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SAINT LOUIS COLLEGE OF PHARMACY
POLICY FOR PROTECTION OF
HUMAN RESEARCH SUBJECTS

Section I


46.101 To what do these regulations apply?

A. Ethical Principles

StLCoP is guided by ethical principles regarding all research involving humans as subjects as set forth by the Nuremberg Code, the Helsinki Declaration, the Universal Declaration of Human Rights adopted by and amplified for biomedical research by the report of the National Commission for the Protection of Human Subjects (the Belmont Report).

B. Institutional Policy

1. StLCoP acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this assurance.

2. It is the policy of StLCoP that all research except for these categories specifically exempted (cf. "exempt" in 46.102, Definitions) by 45CFR 46.101 involving human subjects will be reviewed and approved by the StLCoP IRB. Even though these guidelines were developed with direction of HHS, they are to apply to all research on human subjects performed at StLCoP or by people representing StLCoP. The involvement of human subjects in research covered by this policy will not be permitted until the StLCoP IRB has reviewed and approved the research protocol and voluntary and informed consent has been obtained from the human subject.

3. The StLCoP IRB has final authority to determine whether a particular research activity is covered or exempted from these regulations. No presumed exempted research activity may commence until the committee has granted the exempted status to the project.

4. No individuals may perform research at StLCoP or receive College funding for research unless the individual is affiliated with or is sponsored by StLCoP which assumes responsibility for the research satisfying the requirements under the Assurance agreement. (See 46.103.)

5. Compliance with these regulations will in no way render inapplicable pertinent federal, state, local laws or regulations.

6. Each subpart of the regulations contains a separate section describing to what the subpart applies. Research which
is covered by more than one subpart must comply with applicable subparts. The mechanism for compliance will be covered in the sections for StLCoP IRB operating procedures. Assurances for compliance to HHS or other agencies will be detailed in 46.103.

C. Applicability of these Regulations

1. These regulations apply to all research
   a. performed on human subjects at StLCoP regardless of the source of funding support (if any) or
   b. performed, supervised or sponsored by investigators who are faculty, staff or students of StLCoP.

2. Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations unless the research is covered by other subparts of this part:
   a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
      i. research on regular and special education institutional strategies or
      ii. research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

   b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement, survey procedures, interview procedures, or observation of public behavior) unless:
      i. if information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects AND
      ii. any disclosure of the human subjects responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects financial standing, employability, or reputation

   c. Research involving survey or interview procedures except where any of the following conditions exist:

      (1) Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects,
(2) The subject's responses, if they become 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.

(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.

(4) All research involving survey or interview procedures is exempt without exception when the respondents are elected or appointed public officials or are candidates for public office.

D. Research involving the observation (including observation by participants) of public behavior, except where any of the following conditions exist:

(1) Observations are recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subject.

(2) The observations recorded about the individual, if they become 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.

(3) The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol.

E. 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.

F. Unless specifically required by statute (and except to the extent specified in the following paragraph), research and demonstration projects which are conducted by or subject to approval of the United States Department of Health and Human Services, and which are designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs.
If, following review of proposed research activities that are exempt from these regulations under Paragraph (f) the Secretary of the U.S. Department of Health and Human Services determines that a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, then federal funds may not be expended for such a project without the written, informed consent of each participant or subject.

G. Compliance with these regulations will in no way render inapplicable pertinent federal, state, or local laws or regulations.

H. Research that is covered by more than one subpart of this policy shall comply with all applicable subparts.

46.102 Definitions

a. Department or agency head means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated

b. Institution means any public or private entity or agency (including federal, state, and other agencies.)

c. Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research

d. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

e. Research subject to regulation, and similar terms are
intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity. (For example, Investigational New Drug requirements administered by activities which are incidentally regulated by a federal department or agency solely as part of the department’s or agency’s broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

f. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

i. Data through intervention or interaction with the individual, or

ii. Identifiable private information

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject of the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonable expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (For example, a medical record). Private information must be individually identifiable (I.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects)
g. IRB means an intuitional review board established in accord with and for the purposes expressed in this policy.

h. IRB approval means the determination of the IRB hat the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and b other institutional and federal requirements.

i. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

j. Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

46.103 Assurance of compliance with this policy—research conducted or supported by any Federal Department or Agency.

The St. Louis College of Pharmacy (StLCoP) hereby gives written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. that it will comply with the Department of Health and Human Services (HHS) regulations for the Protection of Human Research Subjects.

A. Departments and agencies will conduct or support research covered by this policy only if StLCoP has an assurance approved as provided in this section, and only if StLCoP has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurance applicable to federally supported or conducted research shall at a minimum include:

1. A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to
Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department or agency supported or regulated research and need not be applicable to any research exempted or waived under 46.101(b) or (i).

2. Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.

3. A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member’s chief anticipated contributions to the IRB deliberations; and any employment or other relations between each member and the institution; for example: full-time employee, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with 46.103(a) of this policy, the existence of an HHS approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

4. Written procedures which the IRB will follow

   i. For conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution

   ii. For determining which projects require review more often than annually and which projects need verification from sources other than the investigator so that no material changes have occurred since previous IRB review and

   iii. For ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

5. Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the
department or agency head of:

i. Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and

ii. Any suspension or termination of IRB approval

B. The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes

C. The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head’s evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution’s research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

D. On the basis of evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

E. Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under 46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by 46.103 of this policy has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits,
the application of proposal may be returned to the institution.

46.107 IRB Membership

A. There shall be at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the member’s backgrounds including consideration of racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable laws and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects such as prisoners, pregnant women, handicapped or mentally disabled person, consideration shall be given to the inclusion of individuals who are knowledgeable about and experienced in working with these subjects.

B. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution’s consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

C. The IRB shall include at least one member whose primary concerns are in scientific areas, and at least one member whose primary concerns are non-scientific.

D. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

E. The IRB may not have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

F. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on
the IRB. These individuals may not vote with the IRB.

46.108B Functions and Operations

46.109 STLCOP IRB Review of Research

A. The IRB shall review and have authority to approve, require modifications in (to secure approval) or disapprove all research activities covered by this policy.

B. The IRB shall require that information given to subjects as part of "informed consent" is in accord with 46.116. The IRB may require that information in addition to that specifically mentioned in 46.116 be given to subjects if that information would meaningfully add to the protection of rights and welfare of subjects.

C. The IRB shall require documentation of informed consent or may waive documentation in accordance with 46.117.

D. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

E. The IRB shall conduct continuing review of research covered by these regulations at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

46.110 Expedited Review Procedures for Certain Kinds of Research Involving No More than Minimal Risk, and for Minor Changes in Approved Research

A. The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

B. The StLCoP IRB may use the expedited review procedure to review either or both of the following

1. Some of all of the research appearing on the list and
found b the reviewers to involve no more than minimal risk

2. Minor changes in previously approved research during the period (of one year or less) for which approval is authorized

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 46.108.

A. Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
B. The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution’s or IRB’s use of the expedited review procedure.

46.111 Criteria for StLCoP IRB Approval of Research

A. In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:
   i. by using procedures which are consistent with sound research design and which do not unnecessarily expose subject to risk, and
   ii. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risk to subjects are reasonable in relation to anticipated benefits, if any to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effect of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this
assessment, the IRB shall take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by 46.116.

5. Informed consent will be appropriately documented in accordance with, and to the extent required by 46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of the subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

B. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

46.112 Review by Institution

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials the St. Louis College of Pharmacy. However, those officials may not approve the research if it has not been approved by the StLCoP IRB.

46.113 Suspension or Termination of IRB Approval of Research

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a written statement of the reasons for the IRB's action and shall be reported promptly to the investigator, and appropriate institutional officials.

46.114 Cooperative Research

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another
qualified IRB, or make similar arrangements for avoiding supplication of effort.

46.115 StLCoP IRB Records

A. The StLCoP IRB shall maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and the investigators.

5. List of StLCoP IRB members and, if applicable, alternates according to 46.103(b)(3). Such list must include: name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc.; relationship of the member to the institution (e.g. full-time employee, unpaid consultant, etc.). This list must be maintained current.

6. Written procedures for the StLCoP IRB in the same detail as described in 46.103(b)(4) and 46.103(b)(5) Statements of significant new findings provided to subjects, as required by 46.116(b)(5).

B. The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department agency at reasonable times and in a reasonable manner. WE MAY WANT TO CLARIFY/ELABORATE THIS.
46.116 General Requirements for Informed Consent

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

A. Basic elements of informed consent. Except as provided in paragraphs (c) and (d) of this section, in seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

3. Any additional costs to the subject that may result from participation in the research;

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

6. The approximate number of subjects involved in the study.

C. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or
levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

D. An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

E. The informed consent requirements in are not intended to preempt any applicable Federal, state or local laws, which require additional information to be disclosed in order for informed consent to be legally effective.

F. Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state or local law.

46.117 Documentation of Informed Consent

A. Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the StLCoP IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

B. Except as provided in paragraph (c) of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A short form written consent document stating that the elements of informed consent required by 46.116 have been presented orally to the subject or the subject’s
legally authorized representative. When this method is
used, there shall be a witness to the oral
presentation. Also, the IRB shall approve a written
summary of what is to be said to the subject or the
representative. Only the short form itself is to be
signed by the subject or the representative. However
the witness shall sign both the short form and a copy
of the summary, and the person actually obtaining
consent shall sign a copy of the summary. A copy of
the summary shall be given to the subject or the
representative, in addition to a copy of the short
form.

C. The StLCoP IRB may waive the requirements for the
investigator to obtain a signed consent form for some or all
subjects if it finds either:

1. That the only record linking the subject and the
research would be the consent document and the principal
risk would be potential harm resulting from a breach of
confidentiality. Each subject will be asked whether the
subject wants documentation linking the subject with the
research, and the subject's wishes will govern; or

2. That the research presents no more than minimal
risk of harm to subjects and involves no procedures
for which written consent is normally required outside
of the research context.

3. In cases where the documentation requirement is waived, the
IRB may require the investigator to provide subjects
with a written statement regarding the research.

46.118 Application and Proposals Lao-king Definite Plans
for Involvement of Human Subjects

Certain types of applications for grants, cooperative
agreements, or contracts are submitted to departments or
agencies with the knowledge that subjects may be involved
within the period of support, but definite plans would not
normally be set forth in the application or proposal. These
include activities such as institutional type grants (when
selection of specific projects is the institution's
responsibility; research training grants in which the
activities involving subjects remain to be selected; and
projects in which human subjects' involvement will depend upon
completion of instruments, prior animal studies or
purification of compounds. These applications need not be
reviewed by the StLCoP [the StLCoP reference is added]
IRB before an award may be made. However, except for
research exempted or waived under 46.101(b) or (i), no human
subjects may be involved in any project supported by these
awards until the project has been reviewed and approved by
the StLCoP [reference specific] IRB, as provided in this
policy, and certification submitted, by the institution, to
46.119 Research Undertaken Without the Intention of Involving Human Subjects

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by the StLCoP IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

See CFR 45 Part 46.120 in Appendix.

46.121 [Reserved]

46.122 Use of Federal Funds

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

46.123 Early termination of research support: Evaluation of applications and proposals.

A. The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

B. In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would directly or has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).
46.124 Conditions

With respect to any research project or class of research projects, the funding agencies may impose additional conditions prior to or at the time of funding if the additional conditions are necessary for the protection of human subjects.

[This statement is more appropriate than the statement in the CFR.]

Subpart “B” Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research. (Source: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.)

