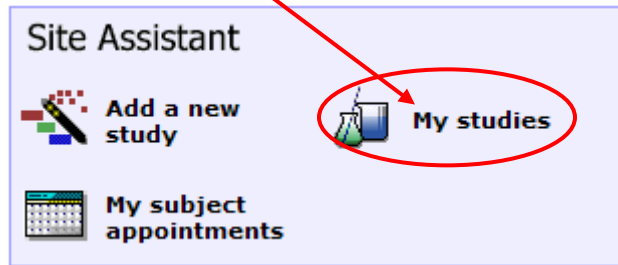


Reporting an Adverse Event in iRIS



iRIS Support 713-500-3800

- Log into iRIS at <http://iris.uth.tmc.edu> using your UT ID and Password.
- To locate the study, click on **My Studies**.



My Studies Ba							
Filter my studies by study status: All							
Click to open	Study State	IRB Number	RB Expiration	Principal Investigator	Study Title	Copy Study	Delete Study
 Open	Active	HSC-MS-04-0026	01/08/2005	Legate, Barbara S.	<i>In like a Lion, Out like a Lamb</i> Lion and Lamb	 Copy	
 Open	Active	HSC-MS-04-0007	02/28/2005	Ryan, Joan	<i>Jammin Joans COOL BLUE study.</i> Cool Blue Study #101	 Copy	

- Click the **Open** icon to access the study.

- Your screen will look something like this:

Study Status: **Active** Study Title: In like a Lion, Out like a Lamb
 Expiration Date: 01/08/2005

Submissions Study Management Subject Management

Protocol Items	Submission Types	Outstanding Submission(s)								
<ul style="list-style-type: none"> Application Informed Consent Other study documents Forms 	<ul style="list-style-type: none"> Initial Review Continuing Review Change Request / Amendments Adverse Events IND safety reports Protocol Deviation 	<table border="1"> <thead> <tr> <th>Track Location</th> <th>Ref Number</th> <th>Request Type</th> <th>Process Submission</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no outstanding submission.</td> </tr> </tbody> </table>	Track Location	Ref Number	Request Type	Process Submission	There are no outstanding submission.			
Track Location	Ref Number	Request Type	Process Submission							
There are no outstanding submission.										

- Click on **Adverse Events**.

- Click on **Add New Form**.

IRB Number: HSC-MS-04-0241 Adverse Event Initial Form Back
 PI: Breslin, Nancy

Add New Form Delete Selected Form(s)

List of records associated with form: Adverse Event Initial Form.
 To view previous versions click on the folder icon

0 result(s) found...

<input type="checkbox"/>	Show Rev	Show Follow-Up	Edit/View	Form Number	Created By	Date Created	Modified By	Date Modified
No records have been created.								

- Type in the **date** of the adverse event or use the **calendar** to select the date.

IRB Number: HSC-MS-04-0241 Adverse Event Initial Form Back
 PI: Breslin, Nancy

Printer Friendly Refresh Constant Fields Save and Continue to the Next Section

Section view of the Form Entire view of the Form

1.0 Report of Serious Adverse Event, Injury, or Unexpected Problem

Report of Serious Adverse Event, Injury, or Unexpected Problem
 Committee for the Protection of Human Subjects (CPHS)
 UCT 750 713-500-3985 (phone) 713-500-0319 (fax)

Protocol Number:	HSC-MS-04-0241
Protocol Title:	iRIS on a Mac in Netscape
Principal Investigator:	Nancy Breslin
Date of Adverse Event:	1/4/2005
Was Adverse Event:	<input checked="" type="radio"/> Expected <input type="radio"/> Unexpected <input type="radio"/> Expected but occurring at a higher frequency
Type of Report:	<input checked="" type="radio"/> Initial <input type="radio"/> Follow-up If follow-up, please select AE number: <input type="button" value="Click here to select the initial Adverse Event we are associating to this follow-up."/>

- If this is an **Initial** report click on Initial.

- If this is a follow-up **select follow-up and click to link.**
- Your screen will look something like this:

IRB Number: HSC-MS-04-0241
 PI: Breslin, Nancy

Back

Return back to the Form Save Selected Event

List of records associated with form: Adverse Event Initial Form.

