



**Logan University**

**Research Division**

**Policies and Procedures Manual**

**Revised February 24, 2023**

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Logan University College of Chiropractic and College of Health Sciences  
Research Division Policies and Procedures Manual

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### **The Mission of Logan University**

Logan University is a diverse and engaging community committed to excellence in health sciences, education and service, guided by integrity, commitment and passion.

### **The Mission of Logan University College of Chiropractic**

Logan University College of Chiropractic prepares students to become doctors of chiropractic who are superbly educated and clinically competent practicing portal of entry chiropractic physicians. This mission is accomplished through our dedicated faculty recognized for student-centered excellence; comprehensive science-driven knowledge-based and information-facilitated curriculum; enhanced by community and public service. The institution is committed to the conduct of research and other scholarly activities.

### **Logan University College of Chiropractic Research Division Mission**

To conduct rigorous clinical research that supports public health care by:

- Investigating the applications and outcomes of chiropractic care in diverse populations.
- Promoting community wellness and quality of life.
- Developing research partnerships through collaboration and practice-based research networks.

### **Logan University College of Chiropractic Research Division Objectives**

- a. To design, conduct, present, and publish studies that are compliant with all current applicable federal and state regulations and ethical principles governing the conduct of research.
- b. To design, conduct, present, and publish studies that investigate the efficacy, safety and/or cost effectiveness of chiropractic interventions on musculoskeletal conditions in diverse populations.
- c. To design, conduct, present, and publish studies that investigate applications of chiropractic care that promote public health and wellness through treatment and prevention of diverse conditions.
- d. To design, conduct, present, and publish studies that investigate the reliability and/or validity of chiropractic diagnostic methods and measures.

- e. To design, conduct, present, and publish studies that investigate opinions, attitudes, attributes and behaviors related to chiropractic education.
- f. To design, conduct, present, and publish studies that develop computer models of spinal biomechanics.
- g. To seek, develop and maintain intra and interdisciplinary collaboration for studies in any of the above areas.
- h. To seek external funding through federal and state agencies, public and private foundations and corporate sponsors.
- i. To promote and support the development of an information literate academic culture on campus for students, faculty and administration.
- j. To serve as mentors/consultants for faculty who wish to engage in scholarship.
- k. To support all Logan University institutional programs.

**Logan University Definition of Scholarship and Research**

1. Scholarship and research are defined at Logan University in a traditional Boyer model of Discovery, Integration, Application and Teaching:
2. Scholarship is creative intellectual work that is validated by peers and communicated within the scientific community. Scholarship includes outcomes, insights, creations, and products arising from activities and creative processes that utilize the methods of inquiry and accumulated knowledge.
3. Scholarship, whether in the domain of discovery, application, integration or teaching, must meet six standards: clear goals, adequate preparation, appropriate methods, significant results, effective presentation, and reflective critique.
4. Research consists of creating of new knowledge (discovery) in an empirical/ scientific paradigm. Examples of research include designing, conducting, presenting and/or publishing experimental, quasi-experimental and non-experimental studies.

- Scholarship in non-research applications consists of Integration, Application, and Teaching utilizing existing knowledge. Examples of non-research scholarship include publication of texts, book chapters or editorials, teaching/learning in classroom or on-line courses, service as an officer in scholarly societies, peer reviewer activities, invited speaker/panelist, policy development panelist, or attainment of advanced degrees, certifications, and achieving diplomate status.

### **Logan University Expectations for Faculty Scholarship and Research**

#### ***Academic/Scholarly Activity or Productivity is one of many criteria considered to qualify for promotion in academic rank***

Logan University encourages and supports scholarship through the Research Division. Scholarship at Logan University is coordinated through the Research Division. The purpose of the Research Division is to directly support the mission of Logan University. This is achieved by sponsoring and coordinating all scholarship and research activities that are conducted or supervised by Logan employees and students.

#### **Animal Research**

The Animal Welfare Act as stated below governs all animal research conducted in the United States, however, Logan University does not conduct any animal research.

“Any project using animal subjects must comply with the federal standards specified in the Animal Welfare Act (Public Law 89-544, 1966, as amended, (Public Law 91-469 and Public Law 94-279) 7 U.S.C. section 2131 et seq. Implementing regulations are published in the Code of Federal Regulations (CFR), Title 9, Subchapter A. Part 1, 2, 3, and 4, and are administered by the U.S. Department of Agriculture).”

