

Signoff and Routing

Assign Key Study Personnel (KSP) Access to the Study in the Application

- Click **Add Principal Investigator**.

Save and Continue to the Next Section

3.0 Assign key study personnel(KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

Select if applicable

Student Department Chair

Resident Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Additional Key Study Personnel:

3.3 * Please add a Study Contact:

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

- Click in the **first text box** and type the first few letters or the entire last name of the principal investigator.

Search User Directory

Directory Browse/Find:

Last Name: bres

First Name:

by Department: All Departments

Search From: LDAP Directory iRIS Database

- Click **Find** in the top right corner of the screen.

Search User Directory

Directory Browse/Find:

Last Name: bres

First Name:

by Department: All Departments

Search From: LDAP Directory iRIS Database

| Select | Name | Department | Email |
|-------------------------------------|----------------|------------------------------------|------------------------------|
| <input checked="" type="checkbox"/> | Breslin, Nancy | Department, Nursing Administration | Barbara.S.Legate@uth.tmc.edu |

- Click in the **box** to the left of the principal investigator's name.
- Click **Select** in the top right corner of the screen.

- The name of the **principal investigator** appears in the application.

Save and Continue to the Next Section

| | |
|--|--|
| <p>1.0 Initial Study Setup</p> <p>2.0 Setup Department(s) Access</p> <p>3.0 Grant key study personnel(KSP) access to the study</p> | <p>3.0 Assign key study personnel(KSP) access to the study</p> |
| <p>3.1 *Please add a Principal Investigator for the study:</p> | <p>Nancy Breslin</p> <p>Select if applicable</p> <p><input type="checkbox"/> Student <input type="checkbox"/> Department Chair</p> <p><input type="checkbox"/> Resident</p> <p><input type="checkbox"/> Fellow</p> <p>If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.</p> <p>Add Principal Investigator</p> |
| <p>3.2 If applicable, please select the Additional Key Study Personnel:</p> | <p>Add Additional Key Study Personnel</p> |

- Click to **Add Additional Key Study Personnel** works in the same manner as adding the principal investigator. This is where you add the Co-PIs and the study coordinator.
- The iRIS default is set to Coordinator. Click [here](#) to change this person to the Co-Investigator.

| | | |
|---|---|---|
| <p>3.2 If applicable, please select the Additional Key Study Personnel:</p> | <p><u>Co-Investigator</u> <u>Coordinator</u> <u>Nurse</u></p> <p><input type="checkbox"/> Rail, Constance <input checked="" type="radio"/> <input type="radio"/> <input type="radio"/></p> <p><input type="checkbox"/> Fall, Fannie <input type="radio"/> <input checked="" type="radio"/> <input type="radio"/></p> | <p>Add Additional Key Study Personnel</p> <p>Delete Key Study Personnel</p> |
| <p>3.3 * Please add a Study Contact:</p> | <p><input type="checkbox"/> Breslin, Nancy</p> <p><input type="checkbox"/> Fall, Fannie</p> <hr/> <p>The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The study contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).</p> | <p>Add Study Contact(s)</p> <p>Delete Study Contact(s)</p> |

- iRIS automatically inserts the PI as the **study contact**. Adding the **study coordinator** as a study contact assures that both the PI and the coordinator receive system notifications.

- Click **Add Department Approvals** to insure that the submission is routed to the person in the department required to sign off on the submission.

| | | | |
|--|--|---------------------------------------|-------------------------------------|
| <p>3.5 If applicable, please select the Designated Department Approval(s):</p> | <p><input type="checkbox"/> Danilowitz, Richard</p> <p><input type="text" value="Department Chair"/></p> <hr/> <p>Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).</p> | <p> Add Department Approvals</p> | <p> Delete Department Approvals</p> |
| <p>3.6 If applicable, please select the Administrative Assistant(s)</p> | | <p> Add Administrative Assistants</p> | |

- Use the **drop down menu** to select a role for the department person who approves the submission.
- This is also where you add additional key study personnel who need to sign off on the submission such as a pediatrician, a thesis/dissertation chairperson, and thesis/dissertation committee members.
- When you have finished adding all the personnel, click **Save and Continue to the Next Section** in the top right corner of the screen.

