

1.13 Student Research and Scholarly Activity and Research (Elective) Rotations during 3rd and 4th year

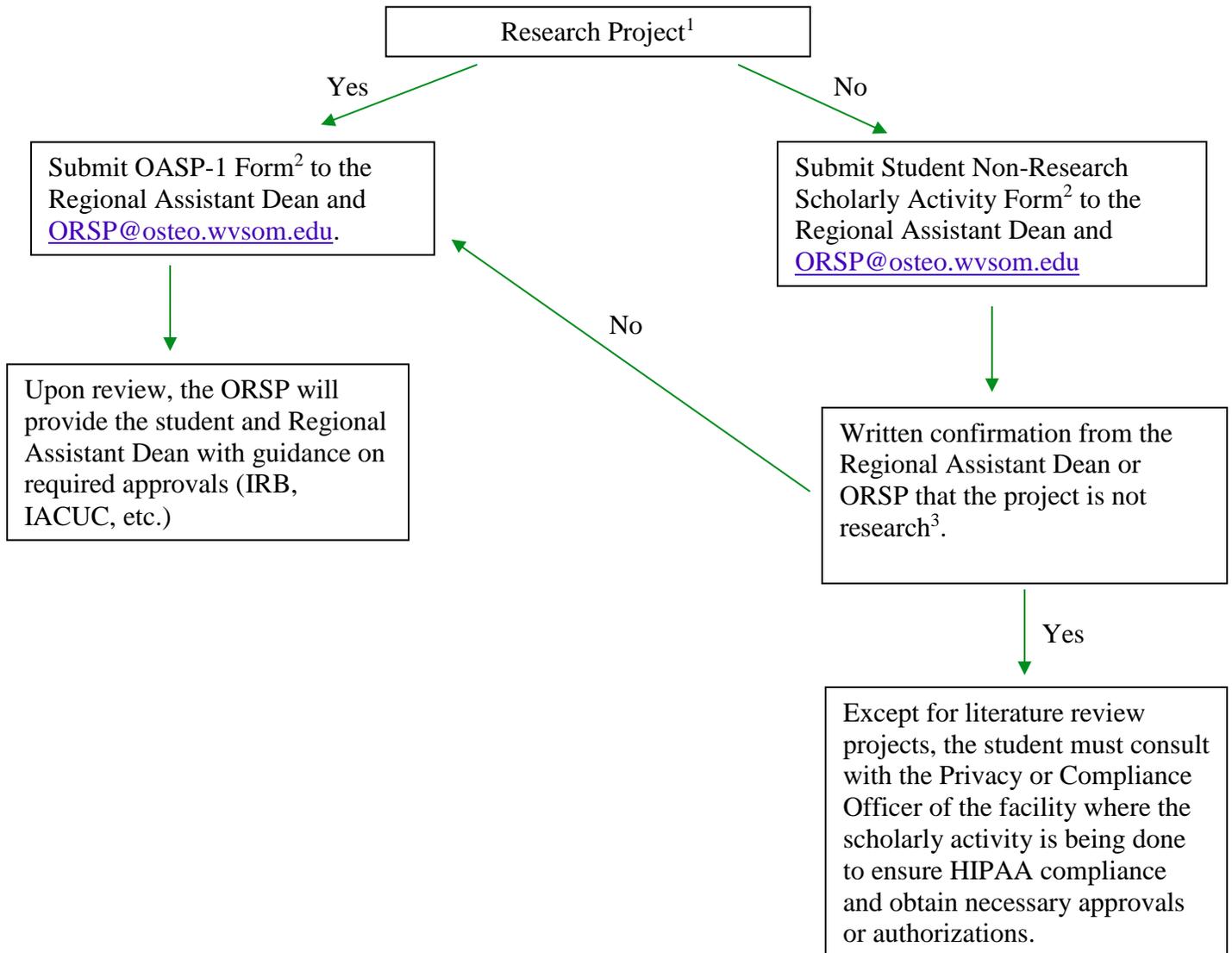
Students are encouraged to participate in research or other types of scholarly activity either as an elective rotation or while completing regular rotations. The federal Common Rule defines research as “a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge”. (Source: Code of Federal Regulations 45CFR46.102). Other types of scholarly activity include Quality Assurance/Quality Improvement (QA/QI) projects, case reports and literature reviews. Students should consult with their Regional Assistant Dean to determine which types of scholarly activity may qualify as an elective rotation. Regulatory and approval processes will differ depending on the type of project as described below.

