	Standard Operating Procedure Title:	ORSA Procedures for Student Research
	Department:	Office of Research & Scholarly Activity
	Sponsor:	Executive Director KERN & Sponsored Projects
	Approval Date:	12/18/2024
	Revision Date:	N/A
	Effective Date:	12/18/2024

STANDARD OPERATING PROCEDURE (SOP)

1. **PURPOSE**

   The Office of Research and Scholarly Activities (ORSA) guidelines establish research expectations for students and faculty at the Kansas Health Science University (KHSU)-Kansas College of Osteopathic Medicine (KansasCOM). The institution is committed to advancing scientific knowledge through research that enhances patient care, medical education, and osteopathic medicine in alignment with our mission and vision statements:

   KHSU Mission Statement

   The Kansas Health Science University is committed to providing exceptional programs that produce forward-thinking, empathetic health care leaders who are dedicated to innovation, research, and finding collective solutions to advance underserved communities.

   KHSU Vision

   To positively transform communities through directly addressing the disparity in access to health care for Kansas and beyond.

   KansasCOM Mission Statement

   The mission of the Kansas College of Osteopathic Medicine is to train the Osteopathic physician of the future to provide effective, empathic, and innovative care to optimize the health of patients and their communities.

   KansasCOM Vision Statement

   Utilize impactful educational methods and technology to train exceptional graduates that are known for service, empathy, and innovation to improve access to a highest standard of care for all.

2. **APPLICABILITY**

   All KHSU-KansasCOM faculty, staff, students, and collaborating researchers conducting research under the auspices of KHSU-KansasCOM.

3. **DEFINITIONS**

   - **Principal Investigators**

     "Principal Investigator", "Submitter" and "Project Leader/Lead" will be annotated as "PI". This role reflects the individual who will be responsible for a project submission. The PI can delegate much of the submission to other team members but ultimately must retain the responsibility for the project's execution.

   - **Funder/Sponsor**

     The organization or person to whom a proposal will be submitted is referenced as "Sponsor".

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4. PROCEDURES

4.1 Institutional Oversight

- **Research Team:** Responsible for creating, monitoring, and reviewing policies and procedures related to the ORSA. The team holds open forums for faculty to discuss research matters, *but does not*:

  o Approve research proposals.
  o Monitor individual research projects.

- **ORSA:** Oversees research activities, ensures policy compliance, and provides project guidance while maintaining adherence to institutional, state, and federal regulations, *but does not*:

  o Guarantee access to or secure funding.
  o Prohibit projects on merit unless egregiously not researchable or compliant with applicable regulations. Faculty should also reference the *Academic Freedom Policy* available on the [Employee Intranet/Policies & Procedures](#) page or request a copy from ORSA if intranet access is unavailable.

4.2 Research Ethics & Compliance

The ORSA will review and monitor research proposals for progress and adherence to compliance requirements based on expertise and necessity. Research conducted must adhere to ethical standards and applicable regulations, including those established by KHSU-KansasCOM, the Institutional Review Board (IRB), and adhere to the following:

- **Institutional Review Board (IRB) Approval:** Required for all human-subject research.

- **Health Insurance Portability and Accountability Act (HIPAA) Compliance:** Ensures protection of health information. If protected health information (PHI) is involved, the project must be reviewed by the Privacy Board.

- **Registration**: All projects must be registered in the [Commons](#) at project initiation to ensure all research conducted at KHSU-KansasCOM has the highest ethical and scientific integrity and that the necessary resources are provided to support and verify compliance.

4.3 Research Integrity

- Researchers are expected to maintain the highest standards of integrity, avoiding fabrication, falsification, and plagiarism.

- Misconduct will be investigated following KHSU-KansasCOM procedures, with appropriate disciplinary action.

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4.4 Funding & Grants

- Researchers are encouraged to pursue external funding. ORSA *assists* with funding identification and grant writing, while project financial management remains the PI's responsibility, supervised by the Office of Finance.

- All funding must be registered with ORSA in the Cayuse Sponsored Projects application.

