

**CLEVELAND
CHIROPRACTIC
COLLEGE**

Kansas City | Los Angeles

Research Policies and Procedures

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ETHICAL ISSUES IN RESEARCH

Cleveland Chiropractic College Policy on Research Misconduct

Well-recognized ethical principles and practices govern the behavior of those engaged in scientific research. These principles and practices ensure the accuracy and integrity of the new knowledge yielded by research endeavors. Departure from these principles and practices impairs the integrity of the investigator, the investigative team and their institution as well.

This policy defines terms related to research misconduct and details the College's protocol for investigation of allegations of misconduct. This policy was derived from the Federal Policy on Research Misconduct¹ and includes all the items required by the Department of Health and Human Services (HHS) Public Health Service (PHS) for the Assurance on Research Misconduct.

The Principal Investigator of a research project holds primary responsibility for ensuring the integrity of all project data and reporting of results. The Principal Investigator 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 investigators serving in any capacity in the project, including as authors in a report of results, are also responsible for the integrity of the data.

However, the Vice President of Research and Scholarship will take responsibility for communicating this policy and its importance to all College personnel involved in any way with research.

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 made in sufficient detail to permit verification by the sponsoring agency or an investigative committee of the College. Records must be retained for a minimum of five years.

Scope and Application

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

Definitions¹

Research misconduct: "...fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."

Research: "... all basic, applied, and demonstration research in all fields of science... this includes... education, medicine, social sciences, and research involving human subjects or animals."

Research institutions: "... include all organizations using Federal funds for research, including colleges and universities... Independent researchers and small research institutions are covered by this policy."

Fabrication: "making up data or results and recording or reporting them."

Falsification: "manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record."

Plagiarism: "appropriation of another person's ideas, processes, results, or words without giving appropriate credit."

Good faith: believing in the truth of one's allegations, based on the information one was in possession of at the time the allegations were made.

Research record: "the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles."

Investigation: the formal development and examination of a factual record leading to a finding.

Determination of Research Misconduct

Research misconduct does not include honest error or differences of opinion. A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community; and
- The misconduct be committed intentionally, or knowingly, or recklessly; and
- The allegation be proven by a preponderance of evidence.

Responsibility for Research Misconduct

Federal agencies have ultimate authority for Federally funded research, but research institutions are responsible for preventing, detecting, and making inquiries into suspected cases of research misconduct that have occurred within or in association with their own institution.

Investigation of Allegations of Research Misconduct

All records of allegations of research misconduct, and any subsequent inquiries and investigations, will be maintained in a secure file for a minimum of three years.

1. Inquiry. Allegations of possible research misconduct should be reported to the Vice President of Research and Scholarship, who will consult with the Vice President for Academic Services on whether a formal inquiry is warranted. This determination is based on whether the allegation a) falls within the definition of “research misconduct,” and b) is sufficiently credible and specific to allow identification of evidence.

To pursue an inquiry, the Vice President of Research and Scholarship 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 Institutional Review Board with a copy of the allegation.

Each inquiry shall be completed within 60 calendar days from the receipt of allegation, including preparation of a written report. The report will be provided to the individual involved in the allegation, the Principal Investigator of the project involved, the Chair of the Institutional Review Board and the sponsoring agency (if applicable).

2. Investigation. Investigation will be conducted if the results of the inquiry indicate that it is warranted.

The Vice President of Research and Scholarship, in consultation with the Vice President of Academic Services, will name a panel composed of at least three individuals, all of whom must 1) have adequate expertise to evaluate the evidence; and 2) 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 location.

The results of the investigation will be reported in writing and provided to the individual under investigation, the Principal Investigator of the project involved, the Chair of the Institutional Review Board and the sponsoring agency (if applicable). The investigation will be initiated within 30 calendar days of the completion of the inquiry, and must be completed within 120 calendar days.

Consequences of Research Misconduct

The decision concerning appropriate disciplinary action is the responsibility of the sponsoring agency, in the case of externally funded research. In the case of internally funded research, appropriate disciplinary action is the responsibility of the President of the College and will be consistent with the College’s grievance policy.

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. These include protection against retaliation for informants who make good faith allegations 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; and the opportunity to respond to allegations.

Confidentiality During the Investigation. To the extent possible, knowledge of the identity of subjects and informants will be limited to those who need to know. V. Agency

Notification of Federal Agencies: Applicable to Federally Funded Research

The Vice President of Research and Scholarship 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 College 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.

