RESEARCH HANDBOOK

SHERMAN COLLEGE OF CHIROPRACTIC

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RESEARCH AT SHERMAN COLLEGE

RESEARCH MISSION

The Research Component of the College Mission is as follows:

Faculty members engage in research and scholarly activities that contribute to the body of pedagogical and clinical knowledge which advances chiropractic education and the chiropractic profession. https://www.sherman.edu/about/our-mission-vision/

OBJECTIVES

1. Conduct research in one or more of the following:
    a. The physical manifestations of vertebral subluxation.
    b. The effects of the chiropractic intervention in the correction of vertebral subluxation.
    c. The validity and reliability of the various procedures used in the analysis and correction of vertebral subluxation.
    d. Instructional pedagogy
    e. Other types of research that help to expand the body of knowledge, practice, or instruction of chiropractic.

2. Teach students to read and interpret scientific literature (to be able to determine that the conclusions drawn by the investigator are supported by collected data).

3. Provide continuing education related to research to the College constituency through seminars, workshops and exhibits.

4. Seek external support for research activities through gifts, grants and contracts.

5. Encourage the faculty to participate in research that results in publication.

6. Provide a research liaison with other chiropractic colleges, professional organizations and the scientific community.

7. Provide the resources – human, material and financial – to support research activities.

DEPARTMENTAL MISSION

The Center for Scholarly Activity is committed to improving the teaching and practice of chiropractic in a salutogenic, evidence-informed context focused on the analysis and correction of vertebral subluxations.
Obsessed with Student Success

Center personnel will:

1. Create and maintain a positive, nurturing culture among students toward research and scholarly activities (RASA) as well as evidence-informed, vertebral subluxation centered practice in a vitalistic, salutogenic model.

2. Assist students in coordinating and integrating college resources to achieve their academic and clinical goals related to research and evidence-informed practice.
3. Provide support for students seeking assistance with literature search, research design and implementation, and manuscript preparation.
4. Provide support for students seeking assistance with literature retrieval, clinical assessment, and research to empower them with critical thinking skills necessary for success in the Health Center and private practice.
5. Integrate feedback from students and faculty to ensure relevance, excellence, and accountability in evidence-informed curriculum and practice.

INTEGRATING EVIDENCE-INFORMED PRACTICE

Evidence-Informed curriculum and practice is an essential element of implementing these core values. The process involves the following steps:

1. Evaluate the evidence base for each course. Is the material taught supported by textbooks, scientific literature, individual expertise, or a combination of these?
2. Identify any gaps in the evidence for what is taught.
3. Review the available literature to see which gaps can be filled.
4. This will lead to recommendations for curriculum and policy change, and help develop a research agenda to fill the gaps that remain.

RESEARCH AND SCHOLARLY ACTIVITY (RASA) EXPECTATION OF FACULTY

Each faculty member is expected to plan, propose and complete scholarly or scientific achievements as part of their routine responsibilities. [Faculty Handbook, 2022, pp. 26-28]

Faculty members will consult with the respective deans during the planning of scholarly and/or scientific achievement in order to secure the necessary resources (release time, guidance, training, equipment, materials, statistical analysis, etc.) and obtain approval to pursue the project. The deans will consider the complexity of the proposed project and the guidelines below when considering allocation of resources and approval of the project. The deans will also be responsible for monitoring the planning and progress of scholarly efforts in conjunction with the faculty evaluation process. Faculty members are expected to be continuously involved in the advancement of their respective scholarly or scientific activity as evidenced by the categories described below.

Definitions of Scholarship

Research and Scholarly Activity are understood to be intellectual works whose significance is validated by peers, and which has been made accessible to the scholarly community. The principle of peer review and recognition becomes increasingly important as the faculty member progresses through the academic ranks. Scholarship emphasizes project-oriented behavior that results in a measurable product or outcome (e.g., a publication, written report, manual, or protocol). This activity includes, but is not limited to, the following types of academic work:

- Scholarship of discovery; pursuit of knowledge through original research, most often by application of the scientific process;
- Scholarship of integration; work that pulls together knowledge, views information in creative ways, often using interdisciplinary methods;
- Scholarship of application; develops knowledge through practice and systematic or scientific research, then applies knowledge to real-world problems;
- Scholarship of teaching; problem posting about an issue of teaching or learning, study of the problem through methods appropriate to disciplinary epistemologies, application of results to practice, communication of results, self-reflection, and peer review.

Parameters of Scholarship

Acceptable scholarship must have the following characteristics:

- A rationale for how the activity or behavior supports the Mission of the College;
- Documented evidence that the activity was performed and completed;
- Criteria that establishes that the outcome or result met an acceptable standard of quality.

Classifications Which Qualify as Research and/or Scholarly Endeavor

- Papers clearly intended for publication in peer-reviewed journals.
- Investigation – any report of new research findings concerning the art, science and philosophy of chiropractic, teaching, learning, administration, faculty governance and any other aspect of chiropractic education stemming from original research, investigation and data analysis in the faculty members respective field, discipline, or area of interest.
- Case studies in education – descriptive papers regarding any aspect of the science, art and philosophy of chiropractic, where before and after data is analyzed in a non-controlled environment.
- Model lessons – descriptions of lesson plans and discussions of implementation showing the adaptation of material to meet the needs of the chiropractic student through the use of instructional strategies, selection of emphasis in content, attitude development, and development

of unique skills to chiropractic.
- Articles – insightful, appropriately referenced articles pertaining to current issues in chiropractic.
- Literature reviews – critical assessment of current knowledge of a particular subject of interest related to education or chiropractic practice. Studies should demonstrate exhaustive content.
- Conference presentations – chiropractic or educational conference presentations, particularly abstracts of presentations prior to publication in conference proceedings or elsewhere.
- Case Reports and/or case series – case reports which reflect the account of care of unusual, difficult or otherwise interesting cases that may have independent educational value or may contribute to further understanding of the science, philosophy and art of chiropractic.
- Observational and experimental investigations – i.e., intervention studies, cohort studies, case-control studies, cost-effective analysis, epidemiologic evaluations, studies of analysis tests. These studies should follow the current relevant guidelines typically found in peer reviewed journals.

Other Examples of Scholarship

Other examples of scholarship that may meet parameters above include, but are not limited to, the following activities:

- Organizing or participating in (to a substantial degree), and reporting the results of professional symposia, colloquia, consensus panels, workshops, and the like;
- Developing, writing and implementing protocol manuals, policies, procedures, reports and similar documents that have a measurable impact on educational outcomes or processes; otherwise engaging in professional activity in a timely manner that meets the above definition of scholarship, research, and creative activity
- Conducting a presentation of 30 minutes or more, at a faculty in-service activity
- Editorships of journals or serving on Editorial Board of Peer Reviewed Journals
- Author of article in professional trade journal
- Develop a course of study for post-graduates.

Categories of Scholarship

Scholarship will be categorized or graded as "A", "B", or "C". Categorization will depend on the level of importance to the mission of the College, degree of effort involved, timeliness of effort, and degree of quality, especially with respect to the parameters listed above. Scholarship activities not listed below, and the value thereof, will be categorized on the following lists.

These categories are meant as a general guide. The width and depth can transcend the categories and will be judged on its individual merits.

A-Level Scholarship:

Normally, A-Level scholarship includes, but is not limited to, the following:

- Primary author of a paper accepted for publication in a peer-reviewed scholarly journal indexed in the Index to Chiropractic Literature or PubMed.
- Primary author/editor of a published textbook (not self-published)
- Primary author/editor of a monograph accepted for publication (not self-published)
- Primary author of an awarded proposal submitted for external funding

B-Level Scholarship:

Normally, "B" level scholarship includes, but is not limited to, the following:

- Co-author of a paper accepted for publication in a peer-reviewed scholarly journal indexed in the Index to Chiropractic Literature or PubMed
- Primary or co-author of a paper accepted for publication in a peer-reviewed journal not indexed in the Index to Chiropractic Literature or PubMed.
- Primary author of a contributed poster or platform presentation documented in the published proceedings of a meeting.

- Primary author of a chapter in a published textbook (not self-published)
- Co-author of an awarded proposal submitted for external funding
- Co-author/editor of a published textbook (not self-published)
- Co-author/editor of a monograph accepted for publication (not self-published)
- Primary developer of a new course proposed and accepted by the College for curricular implementation

C-Level Scholarship:

Normally, "C" level scholarship includes, but is not limited to, the following:

- Co-author of a paper accepted for publication in a B-Level Journal
- Co-author of a contributed poster or platform presentation documented in the published proceedings of a meeting
- Co-author of an invited presentation documented in the published proceedings of a meeting
- Co-author of a chapter in a published textbook (not self-published)
- Co-author of a self-published textbook
- Primary author of a proposal submitted for external funding
- Co-developer of a new course proposed and accepted by the College for curricular implementation
- Developer of an innovative presentation of a substantial amount of course information
- Abstracts published in proceedings of a meeting
- Primary author of a self-published textbook
- Co-author of a proposal submitted for external funding

RESEARCH RELEASE TIME

In the interest of professional development, the institution encourages faculty members to be active participants within scientific bodies in their disciplines. The College will provide reasonable release time for attendance at conventions, seminars, and workshops, provided it does not unduly interfere with the faculty member's duties and assignments and may provide funds to defray travel expenses as the College budget permits.

At times, the College may agree to a reduction in a faculty member's teaching load in order that the time subsequently released may enable the faculty member to undertake research, major course revision, curricular revision or institutional self-studies. It is assumed that all faculty recognize the responsibility to constantly update their instructional materials without requiring release time to do so. However, the nature of restructuring may be such that release time is advisable.

Requests for release time must have prior approval of the Vice President for Academic Affairs. The request should be made in writing to the Vice President for Academic Affairs through the respective department dean and should include a statement of purpose as well as information on how class responsibilities will be met. Requests should be made at least one academic term in advance of the anticipate release time.

(*See Appendix: Application for Research Release Time*)

RESEARCH GRANTS

Recognizing that institutions can become dependent on external funds for their normal operations, the following policies are designed to maintain the financial autonomy of the institution:

1. Any person, faculty or staff, who is hired by Sherman College into an externally funded program and compensated with external funds, must be told that employment is contingent on that external funding.
2. Any other use of an externally funded person outside of the funded project, must be compensated by supplemental contract.
3. Indirect cost allowances may not be used to increase the department's operating budget.

While the College encourages faculty to seek external funding for grants and contracts whenever appropriate, it also recognizes that external funding can pose serious problems for the College and the achievement of its goals and objectives. Because external funding usually involves a contractual relationship between the funding agency and the College, it is imperative that the terms, conditions, the expectations of any contract must conform to and promote the stated purposes of the College. Grantors and contractees may not use the Sherman name in any advertisement programs as endorser of any product or technique.
However, any material placed in the public domain by publication may be quoted as long as appropriate credit and citation is provided. It may be announced that such work was done at Sherman College only after such data has been published.

