



Office of Grants & Sponsored Research

Grants Bulletin

Fall 2020

The Office of Grants and Sponsored Research (OGSR) represent the *pre-award* administration office and non-financial post award administration at St. John's University. We provide service and support related to research activities across all schools and units at the University and work closely with the Office of Business Affairs regarding post-award items such as the financial management of sponsored projects.

Sponsored programs include research, instruction and training, public service, evaluative testing, and other scholarly and creative activities conducted under the direction of University faculty and staff and funded by organizations external to the University in accordance with award regulations.

Please visit our website for more in depth information at:

<https://www.stjohns.edu/academics/research/grants-and-sponsored-research>

FALL 2020 OGSR WORKSHOPS

#1. Elements for Grants Success

Monday, October 26, 2020

2:00 pm – 3 pm

Via WEBEX

The Elements for Grants Success workshop will inform you of the “do’s and don’ts” of proposal writing and submission preparation. Enhance your understanding of sponsor review criteria, provide constructive proposal building techniques and much more.

#2. So You Want To Do Research?

Thursday, November 5, 2020

2 pm – 3 pm

Via WEBEX

This workshop is designed to introduce students to sponsored research opportunities and application process, with an emphasis on NIH mechanisms designed to increase experiential learning.

To attend a place for either of these workshops, please contact Adrianna Berlingiero x6276 or berlinga@stjohns.edu

AWARDS SPOTLIGHT

NIH R01

Seeking to better understand the relationship between cell membrane proteins and a genetic kidney disease, [Yong Yu, Ph.D.](#), Associate Professor, [Biological Sciences](#), [St. John's College of Liberal Arts and Sciences](#), was recently awarded a \$1.33 million [National Institutes of Health \(NIH\) Research Project Grant \(R01\)](#) to support his research at St. John's University as principal investigator (PI) in collaboration with the University of Maryland (primary institution).

Along with his fellow PI, Feng Qian, Ph.D., of the University of Maryland, this \$2.7 million, multi-PI, five-year grant is entitled, "Ion Channel Function and Regulation of the Polycystin-1/2 Complex in Kidney Physiology and Polycystic Kidney Disease."

The Research Project Grant (R01) provides support for health-related research and development based on the mission of the NIH, and is the original and historically oldest grant mechanism used by that esteemed institution.

"We are working on two cell membrane proteins named polycystin-1 (PC1) and polycystin-2 (PC2)," explained Dr. Yu. "Mutations in the genes coding these proteins lead to autosomal dominant polycystic kidney disease (ADPKD), one of the most common human genetic diseases."

According to Dr. Yu, ADPKD affects one in every 400 to 1,000 individuals. People suffering from ADPKD develop multiple fluid-filled cysts in their kidneys, which affect normal kidney function and may eventually cause kidney failure.

"So far, the roles of these proteins in kidney function and how mutations in these proteins cause this disease are largely unknown," he said. "Understanding the way they work in cells is critical for finding a cure for this disease."

He explained, "In my lab, we try to understand how proteins function as 'molecular machines.' We use state-of-the-art equipment and techniques to detect their structures and monitor their activities, even at the single molecule level. One of the most exciting parts of our research is to figure out how the structure of a protein determines its function, which allows us to explain biological processes or pathogenesis of diseases."

This five-year R01 grant gives full support to a full-time postdoctoral researcher to work in the lab and funds equipment, lab supplies, publication, conference travel, and more.

“The long-term goals of my lab are to understand the biological functions of PC1 and PC2 and figure out why mutations in these proteins lead to ADPKD,” he said. “We hope our results can enhance our understanding of ADPKD and provide guidance in developing more effective treatments for patients.”

INTERNAL REVIEW BOARD (IRB) UPDATES

COVID-19 Human Subjects Research Guidelines

The IRB's mission is to protect human subjects from any harm that could befall them by participating in research. The CORONAVIRUS pandemic provides additional risks to research subjects beyond those they usually encounter.

IRB Certification Course

All researchers working with human subjects must complete a certification course.

The IRB is now using new training course for IRB certification.

The course is through Canvas and the link to access it is below:

<https://stjohns.instructure.com/enroll/YELENP>

Please note: Certificates are valid for 5 years from the issue date.

COVID-19 Human Subjects Research Guidelines

Request to Resume Face to Face Data Collection

The IRB's mission is to protect Human Research Subjects from any harm that could befall them by participating in research. The CORONAVIRUS pandemic provides additional risks to research subjects beyond those they usually encounter.

Since the Spring of 2020, researchers at St. John's University have been prohibited from collected data face-to-face and have been restricted to collecting all data virtually. As the COVID-19 virus infection rate has reduced, and New York State has opened up, some researchers have sought permission to collect data face-to-face. The IRB has agreed to allow this under certain conditions.