Students involved in research projects or other scholarly activity must work with a WVSOM employee who will help guide the student through the approval process and ensure that required permissions are in place, even if the project is not being done as part of an elective rotation. This employee may or may not be the Principal Investigator (PI). For example, if a student works with a PI at a remote clinical facility, the PI at that facility is entirely responsible for the proper conduct of the study. In consultation with the PI, the WVSOM Regional Assistant Dean or other Dean-designated employee will assist the student in obtaining required institutional permissions and will monitor the educational aspects if the project is being done as an elective rotation. Research/Scholarly electives may only be taken in the second six months of the third year during an elective or during the fourth year. All requirements outlined in this document apply to both third and fourth year students who are on-campus or off-campus. No more than a total of eight (8) weeks of elective rotations and/or vacation time may be utilized for a research elective. (Refer to Policy E-16)

Approval Process Overview

The approval process for scholarly activity depends on the nature of the project (summarized in the diagram below). The first step is to determine if the project meets the regulator definition of research. Case reports that are a retrospective analysis of 3 or fewer clinical cases fall into the non-research category. Reporting on more than 3 cases is categorized as research activity and must follow the approval process for research. Quality improvement, which is not classified as research activity, is defined as “a systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product”. Guidance on determining if a project is research or QA/QI can be found at the end of this section and on the ORSP web page. The IRB may be consulted for assistance in making this determination. Steps that must be taken for approval of research projects and other scholarly activity are described below.

Student Scholarly Activity Flow Chart



¹Case reports involving 3 or fewer cases and literature reviews are not considered to be research for regulatory purposes. Refer to the guidance document available on the ORSP web page (<https://www.wvsom.edu/Research/publications>) for additional information on the differences between QA/QI and research.

²These forms are available on the ORSP web page at <https://www.wvsom.edu/Research/ORSP-forms>

³Contact the WVSOM IRB at irb@osteowvsom.edu if assistance in making this determination is needed or to request an official non-human subjects research determination letter.

Timely preparation of all required materials should begin well in advance of project initiation to ensure review and approval by the appropriate Regional Assistant Dean, the PI or supervisor and other administrative departments as needed based on the nature of the project. It is recommended that you begin the approval process at least 60 days prior to the expected start date.

Approval Process for Research Projects

1. A project initiation request form (ORSP-1) must be submitted to the ORSP (ORSP@osteo.wvsom.edu) for all research projects. For projects on which the PI is a WVSOM employee and ORSP approval is already in place, the PI can simply inform the ORSP that the student is being added to the study team. For projects on which the PI is not a WVSOM employee, submit the Project Initiation Request-form (ORSP-1) to ORSP@osteo.wvsom.edu, including all requested details. The form must be approved and signed by the Principal Investigator and the WVSOM liaison (typically the Regional Assistant Dean). WVSOM students may not serve as the Principle Investigator.
2. Following review by the ORSP, students are notified of next steps, including referral for IRB approval and CITI training (which must be completed prior to IRB approval of the project). IRB approval may require a reliance agreement with a remotely located IRB as explained below. Projects that do not involve human subjects may require other approvals such as HIPAA authorization, Animal Care and Use Committee approval or Biosafety Committee approval. Guidance regarding necessary approvals will be provided by the ORSP.
3. If the research is being done as an elective rotation, a Research Plan must then be reviewed and approved by the Regional Assistant Dean. The completed Research Plan must be submitted to your Regional Statewide Campus a minimum of 30 days prior to initiation of the project.