46.201 through 46.207 are part of this document of procedures of St. Louis College of Pharmacy Institutional Review Board and are included in the Appendix of this document.

Subpart “B” Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research. (Source: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.)

46.201 through 46.207 are part of this document of procedures of St. Louis College of Pharmacy Institutional Review Board and are included in the Appendix of this document.

Subpart “D” Additional Protections for Children Involved as Subjects in Research. (Source: 48 FR 9818, March 8, 1983, unless otherwise noted.)

46.401 through 46.407 are part of this document of procedures of St. Louis College of Pharmacy Institutional Review Board and are included in the Appendix of this document.
SECTION II

Procedures to be followed by the Principal Investigator (PI) or Sponsor-Investigator Researchers.

A. The PI is responsible for initiating a review of research activity to insure that it complies with these guidelines. This review must be initiated for all non-exempt research (46.101) and related activities involving human subjects, before the project or pilot work begins, and whether or not it is funded.

The determination of whether or not subjects are at risk, the benefits of the research, and an assessment of the risk/benefit ratio will be made by the PI. The final assessment of the degree of risk will be made by the StLCoP Institutional Review Board.

B. The PI must retain in his files any and all records of his research activity including those records submitted to the I.R.B. The I.R.B. may request to be informed of the location of these materials should the board itself be reviewed by Federal, state or funding agencies. If the PI leaves StLCoP, it is imperative that the location of records be reported to the I.R.B.

C. Records required for review by the I.R.B.

1. Two copies of the Information for Review of a Project Involving Human Subjects (IRB#1) including the signature of the PI.

2. When human subjects are involved, two copies of the consent form should be written in language understandable to the subject. The I.R.B. does not require copies of each signed consent form, but a copy must be retained by the PI. Consent forms are not required for research involving "minimal risk" (see 46.102 (8)) permitting "expedited review" (see 46.110) but the I.R.S. must be given sufficient information to justify these categories of research.

3. When the research activity involves interviews, two copies of the interview(s) must be submitted.

4. If the research activity is to be continued beyond one year, application for renewal must be submitted by memo prior to the expiration of the annual approval. Two copies of the Summary of Investigative Work form (IRB#3) must be provided.

5. If the research involves use of an investigational new drug, the I.R.B. must be assured of clearance by the Food and Drug Administration. The PI must submit two copies of the Investigational Drug Data form and pertinent information on the use of the drug in
animals and humans, including all anticipated side effects and toxic properties.

6. When a newly developed medical device is incorporated in the study, when applicable, clearance from the FDA must be certified.

7. In addition to the StLCoP I.R.B. approval, research conducted in a hospital must also be approved by the I.R.B. of that institution.

8. All correspondence between the PI (or StLCoP researcher) and the I.R.B. (incl. IRB#2)

9. All drug studies must submit one copy of the Investigational Drug Data Form to the StLCoP IRB (Form #4). If more than one drug is involved, one form for each drug is to be submitted.

D. The Administrative staff of the I.R.B. will make an initial determination of whether the procedures to be followed by the PI are in compliance with the StLCoP guidelines. If deficiencies are noted, the project will be returned to the PI for inclusion of missing item. The IRB reviews all research activities, involving human subjects. The use of human subjects is not to be initiated until the StLCoP I.R.B. has completed its evaluation and has recommended that the use of human subjects may proceed.

E. Additional instructions for the preparation of the Research Involving Humans form and submission of documents for review by the IRB.

1. In filling out the required information and answering the questions as indicated on the Project Involving Subject Human form(IRB#1), the Principal Investigator/Researcher must provide information to enable the Chairperson and the IRB to determine whether or not the methods comply with the guidelines.

2. The I.R.B. needs to have a clear plan of investigation about the nature and goals of the project. There is no specific format this description needs to take, but it should include a summary statement of the project, the operational aspects intended to be followed to achieve the stated goals and any information which will enable the I.R.B. to make an independent assessment.

3. Methods of approaching subjects and securing their cooperation should be described in advance. No coercion, explicit or implicit, may be used to obtain or maintain cooperation. Any payments made to the subject should not be large enough to constitute undue inducement for participation of subjects. Plans for
payment of subjects must be specified and will be reviewed by the I.R.B.

4. All activities subject to these Guidelines require that legally effective informed consent be obtained from the human subjects at risk. Care should be given to include information regarding compliance with all of the basic elements of informed consent. The consent agreement may not contain any exculpatory language through which the subject is made to waive or appear to waive any of his legal rights, or to release StLCoP or its agents from liability for negligence.

5. The description of the procedures to be used in obtaining informed consent must be sufficient to permit the reviewers to make the following determinations.

a. The reviewers should be able to determine if the consent required is appropriate in light of the risks to the subject and the circumstances of the project.

b. The reviewers should be able to determine if the information given to the subject, or to qualified third parties in writing or orally, is a fair explanation of the project or activity, of its possible benefits and its attendant hazards.

c. Where an activity involves therapy, diagnosis, or management, and a professional/patient relationship exists, it is necessary to recognize that a patient's mental and emotional condition is important... and that in discussing the element of risk, a certain amount of discretion must be employed consistent with full disclosure of fact necessary to any informed consent.

d. Where an activity does not involve therapy, diagnosis, or management and a professional/subject rather than a professional/patient relationship exists, the subject is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable person might be expected to consider before giving consent.

F. Special procedures and requirements.

Projects funded by HHS and other agencies are subject to special requirements. The StLCoP policy requires that all research involving human subjects, funded or not funded are subject to these special requirements.

**Documentation of informed consent:**

1. There must be a written consent document embodying all of the basic elements of informed
consent. This may be read to the subject or the subject's legally authorized representative, but in any event, the potential subject, or legally authorized representative, must be given adequate opportunity to read it. A copy of the signed consent form is to be given to the subject and a copy is to be placed in the medical record.

For particularly sensitive types of research, the StLCoP I.R.S. has the authority to assign one of its representatives to witness the presentation of information in the consenting process and documentation.