Submission Routing

- Once the document has been signed, the Setup Signoff Submission Routing appears.
- The **Study Coordinators** must be added to the routing form in order for them to receive the conflict of interest forms that they must sign. Click **Add reviewer**.

Study Alias: Submission PI: Breslin, Nancy **Setup Signoff Submission Routing** Back

Add reviewer
 Delete selected reviewer(s)
 Save Submission Reviewer(s)

| Select the personnel required for pre-review signoff | | | |
|--|----------|----------------|---|
| Co-Investigator(s) | Approved | Name | |
| <input type="checkbox"/> | | Constance Rail | |
| Select required personnel | Order | Approved | Name/Role |
| <input type="checkbox"/> | 1 | | Richard Danilowitz |
| | | | <input type="text" value="Department Chair"/> |

Have you completed your selection of required signatures?

Yes

No

Screen Instructions:

This screen enables the selection of personnel required to review this form and the routing order before submission.

- Person(s) designated as Department reviewers on your application are listed on the 'Select required personnel' section to the left of these instructions. You can add or delete reviewers using the instructions below:

- When all required review information is entered, select 'Yes' on the question above and click the **Save Submission Reviewer(s)** link on the top panel.

- NOTE: Protocols are routed to Co-

- Type in the first few letters of the study coordinator's **last name** click **find**.

Search User Directory

Directory Browse/Find:

Last Name:

First Name:

by Department:

Search From: LDAP Directory iRIS Database

Back

find

- Click the **box** to the left of the study coordinator's name.

Search User Directory

Directory Browse/Find:

Last Name:

First Name:

by Department:

Search From: LDAP Directory iRIS Database

Back

find

select

| Select | Name | Department | Email |
|-------------------------------------|--------------|----------------|------------------------------|
| <input checked="" type="checkbox"/> | Fall, Fannie | Anesthesiology | barbara.s.legate@uth.tmc.edu |

- Click **Select** in the top right corner of the screen.
- Use the drop down **arrow** to select the study coordinator role.

Add reviewer Delete selected reviewer(s) Save Submission Reviewer(s)

Select the personnel required for pre-review signoff

Co-Investigator(s)

| Approved | Name |
|--------------------------|----------------|
| <input type="checkbox"/> | Constance Rail |

Have you completed your selection of required signatures?

Yes No

Screen Instructions

This screen enables the selection of personnel required to review this form and the routing order before submission.

- Person(s) designated as Department reviewers on your application are listed on the 'Select required personnel' section to the left of these instructions. You can add or delete reviewers using the instructions below:
- When all required review information is entered, select 'Yes' on the question above and click the Save Submission Reviewer(s) link on the top panel.
- NOTE: Protocols are routed to Co-

Select required personnel

| Order | Approved | Name/Role |
|----------------------------|----------|--|
| <input type="checkbox"/> 1 | | Richard Danilowitz Department Chair |
| <input type="checkbox"/> 2 | | Fannie Fall Study Coordinator |

- When you have finished adding reviewers, click **Yes**.
- Click **Save Submission Reviewer(s)** in the top right corner of the screen.

- The Workflow-Submission Tracking screen will appear indicating that the submission has gone to the Co-Investigator(s) for signoff.