¹ Office of Science and Technology Policy. Federal Policy on Research Misconduct. *Federal Register* 2000;December 6,65(235):76260-4.

Guidelines for Ethics in Authorship for Scientific Publications

There are generally accepted ethical principles underlying the publication of scholarly and scientific articles.¹ 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 coauthors on any publications resulting from the project.

Authorship requires that one make a substantive scientific contribution to the manuscript, 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, 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.

Staff members are not required nor expected to be authors or coauthors of such presentations or publications but they may do so (in fact we encourage them to do so) if it is clearly demonstrated that they have had substantive scientific input into a given activity/aspect of the project.

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.

¹ Source: Elsevier Publishing Company. Ethics in Publishing: Instructions to Authors. Reprinted in *Journal of Manipulative and Physiological Therapeutics*, 2005.

Informed Consent

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. According to the U.S. Department of Health and Human Services¹ 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
- 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 and an explanation as to whether any medical 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.

¹ <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>

Informed Consent Form Template. For all research conducted at Cleveland Chiropractic College involving human subjects, an informed consent document must be prepared and submitted to the Institutional Review Board along with the Research Proposal Application. A template, with instructions, is provided to assist investigators in developing this document, in the section. This template includes all the required elements of informed consent.

Informed Consent Template

This template includes all the required elements of informed consent. Investigators should use the headings provided. Suggested text is shown in regular font and explanations are italicized and shown in brackets or boxes.

[Insert title of study] Consent Form

Introduction. You are invited to be in a research study of *[insert general statement about study]*. You were selected as a possible participant because *[explain how the subject was identified]*. We ask that you read this document and ask any questions you may have before agreeing to be in the study. This study is being conducted by *[indicate College affiliation]*.

Advice:

- *Invite participation. For relative or parent, the document should read, “your relative” or “your child.” Use 12-point font size or larger. For populations, such as the elderly, who may have difficulty with small print, increase font size.*

2. Background. The purpose of this study is *[explain research question and purpose in lay language]*.

Advice:

- *Define or explain research terms. Use declarative sentences and eighth-grade reading level (use the “show readability statistics” function in Word, which will display the Flesch-Kincaid grade level).*
- *Keep the description as brief as possible. Include key elements of the research process and duration of the study. Explain if the drug or device being tested is experimental (**required** if applicable). Give enough information to make an informed decision, but not so much (or so technical) that the reader becomes confused. Describe quantities in lay terms, e.g., teaspoons.*

3. Procedures. If you agree to be in this study, we will ask you to do the following things: *[explain tasks and procedures from the subject’s point of view [what will he/she be expected to do?]*.

Advice:

- *Estimate the total amount of time for the person involved in the study. Describe the frequency of procedures.*
- *Explain how the person is assigned to groups. Disclose any additional costs or charges for the research procedures with estimated amounts. Describe “randomization” in lay terms. State the probabilities of assignment of each group.*
- *For survey/questionnaire studies, state that not all questions need to be answered in order to participate. State that procedures are experimental, if applicable (required if applicable). Identify additional procedures specific to “research” participation, distinct from “treatment” procedures.*

4. Risks and Benefits. This study has the following risks: *[explain risks, hazards, or discomforts, including risk likelihood. Be honest and accurate]*. The benefits of participation are: *[describe any benefits to the subject or others that may reasonably be expected to benefit from the research]*.

Advice:

- *If there are significant physical or psychological risks (such as stress or invasion of privacy), describe conditions under which the investigator will terminate the study. Identify risks of being in the placebo group (if applicable). If there is no benefit to the subject, say so. If injury may result from the research, include information as to the medical treatment and compensation.*
- *If there is an incentive or compensation for participation, specify terms of disbursement on the document. FDA regulations require that payment to subjects be prorated over time, so that in the event a subject withdraws from a study, prior to termination of the research, he/she receives some compensation for participation. Describe the payment method for subjects, if any.*
- *Do not make payment an inducement, only a compensation for expenses and inconvenience. If the subject is a student who receives class points or some other token, include that information under benefits.*
- *If a person is to receive some money or other token to participate, explain when it will be paid and any conditions of full or partial payment. If there is a monetary incentive being provided to a person who refers the subject, make sure it is disclosed in the consent document.*

5. Alternatives to Participating in This Study. *[State the alternative treatments for the subject and the risks and benefits of alternatives]*.

