

# Reviewing an Adverse Event in iRIS



## iRIS Support 713-500-3985

- Login to iRIS at <http://iris.uth.tmc.edu> using your UT ID and password.
- When an Adverse Event has been assigned to you for review a task will appear on your iRIS home page.

- Click the **arrow** to reveal the task.

**You have 1 review assignment**

Open Task	Subject	Received
	Teddy Molloy has been assigned as the Chairperson <b>Study Title:</b> High blood pressure and stroke complications <b>Principal Investigator:</b> Jay Accorsi, M.D., Ph.D. <b>IRB Number:</b> HSC-MS-04-0031 <b>Submission Type:</b> Adverse Event <b>Reference Number:</b> 000984	02/17/2005 09:12:52 AM

- Click **Open Task**.

- ❑ Click the **Review Summary** tab.
- ❑ Click the icon to open the **Adverse Event** form.

**Adverse Event**

IRB Number: HSC-MS-04-0031 Submission Reference Number: 000984

Select history information for this study: --none--

Save the Review Status

General **Review Summary** Correspondence

**Submission components:**

Group	Show History	Open	Date Submitted	Review Process	Outcome
Submission			02/17/2005 09:11:29 AM	Adverse Event Initial Form (Version HSC-MS-04-0031-AE-1.0)	
Attached Document(s)				Sponsor Report1.0	

**Reviewer Check-off:**

Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
Chairperson	Molloy, Teddy	<input type="radio"/> Yes <input checked="" type="radio"/> No	02/17/2005	

- ❑ The **navigation tabs** on the left side of the screen enable you to look at the individual sections of the form or click **Entire view of the Form** to scroll through the entire form.

IRB Number: HSC-MS-04-0031  
PI: Accorsi, Jay, M.D., Ph.D.

**Adverse Event Initial Form**

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Section view of the Form **Entire view of the Form** Review Board Sections

1.0 Report of Serious Adverse Event, Injury, or Unexpected Probl ...

2.0 Definitions of severity ratings of Adverse Events: GRAD ...

3.0 The Principal Investigator must sign off on the following st ...

**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-04-0031

Protocol Title: High blood pressure and stroke complications

Principal Investigator: Jay Accorsi, M.D., Ph.D.

Date of Adverse Event: 02/15/2005

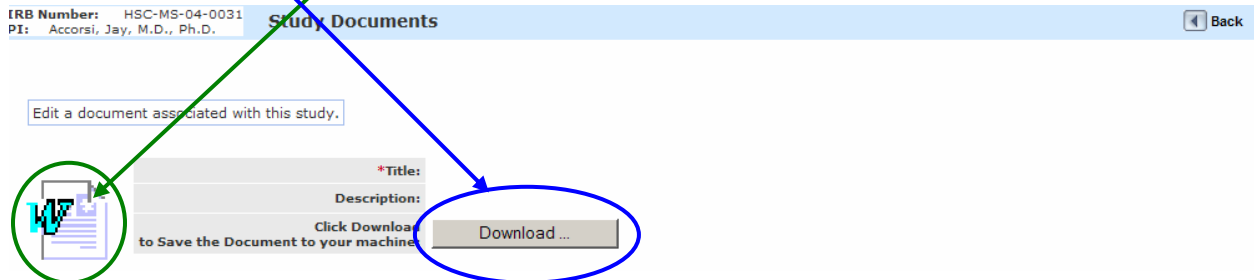
- ❑ Click the **Back** button in the top right corner of the screen to return to the Pre-Review Screening tab to look at any documents associated with the submission.