While the researcher's freedom to investigate and report results must be preserved, the institution must be certain that those activities to which it commits resources are consistent with its stated goals and objectives.

When a portion of the grant or contract is designated as salary, that portion is to be allocated in one of the following methods:

1. If faculty members are being released from institutional duties in order to fulfill the terms of the grant or contract and they are expected to complete the project within their normal working hours, they will continue to be compensated by the College. The funds designated for salaries will be deposited in the payroll fund of the College to reimburse the College for having to replace those now involved in the project.

2. If faculty members are expected to fulfill the conditions of the grant or contract with no reduction of duties and no reduction in their full-time work schedule, funds designated for salary will be disbursed to those faculty members according to the conditions of the grant or contract.

3. If faculty members are released from institutional duties but are still required to work hours in addition to their normal full-time work at the institution in order to fulfill the terms of the grant or contract, the College should receive reimbursement for the released hours.

The College is not obligated for compensation beyond its contractual relationship with the faculty member. It is the responsibility of the person requesting the grant or contract to contact the Vice President for Business and Finance or his designate to be certain that the proper salary amounts are requested in the grant.

SHERMAN COLLEGE OF CHIROPRACTIC CODE OF ETHICS

CODE OF ETHICS

Based upon the statement of ethics of the American Association of University Professors (AAUP), this code, formulated by Sherman faculty, reflects a concern and respect for both the needs of the institution and the academic and personal freedoms of the faculty.

SHERMAN COLLEGE OF CHIROPRACTIC CODE OF ETHICS

The faculty member, guided by a deep conviction of the worth and dignity of the advancement of knowledge, recognizes the special responsibilities placed upon him. His primary responsibility to his subject is to seek and to state the truth as he sees it. To this end, he devotes his energies to developing and improving his scholarly competence. He accepts the obligation to exercise critical self-discipline and judgment in using, extending and transmitting knowledge. He practices intellectual honesty. Although he may follow subsidiary interests, these interests must never seriously hamper or compromise his freedom of inquiry.

As a teacher, the faculty member encourages the free pursuit of learning in his students. He holds before them the best scholarly standards of his discipline. He demonstrates respect for the student as an individual and adheres to his proper role as intellectual guide and counselor. He makes every reasonable effort to foster honest academic conduct and to assure that his evaluation of students reflects their true merit. He respects the confidential nature of the relationship between professor and student. He avoids any exploitation of students for his private advantage and acknowledges significant assistance from them. He protects their academic freedom.

As a colleague, the faculty member has obligations that derive from common membership in the community of scholars. In the exchange of criticism and ideas he shows due respect for the opinions of others. He acknowledges his academic debts and strives to be objective in his professional judgment of colleagues. He accepts his share of faculty responsibilities for the governance of his institution.

As an individual, the faculty member is guided in social, personal, and non-academic contacts with students by the professional and moral obligations and responsibilities inherent in the faculty-student relationship.

As a member of this institution, the faculty member seeks above all to be an effective teacher and scholar. Although he observes the stated regulations of the institution, he retains the right to criticize and seek revision.

As a member of his community, the faculty member has the rights and obligations of any citizen. He measures the urgency of these obligations and responsibilities to his subject, to his students, to his profession and to his institution. When he speaks or acts as a private person, he avoids creating the impression that he speaks or acts for his college or university. As a citizen enhanced in a profession that depends upon freedom for its health and integrity, the professor has a particular obligation to promote conditions of free inquiry and to further public understanding of academic freedom and to demonstrate an understanding of the value of the "whole person" by maintaining family and community relationships so there is a balanced distribution of time and energy between collegiate and non-collegiate professional activities.

FACULTY INITIATION OF RESEARCH

Being essential to the continued growth of the chiropractic profession, research is an activity in which faculty participation is highly encouraged. The following policy states those steps necessary for a faculty member to initiate a research project and to facilitate that process.

1. Any faculty member desiring to become involved in existing research or to undertake a new project shall first discuss the project with the Director of the Center for Scholarly Activity.
2. If it is a new project, the faculty member shall provide a written description of the project to the Director of the Center for Scholarly Activity. (A form will be provided by the Director). If it is an existing project, the Director of the Center for Scholarly Activity will arrange a meeting with the project Director and the faculty member at which the member's participation will be discussed.
3. The Director of the Center for Scholarly Activity will discuss with the faculty member the resources and time commitment that will probably be required for the project. It is expected that for most preliminary studies, the faculty member would utilize hours already assigned for scholarship and development and would not require release time from teaching assignments.
4. For those projects requiring a larger time commitment, a meeting with the faculty member, the appropriate department head or division chair and the Director of the Center for Scholarly Activity will be arranged by the Director of the Center for Scholarly Activity at which release time for the project will be discussed and some mutually agreeable solution will be sought. The final agreement on release time must be recommended by the Vice President for Academic Affairs and shall be for a fixed period of time, i.e., one or two quarters.
5. Acquisition of equipment and materials and allocation of space will be coordinated by the Director of the Center for Scholarly Activity. Funding for an approved project will be provided by the Center for Scholarly Activity, if possible. If the amount exceeds the Center for Scholarly Activity's budget resources, other institutional funding will be sought. If the funding requirements are large enough or the project falls within the funding guidelines specified by an outside agency, outside funding will be sought.
6. Complete the standard research project application form (available in Center for Scholarly Activity) and submit to the Center for Scholarly Activity for approval.

INVENTIONS, PATENTS AND COPYRIGHTS

Policy 3075 COPYRIGHT
Created 04/15/08

POLICY
It shall be the responsibility of every employee of Sherman College of Chiropractic to comply with copyright law. The *Employee Handbook* (p. 31-36) describes copyright definitions, procedures, fair use, and how to obtain permission to copyright.

Any questions regarding copyright compliance should be directed to the director of learning resources, director of human resources, or the vice president for academic affairs.

A. General
Sherman College of Chiropractic owns all domestic and foreign rights in and to any and all inventions and materials made or developed by college personnel, either in the course of employment by the college, or through the use of facilities or funds provided by or through the college. Inventions are considered as having been developed in the course of employment, where conception and/or development derive from the scholarly activities for which the individual is employed. The rights owned by the college include all economic and property rights, as well as the right to patent inventions and to copyright materials. Net proceeds are shared with the inventor as provided in this document (see item D.)

B. Faculty Publication Rights
Faculty members own all rights to materials prepared on their own initiative for classroom, educational or professional purposes, including all royalties from the publication or distribution of such materials. An example might be a textbook or laboratory manual developed on a faculty member's own time, without the use of college facilities or funds. The college owns educational materials developed in the course of college employment. In cases where the college has a proprietary interest in such materials, the professional interest of the faculty member and the reputation of the college require that there be adequate mutual control over their use. The extent of such control and mutual rights with respect to the revision, withdrawal, limitation and termination of the use of such materials, are set forth in a separate agreement between the college and the faculty member.

All scientific publications and presentations by Sherman College faculty must bear an inscription indicating that the work was completed at, and supported by, the Sherman College Center for Scholarly Activity (where appropriate). All on-campus scholarship to be submitted for publication and/or conference presentation by Sherman faculty members must have been approved by the Director of the Center for Scholarly Activity or his designee.

C. Equities of Participating Parties
It is the policy of Sherman College to encourage and recognize the creative efforts of college personnel and, insofar as the administration of the college deems it consistent with the public interest, to share the financial rewards of such efforts on an equitable basis. This general policy may be rescinded or amended at any time by the college, and it is not intended to and does not create any legally enforceable rights whatsoever for any college personnel with respect to any present or future invention, or written or recorded material. The rights of college personnel in and to any inventions or materials belonging to the

college under this policy will be created and exist only through an agreement between the college and the individual(s) concerned.

D. Determination of Equities

When the equities involve the rights in and inventions and material developed by a faculty member: The Sherman College Research Committee makes a recommendation to the President, who determines:

1. When the rights in and to inventions and materials developed by the faculty member belong to the college under the provisions of this policy;
2. Whether any faculty member is entitled to share in the net proceeds of such inventions and materials and, if so,
3. What the respective equities of the college or the faculty member will be.

When the equities involve the rights in and the inventions and material developed by an employee other than a faculty member (i.e. staff, administration): The Administrative Council makes a recommendation to the President, who determines:

1. When the rights in and to inventions and materials developed by college personnel (other than faculty members) belong to the college under the provisions of this policy;
2. Whether any college personnel (other than faculty members) is entitled to share in the net proceeds of such inventions and materials and, if so,
3. What the respective equities of the college or the college personnel (other than faculty members) will be

Notwithstanding any determination by the committee, or any other provisions of this policy, college personnel have no equities or rights whatsoever in inventions and material belonging to the college unless and until a written agreement has been executed by the college and the college personnel consistent with the determination of the President

E. Review of Committee Action

The president of the college may review any determination of the Research Committee, and does so at the request of any interested person. The president may affirm, modify or reject any determination of the committee. If the committee recommends that, in any particular case, the college should have less than one-half interest in the invention or material, a review by the president of the college is final, conclusive and binding upon the college personnel involved, as well as upon the college.

RESEARCH COMMITTEE

PURPOSE of the RESEARCH COMMITTEE

To recommend to the Director of the Center for Scholarly Activity, policies and programs for administration of research and to provide liaison between the Center for Scholarly Activity and the other divisions of the College.

Reports to: The Vice President of Academic Affairs through the Director of the Center for Scholarly Activity

RESPONSIBILITIES

To serve as a liaison between the Center for Scholarly Activity and the academic divisions of the College, promote wide-based faculty and student involvement in research and scholarship, recommend to the Director of the Center for Scholarly Activity policies and programs for the administration of research, review research proposals at the request of the Director of the Center for Scholarly Activity.

The Research Committee:

1. Acts as an advisory body to the Center for Scholarly Activity.
2. Makes recommendations to the faculty concerning policies relative to research activities.
3. Encourages research by both faculty members and students.
4. Assists in the identification and procurement of funds to support research.
5. Provides technical assistance to scholars in developing and carrying out research projects.
6. Approves all research project expenditures to be funded by the college that are above and beyond regular salary and release time.
7. Publishes periodic reports of the research activities of faculty members and students.
8. Determines the ownership of the rights in and to, and the distribution of any equities from any inventions and materials developed by college personnel, subject to review by the president of the college.

