

RESEARCH HANDBOOK

SHERMAN COLLEGE OF CHIROPRACTIC

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RESEARCH MISSION

The research component of the College Mission is as follows:
(<http://www.sherman.edu/edu/mission.asp>)

We shall support and produce research and scholarly activities that contribute to the body of knowledge on chiropractic education, clinical knowledge, health care and the theoretical constructs of vertebral subluxation.

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 promote health care
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.

Sherman College of Chiropractic

Research and Scholarly Activity (RASA) Expectation of Faculty

Suggested areas of inquiry, from research and scholarly activity (RASA) expectation of faculty (Faculty Handbook, 2010, pp. 24-25), include the following:

- 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.

RESEARCH COMMITTEE

PURPOSE:

To recommend to the Director of Research, policies and programs for administration of research and to provide liaison between the Research Department and the other divisions of the College

REPORTS TO: The Vice President of Academic Affairs through the Director of Research

RESPONSIBILITIES:

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

The Research Committee:

1. Acts as an advisory body to the research department
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 research, who serves as chairman, vice president for academic affairs; the assistant director of research, the deans of clinics, basic and 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.

Research Committee Roster (a current roster is held by the Committee Chair)

MEETINGS

Meets as called by the chair.

RESEARCH PROPOSAL PREPARATION

Develop a Proposal

A. 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.

B. 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).

C. 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.

D. 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.

E. 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.

F. 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 are 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.

G. Developing the Research Protocol

How will you select your sample?

Will you 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?

H. 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.)

I. 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

J. 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.

K. 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.

L. 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.

1. Demographic variables which describe characteristics of subjects such as age, sex, race, previous hospitalizations, etc.
2. 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.
3. 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.

M. 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 APPROVAL

Research proposals intended for research release time or other college funding above regular salary are to be approved by the respective dean. If no release time or extra expenditure is sought from the college, then the faculty member would seek approval of his or her proposal from the Director of Research.

For each research proposal, the Director of Research 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:

- **Full Review:** For any new research project, the Principal Investigator (PI) of the project should identify three potential reviewers from the research committee who have expertise in the particular area of the PI's proposed research and submit the names of the reviewers along with the proposal to the research department. The Director of Research then would send the research proposal to the three reviewers for comments. (please find a copy of review sheet in the **Appendix 2**)
- **Expedited Review:** For less complex projects and minor modification of previously approved research projects, the Director of Research will consult with the Assistant Director of Research.

(see **Appendix 2**: Research Proposal Review sheet)

INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH STUDIES

PURPOSE:

The purpose of the Institutional Review Board (IRB) is to protect human research subjects and to comply with federal guidelines for experimental subject protection. The IRB will review the proposals for all research involving human subjects and assess the risks. 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 the project be resubmitted or it may disapprove the project.

Sherman College submitted an update of compliance to the Department of Health and Human Services in a "General Assurance Statement" on August 12, 1994. This document, along with consent forms used for prospective human subjects is available through the Research Director (see attached sample form).

FUNCTION:

The function of IRB is to assist the investigator in the protection of the rights and welfare of human subjects. Investigators should not bear the sole responsibility for determining the standards for ethical conduct of research involving human subjects. It is necessary for others, who are independent of this research, to share this responsibility. The Sherman College of Chiropractic Institutional Review Board (IRB) is this institution's responsible agency for such review.

COMMITTEE COMPOSITION:

1. The Director of Research (for consultation).
2. Five additional members of varying backgrounds.
3. Members must not all be of the same profession.
4. There must be at least one Board member who is not employed by or affiliated with Sherman College of Chiropractic.
5. Board members shall not receive compensation for services rendered.

SELECTION PROCESS:

1. Members shall be selected from nominations submitted by the Director of Research, Director of Basic Science, Director of Clinical Science, or other members of the Research Committee.

2. All five candidates are reviewed and appointed to the Board by the President. The President will appoint a Chair and Vice-Chair. The name of the appointed members and any change in memberships are to be forwarded to the Secretary of the Department of Health and Human Resources.
3. Each Board member shall serve a term of three years. Vacancies, if any, are to be filled by appointment of the President.

MEMBERS OF IRB (a current list of members is held by the IRB Chairperson)

Chairperson: Mitzi Schwartzbauer, DC
Sherman College of Chiropractic
2020 Springfield Road
Spartanburg, S.C. 29304
Phone: 864 578-8770
Profession: Chiropractor, Assistant Professor of Clinical Sciences

MEETINGS: As called by Chair.

LINE OF AUTHORITY: Reports to the Vice President of Academic Affairs.

INVESTIGATIONAL ACTIVITIES REQUIRING IRB APPROVAL

Any systematic investigation involving human subjects that is designed to develop or contribute to general knowledge. This includes investigations conducted by faculty, students, staff or others associated with Sherman College as well as investigations conducted elsewhere by any representative of Sherman College.

SUBMISSION OF RESEARCH PROPOSALS FOR IRB REVIEW

1. What to Submit:
 - a. Request for Review (see **Appendices 3 & 4.**)
 - b. Informed Consent Form (see **Appendix 5.** Sample consent Form)
 - c. Detailed Research Protocol (see Develop a Proposal, page 6).
2. Where to Submit. Proposals that require review must be submitted to the IRB through the Research Department.