**Submission components:**

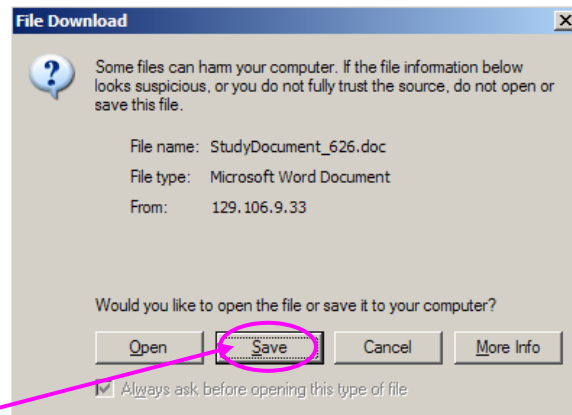
Group	Show History	Open	Date Submitted	Review Process	Outcome
Submission			02/17/2005 09:11:29 AM	Adverse Event Initial Form (Version HSC-MS-04-0031-AE-1.0)	
Attached Document(s)				Sponsor Report1.0	

- ❑ Click the **icon** to view any attached document(s).

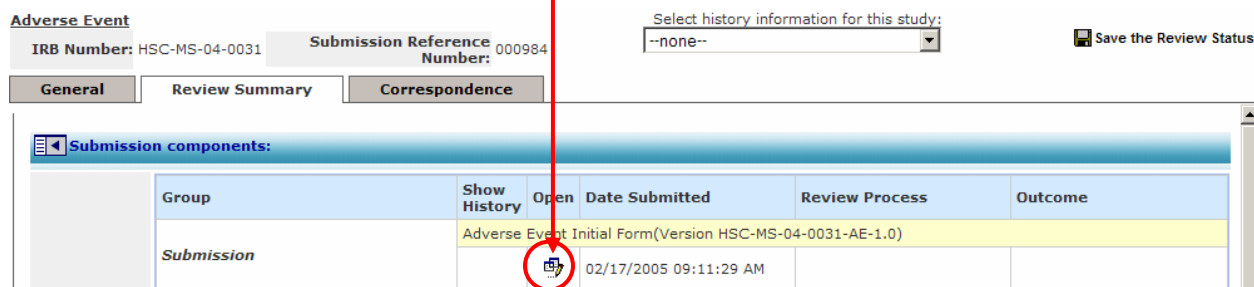
- Click the icon to view the **document** in iRIS.
- Click **Download** to save a copy of the document on your computer.



- If you click **Download** you will see this screen:


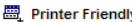
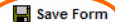


- Click **Save** to save the document on your computer in order to open it using your word processing software.
- Click the **Back** button in the top right corner of the screen to return to the Review Summary tab.
- Click the icon to open the **Adverse Event Initial Form**.



- Click the **Review Board Sections** tab to record your review.

IRB Number: HSC-MS-04-0031  
 PI: Accorsi, Jay, M.D., Ph.D.

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 Printer Friendly  Save Form

**CPHS Section:**

Review Status:

- No further action required
- PI must submit further report
- Recommend to revise informed consent
- Recommend to revise protocol
- Suspend protocol
- Terminate protocol
- Other

If necessary, explain below:

- Click in the appropriate **boxes** and if necessary provide additional information in the **text box**.
- When you have finished recording your review click **Save Form** and then click the **Back** button in the top right corner of the screen.
- You can include comments regarding the submission by clicking on **Members Add your Comments**.

**Submission components:**


Group	Show History	Open	Date Submitted	Review Process	Outcome
<b>Submission</b>			02/17/2005 09:11:29 AM		
<b>Attached Document(s)</b>					