COMMITTEE COMPOSITION

The Research Committee is composed of the Director of the Center for Scholarly Activity, who serves as chairman; the vice president for academic affairs; the Assistant Director of the Center for Scholarly Activity; the dean of clinics; the dean of basic sciences; the dean of clinical sciences; three additional faculty members elected by the faculty, one each from basic sciences, clinical sciences and the faculty at large; and one student member recommended by the Chiropractic Student Government and confirmed by the Committee.

A current roster of Research Committee members is on file with the Office of Academic Affairs.
The current Chairperson of the Research Committee is Christopher Kent, DC, ACP, JD

MEETINGS

Meets as called by the chair.

RESEARCH PROPOSAL APPROVAL

All research proposals require approval by the Director of the Center for Scholarly Activity – either a Full Review or Expedited Review as detailed below.

Additionally, research proposals intended for research release time or other college funding above regular salary are to be approved by the respective dean.
(See *Appendix: Faculty Request for Research Release Time*)

For each research proposal, the Director of the Center for Scholarly Activity has the discretion of a Full Review or an Expedited Review, which is determined by the nature of the proposal. The Director will approve /disapprove based on reviewer comments by the members of the Research Committeee:

- **Full Review**: For any new research project, which does not qualify for exempt status or expedited review, the proposal will be presented to the full research committee for consideration.

- **Expedited Review**: For less complex projects and minor modification of previously approved research projects, the Director of the Center for Scholarly Activity will determine approval.

(See *Appendix: Research Proposal Review Sheet*)

So, You Want to Conduct Research – A Step-by-Step Guide

RESEARCH at SHERMAN ... from Proposal to Publication

The Center for Research and Scholarly Activity is always available to help at every step.

You will be the Principal Investigator (PI). The following is only a basic outline.

I. **Come Up with A Research/Scholarly Idea**
   a. What are you interested in? Be specific.
   b. Literature Search:
      i. One hour will provide a basic understanding of the topic
      ii. You'll do much more later.

II. **Evaluate Resources**
   a. Co-investigators with unique knowledge or experience, or just to divide the work
   b. Consider how much time you have, equipment, funding

III. **Write a Proposal**
   a. See *Appendix: Research Proposal Preparation*
   b. See *Appendix: Research Proposal Format*
   c. Very basically, you will write:
      i. What is known about the topic
      ii. What is NOT known, and why it would be interesting to find out
      iii. How you can research to discover something new (the research method/design)
      iv. How you will analyze the data.

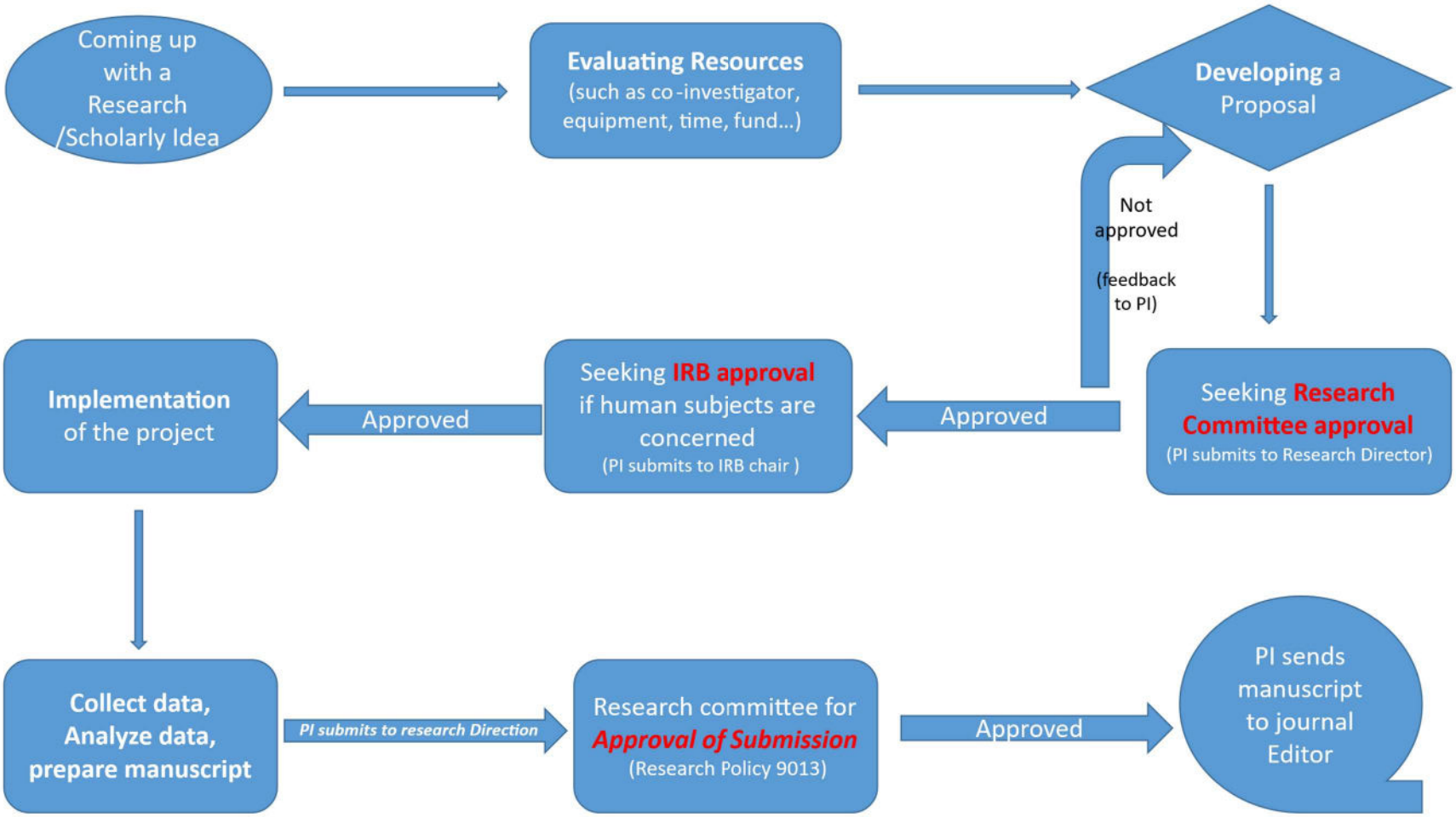
IV. **Seek Research Committee Approval**
   a. Required documents – PI Submits to Research Director
   b. Typically includes:
      i. Informed Consent (see format, edit for your study)
      ii. Research Proposal
   c. A review and decision by the Committee typically takes 2-4 weeks. Extensions may occasionally be needed based on scheduling and/or length and complexity of the proposal. Notification of approval, modifications, or denial will be sent via email.
   d. See also *Appendix: Application for Institutional Approval and Support*

V. **Seek IRB Approval**
   a. Only if human participants or human participant information are involved
   b. Required documents – PI submits to IRB chair
   c. Typically includes:
      i. Informed Consent (see format, edit for your study)
      ii. Research Proposal
      iii. Human Subjects Research Proposal Evaluation
   d. See also *Appendix: Request for IRB Review: Coversheet*
   e. See also *Appendix: Request for IRB Review: Overview Checklist*

VI. **Implement the Project**
   a. Expand literature search, collect data, analyze data, prepare manuscript

VII. **Approval of Submission from Director of the Center for Research and Scholarly Activity**
   a. The Director of the Center for Research and Scholarly Activity needs to approve the final paper before submission to a journal, and the final draft following peer review and acceptance.
   b. You must receive written approval from the Director before submission to any journal
      i. This requirement applies to all research including, but not limited to, clinical studies, case studies, literature reviews, scoping reviews, systematic reviews, meta-analyses, etc.
      ii. This requirement does not apply to "opinion" articles in professional trade publications.

VIII. **Send Manuscript to Journal Editor**
   a. Each journal has its own instructions/preferences


Coming up with a Research /Scholarly Idea
Evaluating Resources (such as co-investigator, equipment, time, fund…)
Developing a Proposal
Not approved
(feedback to PI)
Seeking Research Committee approval (PI submits to Research Director)
Approved
Seeking IRB approval if human subjects are concerned (PI submits to IRB chair)
Approved
Implementation of the project
Collect data, Analyze data, prepare manuscript
PI submits to research Direction
Research committee for Approval of Submission (Research Policy 9013)
Approved
PI sends manuscript to journal Editor

ELEMENTS OF INFORMED CONSENT FORM

(See *Appendix: Sample Consent Form*)

1. Title of Protocol

   The official title of the protocol should be placed at the top of the consent form.

2. Invitation to Participate

   The consent form should begin with a clear invitation (not a request or demand) to them individual to participate in the research study.

3. Basis for Subject Selection:

   The consent form, when appropriate, should state why the prospective subject has been selected (e.g., subjects with specific disease, condition, characteristic, background). This statement should help the subject to assess the nature and importance of participation.
   When appropriate, the approximate number of subjects involved in the study should be stated.
   When appropriate, criteria for subject exclusion should be stated (e.g., pregnancy, age limitations, and health restrictions).

4. Overall Purpose

   The consent form must contain a clear statement of the overall purpose of the research that should help the subject assess the importance of the study relative to individual values.
   When appropriate, this statement should include not only the immediate purpose of the study, but also any larger, ultimate purpose.

5. Explanation of Procedures

   The explanation of procedure section of the consent form should include, where appropriate, the following:

   a. A description of the study design, method of subject assignment to groups and probability of assignment. Despite the fact that subjects may be kept unaware of treatment assignments in blinded studies and research involving placebos, subjects must be made aware of all the possible interventions and the method of assignment. Thus, prospective subjects are invited to remain ignorant of treatment assignment without the element of deception.

   b. A description of each procedure to be applied to human subjects and how often it will be performed. All procedures, both experimental and non-experimental, must be described / disclosed.

   c. Identification of the individual(s) who will perform the procedures and/or interact with the subject. Procedures involving human subjects should be performed only by qualified individuals.

d. A statement of where the research will be conducted, when the research will be conducted, and how much time (per session/in total) will be required of the subject.

e. A statement concerning any medications, therapeutic regimens, foods, or other substances that are contraindicated/disallowed either before or during participation in the study.

f. If the research study involves incomplete disclosure or deception, all subjects must be debriefed as soon as possible after participation. The consent form for nondisclosure/deception studies should normally contain a statement concerning when and where the debriefing session will be held. If, however, debriefing may be harmful to subjects / the investigator may request a waiver of the debriefing requirement.

6. Potential Risks and Discomforts

A risk is a potential harm that a reasonable person, in what the investigator knows or should know to be the subject's position, would be likely to consider significant in deciding whether or not to participate in research.