### **Logan University Protection of Human Subjects Guidelines**

Proposed research projects or experiments involving human subjects that will be conducted on the property of Logan University, or that will utilize Logan University personnel, facilities, resources, or involves Logan University through collaboration with other institutions, are first submitted to the Dean of Research for assistance with conceptual, methodological, and ethical details as well as proper formatting prior to submitting a formal proposal to the Chairman of the Institutional Review Board (IRB) for review. All projects must receive approval by the IRB prior to initiation of the proposed research project.

Any faculty member, clinic personnel, administrator, or student who initiates a research project involving human subjects without prior written approval from the IRB, or who proceeds with such research after the rejection or suspension of the project for any reason

by the IRB, will be subject to disciplinary action. This includes, but is not limited to, immediate dismissal from school or termination of contract, loss of clinic privileges, suspension, or fines.

If any individual is in doubt as to whether his/her project comes within the purview of the IRB, the Dean of Research provides overview assistance prior to submission to the IRB. The Chairman of the IRB will make the final determination whether the project is subject to review by the IRB. No project may be started until the researcher or advisor receives written notification of IRB approval. It will not be a defense to violation of this University policy regarding the review of all research projects that the individual did not know of the policy, or believed that it did not apply to his or her project.

Once an IRB approved research project is initiated, it is the responsibility of the Principal Investigator (PI) to assure and monitor compliance with all research policies and procedures of Logan University. The Dean of Research and/or the IRB Chairman may inspect and/or investigate any aspect of a research project's conduct with or without prior notice.

### **Logan University Institutional Review Board (IRB)**

#### **Function of the IRB**

The function of the IRB is to ensure that research involving human subjects is planned and carried out in accord with ethical guidelines and federal regulations as set forth in the Code of Federal Regulations 45 CFR 46, the National Research Act, Public Law 93-348, the Declarations of Helsinki and the Neurenberg Code. Accordingly, the IRB shall review and approve (or not approve) any project or experiment involving human subjects that is conducted by Logan University faculty, students, staff, clinic personnel or administrators, or which utilizes university resources, facilities, or equipment, or is conducted at other locations through collaboration with other institutions.

#### **The written application for IRB *must* include the following:**

1. The name(s) of the principal investigator and co-investigators.
2. A description of the project and/or experiment in sufficient detail to permit a reasonable understanding of the nature, purpose, scope, and risks of the project.
3. A description of the human subjects to be involved.
4. A description of any potential risks known to exist with respect to the project.
5. A detailed description of the safety precautions that are planned to deal with each of the identified risks.
6. A description of any University facilities or equipment to be used or involved in the project.
7. A description of any equipment or facilities not belonging to the University that will be used in the project.

8. A description of any emergency medical equipment or facilities necessary or appropriate to the project, such as oxygen, stretcher, neck brace, etc.
9. A list of non-University personnel to be involved as researchers or assistants in the project such as pathologist, nurse, engineer, etc.
10. Date of intended initiation of the project.
11. Estimated time necessary to complete the project.
12. Description of the source of any external funding.
13. Estimate of total cost of the project and proposed budget.
14. A copy of the subject Informed Consent document.

### **IRB Membership and Terms**

IRB members will be appointed by the President of Logan. The Logan IRB shall consist of a minimum of five (5) members, both men and women of varying backgrounds, experience, and professions. At least one member shall not be employed by or affiliated with Logan University or be part of the immediate family of a person affiliated with Logan University; at least one member's primary concerns shall be in scientific areas; at least one member's primary concerns shall be in non-scientific areas. No IRB member shall participate in the IRB's initial or continuing reviews of any project in which that member has a conflicting interest, except to provide information requested by the IRB. The IRB may, at its discretion, invite individuals with competence in special areas to assist in review of issues or protected groups (children, prisoners, pregnant women, handicapped or mentally disabled persons) beyond or in addition to that available among the regular IRB members. These invited individuals may not vote. Full review IRB meetings shall consist of a quorum of five (5) members. Expedited review IRB meetings shall consist of three (3) members. A quorum is required when any vote is necessary for project approval. Approval or non-approval will be decided by majority vote. Some exceptions may be granted in the case of expedited reviews.