6. Compensation. *[If the research involves a physically invasive procedure (e.g. manipulation, exercise, acupuncture, etc.), where there is even a slight risk of injury, include the appropriate compensation statement in the consent document.]*

Case 1: *For funded projects where a contract exists agreeing to pay for research-related injuries*

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The study sponsor has some funds available to pay for care for injuries resulting directly from being in this study. If you think that you have suffered a research-related injury and may be eligible for reimbursement of some medical care costs, let the study physicians know right away.

Case 2: *For projects where there is no already identified source of payment:*

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment, and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think you have suffered a research-related injury, let the study physician know right away.

Case 3: *There is no physical component to this research, so there is minimal risk of physical injury:*

A statement concerning compensation for medical treatment is not required.

7. Confidentiality. The records of this study will be kept private. In any report we might publish or present, we will not include any information that will make it possible to identify a subject. Your record for the study may, however, be reviewed by the sponsor [*include study sponsor, if applicable*].

Advice:

- *If data will be made available to anyone other than the participant, the investigator, or the investigator's staff, describe the purpose of the disclosure and the nature of the information to be furnished. Specify the duration of time the data will be retained before erasure or destruction. Disclose use of such data for other purposes, including educational purposes, and obtain permission in a special portion of the consent document. If tape recordings or videotapes are made, explain who will have access; if they will be used for education purposes, state that this is the case, and specify when they will be erased.*

8. Voluntary Nature of the Study. Your decision whether or not to participate will not affect your current or future relations with the College [*or with other cooperating institutions, insert names; or with your instructor (if applicable)*]. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Advice:

- *Be sure the wording reflects the voluntary nature of the participation. Consent is ongoing, so include a sentence about withdrawal; explain any adjustment of monetary benefits due to early withdrawal, if applicable.*

9. New Information. If during the course of this research study, there are significant new findings discovered which might influence your willingness to continue, the investigators will inform you of those developments.

10. Contacts and Questions. The investigator(s) conducting this study is(are) [*insert names*]. You may ask any questions you have now. If you have questions later, you may contact the investigators at [*include phone number with area code*]. If you have questions or concerns regarding the study and would like to talk to someone other than the investigator(s), you may contact Dr. Charles Dorlac, IRB Committee Chairperson, Cleveland Chiropractic College, 751 East 63rd Street, Kansas City, MO 64110; telephone (816) 501-0285.

Advice:

- *If the investigator is a student, include the names and phone numbers of the principal investigator and, where applicable, the faculty supervisor for questions. Include as a contact someone not involved in the study.*

11. Statement of Consent. You will be given a copy of this form to keep for your records. I have read and understand the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature Date _____

Signature of Parent or Guardian Date _____

Advice:

- *Add signature space to the document if children are to participate; however, parental signatures are still required. If the potential subject is not competent, use an assent document with caregiver consent. Do not use a witness.*
- *If you use a witness line, it should clearly describe what the signer is witnessing, e.g., witness to signature.*
- **Give participant a copy of the signed consent form.**

Flesch-Kincaid Reading Ease

for use in preparing informed consent document

The "**Flesch-Kincaid Reading Ease**" test scores passages 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. 8th and 9th grade students could easily understand passages with a score of 60-70, and passage with results of 0-30 are best understood by college 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.

This 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.

Flesch-Kincaid Grade Level

An obvious use for readability tests is in the field of education. The "**Flesch-Kincaid Grade Level Formula**" translates the 0-100 score to a U.S. grade level, making it easier for teachers, parents, librarians, and others to judge the readability level of various books and texts. The result is a number that corresponds with a grade level. For example, a score of 6.1 would indicate that the text is understandable by an average student in 6th grade.

How to access in Microsoft Word

For activating the readability statistics in Microsoft Word:

1. Go to Tools section of Word
2. Select Options
3. Select Spelling & Grammar tab
4. Select "Show readability statistics". You are ready to check the readability statistics of your document.
5. Run Spelling & Grammar from the tools menu. At the conclusion of the spelling and grammar check, a message box will appear, detailing several text statistics, including both the Flesch-Kincaid Reading Ease and Flesch-Kincaid Grade Level.