7. Potential Benefits

A benefit is a valued or desired outcome. Benefits associated with participation in research can be classified generally as those that accrue to the subject directly (e.g., improvement of health status) and those that accrue to society (e.g., acquisition of knowledge). If any substantial benefits to the subject or to others can reasonably be expected, they should be described. It must be stated in the description that the benefits are hoped-for but not guaranteed by the investigator. If there are no benefits to the subject, it must be so stated.

8. Financial Compensation

Any economic incentives or rewards for participation should be clearly stated. Economic incentives are usually cash payments, but may also include, when appropriate, free physical examinations, free treatment, and treatment at lower cost.

9. Assurance of Confidentiality

   This section of the consent form should state that any information that is obtained in connection with the study and that could identify the subject will remain confidential and will be disclosed only with the subject's permission. If the investigator intends to release any information, the consent form must state the person or agency to whom information will be furnished, the nature of the information to be furnished, the purpose of the disclosure, and whether the subject's name will be used as an identifier. When appropriate, the ultimate disposition of data should be described.

10. In Case of Injury Compensation

    For research studies involving more than minimal risk, the consent form must contain the following standard IRB compensation statement: "IF INJURY OCCURS AS A DIRECT CONSEQUENCE OF THE RESEARCH PROCEDURES DESCRIBED ABOVE, THE EMERGENCY CARE REQUIRED TO TREAT THE INJURY WILL BE PROVIDED BY THE COLLEGE AT NO EXPENSE TO YOU, PROVIDING THAT THE COST OF SUCH CARE IS NOT REIMBURSABLE THROUGH YOUR OWN HEALTH INSURANCE. HOWEVER, NO ADDITIONAL COMPENSATION FOR PHYSICAL CARE, HOSPITALIZATION, LOSS OF INCOME, PAIN, SUFFERING, OR ANY OTHER FORM OF COMPENSATION WILL BE PROVIDED AS A RESULT OF NON-NEGLIGENT INJURY."

11. Withdrawal from the Study

    The consent form must contain the following standard IRB non-coercive disclaimer: "Participation is voluntary. Your decision whether or not to participate will not affect your _____ (insert "grade, treatment, or present or future relationship with" as appropriate) the College (and/or other named institution as appropriate). If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time."

12. Offer to Answer Questions

    The consent form must contain an offer by investigators to answer all immediate and subsequent questions that the subject may have. The following should be used:" If you have any additional questions concerning the rights of research subjects, you may contact _____, the principal investigator (include phone number, school email, and campus address), or _____, Chair of the Sherman College Institutional Review Board (IRB), (include phone number, school email, and campus address)."

13. Concluding Consent Statement

    The consent form must contain the following standard concluding consent statement in bold type: "**YOU ARE VOLUNTARILY MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE**

DECIDED TO PARTICIPATE HAVING READ THE INFORMATION PROVIDED ABOVE. YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP."

_____ _____

Signature of Subject Date

_____ _____

Signature of Witness Signature of Investigator (if required)

The signature of a witness is required for all research studies involving more than minimal risk. If possible, the witness should be someone who is not involved in the study.

14. Identification of Investigator(s)

The name, professional degree(s), and office telephone number(s) of the investigator(s) must be provided. For research studies involving more than minimal risk, the home/night phone number(s) of the investigator(s) must be provided.

HUMAN & ANIMAL SUBJECTS

HUMAN SUBJECTS

1. If a research project involves the use of human subjects, the faculty member will submit the appropriate forms to the Institutional Review Board (IRB). The IRB will review the project and assess the risks to the human subjects. If the IRB finds the risks to be acceptable, it may approve the project as submitted. If the risks are unacceptable, the IRB may suggest revisions and request that the project be resubmitted, or the IRB may disapprove the project.

2. After the necessary funding and IRB approval (if necessary) have been obtained, the Director of the Center for Scholarly Activity and the faculty member will develop a schedule for the completion of the project. This schedule will include a timetable for the entire project including data analysis and manuscript preparation.

ANIMAL SUBJECTS

The Center for Scholarly Activity does not pursue animal experimentation other than within the perimeters of procedures utilized with human subjects.

Documentation concerning human subject protocol is detailed elsewhere in this book.

Appendices

Research Proposal Preparation

How to Develop and Research Study
From Concept to Publication

Ask a Research Question:

Begin by stating a question of great interest to you in a simple, nontechnical interrogative sentence.

As you complete the workbook exercises from this point through the development of your hypothesis, you will find it useful to rewrite your research question several times. Each revision should reflect greater precision and probably narrower scope in your search for answer.

The research will require access to these resources. 1.
2.
3.
4.

Is the research feasible? Yes_____No_____

Define the important terms in your statement of the research question. Terms

and definitions

1.
2.
3.
4.

Search for Related Work

List questions you hope are already answered by previous research. List

relevant theories or models.

Other background information you could use.

Likely sources of information (not necessarily in journals).

Justifying the Study

Who is interested in the study? How

is present opinion divided?

How important is it to have the right answers?

What are the implications of various possible answers?

Write a paragraph justifying your study. Consider the questions above but feel free to modify or add to them.

Hypotheses

Hypotheses require the investigator to predict an answer to the research question based on knowledge of the field, logical analysis, and/or anecdotal observations. Purely descriptive studies do not require formal hypotheses. Even so, it is wise to commit yourself to a set of expectations regarding results.

Initial statement of hypothesis.

General relationships implied by your hypotheses.

Can you identify specific alternative relationships or explanations which would serve as competing or rival hypotheses?

Revised statement of hypotheses, considering (if possible) specific competing alternatives to the hypothesized relationships.

Instruments and Data Sources

Complete this inventory of measurements or counts to be made. Then list your proposed instruments or data sources for measuring or counting.

Things to be measured or counted

1.
2.
3.
4.

Proposed instruments or data sources 1.
2.
3.
4.

Cost of instruments requested 1.
2.
3.
4.

If an adequate instrument is not readily available, indicate critical characteristics of instruments to be found or developed.

Preparing the research design

The design of the study refers to the way in which relationships are to be studied. It is wise to seek competent help in preparing a research design, since design options are numerous.

Sampling

Describe the characteristics of the people who will be eligible for participation in the study.

Describe the population (beyond your sample) to which you wish to generalize conclusions.

Now review the two descriptions critically and revise either or both descriptions so that they fit together.

Sample Size

The most important consideration in determining sample size is often how much money you have to spend and how much time you can commit.

Increases in sample size increase the precision of the research. Small samples do not of themselves introduce bias. A large sample should enable you to detect more subtle (but perhaps less important) relationships. When other design features have been worked out, a research consultant should be able to help you arrive at a reasonable sample size. The most helpful information in this decision comes from the results of similar studies and your estimate of the strength of the relationships you expect to find.

Developing the Research Protocol

How will you select your sample?

Will your divide your sample into groups? If so, how?

Describe what will happen to each subject. (Feel free to use a list, flow chart, or diagram.) Who

will gather the data and how?

Eliminating Procedural Bias

Bias refers to sources of systematic error which may affect study results. Unless adequately controlled, bias may render your results uninterpretable. With a general protocol in mind, specific attention should be given to each of the following potential sources of bias. The design should evolve as you add controls for the most serious of these. Those mentioned below are adapted from "Experimental and Quasi-Experimental Design for Research," Campbell DT and Stanley JC, Chicago, Rand McNally College Publishing, 1966.

1. Effects of Historical Events - Can you anticipate events such as personnel changes, remodeling plans, interference by non-participants, etc., which will take place during your data collection phase and which might affect the results?

   No_____Yes_____(If yes, describe problem.)

2. Effects of Maturation - If subjects are to be observed over time, are there changes which might result merely by normal development, growth, natural course of illness, etc.?

   No_____Yes_____(If yes, describe problem.)

3. Effects of Repeated Measurement - If the same measurements are repeated on subjects, are objects likely to remember past responses, prepare differently for the next session, relax procedures?

   No_____Yes_____(If yes, describe problem.)

4. Instrument Decay - Is it likely that test equipment will wear out, observers get bored, protocols get short-cut by investigators, etc.?

   No_____Yes_____(If yes, describe problem.)

5. Effects of Statistical Regression - If subjects are chosen because they lie at the extremes of distribution (e.g., high blood pressure, low compliance with therapy), subsequent measurements will tend to be more nearly average, for purely statistical reasons. Are your subjects chosen or assigned to groups on the basis of their "extremeness"?

   No_____Yes_____(If yes, describe problem.)

6. Subject Selection - Is there anything in the selection of your sample or assignment of subjects to groups which makes one group of subjects unintentionally different from other groups?

   No_____Yes_____(If yes, describe problem.)

7. Loss of Subjects - Subjects lost due to attrition may be different from those who remain. Is your study jeopardized by this possibility?

   No_____Yes_____(If yes, describe problem.)

8. Investigator Bias - Are you in a position to unintentionally "shade" results to confirm your hypotheses or to influence subjects by your attention, attitude, etc.?

   No_____Yes_____(If yes, describe problem.)

Identify the Limitations of the Study

After struggling to achieve a design which is feasible and provides control of the most troublesome sources of bias, you may be left with inadequate controls over other sources of bias. Use the space below to identify these.

Potential sources of bias remaining

Even unbiased studies have limitations in their generalizability. To what kinds of people beyond your study sample can you justify generalizing your conclusions. (It may be easier to identify individuals for whom your conclusions do not necessarily apply.)

Limitations to generalizability

Data Collection Forms

Use the space below to sketch forms you will use to record the data of the study. Alternatively, you may list and describe the forms below and then attach specimens.

Reporting Results

Use the space below to sketch summary data table and/or graphs which you would expect to use in presenting your results. You may include simulated results of the kind you hope to find.

Statistical Analysis

Design and analysis are two sides of the same inferential coin. **Always** seek competent consultation in the design phase or there may not be any analysis worth doing.
You may begin to organize the analysis by listing below all of the variables considered in your design. Separate the variables into the three categories described.

9. Demographic variables which describe characteristics of subjects such as age, sex, race, previous hospitalizations, etc.

10. Variables of the study under the control of the investigator, such as type of instruction given, therapy options, duration of treatment, or other exposures or treatments to which the investigator can assign subjects.

11. Outcome variables or effects potentially related to or caused by 1 or 2 above, such as adherence to instructions, speed of recovery, or client satisfaction.

Discussions, Interpretations, or Conclusions

No workbook exercises are included for this phase of research. Instead it is suggested that the researcher should maintain a notebook or diary in which to capture anecdotes, remarks of subjects, comments by others involved in the project, or any other facts or ideas which might help to make sense out of the phenomena under study. It is often the serendipity of the alert and curious researcher which leads to insightful interpretations and fruitful new hypotheses.

