RESEARCH ETHICS AND MISCONDUCT POLICY

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Responsible Department: Office of Research and Scholarly Activity and the Institutional Review Board (IRB)

PURPOSE & SCOPE

The aim of this policy is to state Rocky Vista University's (RVU's) commitment to ethical standards in scholarly activities and to articulate a procedure for responding to allegations of research misconduct. The policy applies to all RVU faculty, staff, and students engaged in any form of research or scholarly activity.

POLICY STATEMENT & POLICY

RVU faculty, staff, and students must adhere to general principles of ethical research, which include honesty, integrity, objectivity, informed consent, respect for all persons/respondents, beneficence, non-maleficence, responsible publication and dissemination, confidentiality, non-discrimination, transparency, respect for intellectual property, and justice. All research and scholarly activity must be conducted in alignment with such standards from inception, design, implementation, analysis, through reporting. All forms of misconduct will be investigated and adjudicated as necessary. Members of the RVU community including collaborators, visiting scholars, preceptors, adjunct instructors, employees, and students of RVU are expected to understand and adhere to federal, state, and university regulations for research affiliated with RVU. This expectation includes completion of required training before research or scholarly activity can begin.

DEFINITIONS*:

a. *Research Ethics* is defined as the set of ethical guidelines that govern how scientific research is designed, conducted, and disseminated. Furthermore, these are the standards of conduct scholars must follow to responsibly conduct research.

b. *Research Record* is the records or data or results of scholarly activities, including but not limited to research proposals, laboratory records and notebooks (physical and electronic), notes, progress reports, internal reports, abstracts, oral and poster presentations, and material submitted for publication or published in any form.

c. *Research Misconduct* is defined as knowing, intentional or reckless fabrication, falsification, or plagiarism in the conduct of scholarly activity. Research misconduct does not include honest errors or differences of opinion.

- **i.** *Fabrication* includes making up data or results and recording or reporting them as factual.
- **ii.** *Falsification* is the manipulation of research results, equipment, or processes, or changing or omitting data or results such that information is not accurately represented in the research record.
- **iii.** *Plagiarism* is the appropriation of another person's ideas, processes, results, data, or words without giving appropriate credit. Note that self-plagiarism can occur in certain cases based on assignment of copyright by the author.

iv. *Neglect* is another consideration in which errors are egregious and adversely affect research participants.

d. *Complainant* is the individual, department, or entity who, in good faith, makes an allegation of Research Misconduct.

e. *Respondent* is the person against whom the allegation of Research Misconduct is directed or who is the subject of the Research Misconduct inquiry or investigation.

f. *Inquiry* is the preliminary information-gathering and fact finding consistent with this policy.

g. *Investigation* is defined as the formal development of a factual record and the examination of that record leading to a determination of the veracity of misconduct claims.

** Definitions are based on the Federal Policy on Research Misconduct, 42 C.F.R. part 93.*

HUMAN SUBJECTS RESEARCH

If research or scholarly activity involves human participants (including but not limited to case reports, surveys, retrospective chart reviews, public database mining, prospective studies), researcher(s) must seek review and receive a notice of approval or exemption from the Institutional Review Board (IRB) before beginning their research.

RVU follows the Department of Health and Human Services Office of Human Research Protections (DHHS OHRP) Revised Common Rule found at 34 CFR Title 45, Part 46.

The National Research Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was tasked with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects. It was also tasked with developing guidelines that should be followed to assure that such research is conducted in accordance with these ethical principles.

The Commission drafted the Belmont Report, a foundational document for the ethics of human subjects research in the United States, and it may be viewed at the following link:
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

