PERSONNEL CHANGE SCREENSHOT GUIDE

Within your submission, select IRB Study Amendment



Click on Add a new Form on the top right

| My Workspaces Study Alias: TEST PI: Arvizo, Myrna, BMS, CIP, CH | RC Study Assistar | IRB St | tudy Amendment Form | | | | | Back |
|---|---------------------------------|--------------------|-------------------------------|---------------|------------|--------------|--------------------------------|-------------------------------|
| Study Status: Draft | Study Title : | TEST Applicati | ion 02/03/2021 | | | | | |
| | | | | | | Copy Form | Add a New Form Compare Two Ver | sions Delete Selected Form(s) |
| ist of records associated with form: IRB Study Amendm To view previous versions click on the folder icon | ent Form. | | | | | | | |
|) result(s) found | | | | | | | | |
| Show Edit/ Rev View Details Apply Sub. Tr Multiple | ack Process ation Submission | Submission Date | Update Date | Update Number | Created By | Date Created | Modified By | Date Modified |
| | | | No records have been created. | | | | | |

Section 1.0-Is prepopulated

| | | Cave and Continue to Next Decitor |
|--------------------------|---|-----------------------------------|
| Section view of the Form | Entire view of the Form | |
| 1.0 🖻 Study Information | 1.0 Texas Tech University Health Sciences Center El Paso Institutional Review Board Study Modification Form | |
| | 1.1 IRB Number: | |
| | 1.2 Sponsor: | |
| | Anesthesiology(Anes) | |
| | 1.3 Study Title: | |
| | TEST TEST Application 02/03/2021 | |
| | 1.4 Principal Investigator: | |
| | Myrna Arvizo, BMS, CIP, CHRC | |
| | 1.5 Study Contact: | |
| | Myrna Arvizo, BMS, CIP, CHRC | |

Click on Save and Continue to Next Section



Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section

Section 2.0-Enter date, modification number (depends on previously submitted), and select Personnel Change Request

| My Workspaces | Study Alias: TEST PI: Arvizo, Myrna, BMS, CIP, CHRC Study Assistant | IRB Study Amendment Form - (Version 1.0) | | | 🚺 Ba | ck |
|--|--|--|----------------|-------------------------|--|----|
| | | | Print Friendly | Refresh Constant Fields | Save Section Save and Continue to Next Section | on |
| Section view of the For | n Entire view of the Form | | | | | |
| 1.0 Study Information 2.0 General Information | 2.0 General Information | | | | | |
| | 2.1 * Date of Modification: | | | | | |
| | 09/23/2021 | | | | | |
| | 2.2 * Modification Number: | | | | | |
| | 3 | | | | | |
| | 2.3 * Type of Modification: | | | | | |
| | Personnel Change Request Protocol modifications | | | | | |
| | Recruitment materials | | | | | |
| | Updated investigator brochure | | | | | |
| | Changes to study application | | | | | |
| | Changes to study documents (questionnaires, s Other | urveys, etc.) | | | | |
| Click on S | ave and Continue to | Next Section | | | | |
| | | | | | | |

| Print Friendly Refresh Constant Fields Save Section Save and Continue to Next Section | |
|---|--|
|---|--|

Section 3.0-Click on Setup Key Study Personnel Request on the right

| My Workspaces 🗷 📴 | dy Alias: TEST Arvico, Myrna, BMS, CIP, CHRC Study Assistant IRB Study Amendment Form - (Version 1.0) | | | • |
|--|---|-----------------------------|------------------|------------------------------|
| | Print F | riendly Refresh Constant Fi | Ids Save Section | Save and Continue to Next Se |
| Section view of the Form | Entire view of the Form | | | |
| 1.0 🖹 Study Information 2.0 🖹 General Information | 3.0 Personnel Change Request | | | |
| 3.0 Personnel Change Request | Indicate ONLY personnel you are adding or deleting from the study. | | | |
| | Assign key study personnel(KSP) Request to the study | Setup Key Study Personnel F | tequest | |
| | If applicable, please add the new Principal Investigator for the study: | | | |
| | If applicable, please select the new Research Staff personnel: | | | |
| | A) Additional Investigators | | | |
| | | | | |
| | B) Research Staff | | | |
| | If applicable, please add any new Study Contact: | | | |
| | | | | |
| | The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Internatives). | ivestigator | | |
| | If applicable, please select any existing Personnel you wish to remove: | | | |
| | | | | |
| | | | | |