Research Proposal Format

Proposal Title

Lead Investigator: XXX
Co-investigator: XXX if appropriate

Below is an **outline for Research Project Proposal:** when writing, please use section headings to indicate where the information can be found. Subheadings need not be used, though in long sections they may facilitate organization.

1. Introduction

Explain the issue you are examining and why it is significant.

- Describe the general area to be studied
- Explain why this area is important to the general area under study

2. Background/Review of the Literature

A description of what has already known about this area and short discussion of why the background studies are not sufficient.

- Summarize what is already known about the field. Include a summary of the basic background information on the topic gleaned from your literature review (you can include information from classes, but the bulk should be outside sources/research)
- Discuss several critical studies that have already been done in this area
- Point out why these background studies are insufficient. In other words, what question(s) do they leave unresolved that you would like to study?
- Choose (at least) one of these questions you might like to pursue yourself. (Make sure you do not choose too many questions)

3. Rationale

A description of the questions you are examining and an exploration of the claims.

- List the specific question(s) that you are exploring.
  - Explain how these research questions are related to the larger issues raised in the introduction.
  - Describe what specific claim, hypothesis, and/or model of chiropractic you will evaluate with these questions.
- Explain what it will show about chiropractic if your hypothesis is confirmed.
- Explain what it will suggest about chiropractic if your hypothesis is disconfirmed.

4. Method and Design

A description of how you would go about collecting data and test the questions you are examining. You are not required to come up with a new or original method (though you can try!). Look for journal articles to determine what methods are standardly used to assess knowledge of language in your chosen area and adapt one of these for your needs.

Method:

- How would you collect the data and why?
- Describe the general methodology you choose for your study, in order to test your hypothesis(es).
- Explain why this method is the best for your purposes.
- Participants: Who would you test and why?
- Describe the sample you would test and explain why you have chosen this sample. Include

age, and language background and socio-economic information, if relevant to the design.
- Are there any participants you would exclude? Why, why not?

Design:
- What would the stimuli look like and why?
- Describe what kinds of interventions you would make or test for in order to test your hypothesis(es).
- Describe the factors you would vary.
- Explain how varying these factors would allow you to confirm or disconfirm your hypotheses.
- Explain what significant differences you would need to find to confirm or disconfirm your hypothesis(es). In particular, how could your hypothesis(es) be disconfirmed by your data?
- Controls: What kinds of factors would you need to control for in your study?
- Describe what types of effects would be likely to occur which would make your results appear to confirm, or to disconfirm your hypothesis(es).
- Describe how you can by your design rule out or control for apparent effects.

Procedure
- How are you going to present the interventions?
- What is the participant in the experiment going to do?

Analysis
- How will you analyze the results?
- What kind of results would confirm your hypothesis?
- What kind of results would disconfirm your hypothesis

5. Risks/Benefits: any potential risks and benefits

6. Costs: any cost will be associated with your research? How will your research be funded?

7. **Significance and Conclusion**

Discuss, in general, how your proposed research would lead to a significant improvement over the original studies, and how it would benefit the field.

In other words, why should someone care? If you were applying for money to do this, why would someone fund you? If you wanted to publish your results, why would they be interested?

8. References

Include all references

Sherman College of Chiropractic
Application for Institutional Approval and Support

DATE RECEIVED_____

1. Title of Project (Please type in the space provided.)

_____

2. Principal investigator, Title, Department, Phone Extension

_____

3. Human Subjects? _____Yes _____No
4. Dates of Entire Proposed Project From: _____ _____

5. Vertebrate Animals Involved __Yes _____No
   If yes, identify by common names and underline primates.

6. If a Portion of The Project Will Be Done off Campus, Estimate the Amount of Time/Week: _____

7. Does the Proposal Contain Potential Patentable Ideas?
   _____Yes_____No

   Potential Copyright?_____Yes_____No

8. If Health Center is to be Used, the Estimated Costs are Included?_____Yes_____No

9. Will the Project Result in the Submission of a Proposal to an External Funding Agency?
   _____Yes_____No

10. Principal Investigator Assurance: I agree to accept responsibility for the scientific conduct of this project and to provide the required progress reports to the Director of the Center for Scholarly Activity or his designee.

_____ _____
SIGNATURE OF PRINCIPAL INVESTIGATOR Date

Sherman College of Chiropractic
Research Proposal Review Sheet
(Optional)

Reviewer Name: _____

My confidence in reviewing this proposal: 1 2 3 4 5
(1: very low - 5: very high)

Proposal Title:

Conclusion:

Approve without revision
Approve with minor revision
Approve with major revision (see below)
Reject (see below)

Technical Merit:

1. How important is the proposed research to advancing chiropractic knowledge and understanding within the field or across different fields? (Importance of the problem)

2. To what extent does the proposed research activity suggest and explore creative and original concepts? (Originality of approach)

3. How well conceived and organized is the proposed research? (soundness of approach and organization of the research plan)

4. How well conceived is the evaluation plan?

5. How much impact do you think the results will be on society and/or increasing scientific and technological understanding?

6. Any comments for improvement in the proposal for a future submission?

Sherman College of Chiropractic
Sample Informed Consent Form

INVITATION TO PARTICIPATE

You are invited to participate in this research project because you are an adult (18 years or older) and are under chiropractic care. Your decision to participate in this study will not affect the care received at the Sherman College Health Center in any way.

PURPOSE OF THE STUDY

The purpose of this study is to compare two chiropractors or two interns in terms of their techniques in analysis of the vertebral subluxation.

EXPLANATION OF PROCEDURES

If you agree to participate, you will be examined by two chiropractors or interns at your first visit to the clinic (normally this procedure is performed by only one chiropractor or intern). After the initial examination, an x-ray will be taken depending on the judgment of the chiropractor or intern. Then an adjustment plan will be formulated by the chiropractor or intern. There will be no adjustment applied to you in this experiment.

POTENTIAL RISKS AND DISCOMFORTS

These are all standard clinic procedures and there are no unusual risks and discomfort involved.

POTENTIAL BENEFITS

There are no direct benefits of participation to you except the analysis of subluxation may be more accurate because two chiropractors are involved. However, data gathered in the study may provide information for a better service to you and other people in the future.

ASSURANCE OF CONFIDENTIALITY

I agree that any data collected as a result of my participation in this project may be used for educational or scientific purposes. I understand that only group results will be reported in any published account that may result from this study and that I will not be identified by name or circumstances. I understand that all efforts will be made to protect my anonymity, that my identity will be known only to the experimenter and members of the research team, and that all information I contribute will be considered confidential.

IN CASE OF INJURY COMPENSATION

If injury occurs as a direct consequence of the research procedures described above, the emergency medical care required to treat the injury will be provided by the College at no expense to you, providing that the cost of such medical care is not reimbursable through your own health insurance. However, no additional compensation for physical care, hospitalization, loss of income, pain, suffering, or any other form of compensation will be provided as a result of non-negligent injury.

WITHDRAWAL FROM THE STUDY

Participation is voluntary. Your decision whether or not to participate will not affect your present or future care. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

OFFERS TO ANSWER QUESTIONS

If you have any additional questions concerning the rights of research subjects, you may contact the Principal Investigator (include phone number and campus address) or the Chairperson of the Sherman College Institutional Review Board (IRB).

YOU ARE VOLUNTARILY MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE HAVING READ THE INFORMATION PROVIDED ABOVE. YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

_____ _____

SIGNATURE OF SUBJECT DATE

_____ _____

SIGNATURE OF INVESTIGATOR DATE

_____ _____

SIGNATURE OF WITNESS DATE
(Required if presented orally)

Sherman College of Chiropractic
Faculty Request for Research Release Time

DATE RECEIVED_____

1. Title of Project _____

   _____

2. Investigator _____

3. Department _____ Phone Extension _____

4. Justification of Proposed Release Time:

   _____

   _____

   _____

   _____

5. Dates of Entire Proposed Project From:_____Through:_____

6. Estimate the Amount of Time Required:_____

7. Principal investigator Assurance: I agree to accept responsibility for the scientific conduct of this project and to provide the required progress reports to the Director of the Center for Scholarly Activity or his designee.

   _____ _____



Institutional Review Board (IRB) Manual

2022

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IRB OVERVIEW

Sherman College of Chiropractic
2020 Springfield Road, PO Box 1452
Spartanburg, SC 29304
IRB Chair: Jaime Browning, DC, DCCJP
jbrowning@sherman.edu

Sherman College of Chiropractic has established an Institutional Review Board to fulfill the college's commitment to protecting all subjects of research, regardless of the source of funding and/or the methodology used. Federal regulations for these ethical research concerns originate from the Office for Human Research Protections (OHRP), a part of the Department of Health and Human Services (DHHS), and the Sherman College IRB Manual, focus is derived from the Belmont Report from the National Commission for the Protection of Human Rights, and the Code of Federal Regulations Title 45 – Public Welfare, Part 46 – Protection of Human Subjects (please visit the OHRP website for further information). Whether an Exempt, Expedited or Standard research submission, the mission of Sherman College's IRB is to maintain protection of human subjects and sound research practices integrated into all research projects.
All investigators utilizing Sherman College's IRB are required to complete a human protections certification prior to research approval. This educational initiative not only validates the integrity of human based research at Sherman College, but it also strengthens the researchers' understanding of the social and historical bases for human subjects' research protections.

EDUCATIONAL REQUIREMENT
All submissions to IRB regardless of type must accompany a copy of human protections certification.
As of now, the only complementary human protections certification can be found at the following website:
https://acrpnet.org/courses/ethics-human-subject-protection/
Investigators will submit copies of certification to the IRB.

CODE OF FEDERAL REGULATIONS

The federal regulations are disseminated by the Office for Human Research Protections (OHRP, formerly the Office for Protection from Research Risks [OPRR]), an administrative unit within the Department of Health and Human Services (DHHS), organizationally located in the Office of Public Health and Science, under the direction of the Assistant Secretary for Health. Further information and frequently asked questions may be found at http://www.nihtraining.com/ohsrsite/info/sheet8.html. The regulations apply to all research involving human subjects and provide definitions for the terms research and human subject. The regulations define research as a systematic investigation designed to develop or contribute to generalizable knowledge. Human subject is defined as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. The federal regulations describe four basic requirements for the conduct of an IRB: (a) a statement of principles, (b) designation of one or more IRBs, (c) appointment of IRB members, and (d) written procedures for the IRB. It is within these parameters that the Sherman College IRB operates.