Institutional Review Board

Statement of Purpose. Cleveland Chiropractic College, by virtue of its mission, acknowledges its responsibility to conduct research in the basic sciences, and to carry out clinical studies involving human subjects, in an effort to provide a firmer basis for the various types of care rendered by chiropractors.

In conducting studies involving persons, Cleveland Chiropractic College fully commits itself to the protection of these persons and acknowledges its obligations to abide by federal and state regulations and guidelines germane to research involving human subjects.

Pursuant to this commitment and acknowledgement, Cleveland Chiropractic College hereby establishes the Institutional Review Board (IRB) to oversee human subject research and to protect the rights and well-being of these subjects. The IRB is established upon a base broad enough to provide those safeguards deemed by Cleveland Chiropractic College to be essential to the research process, and is empowered to review, supervise, and control the procedures attendant thereto.

Description of IRB Function. In order to implement the Statement of Purpose, the IRB shall:

1. Review and possess authority to approve, require modifications in, or disapprove all research involving human subjects which is conducted at or sponsored by Cleveland Chiropractic College.
2. Conduct continuing review of the research after initial approval, and possess authority to suspend, and if appropriate, terminate approval of research that is not being conducted in accordance with the determinations of the IRB or in which there is unexpected harm (of any type) to subjects. Any such suspension or termination of approval must be reported to the Principal Investigator (PI), the appropriate institutional officials, and the Secretary of the Department of Health and Human Services (DHHS), and must include a statement of the reasons for the IRB's action. As part of its continuing review responsibility, the IRB must have authority to observe the consent procedure or the research itself, on a sample basis, or have an authorized third party do so. Continuing review shall be undertaken at intervals appropriate to the degree of risk, but not less than one such review annually.
3. Be responsible for reporting to the appropriate institutional officials and the Secretary of DHHS, any serious or continuing noncompliance by investigators with the requirements and determinations of the IRB.
4. Perform such other duties as may be assigned by the institution or the Secretary of DHHS.

IRB Membership and Terms. The Cleveland Chiropractic College Institutional Review Board shall be comprised of the following membership: A minimum of five (5) members, both men and women, of varying backgrounds, experience, and profession; At least one (1) member shall not be employed by or affiliated with Cleveland Chiropractic College; At least one (1) member's primary concern shall be in non-scientific areas. One (1) member shall also be a member of the Cleveland Chiropractic College Research Committee. This member shall serve in the capacity as correspondent and be responsible for the functions as described in Section Four. Selection of members can be through invitation of the Chair, by request or volunteer, or through appointment by the President of Cleveland Chiropractic College. Membership is considered a responsibility of faculty employment at Cleveland Chiropractic College. Each member must be approved by the President of Cleveland Chiropractic College prior to accepting responsibilities on the Board.

IRB members shall not receive compensation for the services rendered as members; out-of-pocket expenses, evidenced by written receipt, shall be reimbursed; IRB members shall serve a term of two (2) years. Terms are renewable with the approval of the President of Cleveland Chiropractic College.

A quorum shall consist of three (3) members. A quorum is required when any vote is necessary for project approval. An exception is granted in the case of an expedited review.

IRB Officers:

1. Chairperson
2. Secretary
3. Correspondent.

The IRB shall be managed by three (3) officers who shall implement and enforce the policies and procedures as approved by the Cleveland Chiropractic College and the DHHS regarding research involving human subjects. As part of this design, each officer shall be responsible for the following specific functions:

Functions of the Chairperson: The Chairperson for the IRB shall be appointed by the president of Cleveland Chiropractic College and shall serve a two-year term. The functions of the Chairperson include: Preside over IRB meetings; direct and implement the procedures of the IRB; initiate appropriate amendments to IRB procedures; Other such duties as the Board deems necessary to perform the purposes of the IRB; Report all proceedings of the IRB to the President; and The Chairperson may elect to be responsible for the functions as Secretary or may appoint a member to provide the functions as described below. The Chairperson may also elect to be responsible for the functions as Correspondent or may appoint a member to provide the functions as described below.

Functions of the Secretary. The functions of the secretary are as follows: To record and preserve IRB decisions regarding research applications; Cause to be published

IRB determinations or to otherwise provide applicant with notice of IRB decisions; Contact IRB members with notice of IRB meetings; and other duties as imposed or recommended by the IRB. The Chairperson may act as the secretary of the IRB.