1 result(s) found...

	Version	Created By	Date Created	Modified By	Date Modified
<input checked="" type="radio"/>	HSC-MS-04-0241-AE-1.0	NancyBreslin	01/04/2005 11:48:48 AM	NancyBreslin	01/04/2005 01:20:40 PM

- Click the **radio button** in front of the adverse event to link a follow-up report to an initial report.

Does this AE involve your subject?	<input checked="" type="radio"/> Yes (local) <input type="radio"/> No (other site)
Is this AE being reported within 5 working days of its occurrence?	<input checked="" type="radio"/> Yes <input type="radio"/> No If NO, explain why the adverse event was not promptly reported to the CPHS: <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>

- Click **Save and Continue to the Next Section** when you have finished.

Printer Friendly Refresh Constant Fields **Save and Continue to the Next Section**



Entire view of the Form

Did the event involve or result in any of the following? Check all that apply.	<input type="checkbox"/> Death <input type="checkbox"/> Cancer <input type="checkbox"/> Hospitalization <input type="checkbox"/> Prolonged hospitalization <input type="checkbox"/> Medical or surgical intervention <input type="checkbox"/> If already hospitalized, increase in level of care <input type="checkbox"/> Life threatening experience <input type="checkbox"/> Protocol Deviation (including overdose) <input type="checkbox"/> Persistent or significant incapacity/disability <input type="checkbox"/> Loss of limb <input type="checkbox"/> Congenital anomaly/birth defect Description of Adverse Event: <div style="border: 1px solid gray; height: 40px; width: 100%;"></div>
---	---


- Use these definitions to determine the severity of the adverse event.

2.0 Definitions of severity ratings of Adverse Events:			
<ul style="list-style-type: none"> • GRADE 1 - MILD: Transient or mild discomfort; no limitation in activity; no medical intervention/therapy required • GRADE 2 - MODERATE: Mild to moderate limitation in activity, some assistance may be needed; no or minimal medical intervention/therapy required • GRADE 3 - SEVERE: Marked limitation in activity, some assistance required; medical intervention/therapy required, hospitalization possible • GRADE 4 - LIFE THREATENING: Extreme limitation in activity, significant assistance required; significant medical intervention/therapy required; hospitalization or hospice care probably 			
2.1 Rate the severity of the AE:	<input type="radio"/> Grade 1 - MILD <input type="radio"/> Grade 2 - MODERATE <input type="radio"/> Grade 3 - SEVERE <input type="radio"/> Grade 4 - LIFE THREATENING		
2.2 Follow-up:	If this adverse event involves your subject at your site, please indicate whether this event: <input type="radio"/> Is not resolved and requires follow-up <input type="radio"/> Is resolved and does not require follow-up		
2.3	If this adverse event involves your subject at your site, please indicate whether the subject is: <input type="radio"/> Permanently off the study protocol <input type="radio"/> Has already completed the study <input type="radio"/> Remains on the study		
2.4	Has this type of adverse event occurred previously? <input type="radio"/> Yes <input type="radio"/> No If YES, please provide incidence data: <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		
2.5	Did the subject receive medical treatment or increased medical treatment as a result of this event? <input type="radio"/> Yes <input type="radio"/> No If YES, include explanation: <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		

