

UT-SPH - Student Sign-Off Policy for New iRIS Submissions

The following policy statement outlines the routing and signatures required for SPH students submitting new applications into iRIS. Refer to additional online documentation for detailed instructions for completing applications, change requests, continuing reviews, terminations, etc.

Please note that the Office of Research Support Committees (ORSC) pre-screens iRIS submissions and returns for corrections those submissions that are inaccurate and/or **incomplete**.

All initial submissions require the following signatures:

- **Principal Investigator** - The student is the PI on thesis and dissertation studies.
- **Faculty Advisor** – Only one faculty name is required for the iRIS application. This can be either your Thesis/Dissertation Advisor or your Academic Advisor. The faculty advisor must be a salaried UT-SPH employee.
- **Associate Dean for Research** - Rebecca Novak must be listed as the person signing off on behalf of the Associate Dean for Research.

Some submissions will require the following:

- **Pediatric Risk Assessor** - This signature is required for ALL studies that use children (subjects younger than 18 years of age).
- **Study Contact(s)** – This field should be used if a project manager or other person is needed to assist with the iRIS application or follow-ups. Study Contacts will receive all of the same communications as the PI. The student may choose to add the Faculty Advisor as a Study Contact; however, this is not required.
- **Key Study Personnel** - This field must be used if there are additional key personnel (typically Co-PIs) responsible for oversight of the thesis/dissertation study.
- **Administrative Assistant** – This field is optional. The Administrative Assistant will have read-only access to the study and its associated documents.

iRIS System Instructions for SPH students

Departments

Generally, when students log onto iRIS, their department will be listed as “UT-H – GEN – Default Department Code.” This will appear with your name at the top of the main screen in iRIS.

Account: Jimmy Richardson
Department: UT-H - GEN - Default Department Code

When entering an iRIS protocol, you will need to associate your study with the appropriate department. For thesis and dissertation approvals you need to be associated with the academic training provided at SPH for your degree. Therefore, the department named “**UT-H - SPH - Academic Programs**” needs to be added.

From the iRIS application, Section 2.0 - Add Department(s), the following screen will appear:

| 2.0 Add Department(s) | | | | | |
|--|--|-----------------|-----------------|--------------------------|--------------------------------------|
| 2.1 List Departments associated with this study: | <table border="1"><thead><tr><th>Primary Dept?</th><th>Department Name</th></tr></thead><tbody><tr><td><input type="checkbox"/></td><td>UT-H - GEN - Default Department Code</td></tr></tbody></table> | Primary Dept? | Department Name | <input type="checkbox"/> | UT-H - GEN - Default Department Code |
| | Primary Dept? | Department Name | | | |
| <input type="checkbox"/> | UT-H - GEN - Default Department Code | | | | |
| | <p>Add Departments Delete Departments</p> | | | | |

- To change the department, click on “**Add departments**”.


The following screen will appear:

| Departments to Add: | Added Departments: |
|--|--------------------|
| <ul style="list-style-type: none">UT-H - SPH - Health Promotion/Health EducUT-H - SPH - Health Services OrganizationUT-H - SPH - Human Genetics CenterUT-H - SPH - Human Nutrition CenterUT-H - SPH - Humanities & Tech In Hlth CareUT-H - SPH - Information TechnologyUT-H - SPH - International & Family Health | |



- Scroll through the list until you find the department you need.
- Highlight the department name and press the **>>** button.

The department you selected will move to the “Added Departments” panel on the right side of the screen.

| Departments to Add: | Added Departments: |
|--|--|
| <ul style="list-style-type: none"> MHHS - MH - Corporate MHHS - MH - Fort Bend MHHS - MH - Hermann Children's MHHS - MH - Hermann Hospital MHHS - MH - Katy MHHS - MH - LTACH MHHS - MH - Memorial City | <ul style="list-style-type: none"> UT-H - SPH - Human Genetics Center |

- Press the  button. You will be returned to section 2.0 of the application. Notice that the new department now appears on the panel.