Functions of the Correspondent. The IRB Correspondent will be a member of both the Research Committee and the IRB. The functions assigned to this person include: To work with the Research Committee to accomplish the following: Receive research applications; Present applications to the IRB for its review in a manner consistent with IRB procedure; follow-up on approved research projects so as to: Report to the IRB on compliance with approved research program; report to the IRB for continuing approval; report to the IRB regarding the progress of approved research projects; perform other duties as imposed or recommended by the IRB for the purpose of corresponding with the IRB and the Research Committee. The Chairperson may act as the Correspondent of the IRB.

IRB Members 2007

Dr. Charles Dorlac – Chair – charles.dorlac@cleveland.edu
Fran Stous - dstous@kcnet.com
Dr. Michael Whitehead – Michael.whitehead@cleveland.edu
Dr. Victor Tong – victor.tong@cleveland.edu
Dr. Stephan Mayer – Stephan.mayer@cleveland.edu
Dr. Thomas Nichols – tom.nichols@cleveland.edu
Marcia Thomas – marcia.thomas@cleveland.edu
Kimberly Morris – Kimberly.morris@cleveland.edu
Marjorie Bradshaw – Marjorie.bradshaw@cleveland.edu

Research Committee Composition

Each campus will have a Research Committee composed of:

- Research Director (Chair)
- Academic Dean or his/her designated representative
- IRB representative
- 1 faculty representative designated by the faculty council chair

Policy on Incentives for Scholarly Publications

Composition of Faculty Scholarship Incentive Award Committee

The committee for each campus will be composed of the members of the Research Committee, with additional ad hoc members if deemed necessary by the chair; to be appointed by the chair. If a member of the committee is applying for the award, he/she will be recused and the Chair will appoint an ad hoc member as replacement.

More than 50% of committee members must be present to make a recommendation on any award. Meetings may be conducted electronically, by phone, or in person.

The Incentive Award Committee will take each request under consideration and make a recommendation to the Vice President of Research and Scholarship, who will make the final determination of the award, based on availability of funding. Funding is subject to College budgetary constraints and may be suspended or decreased by the Chief Financial Officer if necessary. *Note: Funding for all awards will be drawn from funds set aside in the Multicampus Research budget designated specifically for this purpose. Under no circumstances will funds be drawn from any external funds designated for a specific research project.*

Incentive Awards for Scholarly Publications

Eligibility

Cleveland faculty, administrators, staff and students are eligible for this award, with the following restrictions.

- The research project described in the article must have been conducted at or in collaboration with Cleveland Chiropractic College
- The project must have been approved by the Institutional Review Board or appropriate College administrator prior to its conduct.
- This award *does not* apply to commentaries or editorials.
- Students may apply for awards after their graduation if the project in which they were involved started while they were enrolled at Cleveland.
- The publication must state the author's affiliation with Cleveland.

Scholarly Publications of Research Investigations in Scientific Journals (Non-Chiropractic): This category includes the publication of a full-length article describing the results of a research project in a peer-reviewed scientific journal outside the chiropractic profession. When the article is accepted for publication the first author may request an award of \$1000 and each of the coauthors may request an award of \$500, if all eligibility criteria are met.

Scholarly Publications of Research Investigations in Chiropractic Journals: This category includes the publication of a full-length article describing the results of

a research project in chiropractic journals with peer review processes of established quality. These are:

- *Journal of Manipulative and Physiological Therapeutics*
- *Journal of the American Chiropractic Association*
- *Chiropractic and Osteopathy*
- *Clinical Chiropractic*
- *Journal of the Canadian Chiropractic Association*
- *Journal of Chiropractic Education*
- *Journal of Chiropractic Medicine*

When the article is accepted for publication to one of the above-named journals the first author may request an award of \$500 and each of the coauthors may request an award of \$250, if all eligibility criteria are met.

Books, Book Chapters and Monographs: Upon verification of publication by an outside publisher, the senior author or editor is eligible for an incentive award of \$500, separate from any royalty arrangements made with the publisher. First author of a chapter in a book or monograph is eligible for an incentive award of \$250 upon verification of publication. Self-published works or works published by Cleveland Chiropractic College are excluded.

Co-author with First Author at Another Institution: The eligibility requirements above also pertain to publications in which the first author is not a Cleveland employee. However, only coauthors who are employed by Cleveland are eligible for an incentive award.