The StLCoP I.R.B. may approve a consent procedure which does not include, or which alters some or all of the elements, or waives the requirements to obtain formal informed consent (46.116 (4) and 46.117 (3)) for certain types of research particularly research having minimal risk and permitting expedited review.

2. Application and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements or contracts are submitted for funding with the knowledge that subjects may be involved within the period of funding, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants (including bloc grants) where selection of specific projects is the institution's responsibility; research training grants where the activities involving subjects remain to be selected; and projects in which human subject's involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by StLCoP I.R.B. before an award may be made. However, no human subjects may be involved in any project, funded or not funded, until the project has been reviewed and approved by the StLCoP I.R.B.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to use human subjects in the research, the research shall first be reviewed and approved by the StLCoP I.R.B. in accordance with these regulations.

3. Cooperative research

Cooperative research projects are those projects, normally supported through grants, contracts or similar arrangements, which involve institutions
in addition to the grantee or prime contractor (such as a contractor with the grantee or a subcontractor with the prime contractor). In such instances, the grantee or prime contractor remains responsible for safeguarding the rights and welfare human subjects, each cooperating institution shall comply with these regulations as though it received funds for its participation in the project directly except that in complying with these regulations institutions may use joint review, reliance upon the review of another qualified I.R.B. or similar arrangements aimed at avoidance of duplication of effort.

4. Investigational new drugs and devices

When an activity involves an investigational new drug within the meaning of the Food, Drug and Cosmetic Act, the drug shall be identified in the certification together with a statement that the 30-day delay required has elapsed and the FDA has not, prior to expiration of the 30-day delay interval, requested that the PI continue to withhold or to restrict use of the drug in human subjects; or that the FDA has waived the 30-day delay requirements; provided, however, that in those cases in which the 30-day delay interval has neither expired nor been waived, a statement shall be forwarded to HHS upon the expiration or upon the receipt of waiver. No certification shall be considered acceptable until such a statement has been received.

Should the emergency use of a drug or device arise, the PI should contact the Chairperson of the StLCoP I.R.B. to explain the need of the emergency approval. A letter which includes all the facts should be submitted to the Chairperson of the I.R.B. for documentation of written approval. Such emergency includes the alteration of a protocol approved by the I.R.B. or the use of drugs or devices which are not approved for general use by physicians providing emergency medical care. If it is anticipated that such emergencies may occur for future experimental subjects, the protocol must be amended and resubmitted to the I.R.B. Committee for review. Emergency medical care otherwise may be provided to the extent a physician is permitted to do so under applicable federal, state or local law.

Medical device (see 46.121 in Appendix I, Food and Drug Administration (FDA) Regulations Regarding Medical Devices)

5. Continuing responsibility and changes in program
a. During conduct of the research activity, if there should be later changes in its design that affect the assurances given in the statement to the I.R.B., it is the PI's responsibility to initiate review of the changes by submitting a new statement of research protocol and, as changes indicate, a reviewed informed consent for participants and the revised plan of investigation to the I.R.B. Proposed changes may not be adopted until final approval from the StLCoP I.R.B. is received by the PI.

In the event the PI is associated with another organization/sponsor and the revised research protocol has been approved by the appropriate I.R.B., the StLCoP researcher(s) participating on the project is to provide documentation of the I.R.B. approved protocol revisions to the StLCoP I.R.B. for file purposes.

b. A summary of investigative work form (IRB#3) shall be sent to the I.R.B. annually to certify that the project is being carried out as reviewed and approved, and/or upon completing or discontinuing a project.

In the event the PI is associated with another organization/sponsor, the StLCoP researcher(s) participating in the project is to provide this documentation to the StLCoP I.R.B. for file purposes.

c. The PI shall use the summary of investigative work form (IRB #3), a sponsor's form, or a detailed letter to promptly report any emergent or unanticipated problems and any complaints by subjects or their legally authorized representatives. This shall include any adverse reactions to biologicals, drugs, radiisotope labeled drugs or to medical devices. The I.R.B. will receive two copies of the document as part of the continuing review process and shall evaluate and seek to resolve emergent problems or complaints not satisfactorily resolved by the PI. The I.R.B. Committee will review all cases in which there are problems or complaints. If the problem cannot be resolved by the I.R.B. the Dean will follow up to assure resolution.

In the event the PI is associated with another organization/sponsor, the StLCoP researcher(s) participating in the project shall conform to the problems and complaints, resolution policies affecting the PI. The StLCoP
researcher(s) are to provide appropriate documentation to the StLCoP I.R.B. for file purposes.

d. In addition to all pertinent data and a complete copy of operational aspects of proposed activity, the PI shall obtain and keep on file, in accordance with these guidelines, all documentary evidence of the subject's informed consent, subject to immediate examination by the I.R.B. or granting agency.

e. In protection of privacy of human subjects, the I.R.B. Committee will be guided by the Nuremberg Code, the Declaration of Helsinki, the Universal Declaration of Human Rights adopted by the United Nations and the National Commission for the Protection of Human Subjects (the Belmont Report).

f. If a PI and the I.R.B. cannot resolve their differences, the PI or StLCoP researcher(s) may appeal to the Dean of the College or his designate. If such appeal is not satisfactory to the investigator, the appeal will be referred to the President of the College for his resolution.

6. Documents of research involving human subjects

In addition to all pertinent data and a complete copy of operational aspects of proposed activity, the PI shall obtain and keep on file, in accordance with the Guidelines, all documentary evidence of the subject's informed consent, subject to immediate examination by the I.R.B. or granting agency.

7. Advisory consultation

Some PI's may feel their particular project designs require consultation on problems of the application of these Guidelines to their particular activities. The PI may consult the I.R.B. and, if desired, may submit a project plan to the I.R.B. for advisory consultation and opinions before formal approval is sought.