THE IRB REVIEW PROCESS

1. Determination of Risk:

The IRB will make a decision based on common sense and sound professional judgment as to whether or not the proposed research places the subject "at risk." A subject is considered to be at risk if he/she may be exposed to the possibility of harm, whether physical, psychological, sociological, economic, or other, as a consequence of any activity which goes beyond the application of those established methods necessary to meet his/her needs.

2. Risk/Benefit Analysis:

- a. In research involving a non-therapeutic intervention, the potential risk to the subject must be outweighed or balanced by the potential benefit to the subject and /or by the knowledge to be gained.
- b. In therapeutic research involving more than minimal risk, the potential risk should be outweighed or balanced by the potential benefit to the subject.
- c. In research where no direct benefit to the subject is anticipated, the IRB will evaluate whether the risks and/or discomfort presented by procedures performed solely to obtain general knowledge are ethically acceptable.
- d. In research involving pregnant women as subjects, the following condition must be met: 1) the purpose of the research is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or, 2) the risk to the fetus is minimal. Only those research procedures that would be acceptable for a fetus going to term may be performed. In addition, whenever there is a potential conflict of interest, the investigator must not be involved in any decision as to the timing, method, and procedures used to terminate the pregnancy or the determination of viability of the fetus at termination of pregnancy.

3. Review of Prospective Subject Population

The IRB will review the prospective subject population and must be assured that the subject population and number of subjects is appropriate with respect to the nature and goals of the research and the selection of subjects is equitable with regard to the potential risks and benefits.

4. Review of Investigator Qualifications

The IRB will review investigator qualifications and must be assured that the investigator has the appropriate qualifications and/or licensure to carry out the procedures involving human subjects with an acceptable degree of potential risk and the investigator has adequate facilities and equipment to conduct the research with an acceptable degree of potential risk.

5. Review of Experimental Design and Scientific Merit

The IRB will review experimental design in order to be assured that the potential risks to the subjects are minimized and the potential benefits maximized by using procedures consistent with sound research design.

6. Review of Informed Consent

The IRB will review the consent procedure and the informed consent form to determine if it conforms to Sherman College IRB standards and contains all appropriate elements of informed consent as required by Federal regulations.

CATEGORIES OF RESEARCH THAT QUALIFY FOR EXPEDITED REVIEW

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods), may be reviewed by the IRB through the expedited review procedures authorized in 45 CFR 46:110.

1. 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.
2. Recording of data from subjects 18 years of age or older using non-invasive 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 also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
3. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
4. Voice recordings made for research purposes such as investigations of speech defects.
5. Moderate exercise by healthy volunteers.
6. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
7. Research on individuals or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subject's behavior and the research will not involve stress to subjects.

CATEGORIES OF RESEARCH THAT QUALIFY FOR *EXEMPT STATUS*

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the requirements of 45 CFR 46 and full IRB review. However an IRB Protocol Form must still be submitted. The exempt categories as specified in 45 CFR 46:101(b) however do not apply to research involving deception of subjects (the research deceives the subject with regard to the purpose of the research and/or the results of the subject's actions in the study), intervention research (subject behavior is manipulated and the change measured), or to research involving those classified as mentally infirm. When children are involved as subjects in research, only exemptions # 1, 2, 5 and 6 are applicable. Exemption #4 is applicable where the investigator does not participate in the activities being observed. Exemption #3 is not applicable in child research. Some exemption categories as determined by the IRB may not apply to research activities involving other subject populations considered vulnerable or to research involving sensitive aspects of the subject's own behavior (e.g. drug and alcohol abuse, sexual activity).

Exempt Categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (1) research on regular or special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interview procedures, EXCEPT where all of the following exist: (1) responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subject; (2) the subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.
4. Research involving the observation (including observation by participants) of public behavior, EXCEPT where all of the following conditions exist: (1) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (2) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (3) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available

or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

6. Unless specifically required by statute, research and demonstration projects which are conducted by or subject to the approval of the Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (1) programs under the Social Security Act, or other public benefit or service under those programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) possible changes in methods or levels of payment for benefits or services under those programs.
7. All exempt research involving human subjects must maintain an adequate standard of informed consent and confidentiality of data. In some exempt research projects, standard written informed consent should be obtained.

ELEMENTS OF INFORMED 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 nonexperimental, 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 and campus address), or _____, Chair of the Sherman College Institutional Review Board (IRB), telephone _____."

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 Director of Research will supply the faculty member with the appropriate forms required to submit the project 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 Research 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 Research Department 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.

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 6**: 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 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 and the faculty members should receive compensation from the grant for hours worked beyond those compensated by the institution.

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.

