# INSTRUCTIONS FOR COMPLETING THE RESEARCH AUTHORIZATION FORM (RAF)

#### Section 1: General Project Information

- a. Provide the name of the Principal Investigator. Per SUNY Optometry guidelines, only a faculty or staff member can be a PI of a study (i.e. not an optometry or graduate student).
- b. Provide the full name of the study and any abbreviation, if applicable. This title should match what is on the grant submission, contract, etc.
- c. Provide a brief project overview/abstract of the study aims.
- d. Indicate if the RAF submission is for a new project or a renewal or amendment of a previously approved project. <u>All projects must be re-approved annually prior to IRB/IACUC renewal</u>. Amendments are only required for changes in the study protocol, personnel and/or budget.
- e. Indicate the type of research: Animal, Human or Other. If other, describe (i.e. record review, tissue culture).

### Section 2: Funding Information

- a. Indicate the type of funding and check all that applies. If SIVR funding is requested in addition to the RAF, please submit a Study description and detailed Budget to Dr. Stewart Bloomfield at <a href="mailto:sbloomfield@sunyopt.edu">sbloomfield@sunyopt.edu</a>.
- b. Fill in the name of the funding agency (i.e. NIH, NEI, Alcon Corp, Foundation Fighting Blindness).
- c. Indicate the specific type of grant, if applicable (R01, K23, New Investigator Award).
- d. Indicate the total project period. The project period should match what is on the grant submission, contract, etc. Include the total time from study start-up and conduct through close-out.
- e. Indicate the total funds requested. If the project is longer than one year, include funding for all years. Refer to the <u>Sponsored Programs Guide</u> for the most current Indirect Cost Rates.
- f. Indicate the facilities and administrative (F&A, "overhead") rate. Refer to the <u>Sponsored</u> <u>Programs Guide</u> for the most current rates.

#### Section 3: Shared Resources

- a. Choose Yes or No: if the project will require the use of any additional space or institutional resources beyond the investigator's approved lab space/equipment. If yes, please describe on the space provided.
- b. Choose Yes or No: if additional equipment outside the investigator's lab will be needed. If it will be borrowed from elsewhere in the college, indicate the name of the equipment and location. If it will be loaned from an outside entity (sponsor), indicate the name of equipment and donor (company). Note that if equipment will be loaned from an outside entity, the Loan Authorization Form must be completed prior to receipt of equipment.
- c. Choose Yes or No: if the study will require additional faculty or staff release time (from clinic, teaching or other assignments). All changes in effort must be approved by the Dean and VP of the UEC (for faculty assigned to clinic) prior to grant submission.

#### Section 4: Study Personnel and Compliance

List all key personnel including the Principal Investigator and their corresponding Role in the Study. Key personnel includes any person who will interact with the subjects and/or who contributes to the scientific development or execution of a project in a substantive, measurable

way. This includes faculty, students and staff. Collaborators who are only receiving/reviewing de-identified information may not be considered key personnel.

NEW Mark the Check box if the personnel have completed the <u>Annual FCOI Disclosure</u> for the current Fiscal Year, which is due every November 1<sup>st</sup>. If they have made any changes with their disclosure between November 1<sup>st</sup> and October 31<sup>st</sup>, please enter the last date when they have made the changes. The Principal Investigator should have inquired and confirmed the information with the personnel as per the additional language:

By marking as completed, the Principal Investigator confirms that all listed personnel have an up-to-date and accurate Annual Financial Conflicts of Interest (FCOI) for the current Fiscal year, and that they have completed all required CITI Training Courses.

Mark the Check box if the personnel have completed all the required CITI Training that is related to the Research Study.

Should there be any key personnel that have not submitted the required annual disclosure (new employee, new student, volunteer, etc.), please send an email to <u>RAFsubmissions@sunyopt.edu</u> and indicate the following:

- 1. Statement that an RAF is currently in the process of submission
- 2. Title of Research Study
- 3. First and Last name of Personnel
- 4. Role in the Study

#### Section 5: Animal Subjects Research Information

- a. Complete and attach an <u>NIH style budget page</u>.
- b. List the species of animal being used.
- c. List the strain(s) of animals being used.
- d. List the number of animals for each species/strain.

# Section 6: Human Subjects Research Information

- a. List the maximum number of subjects who will be enrolled and indicate if minors will be enrolled. List the primary inclusion and exclusion criteria or generally describe the population that will be recruited.
- b. List the primary procedures/tests that will be conducted or equipment that will be used for the study. Indicate if treatment will be proved (e.g. vision therapy, medical treatment) and if participants will be billed for anything.
- c. List all locations where subjects will be screened, examined or treated during the study.
- d. Describe the study visits. Include the maximum number of study visits, the estimated duration of each study visit and schedule of study visits. For example: 4 visits, each lasting for 1 hour and scheduled over 2 months; or 2 visits lasting 2 hours and 2 hours each, scheduled one week apart.
- e. Indicate how potential subjects may be recruited. Note that all recruitment materials (including direct to patient emails, flyers, internet postings, etc.) must be approved by the IRB prior to using.
- f. Provide a detailed budget for the study. The following are guidelines for costs associated with each type of clinical research study. If any items are not being covered, please provide the reason on the **Other/Notes** section.

Generally, the budget should consider the following:

- Principal investigator salary offset
- > Offset for other investigators (may be based on FTE or hourly rates)
- Study coordinator costs
- Subject payment costs (including Greenphire electronic subject payment costs, as applicable)
- Start-up/close-out and oversight costs
- > Advertising, recruitment and subject retention costs
- Institutional review board costs

Note: Contracts and allowable costs vary widely by sponsor, but total budgets must be sufficient to cover actual costs or have approved cost-share

### **Section 7: Certification**

a. After completing the form, the PI should read the certification statement and sign.

#### The completed RAF should be emailed to <u>RAFSubmissions@sunyopt.edu</u>. Pls may attach any other relevant documents to the email.