First screen is to add personnel

| | Setup Study Personnel | x |
|--------------------------------------|---|----------------|
| User Search Remove Personnel List | Last Name: First Find User/Ser | arch Directory |
| | Select Training? Name Department Your search criteria returned 0 results. | Email |
| | | |
| | < | > |
| | Selected Study Personnel: | 1 |
| | Principal Investigator | ^ |
| | Name Role | |
| | No Personnel has been selected for this group. | |
| | Additional Investigators | |
| | Name Role | |
| | No Personnel has been selected for this group. | ~ |
| | Clear Key Study Personnel Close Setup of Study Personnel | sonnel |

Enter at least the last name of the person you are trying to add, the click on Find User/Search Directory. The person will display as shown below. If you would like to see the training that has already been completed, click on the graduate icon. Otherwise, click on Select.

| | | Set | up Study Personnel | | | x |
|--------------------------------------|----------------------------|-----------|--------------------------------------|----------------|--------------|----------------|
| User Search Remove Personnel List | Last Nam I Departmen | | First Name: | | Find User/Se | arch Directory |
| | Select | Training? | Name | Department | | Email |
| | 0 | 3 | Arvizo, Myrna, BMS, CIP, (1) CHRC | Administration | | myrna.arvizo@ |
| n | | | | | | |

The next screen will ask to select a role for the person being added and whether you would like for them to also be included as a study contact who receives all system notices. Click Save when complete.

| Add Personnel Role x | | | | | | |
|--|---|--------------|------|--|--|--|
| Gelect the Role for Myrna Arvizo, BMS, CII | P, CHRC : | | | | | |
| O Principal Investigator | | | | | | |
| Additional Investigators | Co-Investigator | \checkmark | | | | |
| Research Support Staff | none Clinical Research Associate | | | | | |
| Study Contact | Study Coordinator Nurse | | | | | |
| | Participating Clinician Biostatistician Technician/Post Doc | | | | | |
| /ould you like to include as a Study Contact ? \bigcirc Ye | Volunteer s Regulatory Specialist Research Assistant | | | | | |
| | Laboratory Personnel Participating Researcher | | | | | |
| | IBC License Holder Hazmat Trained Shipper | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | ſ | Cancel | Save | | | |
| | l | Cancel | Jave | | | |

Once the selection is made, the person being added will display below, under the category selected.

| | | Set | tup Study Personnel | | x |
|--|------------|-------------------------------------|----------------------------------|--------------------|-------------------------------|
| User Search Remove Personnel List Create My Personnel Pool | | ne: arvizo by All Departm | First Name | me: | Find User/Search Directory |
| | Select | Training? | Name | Department | Email |
| | 6 | 3 | Arvizo, Myrna, BMS, CIP, CHRC | Administration | myrna.arvizo@ |
| | Research S | Study Perso upport Staff Name | onnel: | Role | > |
| | 8 | Arvizo, Myrna, | BMS, CIP, CHRC | Clinical Rese | earch Associate |
| | Contact | | | | |
| | | Name | | Role | |
| | 8 | Arvizo, Myrna, | BMS, CIP, CHRC | Study Conta | act 🗸 |
| | | | Clear K | ey Study Personnel | lose Setup of Study Personnel |

To remove existing personnel from the study, click on the second tab on the left, in red, Remove Personnel List. This will change to white and will display everyone currently listed. Select those that are being removed.