2.0 Add Department(s)

| 2.1 List Departments associated with this study: | <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 15%;">Primary Dept?</th> <th style="width: 75%;">Department Name</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input type="radio"/></td> <td>UT-H - GEN - Default Department Code</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="radio"/></td> <td>UT-H - SPH - Human Genetics Center</td> </tr> </tbody> </table> | | Primary Dept? | Department Name | <input checked="" type="checkbox"/> | <input type="radio"/> | UT-H - GEN - Default Department Code | <input type="checkbox"/> | <input checked="" type="radio"/> | UT-H - SPH - Human Genetics Center | <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  </div> <div style="text-align: center;">  </div> </div> |
|---|--|--------------------------------------|---------------|-----------------|-------------------------------------|-----------------------|--------------------------------------|--------------------------|----------------------------------|------------------------------------|--|
| | Primary Dept? | Department Name | | | | | | | | | |
| <input checked="" type="checkbox"/> | <input type="radio"/> | UT-H - GEN - Default Department Code | | | | | | | | | |
| <input type="checkbox"/> | <input checked="" type="radio"/> | UT-H - SPH - Human Genetics Center | | | | | | | | | |

- To remove the “GEN – Default Department Code” click the **box** located to the left of the name and press the **“Delete Departments button”**.
- Select the **radio button** to choose a primary department.

2.0 Add Department(s)


| 2.1 List Departments associated with this study: | <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 15%;">Primary Dept?</th> <th style="width: 75%;">Department Name</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="radio"/></td> <td>UT-H - SPH - Academic Programs</td> </tr> </tbody> </table> | | Primary Dept? | Department Name | <input type="checkbox"/> | <input checked="" type="radio"/> | UT-H - SPH - Academic Programs |
|---|---|--------------------------------|---------------|-----------------|--------------------------|----------------------------------|--------------------------------|
| | Primary Dept? | Department Name | | | | | |
| <input type="checkbox"/> | <input checked="" type="radio"/> | UT-H - SPH - Academic Programs | | | | | |

Key Study Personnel

Section 3.0 of the application allows you to enter the names of the key study personnel. **Section 3.1** asks you to choose a Principal Investigator. The student will be the PI for the study.

- Press “Add Principal Investigator”:

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

| | | |
|--|--|--|
| 3.1 *Please add a Principal Investigator for the study: | <p>Select if applicable</p> <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Student <input type="checkbox"/> Resident <input type="checkbox"/> Fellow </div> <div> <input type="checkbox"/> Department Chair </div> </div> <p>If the Principal Investigator is a Student, Resident, or Fellow, the name of the Faculty Advisor must be supplied below.</p> | <div style="display: flex; justify-content: center;"> <div style="border: 2px solid blue; border-radius: 50%; padding: 10px; margin: 10px;">  </div> </div> |
|--|--|--|

A search tool will appear.

Search User Directory

Directory Browse/Find:

Last Name:

First Name:

by Department:

Search From: LDAP Directory
 iRIS Database

- Type in part of the person's last name (the tool does a partial search).

Last Name:

- Press the  button.

A list of names that match the criteria will appear.

| Select | Name | Department | Email |
|--------------------------|--------------------|--|---------------------------------|
| <input type="checkbox"/> | Molandes, Jennifer | Doctor of Dental Surgery | Jennifer.M.Molandes@uth.tmc.edu |
| <input type="checkbox"/> | Molina, Jennifer | GSBS Dean's Office , Doctor of Philosophy In Biomedical Sciences | Jennifer.R.Molina@uth.tmc.edu |
| <input type="checkbox"/> | Molina, Martha | Doctor of Medicine | Martha.M.Molina@uth.tmc.edu |
| <input type="checkbox"/> | Molina, Jose | Biochemistry & Molecular Biolo | Jose.G.Molina@uth.tmc.edu |
| <input type="checkbox"/> | Moll, Kate | Master of Science In Nursing (Nurse Anesthesia/Clinical) | Kate.Moll@uth.tmc.edu |
| <input type="checkbox"/> | Molloy, Melissa | Research/Wassef | Melissa.S.Molloy@uth.tmc.edu |
| <input type="checkbox"/> | Molony, Anna | Neurology | Anna.Molony@uth.tmc.edu |
| <input type="checkbox"/> | Molony, Donald | Internal Medicine, Renal Disea | Donald.A.Molony@uth.tmc.edu |

- Check the box** next to the correct name and press the **"Select"** button in the upper right corner of your screen.


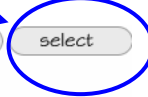
Directory Browse/Find:

Last Name:

First Name:


by Department:

Search From: LDAP Directory
 iRIS Database

| Select | Name | Department | Email |
|-------------------------------------|---------------------|-----------------|------------------------------|
| <input type="checkbox"/> | Molloy, Melissa | Research/Wassef | Melissa.S.Molloy@uth.tmc.edu |
| <input checked="" type="checkbox"/> | Molloy, Teddy, M.D. | Anesthesiology | Barbara.S.Legate@uth.tmc.edu |

The name will then appear in section 3.1 of the Key Study Personnel panel.


| | | |
|--|--|---|
| 3.1 *Please add a Principal Investigator for the study: | Teddy Molloy, M.D. <hr/> <p>Select if applicable</p> <p><input checked="" 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> |  |
|--|--|---|

- Students should check the box next to the “**Student**” option.