4.5 8. Intellectual Property

- Research outputs fall under KHSU-KansasCOM's *Intellectual Property Policy*, which facilitates patent development, licensing, and commercialization. Faculty and staff can access the policy through the Employee Intranet/Policies & Procedures or request a copy from ORSA if intranet access is unavailable.

- Faculty, staff, and students who develop intellectual property must disclose their findings to ORSA.

4.6 Collaboration and Interdisciplinary Research

- KHSU-KansasCOM promotes collaborative research with other institutions and research centers, especially projects advancing osteopathic principles and practices.

- If the research is conducted in a collaborating institution's facilities and with direct oversight of the collaborating institution, that collaborating institution's IRB will be the IRB of record. All KHSU-KansasCOM students and faculty-led research, regardless of where it is conducted, must also be registered with the KHSU-KansasCOM IRB. Please reference the *IRB Handbook* for further guidance.

4.7 10. Research Dissemination

- Researchers are encouraged to publish their findings in peer-reviewed journals and present their work at conferences.

- The International Committee of Medical Journal Editors (ICMJE) recommends that authorship be based on the following four criteria:

  o Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work.
  o Drafting the work or revising it critically for important intellectual content.
  o Final approval of the version to be published.
  o Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

- AI Tool Usage and Attribution Disclosure Requirements

  o All AI tool usage must be documented and disclosed in manuscripts.
  o Include specific versions/models of AI tools used.
  o Detail the extent and nature of AI assistance.
  o Document verification methods for AI-generated content.

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- Additional authorship guidelines can be found in the [KHSU-KansasCOM Medical Library](#).

- The KHSU-KansasCOM will facilitate the dissemination of published research through the [Commons](#), ensuring that significant findings are accessible to the broader medical and scientific communities.

4.8   Student Research Involvement

- KHSU-KansasCOM fosters an environment where students can actively participate in research projects, gain exposure to medical research methodologies, and contribute to the advancement of osteopathic medicine.

- Research conducted outside required coursework during OMS I is discouraged to ensure academic focus.

- Students must maintain good academic standing and cannot serve as PIs or initiate publications independently.

- Every KHSU-KansasCOM student participating in research, both on campus and with other organizations, must have a faculty sponsor who is aware of the project. This sponsor will be there to guide students in their research efforts, ensuring academic rigor and adherence to ethical standards.

- There are no authorship expectations for this role, albeit this may be appropriate and desired by the faculty sponsor. Student researchers are encouraged to have this discussion with their sponsor early on in their project. Students should strive to have both research and clinical (or topical) expertise between the PI and sponsor.

4.9   Faculty Sponsor

- Faculty sponsors guide research efforts by ensuring project submissions to the IRB/Privacy Board, overseeing activities, and holding regular team meetings.

- The responsibilities of a faculty sponsor may vary from project to project and also be dictated by both the experience of the student and the breadth of the project.

4.10   PI vs. Sponsor

- The PI has the ultimate responsibility for oversight and contribution to the project. If the PI is KHSU-KansasCOM, they can serve as the sponsor.

- PI responsibilities include, but are not limited to:

  o Discussions of authorship.
  o Ensuring projects are submitted to the IRB/Privacy Board and are reviewed and approved in the Cayuse system.
  o Actively involved in directing and contributing to the project at all stages.

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4.11 Conflict of Interest

- Researchers must disclose any financial or personal conflicts of interest that may influence their work.

- The KHSU-KansasCOM *Conflict of Interest Form* is available in the Cayuse Human Ethics platform in the IRB submission section.

5. REFERENCES & RESOURCES

- Cayuse SP: https://kansashsc.app.cayuse.com/ (Using your SSO)

- KERN: https://www.kansasern.org (Using your SSO)

- Office of Research and Scholarly Activities email: khsuresearch@kansashsc.org

- PIVOT: https://pivot.proquest.com/session/domain_login (Using your SSO)

- Link to the Grants Management & Compliance Webinar from 12/5/2024.