The IRB encourages all researchers to collect data virtually when possible. All researchers who wish to collect data face-to-face must explain to the IRB why the data for their project cannot be collected virtually.

I. IRB COVID-19 Application Requirements

- a. Consistent with the University's global mission, researchers at St. John's University collect data across many jurisdictions. The rates of COVID-19 infections vary widely by location. Therefore, the IRB requests that researchers specify the geographic area where they plan to collect data. Researchers must indicate the country, state, county, and city or town where they intend to collect data and describe the extent of the COVID-19

pandemic disease in that area. One possible source of this information is the Johns Hopkins University CORONAVIRUS Resource Center (<https://coronavirus.jhu.edu/>). However, researchers are free to use other sources of information.

- b. Researchers must also describe any statistics indicating the degree of infection or any regulations concerning quarantine or health guidelines provided by the state or local government where they intend to collect data. For example, New York State hosts a website that gives information on the rates of infections, positive test results, and reopening guidelines for ten regions throughout the state (<https://forward.ny.gov/>). If researchers are collecting data in other jurisdictions, they should consult the local government's websites. If researchers are collecting data in more than one area, their IRB application should provide this information for each location to collect data.
- c. We recognize that the rate of CORONAVIRUS infections varies widely by the type of building or facility where researchers might encounter subjects. All applications should describe the type of facility where the researchers will recruit subjects and whether that type of facility is known to have a higher infection rate or houses people who are at higher risk of infection or mortality.
- d. Researchers must comply with all St. John's University COVID-19 policies based on federal and state public health regulations (e.g., physical distancing, face coverings, cleaning/disinfection, etc.). In addition to these policies, researchers must obey all the facility regulations where they conduct their study. These policies and how researchers will comply with them must be stated in the application for approval.
- e. All researchers must specify how they will comply with any Federal, State, or local government safety guidelines. The researchers are responsible for discovering what regulations exist in any location where they will collect data. The US Government's Center For Disease Control and Prevention (CDC) provides an extensive website with information on preventing CORONAVIRUS infection (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html>). The local jurisdiction where researchers wish to collect data might have additional guidelines or requirements about behaviors that could control the disease's spread. For example, New York State provides a web site that describes the State's re-opening guidelines and regulations to prevent infections (<https://forward.ny.gov/>). Researchers must describe in detail what procedures they will take to comply with the CDC, State, and any local governmental requirements. Such statements will include the use of Personal Protective Equipment (PPE), social distancing, partitions that separate the researchers and subjects from each other, and any other any federal, state, or local restrictions.
- f. All researchers will provide a comprehensive COVID-19 safety plan in the methods section of their Cayuse application.
- g. Researchers must comply with all St. John's University COVID-19 policies based on

federal and state public health regulations (e.g., physical distancing, face coverings, cleaning/disinfection, etc.). In addition to these policies, researchers must obey all the facility regulations where they conduct their study. These policies and how researchers will comply with them must be stated in the application for approval.

- h. All researchers must specify how they will comply with any Federal, State, or local government safety guidelines. The researchers are responsible for discovering what regulations exist in any location where they will collect data. The US Government's Center For Disease Control and Prevention (CDC) provides an extensive website with information on preventing CORONAVIRUS infection (<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html>). The local jurisdiction where researchers wish to collect data might have additional guidelines or requirements about behaviors that could control the disease's spread. For example, New York State provides a web site that describes the State's re-opening guidelines and regulations to prevent infections (<https://forward.ny.gov/>). Researchers must describe in detail what procedures they will take to comply with the CDC, State, and any local governmental requirements. Such statements will include the use of Personal Protective Equipment (PPE), social distancing, partitions that separate the researchers and subjects from each other, and any other any federal, state, or local restrictions.
- i. All researchers will provide a comprehensive COVID-19 safety plan in the methods section of their Cayuse application.
- j. Our website on informed consent statements includes some elements related to the risks of infections when participating in research at this time. (<https://www.stjohns.edu/academics/research/grants-and-sponsored-research/human-participants-irb-animal-use-research> a description of any reasonably foreseeable risks or discomforts to the subject). All consent forms in studies with face-to-face data collections must specify that "participating in this study puts me at risk for exposure and contracting COVID-19." Also, informed consent statements should include a section indicating that the study could be terminated if a serious rise in COVID-19 infection rates occurs. Such termination will affect any treatment that the study provides to the subject.

II. IRB COVID-19 Guidelines Following IRB Approval

The CORONAVIRUS is an exceptionally infectious disease, and the rates of infection can change quickly in any location. Because of this potential rapid change in infection rates, we ask all researchers to take the following actions.