**Reviewer Check-off:**

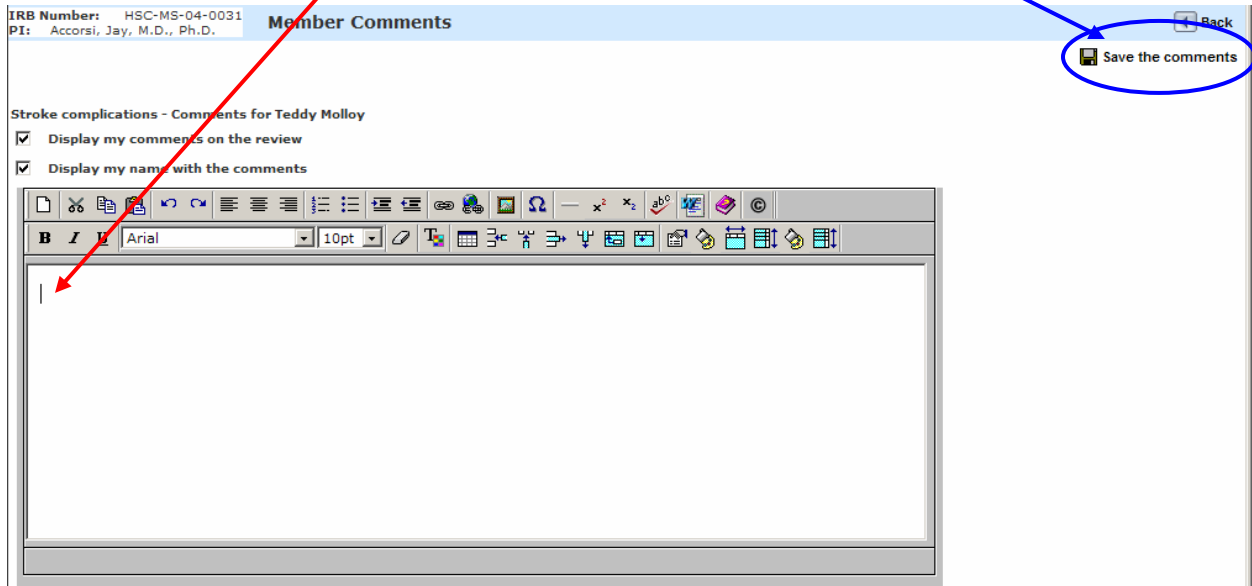
Reviewer Role	Reviewer	Completed ?	Date Notified	Date Completed
Chairperson	Molloy, Teddy	<input type="radio"/> Yes <input checked="" type="radio"/> No	02/17/2005	

**Member Comments:**

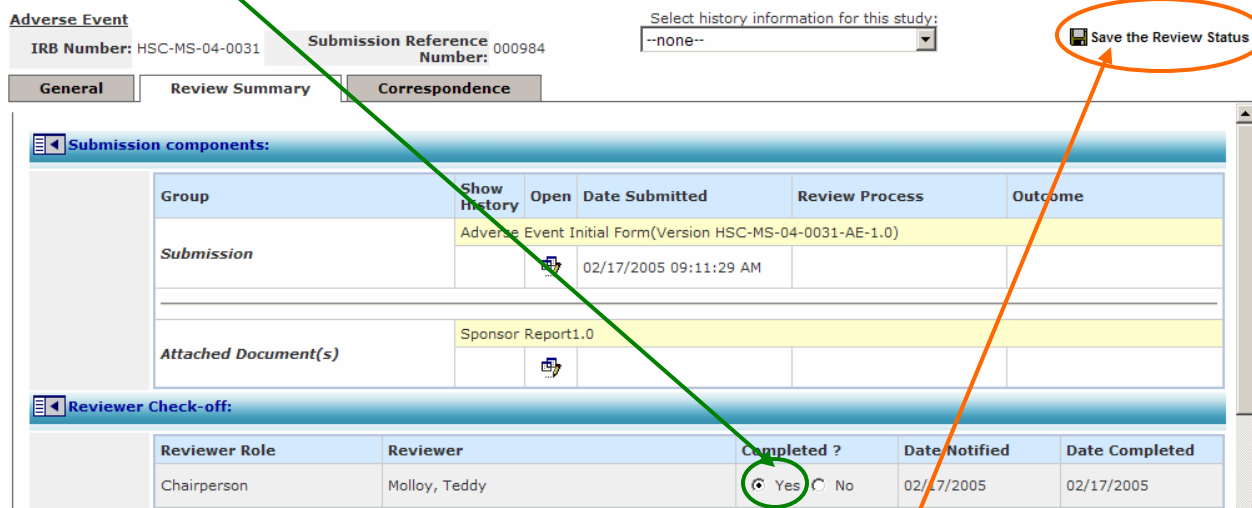
No Comments entered

 Members Add your Comments:

- Type your comments **here** and then click **Save the comments**.



- Click **Yes** to indicate you have completed your review.



- Click **Save the Review Status** in the top right corner of the screen.

- Click the **Back** button to return to your iRIS homepage or click the **Logout** button.