### **Functions of the IRB Chairperson:**

- Preside over IRB meetings;
- Direct and implement the procedures of the IRB
- Initiate appropriate amendments to IRB procedures
- Determine when projects are completed or review requests for extension
- Investigate or inspect any aspect of research projects with or without prior notice as deemed appropriate
- Perform duties as the Board deems necessary to the purposes of the IRB
- Record and report all proceedings of the IRB to the President

**IRB members:**

- Shall perform duties as directed by the Chairman
- Shall not receive compensation for services rendered as members. Out-of-pocket expenses evidenced by written receipt, shall be reimbursed.

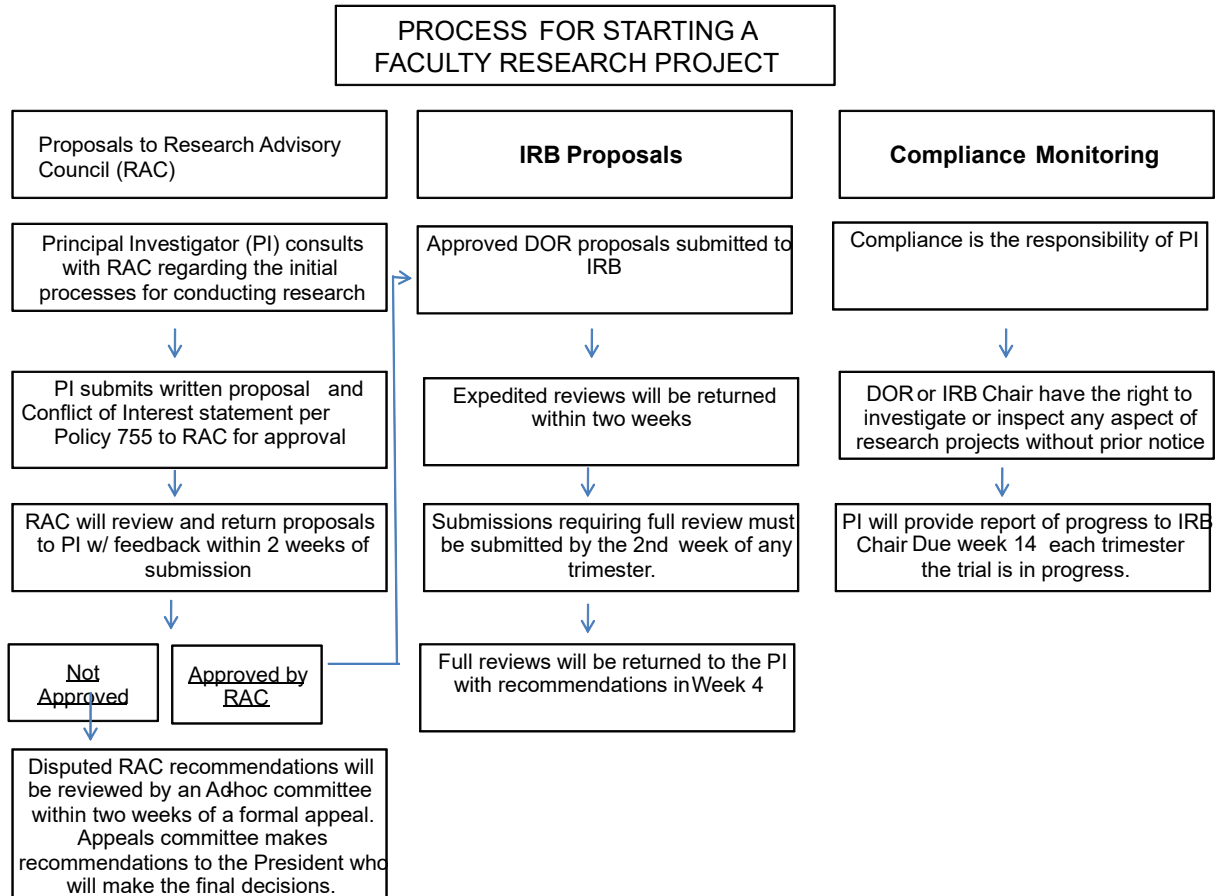
**Logan University IRB Members 2023 - Current**