8. Conditions

With respect to any research project or class of research projects, the funding agencies may impose additional conditions prior to or at the time of funding if the additional conditions are necessary
for the protection of human subjects. The Saint Louis College of Pharmacy I.R.B. may also impose additional conditions depending upon its own independent analysis.

G. Procedures for Review by the Saint Louis College of Pharmacy I.R.B. and Certification by Saint Louis College of Pharmacy

1. Each PI shall complete the grant forms following instructions enclosed in each grant packet which is received.

   a. At all times, regardless of whether the grant is pending, being processed or approved and completed, the PI shall keep a complete and up-to-date record of any and all pertinent data, regardless whether a funded or nonfunded project.

   b. In order that sufficient time may be allowed for review and any modifications of the project design to achieve conformity with the Guidelines, it is requested that the PI submit all research proposals to the StLCoP I.R.B. at least one month prior to the desired date of approval.

   c. For funded activities, the review should be completed prior to submission of the proposal.

   d. When necessary to allow the STLCOP I.R.B. the time needed to consider and complete the review of applications and ongoing projects, HHS has made provisions for institutions to certify completion of review within 30 days if requested by HHS in writing or in any event within 60 days following specified deadlines, or if no deadline, or if no deadline has been specified, the application submission date. Whenever it appears likely that StLCoP I.R.B. will be unable to complete review and approval of an application or proposal submitted or concluded that it will require revisions that will significantly alter the conduct, scope or direction of a proposed project or activity, the agency to which the application has been submitted should be informed promptly by letter by the PI.

   e. The use of human subjects is not to be initiated until the STLCoP I.R.B. has completed its evaluation and has recommended that the use of human subjects may proceed.
2. Saint Louis College of Pharmacy I.R.B. forms may be obtained from the Office of the Dean.

3. The following materials are submitted to the Saint Louis College of Pharmacy I.R.B. office for approval of proposed activities involving human subjects:

   a. Two copies of the form, Information for Review of a Project Involving Human Subjects (IRB#1).

   b. The Informed Consent Form, the research project, and, if the project involves administration of an investigational drug, two copies of the Investigational Drug Data Form.

   c. When a newly developed medical device is incorporated into the study, where applicable, clearance from the FDA must be certified.

   d. If research involves using a new drug, StLCoP I.R.B. must be assured of clearance by the FDA. Two copies of pertinent information on the use of the drug in animals and humans, including all anticipated side effects and toxic properties are submitted to StLCoP I.R.B.

4. Following approval from StLCoP I.R.B., a copy of their approval is sent to the Dean for his approval.

5. I.R.B. approvals are valid for one year unless a shorter time is so stipulated. Any modifications or stipulations by the StLCoP I.R.B. shall be included in the approval and the PI notified. Other stipulations may be indicated (e.g., number of subjects studied, approval by legal counsel, etc.)

6. Any revisions or deviations from the approved proposed activity must be submitted to StLCoP I.R.B. for approval before initiating the change. The StLCoP I.R.B. will notify the PI of their approval of the revision.

7. StLCoP I.R.B. is assigned the responsibility of determining that project design meets the guidelines. In reviewing a proposed activity, should the project design not meet the requirements of the guidelines, StLCoP I.R.B. shall notify the PI in writing of the necessary modification. The PI shall then have thirty days to submit the requested modifications for approval. Following approval of the modifications, StLCoP I.R.B. will notify the PI of the final approval and work on the proposed activity may then proceed.

8. In any of the review processes, should a proposed
activity be disapproved, the StLCoP I.R.B. shall notify the PI of the reasons for disapproval. Should the PI choose to respond to the disapproval and make the required modifications, the proposed activity may again enter the review process.

9. Upon completing or discontinuing a project, a summary of investigative work shall be sent to the I.R.B. (IRB#3)

H. Suggested Experimental drug protocols

1. Attending physician must indicate acceptance of research protocol on Physician's Order Sheet by cosigning order written by the investigator indicating that the patient has been entered into the research protocol. The medical record must contain information as to the location of the complete research protocol.

2. Investigator has made a statement to the physician's progress notes that informed consent has been obtained. Original consent forms are kept in the investigator's office. One copy of the consent form must be present in the patient's medical record.

3. Investigator or designee (or both of them) has explained drug protocol to the involved head nurse or designee, e.g., possible adverse reaction, drug storage preparation and precautions. Acknowledgement of the protocol explanation or any changes thereto, will be documented in the medical record by the involved head nurse or designee.

4. The investigator will provide drug for administration and a copy of the Investigational Drug Data Form. If drug is from the pharmacy, the Investigational Drug Data Form is sent to the floor with the drug. Upon completion of study, drugs are returned to the investigator or Pharmacy, whichever originally provided the drug.

5. All medication in related treatment protocol orders will be written on participating patient's order sheet.

6. The investigator has written on the participating patient's order sheet the name and telephone number of a resource person to be contacted at any time, on a 24-hour-a-day basis, should a problem or question arise in connection with the drug.
SAINT LOUIS COLLEGE OF PHARMACY
POLICY FOR PROTECTION OF
HUMAN RESEARCH SUBJECTS

SECTION III

Saint Louis College of Pharmacy Institutional Review Board
Function and Requirements

A. The IRB reviews research in accordance with the new regulations of the Department of Health and Human Services (HHS), Title 45 CFR 46. The IRB meets monthly or more frequently when necessary.

The IRB provides a central focus for principal investigators (PI), administration for processing protocols, communicates other information concerning research involving human subjects and responds to proposed changes in regulations.

The StLCoP IRB is to review all activities which, in whole or in part, involve research with human subjects, including "pretests", if:

1. The research is sponsored by StLCoP or
2. The research is conducted by or under the direction of any employee or his agent of StLCoP in connection with his or her StLCoP responsibilities, or
3. The research is conducted by or under the direction of any employee or agent of StLCoP using any property or facility of StLCoP or
4. The research involves the use of StLCoP nonpublic information to identify or contact human research subjects or prospective subjects.

