



Research Office 2017 Report to the Academic Departments

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Research Office 2017 Report to the Academic Departments

Research Office (RO), on behalf of the ADU research committees: Scientific Review Committee (SRC), Institutional Review Committee (IRB), External Funding Steering Committee (EFSC), and Environmental Health and Safety Office (EHS); compiled the following Research Office 2017 Report for the Academic Departments. This report is a summary of the accomplishments and challenges that the research committees faced during our pilot year of the new ADU research process. Also, this report includes some improvements made to minimize issues for the next school year.

The goal of this report is to bring communication between all research committees and the research course instructors who are responsible to educate and coordinate research efforts for the faculty and students in their departments. Also, we would like to elicit your inputs to enhance the ADU research process and application form.

Following are the challenges faced by the various research committees:

1. Submitted application form missing/erroneous information:

- Some student applications submitted identified supervisors who were not ADU Faculty. All students must have an ADU faculty (full-time, adjunct, part-time, affiliated) as supervisor.
- Literature review was only an annotated bibliography. The investigators must provide a brief literature review with references.
- Problem statements and/or hypotheses and/or aims of the studies do not flow with the underline purpose of the study. There needs to be a logical sequence of thoughts and methodology to answer the research question.

- Incomplete narration for research design and methods. Instrumentation for data collection, how the study will be conducted, type of data / samples (where and how the samples will be collected, stored, and analyzed) need to be described with clear details.

2. Missing documents during the application submission:

2.1 CITI Certificates:

- Incomplete CITI certificates attached to the web application form. All investigators identified in the submission must upload all the required CITI certificates. The minimum requirement from ADU is:
 - Question 1 – Human Subjects Research. You are required to complete only one of the following modules: Biomedical Research Investigators OR Social & Behavioral Research Investigators OR IRB member.
 - Question 2 – Health Information Privacy and Security (HIPS).
 - Question 3 – Responsible Conduct of Research. You are required to complete only one of the following modules: Faculty OR Staff OR Students OR IRB members.

Other CITI modules are dependent on the type of study. These modules are:

- Question 4 – Good Clinical Practice
- Question 5 - Biosafety/Biosecurity

The RO will advise the investigators on any additional needed modules. For detailed information, please see ADU Research Project Submission Guideline attached.

- FH CITI or any other institution CITI will NOT be accepted by ADU. Each institution has its own regulations and required CITI modules. However, when seeking external CITI certification, overlapping modules are recognized by CITI and will not need to be repeated. For more information on ADU and FH CITI modules, please see the FH and ADU CITI document attached.

2.2 Instrumentation:

- Some submissions were missing instrumentation attachments. Any survey, questionnaire, or other instrumentation to gather data is necessary to upload with the application submission.
- Instrumentation used was not validated. It is expected that any instrumentation is properly validated as much as possible.
 - Please, make sure to search for validated instruments that can produce accurate and precise results within the scope of its intended use.
 - Using validated instrumentation helps in dissemination efforts into a scientific/professional conference and/or journal.
 - If the investigators describe in the submission form that plan to submit the study to any scientific journal, SRC will look for validated instrumentation to assure quality expected for publication.
 - Only use non-validated instruments if validated ones are not available. Please indicate this in the application form.

2.3 Consent Form:

- Some submissions involving human subjects did not include the Consent Form. All research involving human subjects must provide a document to elicit agreement from participants with full knowledge of their voluntary participation, study purpose, study procedures, any potential discomfort, risk, and benefits, confidentiality, costs and compensation for participation, and contact information.
 - ADU IRB Policies and Procedures provides the definition: “Human subjects are defined as living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [Federal Policy 45 CFR §46.102(f)].

- Examples of the collection of human subject data include: face-to-face surveys, email surveys, or by any other type of data collection interaction with the subject; focus groups with qualitative data analyses; or treatment studies.

2.4 Study Site Director Approval Letter:

- Some submissions were missing the Study Site Director Approval Letter. This is to assure that the investigators will not violate any of the site's expectations and regulations. This letter acknowledges that the investigators have received approval to conduct the research at the identified study site. This letter needs to have the Principal Investigator's name, project title, facility's name, facility director's name, contact information, and signature. The Study Site Director Approval Letter is necessary:
 - When the study is collecting data outside of ADU, for example, Cardiology Center of FH.
 - When the study collection and/or data analysis take place in an ADU Center, Laboratory, or department that is external to the PI.
- See Study Site Director Approval Letter template attached.

2.5 Quotes for Grant purposes:

- Some grant submissions did not include supporting documents. All itemized grant application must be accompanied by rationale and documented quotes of costs.

3. Statistical Analysis

3.1 Sample size:

- Some submitted projects indicated small sample sizes. Sample size is often a concern in research publications. Therefore, it is prudent to determine necessary sample size in accordance to study design by consulting a statistician prior to submission.

3.2 Data analyses and rationale:

- Limited description of the data analyses. Please, list the study variables and describe the specific method(s) / tests for your data analysis along with their underlying justification. Please consult a statistician for assistance if needed.

Following are the improvements that will be in place by the beginning of fall 2017, based on the challenges listed above:

1. Submitted application form missing/erroneous information:

- The **Web Application Form** was reviewed from the RO and research committees chairs. Improved instructions and explanation for each section were made.
- A **Working Document** was created to build a draft for online submission. It may be used to collaborate and communicate between supervisor and co-investigators. The finished document can be copied and pasted to the web application form. See the document attached.

2. Missing documents during the application submission:

- To minimize the missing documents in the application submission, the research web application form was updated with the creation of mandatory parts, including the necessary upload documents.
- The **Research Project Submission Guideline** has been updated. This guideline provides information on:
 - ADU Research Project Submission Process and Timeline
 - Requirements for application to ADU Research Project Submission Process
 - Research Project and Professional Projects Definitions and Criteria
 - Required application documents
 - Web-based Research Project Submission steps

See the document attached.

- A **Study Site Director Approval Letter template** has been created. See the document attached.

3. Statistical Analysis:

- Research Office holds a **Generic Laptop with Statistical Analysis Software (concurrent license)** for a loaner. There is an open login and it currently has the SPSS and NVivo software.

4. Research Communication

- **The information was updated in MyADU – University Research and contains all the documents described in this report.**
- The Research Office will produce the **ADU Research Newsletter** that will be launched annually. It will provide information of our annual achievements and contributions from various ADU departments and Centers of Excellence. It will also provide a variety of research nuggets.
- Research Office is available for consultation on research matters.
- Research Office recommends that research courses include discussion of the **Research Project Submission Guideline**.

5. Scientific Review Committee (SRC)

- The number of SRC members were increased.
- The types of approvals were reviewed and updated to:
 - Approved as submitted
 - Approved with recommendation(s)
 - Approved pending required change(s)
 - Change(s) required for resubmission