<b>IRB Member</b>	<b>Title</b>	<b>Affiliated with Logan</b>	<b>Gender</b>	<b>Current Term Dates</b>
<b>Norman W. Kettner, DC, DACBR, FICC, DCBCN</b>	<b>Chair</b>	<b>Yes</b>	<b>Male</b>	<b>November 8, 2019 – open ended</b>
<b>Jeffrey Kamper, DC, DCBCN, MHPE</b>	<b>Co-Chair</b>	<b>Yes</b>	<b>Male</b>	<b>November 8, 2019 – August 31, 2023</b>
<b>Daniel Haun, DC, DACBR</b>	<b>Alternate Member</b>	<b>Yes</b>	<b>Male</b>	<b>November 8, 2019 – August 31, 2023</b>
<b>Erika Evans, DC</b>	<b>Scientific and Vulnerable Populations Member</b>	<b>Yes</b>	<b>Female</b>	<b>April 1, 2022 – April 1, 2025</b>
<b>Peter Ruger, JD (Attorney at Law)</b>	<b>Non-Affiliate and Non-Scientific Member</b>	<b>No</b>	<b>Male</b>	<b>November 8, 2019 – August 31, 2023</b>
<b>April Taylor, DBA, JD</b>	<b>Non-Scientific and Vulnerable Populations Member</b>	<b>Yes</b>	<b>Female</b>	<b>September 22, 2022 – August 31, 2025</b>
<b>Brian McAulay, DC, PhD</b>	<b>Scientific Member</b>	<b>Yes</b>	<b>Male</b>	<b>February 8, 2023 – August 31, 2026</b>
<b>Erica Collier Administrative Assistant to Dr. Kettner</b>	<b>Secretary to IRB</b>	<b>Yes</b>	<b>Female</b>	<b>November 8, 2019 -</b>



**Logan University IRB Past Members 2019 - 2022**

Logan University Institutional Review Board (IRB) Committee Members				
IRB Member	Title	Affiliated with Logan	Gender	Current Term Dates
Norman W. Kettner, DC, DACBR, FICC, DCBCN	Chair	Yes	Male	November 8, 2019 – open ended
Jeffrey Kamper, DC, DCBCN, MHPE	Co-Chair	Yes	Male	November 8, 2019 – August 31, 2023
Meadow Campbell, PhD	Scientific Member	Yes	Female	November 8, 2019 – August 31, 2023
Daniel Haun, DC, DACBR	Alternate Member	Yes	Male	November 8, 2019 – August 31, 2023
Kimberly O'Reilly, DHEd, MSW	Scientific and Vulnerable Populations Member	Yes	Female	November 8, 2019 – August 31, 2021
Peter Ruger, JD (Attorney at Law)	Non-Affiliate and Non-Scientific Member	No	Male	November 8, 2019 – August 31, 2023
Jennifer Starks, MS	Non-Scientific and Vulnerable Populations Member	Yes	Female	January 1, 2020 – August 31, 2023
John Gutweiler, PhD	Past Chair	Yes	Male	November 8, 2019 – August 31, 2020
Erica Collier Administrative Assistant to Dr. Kettner	Secretary to IRB	Yes	Female	November 8, 2019 -



**Logan University Ethical Issues in Research**

**Policy on Research Misconduct**

Logan University maintains and enforces the ethical principles and practices governing the conduct of research as defined by the Misconduct Office of Science and Technology Policy. Federal Policy on Research Misconduct, *Federal Register* 2000; December 6, 65(235):76260-4 including all the items required by the Department of Health and Human Services (HHS), Public Health Service (PHS) and/or the Assurance on Research Misconduct. These ethical principles and practices are designed to ensure the safety and protection of human subjects as well as the accuracy and integrity of the new knowledge yielded by research projects.

The Principal Investigator (PI) of a research project holds primary responsibility for ensuring the integrity of all project data and reporting of results. The PI is responsible for the proper conduct of all procedures related to the project, whether or not they are directly performed by him or her. All other investigators serving in any capacity in the project, including co-

authors who participate in reporting results in conference presentations and/or publications, are also responsible for the integrity of the data. The Dean of Research will take responsibility for communicating this policy and its importance to all University personnel involved in research projects in any capacity.