Study Alias: Submission Workflow - Submission Tracking Back
 PI: Breslin, Nancy

| Status | View Details | Event Description | Date Received | Date Completed |
|------------|--|--|------------------------|------------------------|
| In Process | Submission Signoff | Initial Review Submission Routing for review Reviewer's Name: Constance Rail, Co-Investigator Principal Investigator: Nancy Breslin Study Title: Entering a Submission | 01/24/2005 03:33:24 PM | |
| In Process | Department Routing Review and Signoff in process | Assign Department Personnel for Signoff | 01/24/2005 03:33:23 PM | 01/24/2005 03:54:52 PM |
| Completed | Submission Signoff | Review and Signoff: Initial Review Submission Signoff: Nancy Breslin as Principal Investigator Study Title: Entering a Submission | 01/24/2005 03:01:57 PM | 01/24/2005 03:33:22 PM |
| Completed | | Study Title: Entering a Submission Submission Type: Initial Review Reference Number: 000912 | 01/24/2005 02:57:13 PM | 01/24/2005 03:33:23 PM |

- If the Workflow-Submission Tracking screen looks like this it means you have not clicked "Yes" and the submission is not complete. **Click here to Finalize List.**

| Status | View Details | Event Description | Date Received | Date Completed |
|------------|--|--|------------------------|------------------------|
| In Process | Waiting on Finalization of Signoff List Click here to Finalize List | Assign Department Personnel for Signoff | 04/28/2005 10:58:56 AM | |
| Completed | Submission Signoff | Review and Signoff: Initial Review Submission Signoff: Constance Rail as Principal Investigator Study Title: Happy Days are Here again! | 04/28/2005 10:58:33 AM | 04/28/2005 10:58:54 AM |
| Completed | | Study Title: Happy Days are Here again! Submission Type: Initial Review Reference Number: 001243 | 04/28/2005 10:58:25 AM | 04/28/2005 10:58:56 AM |

- Click **Yes**.

Select the personnel required for pre-review signoff

| Co-Investigator(s) | Approved | Name |
|--------------------------|--------------------------|----------------|
| <input type="checkbox"/> | <input type="checkbox"/> | Constance Rail |

Have you completed your selection of required signatures?

Yes
 No

- Click **Save Submission Reviewer(s)** in the top right corner of the screen.

Department Chair Signature

- When the department chair logs into iRIS, this message will appear:

You have 7 Submissions for your review and signoff

| Open Task | Subject | Received |
|-----------|--|---------------------------|
| | Initial Review Submission Routing for review Reviewer's Name: Richard Danilowitz , Department Chair Principal Investigator: Nancy Breslin Study Title: Entering a Submission | 01/24/2005 03:57:11 PM |

- Clicking the **Open Task** icon will bring up the Submission Signoff Sheet.

- Click to **review** the documents and click to **approve** the submission.

Submission Signoff Sheet Back

Save Signoff

Study Title: Happy Days and Here again!

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

Teddy Molloy, M.D. as Department Chair do you Approve or Deny this submission? Approve Deny

[click here to add comments.](#)

[click here to sign the document](#)

Department Reviewer Sign-off Form

CERTIFICATION OF DEPARTMENT or DIVISION CHAIRPERSON:

- I, or my departmental research review committee, have performed a comprehensive review of this protocol and have found that this study is scientifically meritorious and clinically relevant and that the methods are sufficient to address the stated hypothesis.
- I certify that the principal investigator and the co-investigators have the proper education, experience, and expertise to conduct the study.
- I will ensure that the conduct of this protocol will adhere to all UTHSC-H policies and procedures.
- I certify, by signing this form, that the above titled research has been and will be conducted in full compliance with the federal regulations and institutional policies governing human subject research.
- I understand that a CPHS continuing review is required annually in order to maintain approval and that any change(s) in the study that affects the subjects involved must be approved by the CPHS prior to implementation.