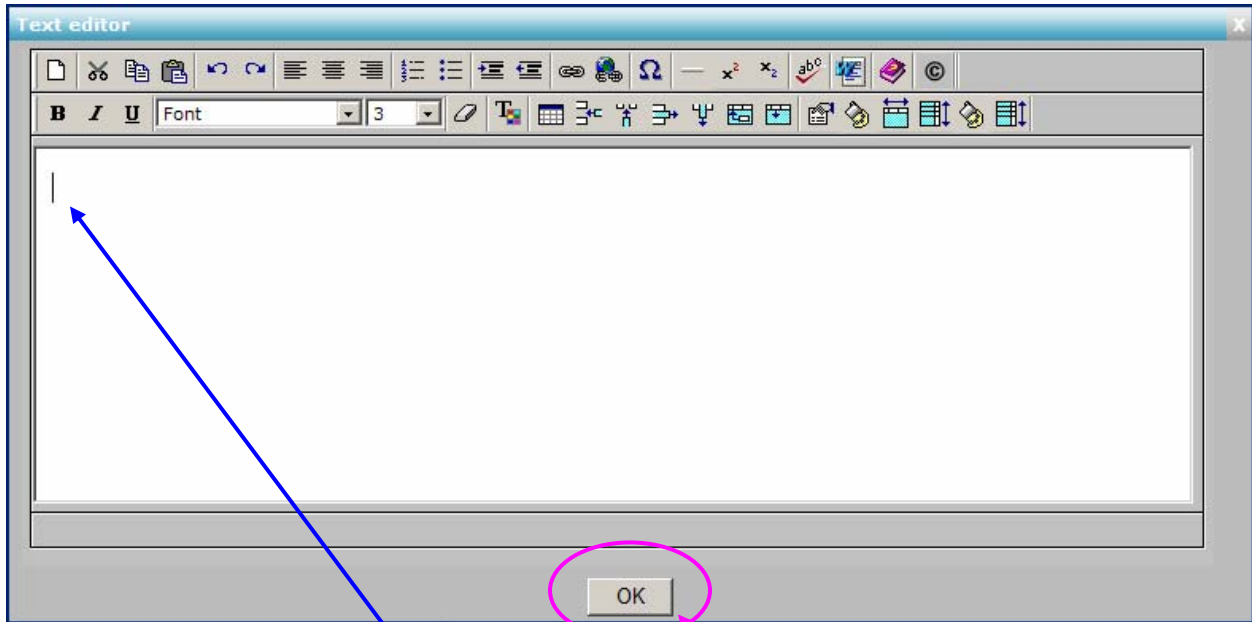
2.6	<p>Does your protocol have a Data Safety Monitoring Board (DSMB)?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If YES, have you or will you notify the DSMB?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If NO, please explain below:</p> <div data-bbox="505 516 1312 625" style="border: 1px solid black; height: 50px;"></div>		
2.7	<p>Was the AE a result of a protocol deviation?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If YES, include an explanation below:</p> <div data-bbox="505 751 1312 861" style="border: 1px solid black; height: 50px;"></div>		
2.8 Assessment of Cause:	<p>In the judgment of the sponsor, what is the likelihood that the event was related to the study:</p> <p><input type="radio"/> Definitely</p> <p><input type="radio"/> Probably</p> <p><input type="radio"/> Possibly</p> <p><input type="radio"/> Not related</p> <p><input type="radio"/> Unknown</p> <p><input type="radio"/> No assessment provided by the sponsor</p>		
2.9	<p>In the judgment of the LOCAL principal investigator, what is the likelihood that the event was related to the study:</p> <p><input type="radio"/> Definitely</p> <p><input type="radio"/> Probably</p> <p><input type="radio"/> Possibly</p> <p><input type="radio"/> Not related</p> <p><input type="radio"/> Unknown</p> <p>Provide brief rationale for decision:</p> <div data-bbox="505 1497 1312 1606" style="border: 1px solid black; height: 50px;"></div>		

2.10	<p>In the judgment of the LOCAL principal investigator, does this development indicate an increased risk for currently enrolled subjects OR future subjects?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If YES, provide an explanation below:</p> <div style="border: 1px solid black; height: 40px;"></div>	
2.11	<p>In the judgment of the LOCAL principal investigator, should the study protocol be changed as a result of this AE?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If YES, submit a change request for an amendment to the protocol. If NO, justify why an amendment to protocol is not necessary below:</p> <div style="border: 1px solid black; height: 40px;"></div>	
2.12	<p>In the judgment of the LOCAL principal investigator, should the currently approved informed consent form be revised as a result of this adverse event?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If YES, please submit a change request with the updated informed consent document. If NO, justify why changes to the informed consent document are not necessary below:</p> <p> Click here to access the text editor.</p>	
2.13	<p>In the judgment of the LOCAL principal investigator, should the currently enrolled subjects be notified of this event and/or be re-consented?</p> <p><input type="radio"/> Yes <input type="radio"/> No</p> <p>If YES, include the method and details of contract/re-consent below. If NO, include justification as to why subject do not have to be notified:</p> <p> Click here to access the text editor.</p>	

Using the Text Editor

<p>In the judgment of the LOCAL principal investigator, should the currently enrolled subjects be notified of this event and/or be re-consented?</p>	<p><input checked="" type="radio"/> Yes <input type="radio"/> No</p> <p>If YES, include the method and details of contract/re-consent below. If NO, include justification as to why subject do not have to be notified:</p> <p> Click here to access the text editor.</p>
---	--

[Click here to access the text editor](#) brings up this screen:



- When you have finished **typing** in your text, click **OK**.
- When you have finished answering these questions, click **Save and Continue to the Next Section** in the top right corner of the screen.