THE BELMONT REPORT

The Belmont Report was developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. This commission was created when the National Research Act (PL 93- 348) was passed in 1974. The Belmont Report summarizes the general ethical principles identified by the Commission that should underlie the conduct of biomedical and behavioral research involving human subjects.
In carrying out its mission, the Commission considered the boundaries between biomedical/ behavioral research and the accepted routine practice of medicine, the role of the assessment of the risk and benefit balance in determining whether humans should be used in the research, guidelines for the selection of human subjects, and the nature and definition of informed consent.
Since research and practice often occur together, it is necessary to distinguish between these two terms in order to know what activities ought to be reviewed for the protection of human subjects. The term *practice* is used to mean a commonly accepted intervention or procedure that is designed to enhance the well-being of an individual or client and is considered by the practicing community to have a reasonable expectation of success. *Research* is used to mean an activity designed to test a hypothesis or answer research questions, so that conclusions may be drawn and contributions to the general knowledge of a field may be made. While research and therapy or research and education may be carried out together, for

example, when evaluating the safety and efficacy of a therapy or of an educational strategy, this need not cause confusion regarding whether the activity requires review by the IRB. The general rule is that if there is an element of research in any activity involving human subjects, the activity should be reviewed.
The following summary identifies the boundaries between medical/behavioral research and the practice of medicine, and the three basic ethical principles which, when practically applied, lead to informed consent, assessment of risk and benefits, and the selection of subjects. The three principles identified by the Commission as generally accepted in our cultural tradition are labeled: (a) respect for persons, (b) beneficence, and (c) justice. These principles are stated in a sufficiently general manner to allow scientists, subjects, reviewers, and informed citizens to understand the ethical issues that are an integral part of research using human subjects. In stating these principles, the objective is to provide an analytical framework that will guide the resolution of ethical problems involving research with human subjects.

Respect for Persons
The first principle, which in its practical application gives rise to the idea of informed consent, is respect for persons. There are two ethical convictions that serve as the basis of this principle. First, individuals should be treated as autonomous agents. Second, individuals with diminished autonomy are entitled to protection.
This principle carries two moral requirements: that we acknowledge the autonomy of individuals and protect those individuals with diminished autonomy. The autonomous person is capable of choice, that is, capable of deliberation about personal goals and acting freely in the pursuit of those goals. To respect that autonomy is to allow the individual the freedom to pursue those goals without interference when there are no compelling reasons not to do so.
Although the capacity for self-determination is expected to be part of the normal maturation process, some individuals lose this capacity because of illness or mental disability. So, not every individual is capable of self-determination, and some individuals require extensive protection. The extent of the protection afforded individuals who are considering participation in a research activity depends upon an assessment of the risk of harm and the likelihood of benefit from the research. These individuals must also enter into the research activity voluntarily and with adequate information.
In its practical application, this principle requires that autonomous individuals, insofar as they are capable, be given the opportunity to choose what will and what will not happen to them. The possibility of this occurring is maximized when three standards for informed consent are satisfied. The first of these standards is information, generally including the procedure, purpose of the research, possible risks, anticipated benefits, and opportunity to ask questions and withdraw from the research. A simple listing of these items does not convey the full meaning of the term information. A general rule often used to determine what information to give requires the researcher to provide information that reasonable persons would wish to know in order to make a decision regarding their care.
Even then, subjects should clearly understand the range of the probable risks and the voluntary nature of their participation. Information concerning risk should never be withheld for the purpose of eliciting the cooperation of subjects, but care should be taken to avoid disclosures that would invalidate the research.
The second standard to ensure informed consent is comprehension. This standard is met when the information is conveyed in a manner that the subject can understand. This means that the researcher must adapt the presentation of the information to the subject's capacities for intelligence, rationality, language, and level of maturity. The obligation of the researcher to determine whether or not the subject comprehends the information increases with the seriousness of harm and probability of risks.
The third standard for informed consent is voluntariness. Agreement to participate in research is valid only if the consent is voluntary. This means that the consent must be obtained without coercion, undue influence, unjustifiable pressure, or deception.

Beneficence
The second principle that the Commission established to guide resolution of ethical issues inherent in research was the principle of beneficence. This is the obligation to secure the well-being of participants in research by maximizing possible benefits and minimizing possible harms. In practical terms, this involves determining when it is justifiable to seek certain benefits despite the risks and when the benefits should be abandoned because of the risks.
The assessment of benefits and risks is concerned with the probabilities and magnitudes of possible harms, such as psychological, physical, legal, social, and economic harm, measured against the possible benefits to the subject and to society. This assessment of risks and benefits requires the researcher's careful consideration of data, including consideration of alternate means of obtaining the same research information, and concern for the subject, subject's family, and society at large. This is accomplished by a systematic, non-arbitrary approach by the reviewing committee that requires those making decisions about the justifiability of the proposed research to be thorough in gathering and assessing information about all aspects of the research.
This includes a determination of the presuppositions of the research, clarification of the probability and magnitude of risk, and estimation of compliance with five considerations: (a) brutal and inhumane treatment is never justified; (b) risks are

reduced to those necessary to obtain the research goals; (c) if risk involves the possibility of serious impairment, review committees should require a very high level of justification; (d) the use of vulnerable populations must be justified; and (e) relevant risks and benefits must be communicated to the subject in the appropriate language.

Justice

The third principle is justice, which requires that there be fair procedures and outcomes in the selection of research subjects. The question is: Who ought to receive the benefits of research and who ought to bear its burdens? This principle is applicable at both individual and social levels.

At the individual level, research is constrained to offer the benefits of research to all subjects and not to seek *vulnerable* subjects for research procedures involving higher levels of risks.

Social justice requires that a distinction be made with respect to the ability of the social class selected for research to bear the burdens of the research. For example, this moral requirement would require the selection of adults before children, all other factors being reasonably equal. Thus, the selection of research subjects needs to be examined in order to determine whether some classes (racial and ethnic minorities, welfare recipients, children, or prisoners) are being selected simply because of their easy availability, rather than for reasons directly related to the problem under investigation. Except where research is directly related to the specific conditions of the class involved, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits of the research.

Justice demands that benefits coming out of publicly funded research be available to all individuals and not just to those who can afford the benefits, and that publicly funded research not be confined to groups of individuals who are unlikely to be among the recipients of the benefits.

This principle is more often than not overlooked. Therefore, the IRB must exercise a heightened degree of vigilance to ensure that the principle of justice is fully applied to proposed research.

Summary

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. The Commission was charged to consider the boundaries between medical/behavioral research and medical practice, the role of risk benefit assessment, the appropriate guidelines for selection of human subjects, and the nature and definition of informed consent.

The Report is a statement of basic ethical principles and guidelines to assist scientists in resolving the ethical problems surrounding the conduct of research with human subjects.90

TYPES OF HUMAN SUBJECTS REVIEW

All research involving interaction with vulnerable populations, such as children below the legal age of 18, will be either expedited or standard IRB submission.

There are three types of human subjects review: exempt, expedited, and standard. The criterion for each review follows.

EXEMPT REVIEW

The following categories of research qualify for exempt human subjects review:

1. Any form of research which does utilize human subjects such as historical and library research.
2. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available.
3. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, and the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, such as in content or secondary data analyses.
4. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular or special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior, and the subjects are elected or appointed public officials or candidates for public office.

6. Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior, and:
    a. the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **and**
    b. any disclosure of the human subjects' response outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

7. Taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXPEDITED REVIEW

The following categories of research involving human subjects and no more than minimal risk qualify for expedited human subjects review:

1. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It includes such procedures as testing sensory acuity and weighing, and procedures such as electrocardiography, electroencephalog-raphy, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography, when performed by an individual licensed to perform such procedures. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

2. Voice recordings made for research purposes such as investigations of speech defects.
3. Mild exercise by healthy volunteers.
4. The study of existing data, documents, records, or pathological or diagnostic specimens.
5. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
6. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction, and collection is made by an individual licensed to perform such procedures.
7. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor, and collection is made by an

individual licensed to perform such procedures.

STANDARD REVIEW
Any type of research involving human subjects that does not meet the criteria for either exempt or expedited human subjects review must be processed through standard review procedures.

[All review types will take 2-4 weeks to process, after all documentation has been received. Notification of approval, modifications, or denial will be sent via email.]

DETERMINING WHICH IRB APPLICATION TO FILE
To determine which IRB application to file for the proposed research, answer each of the questions below with yes or no. Then follow the directions listed after each set of questions to complete the appropriate IRB application.
Does the proposed research involve:
1) **Y N** the use of human subjects or information about human subjects?
Check: *If you answered no to question 1 STOP. You may complete the Exempt Review Application following procedures listed in this Manual. If you answered yes, continue to questions 2 through 7 that follow.*
2) **Y N** the collection or study of existing data, documents, records, or pathological or diagnostic specimens, from publicly available sources?
3) **Y N** the collection or study of existing data, documents, records, or pathological or diagnostic specimens, and the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects?
4) **Y N** normal educational practices, such as research on regular or special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods in established or commonly accepted educational settings?
5) **Y N** the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior, and the subjects are elected or appointed public officials or candidates for public office?
6) **Y N** the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior and the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, **and** any disclosure of the human subjects' response outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?
7) **Y N** taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

Check: *If you answered yes to any of questions 2 through 7 STOP. You may complete the Exempt Review Application following procedures listed in this Manual. If you answered no to all questions 2 through 7, continue to questions 8 through 14 that follow.*
8) **Y N** recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice? This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It includes such procedures as testing sensory acuity and weighing, and procedures such as electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electro-retinography, when performed by an individual licensed to perform such procedures. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
9) **Y N** voice recordings made for research purposes such as investigations of speech defects?
10) **Y N** mild exercise by healthy volunteers?
11) **Y N** the study of existing data, documents, records, or pathological or diagnostic specimens?
12) **Y N** individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects?
13) **Y N** collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction, and collection is made by an individual licensed to perform such procedures?
14) **Y N** collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor, and collection is made by an

individual licensed to perform such procedures?

Check: *If you answered yes to any of questions 8 through 14 you may complete an Expedited Review Application. If you answered no to all questions 8 through 14, you must complete a Standard Review Application.*

VOLUNTARY INFORMED CONSENT

Except for Exempt research, no researcher may involve a human being as a subject in a research study unless the researcher has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism ensuring respect for persons through provision of thoughtful consent for a voluntary act.
The procedures used in obtaining informed consent should be designed to educate prospective subjects in terms they can understand. Therefore, the language and its documentation (especially the explanation of the study's purpose, duration, experimental procedures, alternatives, risks, benefits, and so on) must be written in simple language that is fully understandable to the people being asked to participate. The written presentation of information is used to document the basis for consent and for the subjects' and researcher's future reference.

Three parts to keep in mind for the informed consent form:

1) A short description of the project. This can be just a couple of lines. For example, the form could start with…."You are being asked to participate in a study to determine if fill in what is needed here).