The Research Plan must include:

- a. The name of the Principal Investigator with contact address, phone and e-mail;
- b. A copy of the ORSP-1 form and ORSP approval;
- c. A copy of IRB or other approval letters or exempt determination letter;
- d. A detailed description of the student's role in the project; and
- e. Written acceptance of the student into the project by the PI.

All research involving human subjects must be reviewed by the WVSOM IRB, which will make a determination regarding approval and assess whether an IRB agreement is needed with any local IRB. Such an agreement may be needed if a student plans to work under the supervision of a PI who has received IRB approval from a local IRB. If this is the case, then a reliance agreement must be in place between WVSOM's IRB and the local IRB. Note: Any such agreement must be in place before the student may begin working on the study.

QA/QI Projects and other Scholarly Activity

A Non-Research Scholarly Activity form must be submitted to the Regional Assistant Dean who will confirm, in consultation with the ORSP or IRB as needed, that the project is not classified as research. The student will be notified in writing of this assessment. An official non-human subjects research determination letter may be requested of the IRB by checking the correct box on this form. These letters are required by some journals for publication and must be written prior to initiation of the study. If the project is determined to be research, the student must follow the procedures described in the above section. If the project is not classified as research, the student must still consult with the Privacy Officer of the facility where the project is being done to obtain any necessary authorizations or waivers regarding use of private health information data.

For scholarly activity being done as an elective rotation, a project plan must then be reviewed and approved by the Regional Assistant Dean. This plan must be submitted a minimum of 30 days prior to initiation of the project and must include

- a. a copy of the Non-Research Scholarly Activity Form
- b. A detailed description of the project and the student's role in the project
- c. For projects involving use of patient data, a copy of any necessary agreements, authorizations, waivers and/or a letter from the facility Privacy Officer approving use of data for the project.
- d. Written agreement from the supervisor/mentor to oversee the student project.

As this is an elective portion of the WVSOM program, the following must be understood and agreed to:

- All expenses associated with a special elective or other scholarly activity are borne by the student, i.e., travel, meals, board, and required or optional materials.
- Proof of active health insurance is required.
- Scheduled rotations will not be revised to accommodate a special elective.
- Elective rotations must be overseen by a DO or MD for grading.
- For elective rotations, the final data, article or report must be submitted to the Regional Assistant Dean and the Associate Dean for Predoctoral Clinical Education within 6 weeks of completion of the rotation. For research projects, a copy must also be sent to the Associate Dean for Research and Sponsored Programs who must approve it in order for the student to receive credit for the rotation.
- The term "research" should not be used in any presentations or publications regarding QA/QI projects.
- Students can consult with the Principal Investigator or Associate Dean for Research and Sponsored Programs to inquire about potential funding or travel expenses to present scholarly activity

Summary Checklist for Research or Scholarly Activity Elective Rotations

Submit the following documentation to the Regional Assistant Dean:

- A. Copy of the ORSP-1 or Student Non-Research Scholarly Activity form and letters of approval
- B. Copy of any additional necessary approvals (IRB approval, HIPAA authorization, etc.)
- C. Verification/evidence that the PI has approved student participation in the research project and added the student to the IRB protocol when relevant. For other types of scholarly activity, verification that a supervisor/mentor has agreed to oversee the project
- D. Copy of the research protocol or project plan
- E. A one-page summary of the educational benefit of the rotation and a signed Elective/Selective Rotation (ESR) Form approving the scholarly activity with the evaluation form.

For elective rotations, a final article or report must be submitted to the Regional Statewide Campus Office upon completion in order to receive academic credit.

For research projects, a copy of the report must also be forwarded to the Associate Dean for Research and Sponsored Programs in order to receive credit.

Institutional Guidance Document*

Quality Assurance/Quality Improvement Projects

1. PURPOSE

The purpose of this guidance is to assist faculty, students and other personnel on the definition of Research versus Quality Assurance/Quality Improvement (QA/QI). In addition, the guidance provides resources to support the development of QA/QI projects. Whenever there is uncertainty as to whether a project is considered to be research or QI, the project leader should request guidance from the WVSOM Institutional Review Board (IRB). **The IRB cannot retroactively approve research.**

It is the responsibility of the project leader who initiates a project to determine if it is research or QA/QI. Research projects must comply with specific policies and regulations designed to protect human subjects and privacy rights. However, it may be difficult for a project leader to determine if his or her project is research or QA/QI. Since this determination may have a significant impact on the project design, procedures, and regulatory compliance, the project leader should not hesitate to ask the IRB for guidance. There are serious consequences for not following WVSOM research policies and procedures and federal regulations when conducting research.