If the PI is entering the adverse event this screen will appear:

3.0 The Principal Investigator must sign off on the following statement:

"I have personally reviewed this report and agree with the above assessment."

If this form is being completed by someone other than the Principal Investigator, it must be routed to the PI for signature.

3.1 Name of preparer:	Nancy Breslin		
3.2	<input type="button" value="Sign and Submit"/>		

- Click **Sign and Submit**.
- Your screen will look something like this:

Submission Signoff Sheet Back

Save Signoff

Study Title: iRIS on a Mac in Netscape

Submission Form(s): [Click here to review the documents you will be submitting](#)

Nancy Breslin as Principal Investigator do you Approve or Deny this submission? Approve Deny

[click here to add comments.](#)

[click here to sign the document](#)

View Other Comments:

- Click **Approve**.
- Click **here to sign the document**.

- Type in your **UT password** to sign the document.

Electronic signature Back

This form requires your electronic signature.

Please Nancy Breslin enter your Password below:

Password:

- Click **Save**.

- Click **Save Signoff**.

Submission Signoff Sheet Back

Study Title: iRIS on a Mac in Netscape

Submission Form(s): [Click here to review the documents you will be submitting](#)

Nancy Breslin as Principal Investigator do you Approve or Deny this submission? Approve Deny

[click here to add comments.](#)

[click here to sign the document](#)





ELECTRONIC SIGNATURE HAS BEEN APPLIED
by Nancy Breslin

[View Other Comments:](#)

- The Workflow – Submission Tracking screen will appear.

Workflow - Submission Tracking Back

IRB Number: HSC-MS-04-0241
PI: Breslin, Nancy


Status	View Details	Event Description	Date Received	Date Completed
 In Progress		Committee for the Protection of Human Subjects received the submission at 01/04/2005 01:21:42 PM	01/04/2005 01:21:41 PM	
 Completed	 Submission Signoff	Review and Signoff: Adverse Event Submission Signoff: Nancy Breslin as Principal Investigator Study Title: iRIS on a Mac in Netscape	01/04/2005 01:20:40 PM	01/04/2005 01:21:41 PM
 Completed		Study Title: iRIS on a Mac in Netscape IRB Number: HSC-MS-04-0241 Submission Type: Adverse Event Reference Number: 000822	01/04/2005 01:20:39 PM	01/04/2005 01:21:41 PM

- If the Study Coordinator is entering the adverse event this screen will appear because the PI must sign and submit the adverse event report:

3.0 The Principal Investigator must sign off on the following statement:

"I have personally reviewed this report and agree with the above assessment."



If this form is being completed by someone other than the Principal Investigator, it must be routed to the PI for signature.

3.1 Name of preparer:	Fannie Fall		
3.2			


- Click **Notify the Principal Investigator**.

IRB Number: HSC-MS-04-0241
PI: Breslin, Nancy


Workflow - Submission Tracking Back


Status	View Details	Event Description	Date Received	Date Completed
In Process		Review and Signoff: Adverse Event Submission Signoff: Nancy Breslin Study Title:	01:29:27 PM	
In Process		Study Title: IRB Number: Submission Reference N	01:29:27 PM	

Microsoft Internet Explorer

 The Principal Investigator has been notified to complete the submission.

- Click **OK**.
- An iRIS task will appear on the PI's home page.

 **You have 1 Submission for your review and signoff**

Open Task	Subject	Received
	Review and Signoff: Adverse Event Submission Signoff: Nancy Breslin as Principal Investigator Study Title: iRIS on a Mac in Netscape	01/04/2005 01:29:27 PM

- When the PI clicks on the **Open Task** icon the Submission Signoff Sheet will appear.