is the name that will appear on the Online Forms, Documents or Printable Forms tab.

In the **Form Type** drop down, select from Web Form, Document, Printable Form or Fax Sheet. Web forms appear in the Online Forms tab. Documents appear in the Document tab. Printable Forms and Fax Sheets appear in the Printable Forms tab. Documents can be uploaded to IRB+ in electronic format. Printable Forms and Fax Sheets can be printed or filed in electronic format.

In the **<u>Submission Type</u>** drop down, pick from Initial Application, Continuing Review, Amendment etc. This will determine the type of submission the online form or document will be added to.

When IRB+ displays forms and documents it displays them in ascending order of the **Form Order** field. Enter a number into this field. A best practice is to count by 10. That way, if you need to create a new form that will appear between two existing forms, it is easy to pick an appropriate Form Order number.

The **Form URL** field lets you override the default behavior for the given form type. You should not edit this field.

The **Instructions** field is useful for the forms that appear in the Online Forms tab as you can tell the researchers any important instructions for filling out the online form. These instructions will appear next to the form name in the Online Forms tab. For Documents, these instructions will

appear on the Submit tab next to the document name. For Printable Forms and Fax Sheets, these instructions will appear on the Printable Forms tab next to the form name.

The **<u>Document Instructions</u>** field contains any instructions for filling out this document. These instructions appear on the Documents tab next to the document name.

If the <u>Auto Create</u> checkbox is checked, this form will automatically be created when the investigator starts the corresponding submission. For example, in the screen shot above, the "Principal Investigator & Co-Researchers" online form is automatically created for each initial application. If you do not check the "Auto Create" check box, make sure one of your online forms has a rule that adds this form to the protocol. Otherwise, the investigators will never be able to access the form (refer to the Edit Rules section below for instructions on how to create rules).

The <u>**Track Date Received</u>** checkbox only applies to Documents. If you want to track the date that the document was received, check this checkbox. If this checkbox is checked the PI will be reminder to upload these documents to the WebKit. These documents will also appear in the Outstanding Documents column in the ESubmission Inbox screen. If you do not want this document to appear in the "Outstanding Document" column, e.g. the protocol can be reviewed without this document, leave the checkbox unchecked.</u>

4.3.2 System Form

The System form is a special online form that stores special fields used by IRB+ i.e. text of emails to be sent out.

This form must not be edited or deleted.

4.4 Edit Fields Screen

To change the questions on a online form, click the "Edit Fields" link to the right of the online form on the Manage Forms & Documents screen. When you click the button, you will see the Edit Fields screen as shown below:



To change an existing field, click on the field name or to create a new field, click on the "New Field" link in the left navigation bar. When you edit or create a field you will see the following screen:

🖉 Edit Fiel	d - Microsoft Internet Explorer provided by Verizon O.	💶 🗖 🔀
🖉 https://ww	vw.irbplus.com/FieldEdit.asp?nFieldId=500	⊻ 🔒
Name:	Alternatives	
Text:	Are there any alternative ways to acquire your research information from human subjects that may avoid the risks identified above?	
Туре:	Yes/No/NA	
List Items:		Add Item
		Update Item Delete Item
Length:		
Required:		
Rules:	If the value of this field is "Yes", the field "Explain why no alternatives" becomes mandatory. New Rule	t using
Indent:	0	
Order:	30	
Save	Cancel	Delete
	🚺 🚱 🚱 Internet	🔍 100% 🔹 💡

Enter the name of the field in the <u>Name</u> box. This is the name that will be shown if the field is required e.g. "Review Process is a required field".

Enter the text of the question in the <u>Text</u> box. You can use the standard HTML tags to format the text of the question. For example, indicates that bold should begin and indicates that bold should end. Other HTML tags worth noting include <U> and </U> for underline and <I> and </I> for italics. HTML is case-insensitive so you can use either upper or lower case letters. However, make sure you correctly end all tags or the generated online form may look different than expected. You can use the
br>

Select one of the following from the **<u>Type</u>** drop down to indicate how the investigator will enter/select the answer.

ick from either a Yes or
ick from either a Yes, n.
ick from one or more
ick from one or more okbox labeled "Other" will
ick from one or m ckbox labeled "Ot

	with an textfield next to the checkbox. If the user checks "Other" they will be required to enter a description in the textfield.
Multi-Line	The investigator will type the answer into a multi-line text box.
Number	The investigator must enter a number.
Date	The investigator must enter a valid date.
Drop Down List	The investigator will pick an item from a drop down list.
Radio Buttons	The investigator will pick one item from a series of radio buttons.
Instructions	This field actually provides instructional text and no answer is expected.

The <u>List Items</u> section lets you specify the items for check boxes, drop down lists, and radio buttons. To add a new item to the list, enter it into the top box and click the Add Item button. To change an existing item, select it from the list, change it in the top box and click the Update Item button. To remove an item from the list, select it from the list and click the Delete Item button. List items will be displayed in the online form in the order they have been entered. *Do not use commas or HTML tags in the list items as this will cause the page to function incorrectly.*

The Length field lets you specify the maximum number of characters for a Text field.

If the investigator must answer this question before they can submit the application, check the **<u>Required</u>** checkbox. Required fields will have a red asterisk next to them in the online form.

You must save the field before the **<u>Rules</u>** section only becomes available. When you return to the field, you will see a New Rule button. Clicking this button will display the following screen.

