

Required Documents for Use of Academic Associate Program

*Please use the templates/samples provided for these documents as you create your own.
Do not hesitate to email or call the program coordinator with questions or clarifications.*

1. **One-page Summary:** This should briefly summarize your study background and objectives. It must be written at an undergraduate level.
2. **Pocket Card:** This will be laminated and spiral-bound with other studies' cards for the students to carry as a quick guide. It should include the following:
 - Contact information for primary contact and alternate contact
 - Brief consent "talking points" (basically an outline of the "script"—see below)
 - Inclusion/Exclusion criteria
 - Languages that the study can enroll (usually English or English/Spanish)
 - Work flow. This will clarify the flow of screening, enrollment and completion of study procedures as appropriate.
3. **PowerPoint Presentation:** A brief, 10-15 minute presentation include the following:
 - Title Page including PI and coordinator contact information
 - Study hypothesis/objective
 - Inclusion and Exclusion criteria for enrollment
 - Work flow summary (can be copied/pasted from pocket card)
 - Detailed checklist of student responsibilities (see below; can be copied/pasted)
4. **Checklist of Student Responsibilities:** This will be used to ensure that our students complete all study procedures. It can be turned in to you (along with any source documents, such as questionnaires) to assist you in tracking enrollment numbers. Please include a space at the bottom for the student to sign.
5. **Data Collection Forms/Source Documents:** If your study involves having the students complete source documents (such as family interviews or logging patient demographics), please submit the form(s)/log(s)/etc. *Note: These documents may or may not need IRB approval. Please check with the IRB or your coordinator.*
6. **IRB-Approved Consent, Parental Permission and Assent Forms.** If your forms are available in a language other than English (such as Spanish), please include all IRB-approved versions.
7. **One-page "Script":** The students may read this document to patients/parents until they become comfortable with the study. The script must include the following required elements of informed consent:
 - Introduction of the student as an Academic Associate or Research Associate
 - We are approaching the patient/parent regarding a research study.
 - Participation is voluntary.
 - Brief explanation of the purpose of the study including identifying the PI/sponsor—whoever the contact person is on the consent form
 - Study procedures (what the patient/parent will be asked to do)
 - Risks/Benefits
 - Cost/compensation
 - Confidentiality statement (in your consent form)
 - Opportunity to ask questions of the student

8. **Two research articles pertaining to the study:** These will be posted for students who would like to learn more about the impetus, background, and/or science behind your study. Students may be asked to critically examine the articles and present them to the group.
9. **5-6 Multiple Choice Questions:** We will use these questions to test the students on their knowledge of your study. Students must pass off on each study before they can approach/enroll patients to that study.

Additional Requirements

- **Teaching commitment:** Up to 4 hours a semester of teaching by the Attending, Fellow, RC, or RA.
 - 1-2 hours is needed during orientation to teach the students about the study procedures in a small group setting
 - Clinical lectures to our second semester students
- **Application and Fee:**
 - Application with basic outline of how the AcA students will be used. **Two options:**
 - Basic service: **\$550/semester** charged at the end of the semester.
 - Assigned Research Assistant to facilitate communication between study team and AcAs. Checks in regularly to ensure that enrollments are on track.
 - Fees are used to hire students to work during the breaks in between semesters and during holiday breaks to ensure coverage and continued enrollment.
 - Comprehensive service: \$1100/semester charged at the end of the semester.
 - Basic services plus a designated Research Assistant to help with creating required documents, consulting on study set up, piloting the study and on-going problem resolution.
- **Piloting the study prior to use:** Studies must be piloted prior to implementation with the AcAs to ensure that the study is ready to go live.
- IRB Amendment to use the AcA students
- IRB Application must be updated in the following parts of the application to explain the use of the AcA program:
 - Consent Process Page: *The group "Academic Associates" should be added to the text box on question 1 of this page. The other questions on this page should be updated to indicate how the process will proceed if an Academic Associate conducts the consent process versus a regular study team member.*
 - *"All students in the Academic Associates Research Program who perform informed consent procedures are listed in the Consent Umbrella application, IRB_00076507, and have completed CITI and COI disclosures under the umbrella application. They are also listed on the study delegation log. All other study personnel obtaining consent who are affiliated with the University of Utah are listed in section 1.3 of the present application (see above)"*
 - Questions 1 and 2 on the "Resources and Responsibilities" page:
 - *Question 1, Resources and Responsibilities page: The Academic Associates are qualified to interact with potential research participants and obtain research consent via the specific research training they receive in the course PED 5900.*
 - *Question 2, Resources and Responsibilities page: The Academic Associates are trained on the details of this specific protocol via the course PED 5900.*