Restrictions

Authors may not hold a publication or defer payment of the award in order to qualify for an incentive award the following year. The monetary sum of incentive awards for publications plus salary supplements for externally funded grants may not exceed 20% of the individual's annual base salary in any given calendar year.

Procedure for Applying for an Award for Scholarly Publications

Incentive awards are NOT automatic. Each author who wishes to receive an incentive award MUST comply with these procedures in order to be considered for an award. *In all instances the study described in the publication and/or author must be identified with Cleveland Chiropractic College.* EACH author must make a separate application to the Committee, and must include the following in this request:

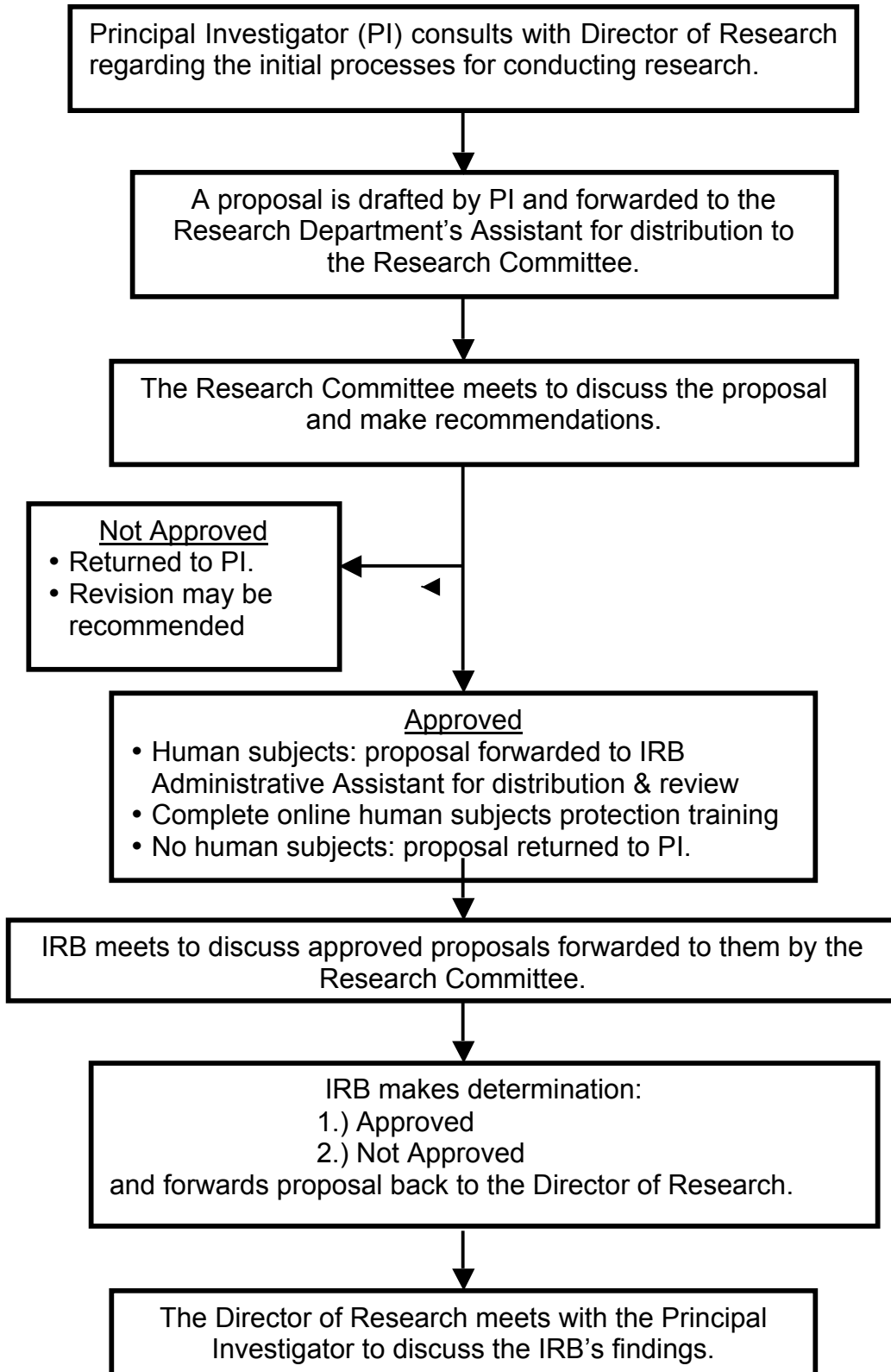
- a. Letter of request providing:
 - Complete citation for article, using this format:
Smith J, Doe J, Smith M. Article name with only first word in caps. *J Manipulative Physiol Ther* 2007;20(1):19-25. OR (in press).
 - Date of acceptance
- b. Copy of acceptance notification
- c. Copy of the publication