CONSIDERATIONS FOR STUDIES USING BIG DATA, ARTIFICIAL INTELLIGENCE, AND MACHINE LEARNING

Advances in high-velocity data analytics and storage capacity have accelerated big data research. These studies apply novel computational tools to large databases from multiple diverse sources to achieve advances in a multitude of research areas. Many times, the data from these sources is either de-identified or in the public domain. Data from multiple sources increases the probability of reidentification. When research uses any human data from any source, the study must be submitted to the IRB for review and determination. Given the nature of research in this area, the potential for the introduction of bias is present at numerous points. Care must be taken in selecting the data used to develop the algorithm to ensure that it is representative of the population in which the results of the algorithm will be applied. The researcher must vet the algorithm for scientific credibility and validity in the population in which it will be used. The researcher must also be able to explain to the IRB the process used in developing the algorithm and potential risks and benefits to the affected populations.
Finally, as found on the RVU Writing Center website: https://www.rvu.edu/writing-center/ , the following policy is followed regarding authorship and the use of AI:

ARTIFICIAL INTELLIGENCE

Non-human contributors, such as artificial intelligence, machine learning, or similar technology, do not qualify for authorship. The use of these systems is not encouraged but may be permitted if this specific technology is part of the study question. Use of artificial intelligence must be included in the acknowledgement section if used in part to write the manuscript, or in the methods section if part of the study. Findings from previous publications cannot be reproduced, and authors have the responsibility of ensuring the accuracy and integrity of the writing or content generated by artificial intelligence systems.

This policy is consistent with statements from the Committee on Publication Ethics (COPE) regarding the use of artificial intelligence in research publications.

ROLES & RESPONSIBILITIES

Vice Provost of Research and Scholarly Activity	Receives reports of research misconduct and sends reports to the IRB if it involves human subjects research. Works with RIO and appoints an Inquiry Committee to investigate non-human subjects research misconduct.
Institutional Review Board (IRB)	Receives reports of research misconduct that involves human subjects research. Inquires and investigates allegations of research misconduct that fall under the IRB. Works in collaboration with the RIO and Inquiry Committee.
Research Integrity Officer (RIO)	Makes inquiries as to allegations of non-human subjects' research misconduct. If an investigation is warranted, they work with an ad hoc appointed Inquiry Committee to investigate.
Inquiry Committee	Formed by Vice Provost of Research and Scholarly Activity or the IRB Chair, respectively. Investigates allegations of research misconduct.
Provost	Notified of allegations of research misconduct. Consulted as to determination made by investigation committee and any sanctions for research misconduct. If Vice Provost of Research is involved in the research or allegations of misconduct the Provost will assume all duties assigned to the Vice Provost.
Student Affairs	Informed of any research misconduct allegations made against a student.
Human Resources	Informed of any research misconduct allegations made against an employee.
President	If an appeal of the findings is filed by the respondent, the President makes the final determination.

RELATED PROCESSES, PROCEDURES, AND/OR DEFINITIONS

- **Appendix 1**: Process for Reporting and Investigating Research Misconduct

POLICY REVISION HISTORY

Appendix 1
Process for Reporting and Investigating Research Misconduct

a. **Reporting:** Allegations of research misconduct concerning human subjects research shall be reported to the IRB via the IRB Compliance Administrator. All other allegations of research misconduct not involving human subject research shall be made to the Vice Provost of Research and Scholarly Activity and/or their designated Research Integrity Officer (RIO). Such reports will preferably be made in writing; however, any form of communication is considered acceptable. If the report is made to a designated RIO, the RIO will notify the Vice Provost of Research who will notify the Provost of the allegations.

b. **Inquiry:**

   i. Within 5 days of receiving the allegation of Research Misconduct, the IRB Compliance Administrator or other designated IRB representative, RIO or the Vice Provost of Research and Scholarly Activity, depending on the nature of the study (i.e., involvement of human subjects), will conduct an inquiry to determine if the allegation meets the definition of Research Misconduct and is sufficiently credible and specific to warrant an investigation. As part of the inquiry the Respondent shall be notified in writing of the allegation and provided a copy of this policy and process. The inquiry official will secure all research records to conduct the investigation, if deemed appropriate, as well as discuss the allegation with the Respondent. The Respondent shall have an opportunity to respond in writing to any allegation within 10 days of being notified of the allegation. The inquiring official may exercise discretion to extend this timeline. The identities of all parties involved in the Research Misconduct allegation shall be held in confidence to the extent that it does not interfere with an effective inquiry.

