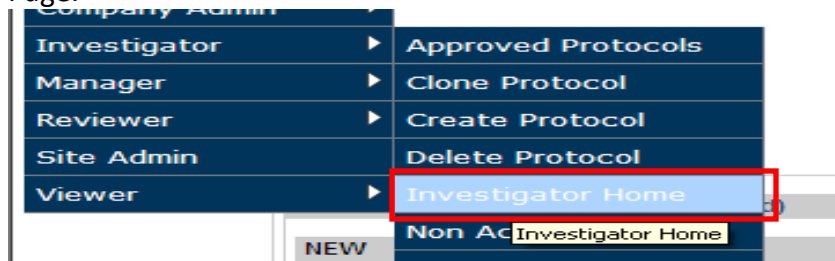


How to Create an SPA Only Form not linked to IRB Protocol

1. Sign into system using User Id and Password.
2. Using left hand drop down menu, ensure you are on the Investigator Home Page.

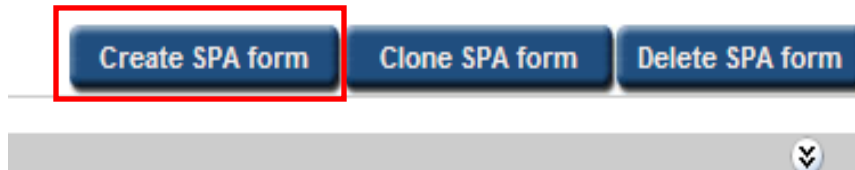


3. Click on the SPA folder tab to go to SPA system. (SPA tab will be black when you are working in SPA.)

Home



4. Click on "Create SPA Form" button.



5. Enter the Study Title.
6. Click the SPA checkbox, if the box is not checked.
7. Click in the circle to left of "SPA Form" to create the SPA Form.

[Home](#) » Create Protocol

Study Title

SPA Only Study Title - This study will not link to an IRB Project

IRB
 SPA

SPA

SPA Form

- a. You will automatically be added as the Principle Investigator; you may change the PI here or later in the form.
- b. You may enter a Study Coordinator and/or SPA Contact here, but these fields are not required.

Principal Investigator*

Allina defines the "Investigator" as an individual who conducts a research study. If the study is conducted by the investigator is the responsible leader of the team (21 CFR § 312.3[b]). Also referred to as the principal invest

Name of Principal Investigator	Degree: (MS/PhD)	Title
Anderson, Carmi .	B.S.	Research Compliance Spe
Email	Phone	Fax
carmi.m.anderson@allina.com	612-262-4927	612-262-4953
Practice Group	Mailing Address	
Research Administration	10105	

8. Click the "Create" button at the top of the form.

All projects must include the following documents in "Attachments" in eProtocol:

- Schedule of Events – Schedule of events marked to identify non-billable services
- PI Assurance
- IRB Approval Letter
- Signed Work Order – SPA will sign and replace with a fully executed version
- Consent Form (prefer approved one, but will accept the one submitted to IRB)
- Lab Manual or protocol if lab services are required

The following are required for device studies or may be requested by SPA at any point for any study as long as it is active within Allina:

- FDA letter(s) listing IDE category
- Protocol
- Billing Guides – if available from sponsor