ETHICS

CODE OF ETHICS

Based upon the AAUP statement of ethics, this code, formulated by the 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 (he or she), 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 Research.
2. If it is a new project, the faculty member shall provide a written description of the project to the Director of Research. (A form will be provided by the Director). If it is an existing project, the Director of Research 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 Research 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 some of the unassigned campus hours 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 Research will be arranged by the Director of Research 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 Research. Funding for an approved project will be provided by the Research Department, if possible. If the amount exceeds the Research Department'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 Research Department) and submit to the Department of Research for approval.
7. Faculty members will be awarded one hundred dollars when his/her research project is approved by the Research Committee.

INVENTIONS, PATENTS AND COPYRIGHTS

A. General

Sherman College of Chiropractic shall own 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 will be considered as having been developed in the course of employment where conception and/or development is in 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 will normally be shared with the inventor as provided in this document.

B. Publication rights of faculty

Faculty members shall own all rights to materials prepared at their initiative for classroom, educational or professional purposes, including all royalties from publication or distribution of such materials. An example might be a textbook or laboratory manual developed on a faculty member's own time, without use of College facilities or funds.

Educational materials developed in the course of College employment shall be owned by the College. 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 use of such materials, shall be set forth in a separate contract 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 Research Department (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 Research 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 in any College personnel in respect to any present or future invention, written or recorded material. The rights of College personnel in and to any inventions and materials belonging to the College under this policy will be created and exist only by virtue of the individuals concerned.

D. Determination of equities

The Sherman College Research Committee shall determine:

1. When the rights in and to inventions and materials belong to the College under the provisions of this policy;
2. Whether the College personnel shall be 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 shall be.

Notwithstanding any determination by the Committee, or any other provisions of the policy, College personnel shall 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 Committee.

E. Review of Committee action:

The president of the College may review any determination of the Committee, and shall do so at the request of any interested person. He/she 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, as the case may be, shall be final and conclusive and binding upon the College personnel involved as well as upon the College.

Appendices

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: _____ Through: _____

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 Research or
his designee.

SIGNATURE OF PRINCIPAL INVESTIGATOR

Date

Sherman College of Chiropractic
Research Proposal Review Sheet

Reviewer Name: _____

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

Proposal Title:

Conclusion:

- | | |
|--|--|
| <input type="checkbox"/> Approve without revision | <input type="checkbox"/> Approve with minor revision |
| <input type="checkbox"/> Approve with major revision (see below) | <input type="checkbox"/> 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

**Institutional Review Board
for the Protection of Human Subjects in Research
REQUEST FOR REVIEW COVERSHEET**

All research involving the use of human subjects must be submitted to the Sherman College Institutional Review Board (IRB) for approval before the initiation of research. A minimum of 2 weeks must be allowed for the review procedure.

Principal Investigator: _____

Faculty _____ Student _____ Other: _____

Secondary Investigator(s): _____

Attach a list of all investigators associated with the research project. Include their institutional affiliations, Academic Degrees, and levels of involvement in the project.

Department: _____ Phone: _____

Title of Project: _____

Proposed Starting Date: _____

Projected Completion Date: _____

For IRB use only

Not approved: _____ **Date** _____

Approved: _____ **Date** _____

(Type or print name)

IRB Chairperson Signature _____

Institutional Approval _____ **Date** _____

Type or print name _____

Position _____

**Sherman College of Chiropractic
IRB Request for Review
Overview Checklist
ATTACH BEHIND COVERSHEET**

1. SUBJECTS: The proposed protocol would involve human subjects who are: (Check all that apply)

_____ none of the following _____ institutionalized persons

_____ minors (persons under age 18)

_____ (wards, mentally disabled)

_____ pregnant women

_____ prisoners

_____ in utero fetuses

_____ Persons under the care or supervision of another institution (hospital, nursing home, group home, convalescent home, etc.)

___ Yes ___ No The protocol involves human subjects who will receive drugs, food, beverages, or other internally administered substances.

___ Yes ___ No The protocol involves human subjects who will receive or be exposed to radioactive materials.

2. Funding: _____ Yes _____ No The protocol is being submitted for federal funding
 ___ Other external funding ___ internal funding
 ___ No external or internal funding is being sought.

EXEMPT OR EXPEDITED STATUS

Tentative determination of exempt or expedited status may be possible by referring to pages 16–18 of the Sherman College IRB policy statement and/or 45 CFR which both list and explain the following categories.

This project qualifies for **exemption** from 45 CFR 46 because the only involvement of human subjects will be in one or more the following categories (as listed on page 17-18 of the Sherman College Research Handbook Guidelines):

_____ (1) _____ (2) _____ (3) _____ (4) _____ (5) _____ (6)

This project qualifies for **expedited review** procedures authorized in 46.1 10 of 45 CFR 46 Part 46 because it involves no more than minimal risk and the only involvement of human subjects will be in one or more of the following categories as detailed 46 FR 8392 of January 26, 1981, and on page 16 of the Sherman College Research Handbook guidelines:

_____ (1) _____ (2) _____ (3) _____ (4) _____ (5) _____ (6) _____ (7)

Sherman College of Chiropractic

SAMPLE CONSENT FORM

Inter reliability study

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
(Required if presented orally)

DATE

Sherman College of Chiropractic

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 Research or his designee.

SIGNATURE OF THE INVESTIGATOR

Date