   ii. After the Respondent has been notified of the allegation and given an opportunity to respond, the official receiving the complaint shall form an Inquiry Committee consisting of at least one member of the IRB (mandatory in the case of human subject's research), RIO, Vice Provost of Research and Scholarly Activity, Institutional Compliance Officer, and any other individuals the inquiring official deems helpful to the inquiry process. The Inquiry Committee will determine if an investigation is warranted by undertaking an initial review of the evidence. The committee may also conduct individual interviews with the Complainant, the Respondent, and any relevant witnesses. Each interview shall be recorded and potentially transcribed for accuracy. Each interviewed individual will be provided with an opportunity to review the recording or transcript for accuracy.

   iii. The Inquiry Committee shall prepare a written draft report to be sent to the Respondent who will then have ten (10) business days to respond, which will be included in the final report. The final inquiry report shall be filed with the IRB, in the case of human subject's research, RIO, Vice Provost of Research and Scholarly Activity, Provost, and Human Resources (in re: employees) or Student Affairs (in re: students). The Respondent will also be notified of the results of the inquiry and determination to investigate. The entire inquiry process should be completed within 60 days of the allegation.

   iv. An investigation will be determined necessary if the inquiry supports that there is a reasonable basis for concluding that the allegation meets the definition of Research Misconduct under the policy and that based on the preliminary fact-finding, they have sufficient substance and merit to warrant further investigation.

v. The Vice Provost of Research and Scholarly Activity or institutional signing official shall at any time appropriately notify federal authorities of allegations of Research Misconduct in human subjects and/or federally supported research.

c. Investigation:

i. If the Inquiry Committee determines that an investigation is warranted, the Investigation shall begin within twenty-one (21) days of the conclusion of the inquiry.

ii. All parties involved in the Investigation and any subsequent proceedings shall, to the extent possible, maintain confidentiality regarding the allegations and evidence of Research Misconduct.

iii. Upon determination that an investigation is warranted and on the recommendation of the Inquiry Committee, the Vice Provost of Research and Scholarly Activity shall request that the University Faculty Senate Chair form a fact-finding committee of at least five (5) but no more than (7) seven unbiased faculty who have been at RVU for at least two years. In cases of human subject research, the committee must include the IRB chair or vice chair. The "Investigation Committee" must include faculty at all ranks (Assistant, Associate, and Full Professor) and have both clinical and basic sciences credentials. The Vice Provost of Research and Scholarly Activity, in consultation with the Provost, will approve the membership of all Committee members. All reasonable steps will be taken to ensure that committee members are unbiased and there are no unresolved personal or professional conflicts of interest with either the Respondent or the Complainant. An administrative assistant or coordinator in the Office of Research and Scholarly Activity (or the Provost's office if one is not available through the Office of Research and Scholarly Activity) shall provide administrative support to the Committee. The Investigation Committee shall elect its own chair who will be responsible for determining the manner of the witness interviews.

iv. The Committee shall have sixty days (60) from the beginning of the formal investigation in which to complete their work.

v. The Committee will be provided with the inquiry report, the Research Record, and any other pertinent information and evidence gathered during the inquiry. The Respondent will be notified of the formation of a fact-finding Committee but will not be made aware of the identities of the Committee membership.

vi. The Committee may seek assistance from RVU legal counsel or the Federal Office of Research Integrity during the course of their investigation, if needed.

vii. The Committee will document and keep records of all its proceedings and will be expected to pursue all significant issues and leads, including evidence of additional instances of Research Misconduct.

viii. Once the investigation is completed, the Committee will prepare a draft investigation report outlining the allegation, Committee's process, the evidence examined, any reasonable explanation or defense provided by the Respondent, and a summary of the facts and analysis that support the Committee's conclusions. Findings of Research Misconduct can only be made upon agreement by the majority of the Committee that there was a significant departure from the accepted research and scholarly practices for the field. Such a conclusion must be supported by a preponderance of evidence. If the Committee reaches a finding of research misconduct, then they may also recommend disciplinary actions (up to and including termination for employees or going before the Honor Code Committee for students).

ix. It is to be noted that Faculty Mentors and Preceptor Mentors may be found dually responsible for research misconduct of a student they are mentoring.