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

Electronic signature Back

save

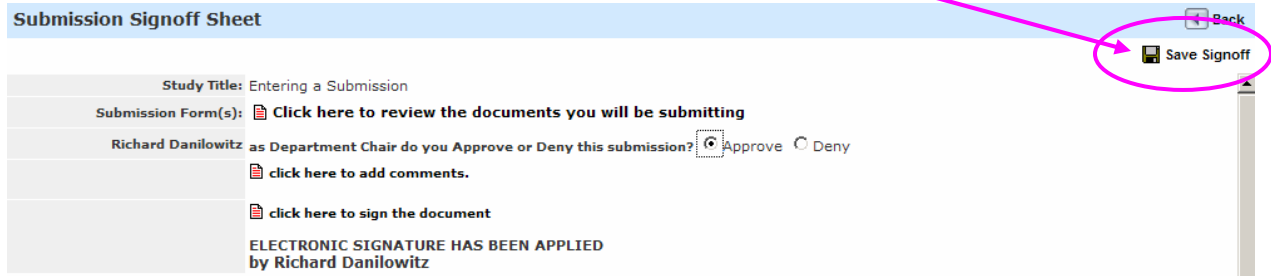
This form requires your electronic signature.

Please Teddy Molloy, M.D. enter your Password below:

Password:

- Type in your **UT password** and click **Save**.

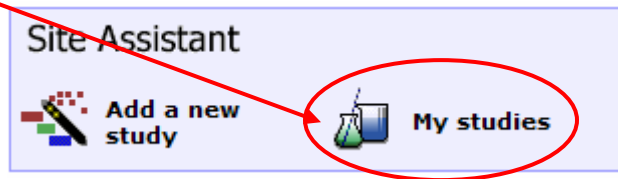
- Once the submission has been signed click **Save Signoff**.



- The submission then goes to the study coordinator and once the study coordinator completes the signoff and the conflict of interest form the submission goes to the CPHS office for review.

Track Locations

- Track Locations allows you to monitor the progress of your submissions.
- Click **My Studies** on your iRIS home page.



- Click the **icon** to open the study.

My Studies Back

Filter my studies by study status:

Most Recently Used:

| Click to open | Study Status | IRB Number | IRB Expiration | Principal Investigator | Study Title/ Study Alias | Copy Study | Delete Study |
|---------------|--------------|----------------|----------------|------------------------|--|------------|--------------|
| Open | Active | HSC-MS-04-0176 | 03/16/2006 | Breslin, Nancy | Correspondence Routing Correspondence | Copy | |
| Open | Active | HSC-MS-05-0053 | | Breslin, Nancy | How not to Route Routing | Copy | |

Study Status: **Active** Study Title: How not to Route
 Expiration Date:

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 Studies Exempt from HIPAA Authorization for Disclosure of PHI IRB Waiver - Retrospective Chart Review or Preparatory to Research IRB Waiver - Screening and Recruitment IRB Waiver ? Decedent Data Memorial Hermann Hospital System Research Application | <ul style="list-style-type: none"> Initial Review Continuing Review Change Request/Amendments Adverse Events IND safety reports Protocol Deviation Study Closure Miscellaneous Miscellaneous Study Discussion/Message Center Submissions History | <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 **Submissions History**.
- Click the **Outstanding Submissions** or **Completed Submissions** tab.

Outstanding Submissions Completed Submissions

Submissions completed

| Show History | Reference Number | Track Location | Request Type | Review Board | View Outcome Letters | Review Process | Meeting Date | Review Outcome | Date Submitted |
|--------------|------------------|----------------|--------------------------|--|----------------------|--------------------------|--------------|---------------------------------------|------------------------|
| | 001036 | | IND Safety Report | Committee for the Protection of Human Subjects | | Process Administratively | | Reviewed - No further action required | 03/09/2005 05:26:01 PM |
| | 001012 | | Initial Review | Committee for the Protection of Human Subjects | | Process Administratively | | Approved | 02/24/2005 04:27:40 PM |

- Click the **Track Location** icon next to the submission you want to track.
- The Workflow – Submission Tracking screen indicates the location of the submission.

IRB Number: HSC-MS-05-0053 Workflow - Submission Tracking Back
 PI: Breslin, Nancy

| Status | View Details | Event Description | Date Received | Date Completed |
|------------------|--------------|---|------------------------|------------------------|
| Completed | | Committee for the Protection of Human Subjects completed the submission with the outcome of Reviewed - No further action required at 03/09/2005 05:33:00 PM | 03/09/2005 05:33:00 PM | 03/09/2005 05:33:00 PM |