🖉 Edit Rule - Microsoft Internet Explorer provid	
https://www.irbplus.com/RuleEdit.asp?nRuleId=253	× 🔒
If the value of the field is:	
Yes	
	~
 Make the following field mandatory: 	
Explain why not using alternatives	
 Add the fellowing form (decomposition the next column) 	
Add the following form/document to the protocol:	~
Save Cancel	Delete
👩 😜 Internet 🔍	100%:

The rule will be triggered based on a specific answer. When the rule triggers, there are two possible actions: make another field mandatory **OR** add a form/document to the protocol. If you choose the first radio button, you will need to select which field becomes mandatory. Since the field has to exist before you can create the rule, the recommended process is to create all the fields first then go back and create the rules. If you choose the second radio button, you will need to select which form/document to add to the protocol. Again, since the form/document must already exist in order for you to create the rule, it is recommended that you create all the forms/documents first before creating the rules.

You can create as many rules as you want for a given field and a given value. For example, if two fields become mandatory when the answer to the current field is "Yes", you can create two rules for the "Yes" answer. To change an existing rule, just click on the rule on the "Edit Field" screen.

Back on the Edit Field screen, the next box under the rule section is the <u>Indent</u> box. The indent box lets you create a hierarchy of questions. Entering "1" in this box gives the question a small indent; entering "2" in this box gives the question a double indent; and so on.

The **Order** field lets you specify the order that the questions will appear on the online form. The questions will appear in ascending order. A best practice is to count by 10 when initially establishing the order. Later, when a new question must be inserted between two existing questions, you can then pick the appropriate order number.

4.5 Edit eSubmission Settings Screen

The Edit eSubmission Settings screen can be found under the Housekeeping menu. The Edit eSubmission Settings screen lets you customize the emails sent out upon acceptance or rejection of a submission, and the values show "All Submissions" tab e.g. All Continuing Reviews, All Amendments etc.

Types of settings:

- <Submission Type> Accepted Settings with a name in this format (e.g. Adverse Event Accepted) contain the format of the emails to be sent to the PI upon acceptance of the submission by the IRB office.
- **<Submission Type> Rejected** Settings with a name in this format (e.g. Adverse Event Rejected) contain the format of the emails to be sent to the PI upon rejection of the submission by the IRB office.
- <Submission Type> Field 1 Settings with a name in this format (e.g. Adverse Event Field 1) contain the name of the online field to be shown as the first column in the "All Submissions" tab to help differentiate different submissions of the same type (e.g. in the All Adverse Events, this field is the Date of Adverse Event).
- <Submission Type> Field 2 Settings with a name in this format (e.g. Adverse Event Field 2) contain the name of the online field to be shown as the second column in the "All Submissions" tab to help differentiate different submissions of the same type (e.g. in the All Adverse Events, this field is the Description of AE).

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🕒 🗸 🖉 https:/	//www.irbplus.com/Setting	jlist.asp 🔽 🔒 🐓 🗙 Google 🖉 🗸
🚖 🏟 🌈 IRB+	👌 🔹 🗟 🔹 🖶 Page 🔹 🔅 Tools 👻	
TRB+	Edit eSubmissior	n Settings
	Name	Setting
Main Menu	Address	
Find Study or Activity	Adverse Event	Dear <pi full="" name="">,</pi>
eSubmission Inbox	Accepted	
New Study		The following online adverse event submission for the above references protocol has been received and will be reviewed.
		AE Date:
Goto Last Study		AE Description>
My Selected Studies		
Invectigatore		In a few days, you can check the status of your AE submission on the web.
Coordinators		
Members	Advance Friedd	If you have any questions, please contact the IKB Office.
	Adverse Event Field	Date of Adverse Event
Missed Deadlines	Adverse Event Field	Description of AF
Meeting Materials	2	
	Adverse Event	Dear <pi full="" name="">,</pi>
Create Letters	Rejected	
Poporto		Your online <submission type=""> submission for the above references protocol can not be processed for the following reason(s).</submission>
Reports		Event Date: <ae date=""></ae>
Housekeeping		Event Description: <ae description=""></ae>
, , , , , , , , , , , , , , , , , , ,		
Logout		<reason></reason>
		The system has unlocked your submission so you can address these issues and re-submit If re-submission is not required
References		this event may be deleted from the pending submissions area.
Need Help?		If you have any questions, please contact the IRB Office.
irbhelp@thirdsky.com	Amendment	Dear <pi full="" name="">,</pi>
	Accepted	Your online <submission type=""> submission for the above references protocol was accented for IRB review</submission>
		real onine seasingsion rypes adminiation for the above relevances protocol was accepted for inclusion with tenew.
		Upon review, you will receive and e-mail notification of the IRB action.

IRB+

Click on the setting name to edit the setting and you will see the Edit Setting screen. Any text within angle brackets (e.g. <PI Full Name>) is dynamic information and will replace automatically replaced with the appropriate information for that submission.

Edit Setting - Microsoft Internet Explorer provided by Verizon Online		
https://www.irbplus.com/SettingEdit.asp?nSettingId=2	~	
The following fields are recognized in the email: <todays date="">, <protocol number="">, < Title>, <pi full="" name="">, <pi 1="" address="">, <sc full="" name="">, <sponsor>, <submission 1<br="">Expires>, <ae date=""> and <ae description="">.</ae></ae></submission></sponsor></sc></pi></pi></protocol></todays>	<protocol Type>, <[</protocol 	Date
Dear <pi full="" name="">,</pi>		~
The following online adverse event submission for the above references protocol has be received and will be reviewed. AE Date: <ae date=""> AE Description: <ae description=""></ae></ae>	en	
In a few days, you can check the status of your AE submission on the web.		
If you have any questions, please contact the IRB Office.		
Save Cancel		~
Done	a 100%	•