B. Responsibilities of PI

1. Determination of human subject involvement.
   a. The PI shall make a determination as to whether research will involve human subjects as defined in 46.102.
   b. When it is not clear whether the research involves human subjects as defined in 46.102, the PI should seek assistance from a member of the IRB.
2. Preliminary determination of exemption eligibility.

The PI shall make the preliminary determination of whether such research which does involve human subjects is exempted from coverage under 46.101.

The PI is strongly advised to consult with a member of the IRB accurately determine that the research protocol is indeed exempt from IRB review.

3. Preparation of protocol.

The PI shall prepare a protocol giving a complete description of the proposed research. In the protocol, the PI shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and insure that pertinent laws and regulations are observed. This requirement is applicable even in cases where research is exempt under 46.101.

4. Scientific merit and ethical consideration.

The PI is responsible for reviewing the protocol for ethical considerations and scientific merit before submitting it to the IRB for review.

5. Submission of protocol to the IRB.

The PI shall be responsible for insuring that all research involving human subjects is submitted to the IRB.

6. The PI shall be responsible for submitting a supplement to the IRB when:

   a. It is proposed to involve human subjects, and the activity previously had only indefinite plans or no plans for involvement of human subjects, or

   b. It is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

7. Complying with IRB decisions.

The PI shall be responsible for complying with all IRB decisions, conditions and requirements.

8. Obtaining informed consent.

   a. The PI is responsible for obtaining informed
consent in accordance with 46.116 and for insuring that no human subject will be involved in research prior to obtaining the consent.

b. Unless otherwise authorized by the IRB, the PI is responsible for insuring that legally effective informed consent shall:

1. Be obtained from the subject or the subject's legally authorized representative;

2. Be in language understandable to the subject or the subject's representative.

3. Be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and

4. Not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the PI, the sponsor, StLCoP or its agents from liability for negligence.

9. Providing basic elements of informed consent.

Unless otherwise authorized by the IRB, the PI at a minimum shall provide the following information to each subject.

a. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; A description of any reasonably foreseeable risks or discomforts to the subject;

b. A description of any benefits to the subject or to others which may reasonably be expected from the research;

c. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

d. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
e. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

f. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subjects; and

h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

10. Providing additional elements of informed consent.

When required by the IRB, the PI shall provide one or more of the following additional elements of information to each subject:

a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

b. Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the research;

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

f. The approximate number of subjects involved in the study.

11. The PI is responsible for documentation of informed consent.

a. The PI shall be responsible for insuring that informed
consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB.

b. The PI shall insure that each person signing the written consent form is given a copy of that form.

c. The PI may use a consent form which is a written consent document that embodies the elements of informed consent required by 46.116. This form may be read to the subject or to the subject's legally authorized representative, but in any event, the PI shall given either the subject or the representative adequate opportunity to read the form before signing it.

12. Retention of signed consent documents.

a. The PI is responsible for keeping the consent documents signed by human research subjects on file for a period of three years following completion of the research project.

b. Following the completion of research involving use of investigational drugs, the signed consent documents should be retained for a period that complies with FDA requirements.

c. After retention of the signed consent documents have been held by the PI for the required number of years (as specified above), the PI will submit these consent documents, or copies thereof, to the StLCoP administration.

13. Submission of progress reports on the research.

The PI is responsible for reporting the progress of the research to the IRB as often as and in the manner prescribed by the IRB but no less than once per year.

14. Submission of injury reports and reports of unanticipated problems involving risks.

a. The PI is responsible for reporting promptly to the IRB any injuries to human subjects.

b. The PI is responsible for reporting promptly to the IRB any unanticipated problems which involve risks to the human research subjects or others.

15. Reporting changes in the research.
a. The PI is responsible for reporting promptly to the IRB proposed changes in a research activity.

b. Changes in research during the period for which StLCoP IRB approval has already been given shall not be initiated by the PI without StLCoP review and approval except where necessary to eliminate apparent immediate hazards to the subject.

16. Reporting of noncompliance.

The PI is responsible for reporting promptly to the IRB any serious or continuing noncompliance with the requirements or the determinations of the StLCoP IRB.

17. Attending StLCoP IRB meetings.

To facilitate the review of research and the protection of the rights and welfare of human subjects, the PI is encouraged to attend StLCoP IRB meetings when invited by the StLCoP IRB.

18. Notifying the IRB concerning investigational new drugs.

The PI shall be responsible for notifying the Food and Drug Administration (FDA) and the IRB whenever it is anticipated that an investigational new drug or device exemption will be required.

C. StLCoP IRB Structure.

1. StLCoP establishment of the IRB.

The IRB is established within StLCoP to review research involving use of human beings as research subjects. IRB membership is appointed by the Dean of the College and is subject to approval by the President of the College. Minimum membership of the IRB shall be five (5) persons.

2. StLCoP IRB membership requirements.

a. The IRB is comprised of members from diverse backgrounds to promote complete and adequate review of research activities and has the professional competence necessary to review the specific research activities which will be assigned to it.

b. The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of
c. When research is reviewed involving a category of vulnerable subjects (e.g. prisoners, children, individuals institutionalized as mentally disabled), the IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects.

d. The IRB includes both male and female members.

e. The IRB includes members representing a variety of professions.

f. The IRB includes at least one member whose primary expertise is in a non-scientific area.

g. The IRB includes at least one member who is not otherwise affiliated with StLCoP and who is not a part of the immediate family of a person affiliated with StLCoP.

h. The IRB may not have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

i. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

D. StLCoP IRB Authorities and Responsibilities.

1. StLCoP IRB review and approval of research.

a. The StLCoP IRB shall have the responsibility to review and the authority to approve, require modification in or disapprove all submitted research protocols or proposed changes in previously approved protocols.

b. The StLCoP IRB shall approve research based on the IRB's determination that the following requirements are satisfied.