x. The draft report should be prepared and presented to the Respondent, who will then have thirty (30) days to respond to the draft report.

xi. A final written investigation report will then be submitted, including the Respondent's response, to the Vice Provost of Research and Scholarly Activity, the Provost, the President, and the department of Human Resources, or Student Affairs, respectively.

xii. The designated Institutional Official will be responsible for communicating any findings of Research Misconduct to the sponsoring agency and/or the Office of Human Subjects Protections as appropriate within 90 days of the beginning of the investigation.

xiii. Should the Committee have a finding of no Research Misconduct, they, in addition to all other institutional officials, shall make every effort to protect and/or restore the reputation of the Respondent. Reasonable efforts will also be made to protect the status of the Complainant as long as the allegation of Research Misconduct was made in good faith. However, if it is found that the Complainant acted in bad faith, appropriate disciplinary action will be taken.

- RVU shall take no action against the Respondent as a result of a Research Misconduct allegation pending the conclusion of the inquiry or investigation, unless it is determined, in consultation with Human Resources, Student Affairs, or the IRB that the presence of the Respondent on campus poses an immediate threat of physical or psychological harm to others or risks human subjects.

d. Respondent's Rights

i. Respondent has the presumption of innocence and need not prove his or her innocence to the Committee but instead has the burden to prove an affirmative defense (e.g., honest error, difference of opinion, mitigating factors, etc.).

ii. The Respondent may be represented by legal counsel that they secure at their own expense. Respondents may counsel with any non-lawyer personal advisers as long as they are not a principal or witness in the case. Such an adviser (legal or non-lawyer) may attend any Respondent interviews but may only act as an observer during the proceedings and may not comment, ask questions, or raise an objection during the proceedings.

iii. The Respondent may present a defense to the allegations including presenting witnesses and evidence for the Committee to consider. The Federal/State Court Rules of Evidence will not formally apply to this proceeding.

iv. The Respondent may challenge the composition of the Investigation Committee should they believe them to be biased or have a conflict of interest. The Investigation Committee shall determine, in consultation with the Vice Provost of Research and Scholarly Activity, the IRB, and/or the Provost, or their designated official, whether bias or a conflict of interest exists and shall request that the Faculty Senate chair replace the Committee member when appropriate.

v. The Respondent has the right to appear at the preliminary conference with the Investigation Committee to set the interview schedule. The Investigation Committee shall endeavor to make reasonable accommodations to allow time for the Respondent to

prepare for the investigation as long as it is consistent with the timeline associated with the investigation.

vi. Respondent will receive all draft reports and be given the time and opportunity to respond in accordance with the schedule of proceedings. Additionally, the Respondent can request supervised access to all evidence gathered during the course of the investigation.

vii. Should Research Misconduct be determined, the Respondent may appeal the disciplinary action on the grounds of process or procedural violations or bias. Such appeals must be made in writing to the University Provost and President. The appeal must clearly state the reasons and must be submitted within ten (10) business days of the Respondent's notice of disciplinary action. The University President will review all reports and investigative evidence and may request additional information. The University President will notify the Respondent, the University Provost, the Vice Provost of Research and Scholarly Activity, the IRB, and the department of Human Resources (in re: employees) or Student Affairs (in re: students) of their decision, which shall be the final decision on the part of the institution.

e. Special Measures:

Once a finding of Research Misconduct is concluded, then the Respondent will reach out and notify the editors and/or conference organizers of any pending publications or abstracts relevant to the research misconduct and shall request the work be withdrawn. If relevant work has already been published, then the Respondent will reach out to the editor to request a correction or retraction be published. If the University determines that additional action is necessary or in cases of Respondent termination, the Department Head or Program Director will be asked to take the above actions.

f. Document Retention:

Rocky Vista University will maintain all records associated with any allegation of Research Misconduct and any subsequent proceedings for a minimum period of seven (7) years.

g. References:

i. Integrity in Scientific Research: Creating an Environment that Promotes Responsible Conduct (https://www.ncbi.nlm.nih.gov/books/NBK208714/).