2) A sentence or two on how the participants may benefit from participating. This can range from something such as …."You may not personally benefit from participating in this study. However, it is possible that the results from this study will be incorporated in your professional training." …to something that includes if they get paid, extra credit, or whatever is appropriate to the situation.

3) A sentence or two about potential harm to the participants. At a minimum, this should include an estimate of how long the participation will last and that there is minimal chance of harm. (It is strongly frowned upon to say there is no chance of harm and the accepted description of the lowest level of harm is usually "minimal.")

   [A sample Informed Consent form is included in this manual and may be altered to fit most forms of research.]

BASIC STEPS FOR SUBMISSION

Please follow these basic steps for IRB submittal (5 items):

- Email research proposal
- Email completed copy of the appropriate IRB Review Application (i.e. Exempt, Expedited, or Standard)-based on guideline criteria in previous pages
- Email a completed copy of the Human Subjects Research Proposal Evaluation
- Email a copy of your NIH completion certificate (a CITI certificate of completion will also be accepted).
- Email a copy of the Informed Consent

Continuing Approval
If the research is not completed within 12 months of the notice of approval from the IRB, the applicant must notify the IRB of the status of the project using the "Revisions and Additions" form included.

External IRB Submittal
External IRB submittal is defined as any research presented to the Sherman College of Chiropractic IRB from anyone other than Sherman faculty, staff or students.

The Sherman College IRB will consider a review from an external researcher if its investigators include a Sherman College faculty/staff member. The Sherman IRB is not specially funded, nor does it charge for services rendered, so the board must meet around the work commitments of its volunteer members. Although members continue to evaluate the option of accepting external submissions, internal research remains its top priority at this time.

At this time, if any external research is accepted for review, the estimated IRB response timeline (**after** all paperwork is received) is 4 - 6 weeks.

[Current IRB manual is considered a "working manual" and is still evolving. Please contact the current IRB chair if any questions arise through this process.]

EXEMPT REVIEW APPLICATION - IRB

HUMAN SUBJECTS RESEARCH – SHERMAN COLLEGE INSTITUTIONAL REVIEW BOARD

(Please TYPE or WRITE CLEARLY)

I. IDENTIFYING INFORMATION

Researcher: Click or tap here to enter text.

Telephone Number: Click or tap here to enter text.

Address: Click or tap here to enter text.

Program: Click or tap here to enter text.

Research Director: Click or tap here to enter text.

Research Title: Click or tap here to enter text.

II. CRITERIA

Click to place an X next to the criterion or criteria under which you are seeking exempt review:

☐ Research which does not utilize human subjects.

☐ Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, from publicly available sources.

☐ Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens, and the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, such as in content or secondary data analyses.

☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular or special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior and the subjects are elected or appointed public officials or candidates for public office.

☐ Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey or interview procedures, or observation of public behavior and, the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, and any disclosure of the human subjects' response outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

☐ Taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or in which a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental containment at or below the level found to be safe by the Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

III. DESCRIPTION

Summarize specifically but concisely HOW the planned research meets the above criteria (attach additional pages as needed). Click or tap here to enter text.

☐ Educational Requirement Completed

IV. SIGNATURES

The researcher's signature indicates that during all phases of the conduct of this research he or she will ensure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Research Director's signature indicates that all IRB application materials have been carefully reviewed and fully approved by the Research Director prior to this submission to the IRB.

Click or tap here to enter text.	Click or tap to enter a date.	Click or tap here to enter text.	Click or tap to enter a date.
Researcher	**Date**	**Director of Research**	**Date**

NOTE: The proposed research may NOT begin until a formal Letter of IRB Approval has been received.

EXPEDITED REVIEW APPLICATION - IRB

HUMAN SUBJECTS RESEARCH – SHERMAN COLLEGE INSTITUTIONAL REVIEW BOARD

(Please TYPE or WRITE CLEARLY)

V. IDENTIFYING INFORMATION

Researcher: Click or tap here to enter text.

Telephone Number: Click or tap here to enter text.

Address: Click or tap here to enter text.

Program: Click or tap here to enter text.

Research Director: Click or tap here to enter text.

Research Title: Click or tap here to enter text.

VI. CRITERIA

Click to place an X next to the criterion or criteria under which you are seeking exempt review:

☐ Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It includes such procedures as testing sensory acuity and weighing, and procedures such as electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography, when performed by an individual licensed to perform such procedures. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

☐ Voice recordings made for research purposes such as investigations of speech defects.

☐ Mild exercise by healthy volunteers.

☐ The study of existing data, documents, records, or pathological or diagnostic specimens.

☐ Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

☐ Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction, and collection is made by an individual licensed to perform such procedures.

☐ Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor, and collection is made by an individual licensed to perform such procedures.

VII. DESCRIPTION

Summarize specifically but concisely HOW the planned research meets the above criteria (attach additional pages as needed). Click or tap here to enter text.

☐ Educational Requirement Completed

VIII. SIGNATURES

The researcher's signature indicates that during all phases of the conduct of this research he or she will ensure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Research Director's signature indicates that all IRB application materials have been carefully reviewed and fully approved by the Research Director prior to this submission to the IRB.

Click or tap here to enter text.	Click or tap to enter a date.	Click or tap here to enter text.	Click or tap to enter a date.
Researcher	**Date**	**Director of Research**	**Date**

NOTE: The proposed research may NOT begin until a formal Letter of IRB Approval has been received.

STANDARD REVIEW APPLICATION

HUMAN SUBJECTS RESEARCH – SHERMAN COLLEGE INSTITUTIONAL REVIEW BOARD

(Please TYPE or WRITE CLEARLY)

I. IDENTIFYING INFORMATION

Researcher: Click or tap here to enter text.

Telephone Number: Click or tap here to enter text.

Address: Click or tap here to enter text.

Program: Click or tap here to enter text.

Research Director: Click or tap here to enter text.

Research Title: Click or tap here to enter text.

II. ABSTRACT

Click or tap here to enter text.

☐ Educational Requirements Completed

III. SIGNATURES

The researcher's signature indicates that during all phases of the conduct of this research he or she will ensure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Research Director's signature indicates that all IRB application materials have been carefully reviewed and fully approved by the Research Director prior to this submission to the IRB.

Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.
Researcher	**Date**	**Director of Research**	**Date**

NOTE: The proposed research may NOT begin until a formal Letter of IRB Approval has been received.

HUMAN SUBJECTS RESEARCH PROPOSAL EVALUATION

HUMAN SUBJECTS RESEARCH – SHERMAN COLLEGE INSTITUTIONAL REVIEW BOARD

Researcher: Click or tap here to enter text. Date: Click or tap here to enter text.

1. Are subjects exposed to any possibility of:

Risk:	**Y**	**N**	**Discomfort:**	**Y**	**N**
physical	☐	☐	physical	☐	☐
psychological	☐	☐	psychological	☐	☐

If yes, describe how subjects are exposed, the methods to be used to protect subjects, and what will be done to restore physical and psychological homeostasis.
Click or tap here to enter text.

2. What are the possible benefits that can be derived by subjects who participate in the research?
Click or tap here to enter text.

3. What are the possible benefits that can be derived by the research?
Click or tap here to enter text.

4. Please indicate below whether subjects are members of a vulnerable population. If yes, explain why the research is not conducted with members of less vulnerable populations, and what special protections or safeguards will be used to protect the welfare of members of a vulnerable population. **Check all that apply.**

☐ No, subjects are not members of a vulnerable population.

Y:	**N:**		**Y:**	**N:**	
☐	☐	children	☐	☐	mentally disabled
☐	☐	economically disadvantaged	☐	☐	pregnant women
☐	☐	educationally disadvantaged	☐	☐	prisoners
☐	☐	institutionalized persons	☐	☐	other (specify) Click or tap here to enter text.

IRB#: Click or tap here to enter text.

Sherman College of Chiropractic
Institutional Review Board
IRB office: jbrowning@sherman.edu or 864-578-8770, ext. 220

REVISION or ADDITION REVIEW FORM

Local Principal Investigator: Click or tap here to enter text. *Email:* Click or tap here to enter text.

The person to contact with questions about the information on this form:
Phone: Click or tap here to enter text. *Email:* Click or tap here to enter text.
Study title currently used by the IRB: Click or tap here to enter text.

1. ***Identify the revision or addition:***
   - *Check all that apply and describe in #2 below.*
   - *Track all proposed changes to previously IRB-approved documents,*
   - *Send electronic copies of any revised and new documents to jbrowning@sherman.edu.*

□ Revision to currently approved sponsor protocol.
New version: Click or tap here to enter text. *New version date:* Click or tap to enter a date.

□ Revision to one or more currently approved consent forms.
List consent form title (e.g., general, parental permission) and the new version date for each: Click or tap here to enter text.

□ Addition of one or more new consent forms.
List consent form title and the version date for each: Click or tap here to enter text.

□ Revision to currently approved IRB Research Plan.
New version date: Click or tap to enter a date.

□ Addition of new or revised Investigator's IRB Application.
New version: Click or tap here to enter text. *New version date:* Click or tap to enter a date.

□ Revision or addition to other study documents.
□ Notification to IRB.
□ Change in enrollment status. *For example: closed, temporarily suspended by PI or sponsor; suspension lifted.*
□ Add or remove study personnel. *Only investigators and key personnel (co-investigators and research staff) who have completed training in human subjects' protections may be involved in research activities.*
□ Other revision or addition.

2. ***Describe what the revision request or addition is:*** *Please explain why the revision is necessary and how it will affect the conduct of the study:* Click or tap here to enter text.

3. ***Does this revision or addition involve only minor changes to the study, including changes to the information provided to participants?***
   □ No □ Yes

4. ***Does this revision or addition change the previously disclosed risks to participants?***

□ This revision does not affect risks to participants.
□ This revision decreases risks to participants.
□ This revision adds a newly identified risk or side effect to the protocol, Investigator's Brochure, or consent form.
□ This revision to the study design or procedures increases risks to participants. Please explain how in the revision description in #2.
□ N/A

5. *Does this revision or addition change the previously disclosed expected benefits, if any, to participants?*
□ No
□ Yes *If yes, please explain how: Click or tap here to enter text.*

6. *If this revision is to the consent form, do you recommend providing currently enrolled participants with the information in the new consent form?*
□ There are no consent form revisions.
□ No *If no, please explain why not: Click or tap here to enter text.*
□ Yes *If yes, please describe the plan to do so: Click or tap here to enter text.*

7. *For clinical trials, indicate the numbers of participants who are:*
Being screened: Click or tap here to enter text.
Receiving study interventions: Click or tap here to enter text.
Only providing long-term data: Click or tap here to enter text.