| | Setup Study Persor | nnel X |
|--------------------------|--|--|
| User Search | | |
| Remove Personnel List | | Save Selections |
| Create My Personnel Pool | Mame Name | Role on the Study |
| | Myrna Arvizo, BMS, CIP, CHRC | Principal Investigator |
| | Myrna Arvizo, BMS, CIP, CHRC | Study Contact |
| | Myrna Arvizo, BMS, CIP, CHRC | Study Author |
| | Myrna Arvizo, BMS, CIP, CHRC | Designated Department Approver(s) |
| | Myrna Arvizo, BMS, CIP, CHRC | Clinical Research Associate |
| | Selected Study Personnel: | |
| | Principal Investigator | ^ |
| | Name | Role |
| | No Personnel has been selected for this group. | |
| | Additional Investigators | |
| | Name | Role |
| | No Personnel has been selected for this group. | × |
| | [| Clear Key Study Personnel Close Setup of Study Personnel |

Once selected, the names will display under the section Remove Personnel List (see below). If the name(s) do not display in this section, the system will not recognize that they are being removed. When complete, click on Close Setup of Study Personnel.

| Print Friendly | Refresh Constant Fields | Save Section Save and Continue to Next Section |
|--------------------------------------|-------------------------------|--|
| | Setup Study Perso | nnel x |
| lser Search Lemove Personnel List | | Save Selections |
| reate My Personnel Pool | Name | Role on the Study |
| | Myrna Arvizo, BMS, CIP, CHRC | Principal Investigator |
| | Myrna Arvizo, BMS, CIP, CHRC | Study Contact |
| | Myrna Arvizo, BMS, CIP, CHRC | Study Author |
| | Myrna Arvizo, BMS, CIP, CHRC | Designated Department Approver(s) |
| | Selected Study Personnel: | |
| | Contact | ^ |
| | Name | Role |
| | Arvizo, Myrna, BMS, CIP, CHRC | Study Contact |
| | Remove Personnel List | |
| | Name | Role |
| | Arvizo, Myrna, BMS, CIP, CHRC | Clinical Research Associate 🗸 🗸 |
| | | Clear Key Study Personnel Close Setup of Study Personnel |

This will return you to section 3.0, Setup Key Personnel Request section. The names of those being added and/or removed will display on this section in the applicable categories.

| Section view of the Form | Entire view of the Form | | | | | | | | |
|--|--|-------------------------|---------|--|--|--|--|--|--|
| 1.0 ➡ Study Information 2.0 ➡ General Information 3.0 ➡ Personnel Changes | 3.0 Personnel Changes | | | | | | | | |
| | Assign key study personnel(KSP) Request to the study | p Key Study Personnel F | Request | | | | | | |
| | If applicable, please add the new Principal Investigator for the study: | | | | | | | | |
| | If applicable, please select the new Research Staff personnel: | | | | | | | | |
| | ir appikable, piease selekt tile new Kesearch Start personnel: A) Additional Investigators | | | | | | | | |
| | A) Auditional Intestigators | | | | | | | | |
| | B) Research Staff | | | | | | | | |
| | Arvizo, Myma, BMS, CP, CHRC Clinical Research Associate V | | | | | | | | |
| | If applicable, please add any new Study Contact: | | | | | | | | |
| | Arvice, Myma, BMS, CIP, CHRC | | | | | | | | |
| | The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves). | | | | | | | | |
| | If applicable, please select any existing Personnel you wish to remove: | | | | | | | | |
| | Anvico, Myma, BMS, CIP, CHRC Clinical Research Associate | | | | | | | | |

Click on Save and Continue to Next Section

| Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section | |
|----------------|-------------------------|--------------|-----------------------------------|--|
| | | | | |

Section 4.0-Enter a description and reason for the modification

Click on Save and Continue to Next Section

| Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section | | | | |
|---|-------------------------|--------------|-----------------------------------|--|--|--|--|
| Section 5.0-Attached a revised protocol and application, if applicable. | | | | | | | |

Click on Save and Continue to Next Section

| Print Friendly | Refresh Constant Fields | Save Section | Save and Continue to Next Section |
|----------------|-------------------------|--------------|-----------------------------------|
| | | | |

Signoff and Submit when complete.