To ensure against any allegation of research misconduct related to fabrication or falsification of data, all original data must be secured, preserved and available for review should such allegation occur. Explicit and detailed procedures for data collection, storage, retrieval, and analysis must be on record. All investigators on the study are responsible for maintaining records of all procedures and data. These records must be kept in sufficient detail to permit verification by the sponsoring agency or an investigative committee of the University. All records must be retained for a minimum of five years.

This policy applies to all research activities conducted in association with Logan University, both externally and internally funded. It applies to any individual affiliated with the University who is conducting research associated with the University, including research personnel, faculty, adjunct faculty, students and consultants, whether paid or unpaid as well as collaborators at other institutions.

### **Investigation of Allegations of Research Misconduct**

All persons involved in research activities on or off campus are required to abide by Logan University's policies and procedures with respect to professional conduct. All records of allegations of research misconduct, and any subsequent inquiries and investigations, will be maintained in a secure file in the Dean of Research's office for a minimum of three years.

#### **1. Inquiry**

Allegations of possible research misconduct should be reported to the Dean of Research, who will consult with the Vice President for Academic Affairs on whether a formal inquiry is warranted. This determination is based on whether the allegation falls within the definition of "research misconduct," and is sufficiently credible and specific to allow identification of evidence.

To pursue an inquiry, the Dean of Research will name a panel of three faculty and will secure the relevant records. He/she will also provide the individual involved in the allegation, the Principal Investigator of the project involved and the Chair of the IRB with a copy of the allegation.

Each inquiry shall be completed within 30 calendar days from receipt of the allegation, including preparation of a written report. The report will be provided to the individual involved in the allegation, the PI of the project involved, the Chair of the IRB and the sponsoring agency (if applicable).

## **2. Investigation**

Investigation will be conducted if the results of the inquiry indicate further investigation is warranted. The Dean of Research, in consultation with the Vice President of Academic Affairs, will name a panel composed of at least three individuals, all of whom must have adequate expertise to evaluate the evidence and be free of conflicts of interest in the case under investigation, ensuring their impartiality. All meetings of the investigative panel must be recorded and the minutes of the meetings maintained in a secure file in the Vice President of Academic Affairs office.

The results of the investigation will be reported in writing and provided to the individual under investigation, the PI of the project involved, the Chair of the IRB and the sponsoring agency (if applicable). The investigation will be initiated within 14 calendar days of the completion of the inquiry, and must be completed within 60 calendar days.

### **Consequences of Research Misconduct**

In the case of externally funded research, the decision concerning appropriate disciplinary action is the responsibility of the sponsoring agency. In the case of internally funded research, appropriate disciplinary action is the responsibility of the President and will be consistent with Logan's grievance policy, including the right to appeal. Disciplinary actions will be commensurate with the nature of the documented misconduct. Such actions may include, but are not limited to, removal from the project; a letter of reprimand placed in the individual's personnel file; restitution of funds; monitoring of future work; salary or rank reduction; suspension or termination of employment.

### **Safeguards**

***Safeguards for Informants*** are necessary to give individuals confidence that they can report allegations of research misconduct to the attention of appropriate authorities without suffering retribution. Safeguards protecting informants who make good faith allegations include confidentiality and fair and objective procedures for resolution of allegations.

***Safeguards for Subjects of Allegations*** are necessary to protect individuals' rights. These include timely written notification of subjects regarding allegations made against them, description of allegations, the opportunity to respond to allegations, confidentiality and fair and objective procedures for resolution of allegations.

***Confidentiality During the Investigation*** Consistent with Logan University's grievance policy, knowledge of the identity of informants and subjects will be limited to those who need to know.

### **Notification of Federal Agencies: Applicable to Federally Funded Research**

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The Dean of Research will take responsibility for ensuring that the appropriate agencies are notified as follows:

- The Office of Research Integrity (ORI), PHS, will be notified in the event that an investigation will be conducted.
- The ORI will be notified within 24 hours of obtaining a reasonable indication of possible criminal violations.
- The University will take appropriate interim administrative actions to protect Federal funds and ensure that the purposes of the Federal financial assistance are being carried out.
- The ORI will be promptly notified of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.
- The ORI will be promptly notified of the final outcome of the investigation with a written report that thoroughly documents the investigative process and findings.

