**Application for Amendment – STAFF CHANGES ONLY**

**(Including name changes for individuals listed in previously approved documents)**

**CAUTION: The IRB must approve all proposed changes in the amendment before implementation.**

1. **To submit the amendment in IRBNet, please do the following:**
	1. Log into IRBNet.
	2. Click on the “**My Projects**” tab, and then select the study.
	3. After opening the study, click on “**Create a New Package**”.
	4. Click on **“Designer”** tab on left menu.
	5. Click on the pencil ****icon for **“SUNY Downstate – Registration Form for DMC/IRB Review”**
	6. Using the drop down menu at the top of the page, jump to the **“Project Personnel”** section.
	7. Edit this section of the form as needed (e.g., click “X” to remove personnel or click “Add Another Individual” at the end of the form)
	8. Once you are finished filling out the form, you must press the **“Save and Exit”** button.
	9. This action will bring you back to the **“Designer”** page where you can begin to add as many documents as you require for this IRB submission.
	10. Attach this completed form. Attach the required documents listed in Section 2C. Be sure to edit the document type for each attachment. If more than just name changes are proposed, use the “IRB Application for Amendment” form.
	11. If you are someone other than the PI, click “**Share this Project**” with the PI, and follow prompts, so the PI may e-sign the package.
	12. The PI must e-sign the submission by clicking “**Sign this Package**” tab.
	13. Click “**Submit this Package**” and follow prompts.
2. **REMINDERS:**
	1. *If adding staff, please ensure all required training and applicable conflict of interest disclosures have been completed. For more information, please see the IRB Guidance on* [*Training and COI Requirements*](http://research.downstate.edu/irb/irb-training.html)*.*
	2. *For information on how to use IRBNet, see the IRB Guidance on* [*IRBNet (IRB Application and Reporting System)*](http://research.downstate.edu/irb/irb-policies.html)*.*
	3. *The PI must electronically sign the package.*
	4. *Each new PI must e- sign the submission, when adding co-PIs.*
	5. *If a PI changes, the Department Chair or Dean must e-sign the submission.*
3. **GENERAL INFORMATION:**
4. **IRBNet #:**
5. **PI:**
6. **Protocol Title:**

1. **SUMMARY OF CHANGES:**
2. **Please explain why these proposed changes are necessary (including any request made by a sponsor):**
3. **Please explain the responsibilities of each new staff member (e.g. data collection, data analysis, recruitment, and the like):**
4. **Please indicate the impact these changes will have on the participants:**
5. **Check the box below if any of the documents require amended changes to named individuals within the forms. Please upload highlighted (tracked) changes and clean (accepted) version of the documents to the Designer page of the package in IRBNet.**

[ ]  **Protocol**

[ ]  **Abstract**

[ ]  **Informed Consent**

[ ]  **Assent**

[ ]  **Parental Permission**

[ ]  **Recruitment materials**

[ ]  **Other: Specify:**

1. **If adding an additional PI to be responsible for the scientific and technical direction for this study, please complete the table below.**

 **(*If additional rows are needed, please include an additional form)***

|  |  |  |  |
| --- | --- | --- | --- |
| **Additional PI Name** | **PI Status?** | **Contact Information:** | **Answer the following:** |
|       | [ ]  Downstate Faculty Member[ ]  KCHC Employee with Clinical Privileges[ ]  Other. Specify:       | **Phone #:**       **Email:**       | **Provide the rationale for adding an additional PI:**      **Description of the roles, responsibilities and the working relationship to the primary PI:**       |

1. **If removing staff, please list the names of the those who are no longer part of the study team:**

1. **If adding staff, complete the following chart with the new staff member’s information (include new Co-PI if listed in question D):**

**(*If additional rows are needed, please include an additional form)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **a.** **Name & degree** | **b.** **Role(s) on Project.**  Examples: Principal Investigator, Co-Investigator, Coordinator, Consultant, Fellow, Resident, Student, Research Staff, Healthcare Operations only, Access to de-identified data only, Specimen shipment, etc. | **c.** **Place of employment**  | **d.** **Will this person be obtaining verbal or written Informed Consent/Authorization?** | **e.****Is this person an “Investigator for the purposes of COI reporting”?***THE PI IS ALWAYS CONSIDERED AN INVESTIGATOR FOR COI PURPOSES.*  | **f.****Will this person aid the shipment of hazardous materials (e.g., dangerous goods, specimens) to be transported by a public carrier?** |
|       |       | [ ]  SUNY Downstate[ ]  KCHC[ ]  Other:       | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** |
|       |       | [ ]  SUNY Downstate[ ]  KCHC[ ]  Other:       | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** |
|       |       | [ ]  SUNY Downstate[ ]  KCHC[ ]  Other:       | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** |
|       |       | [ ]  SUNY Downstate[ ]  KCHC[ ]  Other:       | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** |
|       |       | [ ]  SUNY Downstate[ ]  KCHC[ ]  Other:       | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** |
|       |       | [ ]  SUNY Downstate[ ]  KCHC[ ]  Other:       | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** |
|       |       | [ ]  SUNY Downstate[ ]  KCHC[ ]  Other:       | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** | **[ ]  Yes [ ]  No** |

1. **Provide any additional information for IRB consideration:**