Section 3.3 allows you to select a study contact. The PI is by default the study contact. You can change this to be any person (key study personnel or not) you wish to receive communications regarding your protocol. The PI and the study contact are the **only** ones that will be sent the automatic notifications that come from iRIS (e.g. pre-review corrections, approved pending items, approval letters, etc.).

Section 3.4 allows you to enter the name of your faculty advisor

- Click “Add Faculty Advisor”.

| | | |
|---|--|---|
| 3.4 If applicable, please add a Faculty Advisor: | |  |
|---|--|---|

The system will bring you to the search tool to select the name from the directory. Once you select a person, their name will appear in the box.

| | | |
|---|----------------|---|
| 3.4 If applicable, please add a Faculty Advisor: | Marilyn Monroe |  |
|---|----------------|---|

Section 3.5 allows you to enter the name of “designated department approvals”.

- Using the search tool, add Rebecca Novak who signs off on behalf of the “Associate Dean for Research”.

| | | |
|--|---|----------------------------------|
| <p>3.5 If applicable, please select the Designated Department Approval(s):</p> | <p><input type="checkbox"/> Novak, Rebecca</p> <p> <input type="text" value="Advisor"/> <input type="text" value="Advisor"/> <input type="text" value="Associate Dean for Research"/> <input type="text" value="Co-PI (when adding new Co-PI's to a study)"/> <input type="text" value="Dean"/> <input type="text" value="Department Chair"/> <input type="text" value="Director of Management Operations (DMO)"/> <input type="text" value="Dissertation Chairperson"/> <input type="text" value="Division Chair"/> </p> | <p> Add Department Approvals</p> |
|--|---|----------------------------------|

- Using the drop down menu, select the appropriate role of “Associate Dean for Research”.

If the study involves children under the age of 18, the submission will need to be signed off on by someone designated as a “Pediatric Risk Assessor”.

- Using the search tool, select the name of the individual for this requirement.
- Using the drop down menu, select the role of “Pediatric Risk Assessor”.

When this person receives the submission for review, they will be required to sign off on a special routing form which includes their assessment of risks for studies that involve children.

| | | |
|--|---|----------------------------------|
| <p>3.5 If applicable, please select the Designated Department Approval(s):</p> | <p><input type="checkbox"/> Novak, Rebecca</p> <p><input type="text" value="Associate Dean for Research"/></p> <p><input type="checkbox"/> Hayworth, Rita</p> <p> <input type="text" value="Division Chair"/> <input type="text" value="Director of Management Operations (DMO)"/> <input type="text" value="Dissertation Chairperson"/> <input type="text" value="Division Chair"/> <input type="text" value="Division Director"/> <input type="text" value="Other"/> <input type="text" value="Pediatric Risk Assessor"/> <input type="text" value="Principal Investigator (when changing PI's)"/> <input type="text" value="Principal Investigator (when sign-off is needed)"/> </p> | <p> Add Department Approvals</p> |
|--|---|----------------------------------|

Optional

Section 3.2 allows you to select the name of any Co-Investigators or Study Coordinators if applicable.

- Click on “Add Additional Key Study Personnel”.

| | | |
|---|--|--|
| <p>3.2 If applicable, please select the Additional Key Study Personnel:</p> | | <p> Add Additional Key Study Personnel</p> |
|---|--|--|

The system will bring you to the same search tool where you can do a partial search on the last name to find the names of the individuals you need to add to your study. After selecting the names, they will appear in section 3.2.

The system default is to assign people roles of “study coordinators”. If the person is a Co-Investigator, select the appropriate button.

| | | | | | | |
|---|--------------------------|------------------------------|----------------------------------|----------------------------------|---|-----------------------|
| 3.2 If applicable, please select the Additional Key Study Personnel: | | <u>Co-Investigator</u> | <u>Coordinator</u> | <u>Nurse</u> |  Add Additional Key Study Personnel | |
| | <input type="checkbox"/> | Accorsi, Jay, M.D., Ph.D. | <input checked="" type="radio"/> | <input type="radio"/> | | <input type="radio"/> |
| | <input type="checkbox"/> | Breslin, Nancy | <input checked="" type="radio"/> | <input type="radio"/> | | <input type="radio"/> |
| | <input type="checkbox"/> | Danilowitz, Richard RN, M.D. | <input type="radio"/> | <input checked="" type="radio"/> | | <input type="radio"/> |

PI, Co-PIs & study coordinators are all allowed to submit information to the IRB for the named protocol.