### **Authorship Guidelines for Scientific Publications**

#### **\*See Appendix I for Authorship Responsibility, Financial Disclosure, and Contribution Acknowledgment Agreement**

Like most research institutions and scholarly publications, Logan University adheres to the International Committee of Medical Journal Editors (ICMJE) ethical principles for determining authorship for scholarly and scientific articles. The most recent (2009) standards and instructions to authors are available at on the ICJME website at [http://www.icmje.org/ethical\\_1author.html](http://www.icmje.org/ethical_1author.html): These include:

- The article represents the authors' own original work.
- Short quotes are permitted if appropriately referenced.
- Use of extensive quotes or use of previously published illustrations or tables requires that the author obtain permission from the rights holder.
- Duplicate submission/publication is prohibited.
- The information presented in the article is reported truthfully and completely.
- Appropriate credit is given to the contributions of coauthors and acknowledgements are given to those who contributed to the work in capacities other than coauthors.
- The article is appropriately placed within the context of previous and current research, demonstrated by accurate citation of such literature.
- Authors should not, in their published work, make personally derogatory comments about other professionals.

- Relevant conflicts of interest should be disclosed.

Investigators are responsible for the scientific conduct of the project and for reporting of results in scientific publications and making presentations at scientific conferences. It is expected that the investigators of the project will in most cases be co-authors on any publications resulting from the project.

Authorship requires that one make a substantive scientific contribution to the project, e.g., to the study design, analysis and interpretation of results, literature review, and/or writing of the paper. Data collection, data entry, delivering of interventions, performing physical exams, or other similar activities do not qualify the person(s) performing them for authorship in the absence of a *substantive scientific contribution* as described above.

The first author is usually determined by proportion and significance of contribution to the paper, and is not necessarily the principal investigator of the project. All publications must be approved by all authors in writing *before* submission of the manuscript to a journal. In the event that a co-author does not indicate his or her approval in writing, all authors will give due consideration to the dissenting co-author's reasons for his or her non-approval. If a consensus of agreement cannot be reached, this co-author's name may be removed from the manuscript after the principal author has demonstrated due diligence in contacting him or her for input and approval.

All members of the project team contributing beyond the routine fulfillment of their ordinary job description will be formally acknowledged (with their written permission) by name in the relevant presentations and publications.

### **Informed Consent**

All research conducted at Logan involving human subjects requires that an informed consent document must be prepared and submitted to the Institutional Review Board along with the Research Proposal Application. Informed consent procedures at Logan University are consistent with The Department of Health and Human Services Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects. The principle of respect for persons requires that potential participants give informed consent to participate in any research project. The investigators must disclose information that will be relevant to the participant's decision on whether or not to participate. The following elements must be included, using language the potential participant can understand:

- 1) A statement explaining the following features of the study:
  - a) that it involves research,
  - b) an explanation of the purposes of the research

- c) the expected duration of the subject's participation
  - d) a description of the procedures to be followed
  - e) identification of any procedures which are experimental
  - f) identification of any conflicts of interest in funding
- 2) A description of any reasonably foreseeable risks or discomforts to the subject;
- 3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- 4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- 5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- 6) For research involving more than minimal risk, an explanation as to whether any compensation is available and an explanation as to whether any treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- 7) An explanation of whom to contact:
- a) for answers to pertinent questions about the research and research subjects' rights, and
  - b) whom to contact in the event of a research-related injury to the subject
- 8) A statement that participation is:
- a) voluntary,
  - b) refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and
  - c) the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

### **Additional elements of informed consent**

When appropriate, one or more of the following elements of information shall also be provided to each subject:

- 1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- 2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- 3) Any additional costs to the subject that may result from participation in the research;
- 4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- 5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- 6) The approximate number of subjects involved in the study.

### **Flesch-Kincaid Reading Ease**

The Department of Health and Human Services Code of Federal Regulations Title 45 Part 46: Protection of Human Subjects requires that, "The information that is given to the subject or the representative shall be in language understandable to the subject or the representative." Logan's IRB chair determines whether consent form language is appropriate for the intended subjects or representatives using the Flesch-Kincaid Reading Ease test if necessary.

The "**Flesch-Kincaid Reading Ease**" test has become a U.S. governmental standard. Many government agencies require documents or forms to meet specific readability levels. Most states require insurance forms to score 40-50 on the test. The U.S. Department of Defense uses the Reading Ease test as the standard test of readability for its documents and forms. The test is so ubiquitous that it is bundled with the popular word processing programs such as Microsoft Word. This score is affected significantly more by long words than grade level is.