8. *Study Status:*
□ Enrollment is open
□ Enrollment is closed
□ Other: *Click or tap here to enter text.*

9. *What is the current Funding Source(s)?*
Has the funding source changed since the IRB initial or latest renewal review? □ No □ Yes

If yes: *please provide updated information about the new funding source, revise references to the funding source in the study documents as needed and identify these documents in #1 above.*

Note: If this study is federally funded, please send a copy of the complete grant proposal to the IRB if you have not previously sent one. ***Record the current federal award number here:*** **Click or tap here to enter text.**

Conflict of Interest: Have the interests or relationships of key personnel changed since the study's initial IRB review or last renewal? *Key personnel include the principal investigator, co-investigators, other research team members, and any of their spouses, domestic partners, or dependent children. The interests or relationships are those that may reasonably appear to affect or be affected by the study, especially if they are financial. The PI is accountable for the response below.*
□ No □ Yes

****

Please e-mail all revised and new documents to jbrowning@sherman.edu. If this IRB Revision or Addition form is sent from the PI's e-mail address, no signed paper copy is needed. Scanned versions of the signed form are also acceptable.

Click or tap here to enter text.	*Click or tap here to enter text.*	*Click or tap to enter a date.*
Principal Investigator Signature	*Printed Name*	*Date*

PATIENT CONSENT FOR CARE FORM

HEALTH CENTER

Patient: _____ Case #: _____

I hereby request and consent to appropriate chiropractic case management for me (or for the person named below, for whom I am legally responsible) in the Sherman College Chiropractic Health Center. My intern has explained the following points of information to me:

1. The purpose of chiropractic care is to optimize health by facilitating neurological and biomechanical integrity, which allows maximum expression of the body's innate recuperative abilities.

2. I understand that chiropractic services will be provided by student interns under the supervision of licensed doctors of chiropractic who are employed by Sherman College of Chiropractic.

3. The Sherman College Health Center uses only chiropractic methods that are taught in accredited chiropractic colleges, and appropriate techniques will be selected for my care based upon standard professional protocols. My diagnosis and all proposed procedures will be explained to me and implemented only with my approval. Alternatives and adjunctive recommendations for health promotion will be discussed with me.

4. Chiropractic adjustments are exceedingly safe when applied properly. However, I understand there are some risks to care including, but not limited to, fractures, disc injuries, strokes, dislocations and sprains. I do not expect the doctor to anticipate and explain every risk and complication, but I will rely on the doctor's best judgment to protect my best interests. No guarantees of cure have been implied or given.

5. A small force is introduced into the spine during a chiropractic adjustment that may lead to temporary musculoskeletal discomfort. This is usually minor and transient.

6. The intern and / or case doctor will discuss any further risks inherent for my particular case during a report of findings, and will document this discussion in my case record. Any questions or concerns that I may have will be addressed at this time. I understand that I am an active participant in my chiropractic care, and that I am encouraged to bring up questions or express any concerns.

7. I give my permission for my intern or case doctor to communicate by telephone or email regarding matters of chiropractic care, appointment reminders or scheduling.

8. Sherman College Health Center is compliant with all HIPAA regulations, and takes all reasonable precautions to safeguard your privacy in all matters. I understand that any concern I have regarding privacy and safety of my health information may be discussed with my intern or case doctor.

9. By signing below, I affirm that I have read, or had read to me, this consent document, and I agree to its provisions. I intend this document to cover the entire course of care now and in the future.

10. I am free to refuse care or withdraw my consent and discontinue care at any time.

Patient requested copy _____

_____ _____/_____/_____ Received Patient's Rights_____

Patient/Guardian's Signature Date Patient's Initials

_____

Case Doctor Date

Authorization to Use or Disclose (Release) Personal Health Information for Sherman College of Chiropractic Research Studies

By signing below, I give permission to Sherman College of Chiropractic to use or disclose (release) my personal health information for research studies performed by the college, instructors and/or students. This signed notice gives the clinic permission to disclose my protected health information to researchers when: a) their research has been approved by an institutional review board that has reviewed the research proposal and b) established protocols are in place to ensure the privacy of your protected health information. The information that may be used or disclosed for research purposes may include, but is not limited to, medical history, results of physical exams, lab or imaging results, information related to a particular condition or treatment.

You may withdraw this consent and authorization at any time. Even if you withdraw this authorization, Sherman College of Chiropractic may still use or disclose health information they have already obtained if necessary to maintain the integrity or the reliability of the current research.

To withdraw this authorization, you must do so in writing to Sherman College of Chiropractic.

Please note this authorization does not have an expiration date.

☐ Yes, I give Sherman College of Chiropractic permission to use my personal health information for research study purposes. I understand the type of information that may be used for research purposes and this authorization may be withdrawn at any time.

_____ _____
Patient Signature Date

☐ No, I do **NOT** give Sherman College of Chiropractic permission to use my personal health information for research purposes.

_____ _____
Patient Signature Date

_____ _____
Intern Signature / Intern # Date

_____ _____
Case Doctor Signature Date

CONSENT FORM FOR CASE REPORTS

Sherman College of Chiropractic

Case Report: Click to insert TITLE

Principal Investigator: Click to add name and degrees held
Click to add institution
Click to add contact phone number

You are being asked to consider allowing Dr. (click to insert name) to use information about your (click to insert condition/disease/experience) to write what is called a case report. Case reports are typically used to share new unique information experienced by one patient during his/her clinical care that may be useful for other physicians and members of a health care team. A case report may be published (click to choose in print and/or via internet dissemination) for others to read, and/or presented at a conference. This form explains the purpose of this case report. Please read this form carefully and take your time to make your decision and ask any questions that you may have.

The purpose of this case report is to inform other physicians that (click to insert specific reason i.e. patients presenting to the ER with X) may be related to Y, however, was masked by a common over the counter medication Z).

Your information being used for this case report includes (click to insert specific information here).

Dr. (click to insert name) is obligated to protect your privacy and not disclose your personal information (information about you and your health that identifies you as an individual e.g., name, date of birth, medical record number). When the case report is published or presented, your identity will not be disclosed.

Although your personal information collected or obtained will be kept confidential and protected to the fullest extent of the law, there is a limited risk associated with this case report that could result in a loss of confidentiality by virtue of your unique experience.

You will not directly benefit from participating in this case report. The information that can be shared with other health care professionals, however, may improve the care that is received by others in the future.

Allowing your information to be used in this case report will not involve any additional costs to you. You will not receive any compensation.

Taking part in this case report is your choice (voluntary). You may choose not to take part, or you may change your mind at any time. However, once the case report is written and published, it will not be possible for you to withdraw it. Your decision will not result in any penalty or loss of benefits to which you are entitled including the quality of care you receive.

You will be told about any new information relating to this case report that may affect you.

Your signature below means that you have read the above information about this Case Report and have had a chance to ask questions to help you understand how your information will be used and that you give permission to allow your information to be used in this case report.

If you have any questions please contact (Jaime Browning, DC, DCCJP) at (864) 578-8770.

SUBJECT CONSENT TO PARTICIPATE

Case Report Title: Click or tap here to enter text.

Name of Participant: Click or tap here to enter text.

Participant/Legally Authorized Representative

By signing this form, I confirm that:

- The case report has been fully explained to me and all of my questions have been answered to my satisfaction
- I have been informed of the risks and benefits, if any, of allowing my information to be used in this case report
- I have been informed that I do not have to participate in this case report
- I have read each page of this form
- I authorize access to my personal health information (medical record) as explained in this form
- I have agreed to participate in this case report

_____	_____	_____
Name of Participant/Legally Authorized Representative (print)	Signature	Date

I have carefully explained to the subject the nature of the above project. I hereby certify that to the best of my knowledge the person who is signing this consent form clearly understands the nature, involved in his/her participation and his/her signature is legally valid. A medical problem or language or educational barrier has not precluded this understanding.

_____	_____	_____
Name of Person Obtaining Consent (print)	Signature	Date

INFORMED CONSENT

The purpose of this form is to assure that you are given sufficient information to make an informed decision as to whether you will agree to be a subject in a study involving research.

[Click to enter researcher's name], hereafter referred to as researcher, is conducting a study [click to enter entitled: Title Of Study,] (or click to provide general topic of research instead) [click to enter examining ...] to determine [click to enter purpose of study]. Your participation will involve [click to enter #] session(s) for [click to enter #] minutes, [click to enter #] time(s) per week for [click to enter #] week(s). As a subject, you will be asked to [click to describe procedures to be employed, screening or exclusion tools, tests and/or treatments to be administered, review of medical records, forms to be completed].

The procedures in this study [click to select are/are not] considered experimental. <u>(If experimental, click to describe what is experimental)</u>. There are no more risks or discomforts associated with the procedures involved in this study than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. There may be no direct benefits to you for participating in this research, but your participation could be helpful in [click to describe realistic possible benefits such as testing current or new tests and treatments, developing new tests and treatments, etc ...].

Any information you provide during the course of the study will be recorded in such a way that your identity will remain [click to select confidential/anonymous]. (If confidential) This means that number codes or false names will be used to record your information, no one but the researcher will have access to the information, and it will be securely stored. Your identity will never be revealed and information about the study will be reported in group form only. (If anonymous) This means that your name will not be associated with your information, no one will be able to identify you, and information about the study will be reported in group form only.

Your participation in this study is completely voluntary. If you choose to participate, you may change your mind at any time up to [click to enter #] days after the final study session and withdraw your consent. You can withdraw by notifying [click to enter Name of Person] at [click to enter phone #] of your desire to withdraw. There is no penalty or loss of benefits to which you are otherwise entitled if you withdraw from the study, or if you choose to not participate. If during the course of the study you have questions about the research, tasks, or activities you are asked to perform or complete, or your rights as a research subject, you may contact Jaime Browning, DC, DCCJP (Sherman College IRB Chair) at 864-578-8770, and all your questions will be answered.

(<u>In studies with more than minimal risk or the use of deception and/or coercion</u>). You will receive no payment for participating in this study. The researcher and Sherman College assume no liability for any discomfort or injury you may incur as a result of your participation in this study. If a medical emergency arises during your performance of the procedures in this study, the researcher will assist you in obtaining medical care at your expense. You are responsible for obtaining any other medical care on your own, and at your own expense. You should contact [click to enter Name and Title of Contact Person] at [click to enter phone #], in the event of a research related injury.

You are receiving two copies of this form. Return the signed copy to the researcher and keep the other for your future reference. If you would like to receive a summary of the results of the study upon its completion, record your full address on the reverse side of this form.

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My signature below indicates that I understand the procedures to be employed in this study, all my questions concerning the study have been answered to my satisfaction, and I agree to be a subject in this study. I also agree to allow the researcher to present his or her findings publicly or privately, orally or in written form.

____

Subject's Signature Date

-or

____

Subject's Legal Representative Date