- a. The infection rate could change between the time a researcher receives IRB approval to start their project and the time they begin data collection. All researchers must file an **Update Report** to the IRB on the day they start data collection. This report should specify that the COVID-19 infection rate has not significantly increased where they are collecting data and that there has been no change in the State or local government regulations since the protocol for their study was approved. (This report will be uploaded to your IRB application in

Cayuse.)

- b. Researchers are responsible for informing the IRB if the infection rate changes significantly where they are collecting data and stopping data collection if such a change occurs or if the State or local government imposes restrictions on social contact. The researcher can file an **Incident Report** if such an event occurs.
- c. All researchers should make contingency plans to stop collecting data and switch to virtual data collection if a series of infections arise.
- d. All researchers must submit notification to the IRB when the F2F aspect of their research is completed. (This notification will be uploaded to your IRB application in Cayuse.)

We recognize that the COVID-19 places more responsibility on researchers and that preparing an IRB application involving face to face contact will be more difficult. Each study will be reviewed on a case by case basis.

STUDENT RESEARCH OPPORTUNITY CENTER (SROC)

The **Student Research Opportunity Center (SROC)** is located inside the main entrance of the **D'Angelo Center**, featuring two 50-inch touch-screen monitors that provide listings of research opportunities available to both undergraduate and graduate students.

The SROC was created to engage more students in research and projects (high impact practice) that would afford undergraduate and graduate students internal research opportunities. Students can benefit from these opportunities by gaining knowledge and experience to support their career goals. Our aim is to create the researchers of tomorrow. At St. John's University, you will find a very supportive researcher environment at every level.

We invite and encourage faculty to take advantage of the SROC by filling out the [Research Project Student Request Form](#) information about any opportunities you can offer.

The SROC benefits students as well as faculty by promoting the culture of research on campus. As positions are posted, we will contact students to alert them of new research opportunities available via the SROC.

TIME and EFFORT POLICY

The full institutional Time and Effort policy can be referenced at:

[Time and Effort Policy](#)

In order to certify that effort expended on a project is at least commensurate with the salary charged against the sponsored program, the University employs an after-the-fact effort reporting system for faculty, administrators, and staff who have a portion of their salary or time charged to a sponsored program. Individual effort reports are required for each cycle, as defined below, for all employees who have a portion of their salary or time charged to a federal sponsored program as mandated. The Office of Grants and Sponsored Research (OGSR) shall ensure full compliance with the University's time and effort reporting requirements and along with Business Affairs, maintain full documentation, which will be available for inspection by the University's auditors.

INTERNAL REVIEW PROCESS FOR ALL OUTGOING PROPOSALS

All outgoing proposals being submitted to the attention of an external sponsor (including individual applications and Fellowships) must first be vetted through the Office of Grants and Sponsored Research prior to agency deadlines in order to ensure compliance to institutional and external regulations, adhering fully to this internal review process.

Any awards that subsequently result from independent submissions without prior OGSR administrative review will be automatically deemed as non-compliant with this internal process and run the risk of being declined by the University.

In order to guarantee the submission of all competitive grant proposals, it is required that all final applications for external support be in receipt of the Office of Grants and Sponsored Research for internal review no later than **five (5) business days prior to the applicable agency deadline**.

Sufficient lead time should be provided for institutional review and endorsement, and to accommodate applicable submission mechanics (either electronically or hard copy). The OGSR will do everything possible to ensure that a proposal is submitted complete and on time; however, as the amount of processing time is reduced, so are our chances to take the appropriate actions leading to strong, competitive grant awards.

***All cost share requests must undergo initial vetting and secure the approval of Business Affairs,** and advance time must be afforded them in order to review any and all SJU contributions prior to your submission. All such final proposals (bearing the approvals of your Chair, Dean or Supervisor) should be in receipt of the OGSR no later than **ten (10) business days prior to the agency deadline**.

Once your budget is finalized, the assigned OGSR Grants Specialist will provide you with the electronic **Cayuse SP internal review** platform for routing through administrative channels. Through use of this system, OGSR will initiate an electronic routing chain which will require the initial approvals of (in following order) the PI, Chair, Dean (or applicable Director).

The following supporting documentation should be uploaded into Cayuse for review:

- **Final Budget/Justification**
- **Abstract**
- **Proposal Narrative**

Only after these internal authorizations are in place, the OGSR will submit the complete proposal to the attention of the sponsor.

Proposals not following these described procedures and internal deadlines will be **deemed as non-compliant with institutional process**, and their submission cannot be guaranteed as a result.