Scores are rated on a scale of 0-100. Higher scores indicate material that is easier to read; lower numbers mark harder-to-read passages. As a rule of thumb, scores of 90-100 are considered easily understandable by an average 5th grader while 8th and 9th grade students could easily understand passages with a score of 60-70, and passages with results of 0-30 are best understood by university graduates. *Reader's Digest* magazine has a readability index of about 65, *Time* magazine scores about 52, and the *Harvard Law Review* has a general readability score in the low 30s.



## **Appendix I**

### **Logan University**

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#### **Authorship Responsibility, Financial Disclosure, and Contribution Acknowledgment Agreement**

Each author must read and sign the statement on Authorship Responsibility, Criteria, Contributions, and the statement on Financial Disclosure and Funding Support. The corresponding author must sign the Acknowledgment Statement. This form is available online at the Logan website [www.logan.edu](http://www.logan.edu) under Research Division. More detailed information about authorship can be found at: [http://www.icmje.org/urm\\_full.pdf](http://www.icmje.org/urm_full.pdf)

**Your Name (Print)** \_\_\_\_\_

**Telephone** \_\_\_\_\_ **Fax** \_\_\_\_\_

**E-Mail** \_\_\_\_\_

**Corresponding Author** \_\_\_\_\_

**1. Authorship Responsibility, Criteria, and Contributions.** Each author must meet the criteria in sections A, B, C, and D and indicate general or specific contributions by checking the appropriate boxes.

A. I certify that:

- this manuscript represents original and valid work, and neither this manuscript nor one with substantially similar content under my authorship has been published or is being considered for publication elsewhere, except as described in an attachment with the related manuscript; and
- if requested, I will provide the data and will cooperate fully in obtaining and providing the data on which the manuscript is based for examination and analysis; and
- for papers with more than one (1) author, I agree to allow the corresponding author to serve as the primary correspondent, to review the edited typescript / proof, and to make decisions regarding release of information in the manuscript. If I am the sole author, I take the responsibility of the corresponding author and agree to serve in the roles described above.

B. I approve the submitted manuscript as final.

C. I have participated sufficiently in the work to take public responsibility for (check one below).

- part of the content.
- the complete content.

D. To qualify for authorship, you must check at least 1 box in each of the 3 categories listed below.

I have made substantial contributions to the intellectual content of the paper as described below.

1. (check at least 1 below)
  - conception and design
  - acquisition of data
  - analysis and interpretation of data
  
2. (check at least 1 below)
  - drafting of the manuscript
  - critical revision of the manuscript for intellectual content
  
3. (check at least 1 below)
  - statistical analysis  obtain funding
  - administrative, technical, or material support  supervision
  - no additional contributions  other (specify) \_\_\_\_\_

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**Your Signature**

**Date Signed**

**2. Financial Disclosure and Funding Support.** Please check the appropriate box(es) below (Applies to the past 5 years and foreseeable future):

- a. I have no potential conflicts of interest, including specific financial interests, relationships and affiliations relevant to the subject matter or materials discussed in this manuscript.

**or**

- b. I certify that all my potential conflicts of interest, including specific financial interests, relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (e.g., employment or affiliation, grants or funding, consultancies, honoraria, speakers bureau, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending) are disclosed in the Acknowledgment section of the manuscript.

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**Your Signature**

**Date Signed**

I certify that all funding, other financial support, and material support for this research and/or work are clearly identified in the manuscript.

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**Your Signature**

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**Date Signed**

**3. Acknowledgment Statement.** Authors must obtain written permission from all individuals named in an Acknowledgment, since readers may infer their endorsement of data and conclusions. The corresponding author must sign the following statement:

- I certify that all persons who have made substantial contributions to the work reported in this manuscript (e.g., data collection, analysis, or writing or editing assistance) but who do not fulfill the authorship criteria are named with their specific contributions in an Acknowledgment in the manuscript.
- I certify that all persons named in the Acknowledgment have provided me with written permission to be named.
- I certify that if an Acknowledgment section is not included, no other persons have made substantial contributions to this manuscript.

---

**Corresponding Author Signature**

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**Date Signed**