Add a Sub-Form to an IRB Protocol in Infonetica

There are four types of Sub-Forms you may add to an IRB Protocol:

- **Amendments** are required when requesting IRB approval for changes you would like to make to an already-approved Protocol.
- **Annual/Continuing Review Reports** are required within 30 days of a Protocol's expiration. With the report, you may request a 1-year extension to your Protocol's IRB approval or terminate it if you are finished.
- Adverse Events need to be reported if a harmful incident has occurred as a result of the research outlined in your Protocol.
- **Post-Approval Documentation** may be added to a Protocol even if it's currently locked for edits. This is used when the IRB approves a Protocol in its current state, but requests that you add additional documentation to the record.

1) Log into Infonetica & Select a Protocol

To get started, visit <u>www.fairfield.edu/irb</u> and click Log in on the top-right of the page.



Log into the system by entering your **Fairfield Net ID** and current password before clicking the blue **Log in** button.

| F U | Sairfield NIVERSITY |
|----------------|------------------------|
| Enter your ex | isting Fairfield NetID |
| & Password, | then click the blue |
| "Log in" butto | on. |
| Log in | |
| Fairfield | |
| User Name | |
| Ihenkel | |
| Password | |
| Log in | |
| | |

From the **Work Area**'s list, select the **Project** to which you would like to add a **Sub-Form**.

| Work Area 🕶 | Work Are | ea. | | | | |
|--|----------------------------------|------------------------|-----------|------------------------|------------------|----------------------|
| Actions 🕶 | Notifications | Signatures | Transfers | Shared | | |
| Create Folder Delete Folder Create Project | 1 | 0 | 0 | 1 | | |
| Newto Project Duplicate Project | Folders | | | | | |
| | Closed (Not Activ | Ones I Am Co-PI | | | | |
| | 2 | 1 | | | | |
| | Projects | | | | | |
| | Search Projecta | | | | | |
| | Project Title Samele Protocol | | 0 Proje | ct ID • Owner | Date Created | Date Modified |
| | First impressions and | Memory | 495 | IRB Chair Unda Henkel | 10/03/2017 19:23 | 000100110024 |
| | Shifts in Perspective, M | Andfulness, and Memory | 400 | 189 Chair Linda Henkel | 08/30/2017 02:45 | 08/31/2017 02:54 |
| | Nostalgia and Life Tra | nsitions | 355 | IRB Chair Linda Herkel | 02/24/2016 19:35 | 01/15/2017 0212 |
| | Functions of Reminisc | ence in Young Adults | 178 | IRB Chair Linda Henkel | 01/22/2015 18:38 | 01/22/2015 19:01 |
| | Reviewing Photos | | 84 | IR8 Chair Linda Henkel | 06/23/2014 17:27 | 08/16/2017 19:11 |
| | Changes in Memory R | eports (IRB #82) | 82 | IRB Chair Linda Henkel | 06/20/2014 14:09 | 01/15/2017 02:09 |
| | Quasing 1 to 2 of 2 entries | SSEU ASM DATARS. | 1000 | | | Sector Sector Sector |

2) Designate Which Type of Sub-Form to Create

From your chosen Protocol's Actions menu, click Create Sub-Form.

| | Work Area 🛩 | Sample | Protocol | | | |
|---------|---------------------------|---|------------------------------------|--------------|-------------------------------------|-------------|
| Home | 1 Notifications | Project Tree 🗸 | | | | |
| Project | Actions ~ | © Sample | Protocol search Protocol Applic | ation | | |
| Share | Completeness Sub Check | Form Status mit Not Submitted | | Review Refer | ence | |
| Print | Correspond | Navigation | Documents | Signatures | Collaborators | Submissions |
| | | Researce section Fairfield University | ch Protoc | ol Applic | Cuestions Application for IRB Re | view |

From the dropdown, select which type of Sub-Form you would like to add, then click Create.

| Create Sub-form | × |
|--|------------------|
| Select the sub-form that you would like to app | bly to this form |
| ✓ Annual/Continuing Review Report Adverse Event | ¢ |
| Amendment to Protocol Post-Approval Documentation | Create |

3) Populate and Submit the Sub-Form

Your new Sub-Form will have its own landing page, 'nested' underneath the Protocol's original Research Protocol Application. When on your **Sub-Form**'s landing page, click its blue linked title towards the bottom of the page to open it for completion.

Note: If your Protocol contains multiple **Sub-Forms**, use the hierarchy at the top of the page to confirm you are on the landing page of the one you'd like to populate and submit.

| Sample F | Protocol | | | | | 0495 🕜 |
|--------------------|--------------------------------------|----------------|---------------|---------------------|-----------------|------------------------|
| Project Tree 🗸 | | | | | | |
| Sample F O Res | Protocol earch Protocol Applic | ation | | | | |
| -0 | Annual/Continuing R Adverse Event | eview Report | | | | |
| 0 | Post-Approval Docu | mentation | | | | |
| Form Status | | Review Referen | ce | | ate Modified | |
| Not Submitted | | N/A | | 1 | 0/13/2017 18:06 | |
| Navigation | Documents | Signatures | Collaborators | Submissions | Correspondence | History |
| Post-Ap | proval D | ocument | ation | | | Show Inactive Sections |
| Section | | | Question | s | | |
| Post-Approval Doc | umentation | | Post-Ap | proval Documentatio | n | |

Complete the **Sub-Form** as accurately as possible.

- You may click the **Save** tile to save your progress at any time.
- The **Print** tile will allow you to save and/or print the form as a PDF.
- Click the **Submit** tile to lock your Annual Report and send it to the Fairfield IRB.

| Actions 🛩 | Total number of subjects who have died:" |
|--------------------------------|---|
| Previous Next Navigate | Total number of subjects who are still active in the study:* |
| Print Documents Share | 12 |
| Collaborators Signatures Barre | Date Protocol Closed (if applicable): 07/17/2014 |
| Bubmit | Description of any unforeseen/adverse events (if applicable): |
| | Please select the status of your research study:* Subject Enrollment has not yet begun. Subject Enrollment has begun and will continue. Subject Enrollment is complete, but follow-up with subjects will continue. The study is to be terminated. |