2. APPLICABILITY

This guidance applies to all quality assurance/quality improvement projects undertaken by staff, faculty or students at WVSOM.

3. HOW TO USE THIS GUIDE

The first section provides definitions for Research and Quality Improvement. The second section provides certain characteristics typically associated with research and QI projects. Once you review the definitions and characteristics, you should be able to determine the appropriate category for your project. **If you determine that the project is similar to both definitions, the project is research.**

Section 1. Definitions

What is research? The federal Common Rule defines research as “a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge”. (Source: Code of Federal Regulations 45CFR46.102).

What is Quality Improvement (QI)? Quality improvement is defined as “a systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product. The Institute of Medicine (IOM) defines quality in health care as a direct correlation between the level of improved health services and the desired health outcomes of individuals and populations. Source: Institute of Medicine

Section 2: Characteristics of Research Projects and Quality Improvement Projects

Research	Quality Improvement
<p>Research projects must meet IRB requirements for protection of human subjects. Researchers conducting research must also meet HIPAA and FERPA requirements regarding authorization to use or disclose protected health information.</p>	<p>Quality Improvement projects are not covered by IRB requirements. Members of the workforce are allowed by HIPAA to use protected health information for Quality Improvement projects without patient authorization.</p>
<p>Characteristics of Research:</p> <ul style="list-style-type: none"> • One of the main goals of the project is to advance general knowledge in the academic, scientific, or professional community. • The project will have a specific hypothesis or research question. • The project involves a comprehensive review of relevant literature. • The project will be conducted using a research design that will lead to scientifically valid findings. Elements of a research design include: control groups; random selection of subjects, statistical tests, sample design, etc. • Most of the patients/subjects are not expected to derive a personal benefit from the knowledge gained. • One goal of the project is to generate, evaluate or confirm an expletory theory or conclusion and invite critical appraisal of that conclusion by peers through presentation and debate in public forums. 	<p>Characteristics of Quality Improvement:</p> <ul style="list-style-type: none"> • The project identifies specific services, protocols, clinical or educational practices, or clinical processes or outcomes within a department, clinical program or facility for improvement. • The project team may review available literature and comparative data, or clinical programs, practices or protocols at other institutions in order to design improvement plan, but do not plan a full comprehensive literature review. • The project design uses established quality improvement methods (such as DMAIC, PDSA cycle) aimed at producing change within a health center, hospital and/or community setting. • The project design does not include sufficient research design elements to support a scientifically valid finding. • Most of the patients who participate in the project are expected to benefit from the knowledge gained. • The project does not impose any risk or burden to individuals. • The main goal of the project is to improve patient care, clinical care or services, and/or educational processes.

4. WORKING ON QUALITY IMPROVEMENT PROJECTS WITH CLINICS, HOSPITALS AND OTHER COMMUNITY ORGANIZATIONS

Contacting a clinical mentor or faculty member and also the health care provider (clinic, hospital, social-service agency administrator) where you will be completing a QA/QI project is a good starting point. Health care providers must all meet Health Information and Patient Protection Act

(HIPAA) guidelines and may have specific policy and procedure about accessing health care information at their site. They also will discuss HIPAA training requirements if applicable.

5. OTHER QUALITY IMPROVEMENT RESOURCES

<http://www.carnegiefoundation.org/resources/publications/continuous-improvement-education/>

<http://www.ahrq.gov/research/findings/factsheets/quality/qipc/index.html>

<http://www.squire-statement.org>

<http://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html>

*Guidance developed by WVSOM Ad Hoc Statewide Campus Research Committee in July 2016; revisions at August 2016 Committee meeting; Committee revised document in December 2016.