Requests must be submitted electronically to the committee chair. This letter of request must be submitted within 30 days after being notified of acceptance by the journal, editor, or publisher. Exceptions to this will be made at the discretion of the committee, if accompanied by an explanation.

Release Time:

If a faculty member wishes to obtain release time from his/her normal duties in order to pursue a research initiative or to participate as a team member on an approved research project, he/she should apply in writing to the Academic Dean stating the reason for the release time and the length of time he/she wishes to be released from normal duties. The dean will confer with the Director of Research to ascertain if the request has merit and will likely lead to an approved research project and a published paper. If approval is granted, progress toward the goal stated in the request must be continual and constant with written progress reports submitted to the dean monthly. A faculty member on release time must communicate with the Director of Research at least once a week to assure he/she is proceeding according to established policies and within project approval guidelines.

Flowchart: Application for Research Project Approval



In-House Research Proposal Form Application for Research Project Approval

To be submitted electronically to the Research Committee, and, after approval, to the IRB for approval

Kansas City **Los Angeles**

Title of Project:				
Key Personnel	Role in study	Position*	Department	Phone
	PI			
* faculty, staff, student; if student, indicate trimester number				
Source of funding for project				
<input type="checkbox"/>	internal funding—complete Budget Form (p. 4)			
<input type="checkbox"/>	external funding—attach proposal including budget			
	Source:			
Type of project				
<input type="checkbox"/>	Involves ONLY literature search—do not complete p. 3			
<input type="checkbox"/>	Involves ONLY secondary data, including patient records			
<input type="checkbox"/>	Involves ONLY survey of students in educational setting			
<input type="checkbox"/>	Involves human subjects and/or tissues/bodily fluids. If this box is checked:			
	<input type="checkbox"/> All investigators have completed Human Subjects Protection training and filed a certificate with the Research Department (to be completed at: http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp)			
<input type="checkbox"/>	A copy of the informed consent is attached.			
Certifications: I am familiar with the policies and procedures of Cleveland Chiropractic College regarding human subjects in research. I subscribe to the standards and will adhere to the policies and procedures of the Cleveland Chiropractic College Research Committee and Institutional Review Board. <div style="text-align: center;">and</div> I am familiar with the published guidelines for the ethical treatment of subjects associated with my particular field of study.				
Signature of Principal Investigator			Date	

Application for Research Project
to be submitted to IRB along with informed consent form

Please complete the following on this page using only the space provided. Please do not use continuation pages.

State Project's Purpose and Specific Aims:

Describe the Proposed Subjects (age, sex, ethnicity, diagnosis, other special characteristics):

Describe Subject Recruitment and Selection Procedures:

Summary of Proposed Methods and Procedures: (must fit on this page. Do not use continuation pages.)

Please answer the following with regard to the research activity proposed:		
Does the research involve:	YES	NO
• Nutritional supplements, drugs, or other controlled substances?	<input type="checkbox"/>	<input type="checkbox"/>
• Payment of subjects?	<input type="checkbox"/>	<input type="checkbox"/>
• Access to subjects through cooperating institutions?	<input type="checkbox"/>	<input type="checkbox"/>
• Substances taken internally by or applied externally?	<input type="checkbox"/>	<input type="checkbox"/>
• Mechanical or electrical devices applied to subjects?	<input type="checkbox"/>	<input type="checkbox"/>
• Fluids (e.g. blood) or tissues removed from subjects?	<input type="checkbox"/>	<input type="checkbox"/>
• Subjects experiencing stress (physiological or psychological)?	<input type="checkbox"/>	<input type="checkbox"/>
• Deception of subjects concerning any aspect of purposes or procedures including misleading or withheld information?	<input type="checkbox"/>	<input type="checkbox"/>
• Subjects who would be judged to have limited freedom of consent (e.g., minors, developmentally delayed persons, or those institutionalized)?	<input type="checkbox"/>	<input type="checkbox"/>
• Any procedure or activity that might place the subject at risk (psychological, physical, social)	<input type="checkbox"/>	<input type="checkbox"/>
• Use of survey, interview, questionnaires, audio or video recordings	<input type="checkbox"/>	<input type="checkbox"/>
• Data collection over a period greater than one year	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
Will a written consent form be used?	<input type="checkbox"/>	<input type="checkbox"/>
Will a copy of the consent form be given to the subject?	<input type="checkbox"/>	<input type="checkbox"/>
Approximate number of subjects in the research project, including control subjects:		