(1) Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate by using procedures
already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in research). The IRB shall not consider long-range effects of applying knowledge gained in the research among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment, the IRB shall take into account the purpose(s) of the research, the setting in which the research will be conducted and the population from which subjects will be recruited.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by 46.116.

(5) Informed consent will be appropriately documented in accordance with, and to the extent required by 46.117.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. Documentation of informed consent.

   a. In accord with 46.117, the StLCIRB IRB shall require documentation of informed consent by use of a written consent form, or may waive the requirement for the PI to obtain a signed consent form for some or all subjects if the IRB determines that:
(1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern; or

(2) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

b. When the documentation requirement is waived, the StLCoP IRB may require the PI to provide subjects with a written statement regarding the research.

3. Waiver or alteration of informed consent.

a. The StLCoP IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 46.116 or waive the requirement to obtain informed consent provided by the IRB finds and documents that

(1) The research is to be conducted for the purpose of demonstrating or evaluating:

   (a) Federal, state or local benefit or service programs which are not themselves research programs or

   (b) Procedures for obtaining benefits or services under these programs or

   (c) Possible changes in or alternatives to these programs or procedures; and

(2) The research could not practicably be carried out without the waiver or alteration.

b. The StLCoP IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in 46.116 or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risks
to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

4. Observation of the consent process and the research.

The StLCoP IRB shall have the authority to observe or have a third party observe the consent process and the research.

5. Frequency of review.

a. The StLCoP IRB shall determine in its review of research protocols which projects will require IRB review more often than annually.

b. Except as may be otherwise provided, all convened StLCoP IRB meetings shall be conducted under and pursuant to Robert's Rules of Order.

c. Convened meetings of StLCoP IRB shall occur:

   (1) Once a month on the regularly scheduled meeting date; and

   (2) At the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous; and

   (3) At the call of the chairperson upon the receipt of a joint request of three or more members.

6. Continuing review.

The StLCoP IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

7. Verification of change.

The IRB shall determine which projects need verification from sources other than the PI that no material changes have occurred since previous IRB review.

8. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions and requirements or that has been associated with unexpected serious harm to subjects (see 46.113).
9. Information dissemination and reporting requirements.

The StLCoP IRB shall have the authority and be responsible for promptly reporting information to the Dean of the College on a variety of issues. In conjunction with this requirement, the IRB must be prepared to receive and act on information received from a variety of sources, such as human subjects, the PI or other StLCoP staff. For reporting purposes, the IRB will follow the procedures described below.

a. Any serious or continuing noncompliance by the PI with the requirements of the StLCoP IRB. This information shall be reported promptly to the Dean of the College.

b. Injuries to human subjects - Information received by the StLCoP IRB concerning injuries to subjects shall be reported promptly to the Dean of the College.

c. Serious unanticipated problems - Information received by the StLCoP IRB concerning unanticipated problems involving risks to subjects or others shall be reported promptly to the Dean of the College.

d. StLCoP IRB, when suspending or terminating approval of research protocols shall include a statement of the reasons for the IRB's action and shall report the action promptly to the PI and the Dean of the College.

10. Public Knowledge

The IRB considers approved protocols to be public knowledge unless:

a. The PI specifically requests that information regarding the research protocol be maintained confidential, and reasons for this request are provided, and

b. The majority of IRB members evaluating this request at a regularly scheduled meeting approve the request.

Protocols not approved are considered confidential by the IRB.

11. StLCoP IRB records.

a. The StLCoP IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposal's approved sample consent documents, progress reports submitted by the PI and reports of injuries to subjects.
2. Minutes of IRB meetings which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and the PI.

5. The names and qualifications of the members of each StLCoP IRB in accordance with 46.103.

6. Written procedures for IRB as required by 46.103.

7. Statements of significant new findings provided to subjects, as required by 46.116.

b. The IRB shall maintain records relating to a specific research activity for at least three years after termination of the last IRB approval period for that activity.

c. IRB records shall be accessible for inspection and copying by authorized representatives of the StLCoP, and/or HHS at reasonable times and in a reasonable manner or shall be copied and forwarded to these representatives when so requested by them.

F. StLCoP IRB Procedures.

1. The IRB receives protocols for all research involving human subjects.

2. Administrative Review

a. The IRB chairperson, or designated member, is responsible for reviewing the research protocol submitted by the PI to determine whether the research protocol is exempt from IRB assessment under 46.101.

3. Determination of review procedure.
a. The IRB chairperson, or designated member shall determine whether the research protocol meets the criteria necessary for an expedited review process.

b. The IRB chairperson refers all research protocols to either full committee review or expedited review.

4. Expedited review. (See Section 46.110)

a. Expedited review shall be conducted by the IRB chairperson or by one or more of the experienced IRB members designated by the chairperson to conduct the review.

b. IRB member(s) conducting the expedited review may exercise all of the authorities of the StLCoP IRB except that the reviewer(s) may not disapprove the research. The reviewer(s) shall refer any research protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believes that full committee review is warranted.

c. At a convened IRB meeting, any member may request that an activity which has been approved under the expedited procedure be reviewed by IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue.

5. Full committee review.

a. Research protocols scheduled for review shall be distributed to members of the StLCoP IRB prior to the meeting.

b. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.

c. The IRB initial review and continuing review shall be conducted at convened meetings and at timely intervals.

d. A majority of the membership of the StLCoP IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols.

e. An IRB member whose concerns are primarily in the non-scientific areas must be present at the
convened meeting before the IRB can conduct its review of research.

f. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting.

g. The StLCoP IRB may not have a member participating in IRB initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

h. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meetings shall supersede any decisions made through the expedited review.