BUDGET FORM

Estimated Start Date:		Estimated Completion Date:	
Personnel Time Commitments			
Name	Role in Project	% of time	\$ request
Total personnel expenses requested			

Non-Personnel Expenses	
EQUIPMENT	
SUPPLIES (Itemize by category):	
TRAVEL	
PATIENT CARE – CLINIC	
PATIENT CARE – LABWORK	
PATIENT CARE - X-RAY	
OTHER EXPENSES (Itemize by category)	
Total non-personnel expenses requested	
TOTAL PROJECT EXPENSE (total of both blocks)	

Informed Consent Checklist

use informed consent template to develop document

- Title of Project & names and contact information for Investigators
- Statement that this is “research” or “experiment”
- Gives the purpose/nature of the study
- States duration of the study
- Invites the person to consider participation and denotes participation is voluntary
- States inclusion and exclusion criteria
- Describes the study procedure
- States type of and frequency of visits
- Identifies number of subjects to be recruited to the study
- Discloses foreseeable risks
- Contains statement of unforeseeable risks
- Discloses direct and indirect benefits or no benefit
- Advises subject may withdraw at any time
- Discusses confidentiality
- States compensation policy/treatment in case of injury
- Copy of consent form is provided to subject
- Signature line for subject, witness and investigator
- Readability of the consent for is _____ Flesch-Kincaid (use instructions provided with informed consent template).

Office of Data Management

An Office of Data Management (ODM) has been established for the purpose of managing research data, particularly those collected in clinical studies.

Transmission protocols for data to the ODM will be developed on a study-specific basis. Once data are present in the ODM, standard protocols for security and management will be applied.

The data manager will review forms for completeness and multiple responses; code responses and prepare data dictionaries and keys; prepare forms for data entry; and run validation checks after key entry is completed. All study data will go through a double key-entry verification process and be maintained electronically in a password-protected relational database on a secure network. The ODM data entry (DE) assistants will not have access to this database, as they enter and verify data through a separate software program. After a DE assistant enters or verifies a batch of forms, he or she will log it in via e-mail to the data manager, and then return it to the locked cabinet. Forms will be maintained in a secure steel file cabinet, to which only ODM personnel have access.

A final SPSS dataset will be created at the conclusion of each project and transmitted electronically to the Principal Investigator.

Performance Monitoring in Clinical Studies

Recruitment, enrollment and follow-up will be monitored by means of a relational database set up by the ODM. The database will allow tracking of recruitment, enrollment, missed appointments and follow-up scheduling and generation of reports.

Research Data Security

No project personnel other than the data manager will have access to the actual tables in the relational database. Any reports needed to facilitate efficient project management will be built into the report module. As stated above, electronic data will be stored on a secure, password protected server and hard copy data in a secure file cabinet.

Procedures for Submitting Grant Applications to Federal Agencies

Grants Officer

Marjorie Bradshaw has been appointed as the grants officer for Cleveland Chiropractic College, and will facilitate submission of grant applications for external funding. Ms. Bradshaw has on file the access information for the online submission process for National Institutes of Health (NIH) grants.

Grants.gov registration

Cleveland is now a Federally recognized institution with Grants.gov, a necessary prerequisite for submission of grant applications to NIH.

The Authorized Organizational Representative (AOR) for grants.gov has been identified as the Chief Financial Officer.

eRA Commons registration

Cleveland has authenticated the registration of a Principal Investigator and a Signing Official with the eRA Commons, a necessary prerequisite for submission of grant applications to NIH. The Signing Official (SO) in the eRA Commons system is the same as the AOR in the grants.gov system, and has been identified as the Chief Financial Officer.

Required Software for NIH Submissions

Copies of PureEdge and Adobe Professional, required for submission of NIH grant applications, have been installed on research personnel and grant officer computers.