6. IRB notification of decision(s)

a. The StLCoP IRB shall notify the PI and the Dean of the College in writing of IRB decisions, conditions and requirements.

b. The StLCoP IRB shall also provide to the PI reasons for IRB decision(s) to disapprove a research protocol and an opportunity for the PI to respond. Reasons for disapproval shall also be transmitted to the Dean of the College by the IRB.

7. Appeal of Board review.

An appeal to the decision(s) of the IRB may be made to the Dean of the College. If such an appeal is not satisfactory to the investigator, the appeal may be referred to the Office of the President of the College for final determination.

8. Amendments

Amendments to the Policies and Procedures of the Institutional Review Board. (IRB) may be made by affirmative vote of a simple majority (50% plus 1) of ALL voting members of the IRB on a blind ballot. The vote shall be called by the chairperson or any two IRB members at a regular or special meeting of the IRB. Notification of time and place of proposed amendment vote and copies of the proposed amendment must be distributed by person(s) calling the meeting to all IRB members at least 15 days prior to the meeting. Written amendment proposals will be
considered in response to, but not limited to, faculty member petition, college administration petition, or IRB member petition. Revisions in Federal Regulations may also provide reason for the IRB to consider amendments to these Policies and Procedures.
APPENDIX I

General References

Belmont Report

Title 45 CFR 46
APPENDIX II

Saint Louis College of Pharmacy I.R.B. Forms

1. Information for Review of a Project Involving Human Subjects
2. I.R.B. Protocol Review
3. Summary of Investigative Work
### Part A

<table>
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<tr>
<th><strong>Project Title</strong></th>
<th><strong>Proposal Number</strong></th>
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<tr>
<th><strong>Project Director</strong></th>
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<th><strong>Institution</strong></th>
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3. **Name of Sponsor (If None, So State)**

4. **Identify Source of Funds, If Any (If None, So State)**

5. **Name of Grantee If Other Than St. Louis College of Pharmacy**

### Part B

1. **Purpose or Objectives of Project**

2. **Number of Subjects to Be Used in the Project**

3. **Will Any of the Following Be Subjects?**

   - **Institutionalized Persons**: Yes / No
   - **Incompetent Persons**: Yes / No
   - **Adult Women**: Yes / No
   - **Pregnant Women**: Yes / No
   - **Adult Men**: Yes / No
   - **Women of Child Bearing Age**: Yes / No
   - **Students**: Yes / No
   - **Minors**: Yes / No
   - **Low Income Persons**: Yes / No

   Please circle any categories of subjects to be oversampled. Briefly explain.

4. **Please Explain If Women/Minorities Are Specifically Excluded From Project Protocol.**

5. **State Why Subjects in Item B-3 Are Required.**

6. **State Duration of Participation of Subjects (or Specific Categories of Subjects).**
7. Please state in outline form what will be done to research subjects, use flow charts when applicable, attach pages as necessary please.

8. If blood, other body fluids, or tissue samples will be collected, state method and total quantity required per subject.

9. Identify drugs, appliances or procedures that are experimental or that are classed as investigational by FDA.

10. Identify factors in items 6, 7 and 8 that impose risk. Define the risk.

11. Describe procedures for protecting against or minimizing risk. Assess their potential effectiveness.

12. Identify benefits (personal, social, scientific, etc.)

13. State methods used to insure confidentiality

14. Attach a copy of proposed consent documentation

| Date | Signature of Project Director |
1. FOR THE FOLLOWING REASONS, PRIOR CONSENT CANNOT BE OBTAINED BEFORE THE INVOLVEMENT OF SUBJECTS IN THE PROJECT:

- 

2. THE FOLLOWING PROCEDURES WILL BE USED IN DEBRIEFING WHICH WILL TAKE PLACE IMMEDIATELY FOLLOWING EACH SESSION:

- 

IE: IN THE EVENT THAT THE PROCEDURES REQUIRED TO BE OUTLINED IN 2 (ABOVE) CANNOT APPLY TO THIS PROJECT, A DETAILED EXPLANATION MUST BE ATTACHED, WITH JUSTIFICATION FOR PROCEDURES ANTICIPATED.

DATE | SIGNATURE OF PROJECT DIRECTOR
I.R.B. PROTOCOL REVIEW

_________________________
IRB #

Date Received: Date
Reviewed:

Principal Investigator: _________________________________

Project Title: _________________________________

PART A:

_______ Please contact ________________, ext. ____ at your earliest convenience regarding this protocol.

PART B:

_______ The IRB requires additional information regarding this protocol before a review can be completed. Specifically, please refer to part "D".

PART C:  Protocol is:

____ Not Approved (Please see memo of explanation)

____ Approved

Will be approved if the following changes are made in the protocol. (Please refer to Part "D".) (Documentation verifying the changes must be transmitted to the IRB before final approval will be authorized.)

PART D:
SUMMARY OF INVESTIGATIVE WORK
(Renewal, Completed or Discontinued Projects)

Investigator __________________________ Date ______________

Title of Project:

TRE Number

Previous Risk Assignment
Population Research
High/Low High/Low

1. Status of Data Collection -
Ongoing/Completed/Discontinued (circle one)

Date if completed or discontinued__________

2. Number of subjects contacted during past year:___________

This institution_______ Groupwide (if applicable)_____

3. Describe any significant adverse effects giving a number or percentage in relation to the number accessioned since last submission.

4. Describe changes in study design or objectives during the past year.

5. Describe proposed changes in study design or objective for upcoming year (if project is ongoing).

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Site of action:

Onset: Duration

Metabolism & Excretion:

Dosage:

Potentiating drugs:

Side Effects:

Toxicity: Home phone Hosp. ext.

Antidote:

Investigators:

1. 
2. 
3. 

Double Blind Test: Yes No Duration of Test:

References:
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<th>Type of Information</th>
<th>Committee Action</th>
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**Follow-Up & Date**

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* A = Administrative, E = Expedited, F = Full Committee
** A = Approved, NA = Not Approved

References: