

**INVESTIGATIONAL PROJECT GUIDELINES**

**American College for Advancement in Medicine**

**INSTITUTIONAL REVIEW BOARD**

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## INTRODUCTION

According to 45 CFR 46, any activity (whether funded or not) involving human subjects must be reviewed and approved by the Institutional Review Board. This review and approval must be granted prior to beginning the proposed activity.

One of the Institutional Review Board's main functions in reviewing such activity is to determine the degree of risk to subjects. Risk exists when a subject may be exposed to any possible physical, psychological, or other harm as a result of an activity that is not an accepted and established method of meeting the subject's needs. In addition to the physical risk, any procedures involving discomfort, anxiety, invasion of privacy, or other threats to the subject's dignity fall under the purview of the Institutional Review Board. Thus, the Institutional Review Board will assess risk for:

1. Experimental activities, including surgery, biopsy, new devices, drugs, organ transplants, and other innovations.
2. Use of materials such as organs, body fluids and tissues, obtained during routine services.
3. Trainee education and/or demonstration projects.
4. Use of stored data, such as medical records, that may have been obtained for other purposes.

If the Institutional Review Board decides that an activity will expose a subject to risk, the Board will assure that:

1. The rights and welfare of the subject(s) are protected.
2. The methods used to obtain the subject's or subjects' informed consent are appropriate.
3. The potential benefit for the subject(s) and/or society, to knowledge, outweighs the risks.

The Institutional Review Board may request information on any aspect of a proposed activity. As part of the review process, the Institutional Review Board may seek the advice of consultants, supplementary information, and may request demonstration of the activity. All criteria must be met for the Institutional Review Board to consider approval of the proposed biomedical or behavioral research activity. The Institutional Review Board will request regular progress reports for approved activities and immediate reporting of any unforeseen complications or adverse reactions.

For information regarding review of your project/protocol by the Institutional Review Board, contact Rhonda Diehl, telephone (309) 367-2321. The material required for the IRB to review a project must be submitted six weeks prior to the Institutional Review Board meeting at which it will be reviewed. Upon receipt of the material, you will be notified of the date, time and place of the Institutional Review Board meeting, and will be requested to attend.

After the Board has reviewed the project/protocol, you will be notified in writing of its decision, and/or requested to submit supplemental information if necessary.

Upon Institutional Review Board approval and subsequent notification of approval by the FDA and/or sponsor, a copy of that notification is to be submitted to the Institutional Review Board.

If a project is contingent upon funding, the Institutional Review Board is to be notified when funding is obtained and when the project will begin.

**Institutional Review Board  
Investigational Project Guidelines  
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Please see the "Rules" sheet (enclosed) for full information about submission of your project.

For Institutional Review Board review of your project/protocol, 15 collated copies of the following information will be required:

1. Completed project/protocol Information Sheets. (See pages 3-6).
2. Principal Investigator's Curriculum Vitae, along with any additional information on the investigator's experience in this research area.
3. Copy of formal protocol to be utilized. If a medical device is used, information from the manufacturer will be required.
4. Consent form(s) to be used. (See pages 7-8).
5. The above material is to be submitted to Rhonda Diehl for IRB Chairman Stephen Elsasser, DO, 205 South Englewood Drive, Metamora, Illinois 61548.
6. The \$100 nonrefundable IRB submission fee is to be made payable to and sent to ACAM, c/o Edward A. Shaw, PhD, Executive Director, 23121 Verdugo Drive, Suite 204, Laguna Hills, CA 92653.

Date: \_\_\_\_\_

**PROJECT/PROTOCOL INFORMATION**

Principal Investigator: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

TITLE OF PROJECT/PROTOCOL: \_\_\_\_\_

\_\_\_\_\_

Project/Protocol Sponsor: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_ Contact: \_\_\_\_\_

Funding agency to which project will be submitted and/or funding sources (if any): \_\_\_\_\_

\_\_\_\_\_

Projected date of start up: \_\_\_\_\_

Indicate which of the following will be involved in your project/protocol:

- |                                                              |                                                                 |
|--------------------------------------------------------------|-----------------------------------------------------------------|
| <input type="checkbox"/> Patients as experimental subjects   | <input type="checkbox"/> Nonprescription nutritional substances |
| <input type="checkbox"/> Patients as control subjects        | <input type="checkbox"/> Data, medical records, etc.            |
| <input type="checkbox"/> Non-Patient volunteers              | <input type="checkbox"/> Radiation                              |
| <input type="checkbox"/> Students as subjects                | <input type="checkbox"/> Subjects to be paid                    |
| <input type="checkbox"/> Pregnant subjects                   | <input type="checkbox"/> Charges incurred by subjects           |
| <input type="checkbox"/> Subjects under 18 years old         | <input type="checkbox"/> Charges to third parties               |
| <input type="checkbox"/> Mentally disabled subjects          | <input type="checkbox"/> Fetal or placental tissue              |
| <input type="checkbox"/> Filming, recording subjects         | <input type="checkbox"/> Autopsy tissue                         |
| <input type="checkbox"/> Experimental drugs                  | <input type="checkbox"/> Surgical pathology tissue              |
| <input type="checkbox"/> Placebos                            | <input type="checkbox"/> Approved drugs for new uses            |
| <input type="checkbox"/> Questionnaires, psychological tests | <input type="checkbox"/> Experimental devices                   |









## INFORMED CONSENT

For each project/protocol, the Principal Investigator must submit to the Institutional Review Board the consent form(s) and/or the script for any verbal explanation given. (See *Informed Consent, Disclosure, and Acknowledgement Form for Chelation Therapy Study* attached to the enclosed Sample Protocol for reference.) Consent forms must be retained by the investigator for at least five (5) years (21 CR 56.195[b]). Participation in a study will not be permitted unless the participant gives his/her written consent; retroactive consent will not be permitted. The consent form(s) and verbal information should be clear, legible, and in simple terms, and contain the following:

1. Title of the project/protocol.
2. Date of preparation/revision.
3. Pages numbered.
4. Space for the signatures and dating thereof by the investigator, person obtaining the consent, the participant, a witness, and (where appropriate) space for a minor to sign, in addition to his/her parent/guardian.
- 5.\* Explanation of the purpose and length of the study.
- 6.\* Explanation of the procedures to be used, identifying those that are "experimental."
- 7.\* Description of discomforts, risk, and benefits. When possible give quantified comparative estimates of  
\*\*\* risk versus benefits.
- 8.\* Explanation of any available alternatives (if appropriate) that might benefit the participant.
- 9.\* An offer to answer any questions, including the investigator's address, and telephone number and numbers to call in the event of an adverse reaction or medical emergency.
- 10.\* A statement that the participant may terminate his/her participation at any time, without reprisal or  
\*\*\* conditions that will cause termination of participation.
- 11.\*\* Regardless of whether compensation will be provided by the Principal Investigator or other outside party, the following ACAM statement on compensation must be included in the consent form(s): "I understand that no compensation for participation in this study will be provided by Dr. \_\_\_\_\_, his office, ACAM or the IRB, and I also understand that neither ACAM nor the IRB has a policy to medically treat or compensate for physical injuries incurred as a result of participating in biomedical or behavioral research. I understand and agree that ACAM is not a

participant in the study and that the IRB merely serves as a reviewer and collator of the data produced under this study. I expressly agree, as a condition of my participation in this study, that ACAM and the IRB shall not in any manner be responsible for any physical injuries incurred as a result of my participation in the study and I waive, in advance, any claims against either and both of them."

- 12.\*\*\* A statement that the participant's confidentiality will be protected, noting the regulatory bodies (FDA/IRB) have the authority to inspect all records for the patient's safety. Also a statement that any change in the use of the information obtained other than that to which the patient has consented will first be presented to the patient for his/her approval.
13. Discussion of any extra costs to the participant and/or to an insurer as a result of participation (if applicable).
- 14.\*\* Whether the subject will be compensated for participation (if \*\*\* applicable) and a contractual agreement drawn. The same ACAM statement on compensation cited in 11. above also applies here.
15. Notification that the participant will receive a copy of the signed consent form.
16. A statement that in the event the results of the project will be published as a study, that permission is granted from the patient to be included, provided that his privacy is protected.

\* Required per 45 CFR 46.103(c)

\*\* Required per the compensation element which was added 6/18/91 as the seventh element of consent [45 CFR 46.103(c)(7)].

\*\*\* Required per 21 CFR 50.25

#### TERMINATION OF A PROJECT/PROTOCOL

If a project is completed, discontinued, or other circumstances arise requiring the Principal Investigator to withdraw from an approved study, the Institutional Review Board Secretary is to be notified, in writing, of such completion, discontinuation, or withdrawal within thirty (30) days.

## **Rules: Institutional Review Board American College for Advancement in Medicine**

1. Must be an active member of ACAM, including attendance at a minimum of one meeting per year.
  
2. Write the project following written IRB guidelines and fill out questionnaire..
  
3. In order to be considered for review at the next IRB meeting, Kim Mossburg in Dr. Stephen Elsassers office, must receive two copies of your project/protocol at least six weeks in advance of the meeting.  
  
IRB Meetings are held in conjunction with ACAM's biannual programs in May and November. Please contact either Kim Mossburg or the ACAM office for information about when and where the meetings are to be held.
  
4. When you first submit your project, an initial submission fee of \$100.00 payable to ACAM is required. An initial review of your project will be done by at least two IRB members. They may make suggestions or ask for clarifications on your project. You will be contacted about any needed revisions prior to the meeting. Your revised project (along with 15 additional copies) will then need to be sent to Kim Mossburg at least one week prior to the meeting. At this time a processing fee of \$250 payable to ACAM is required. If you are participating in a multi-center project, the fee is \$200 for review of the project, with \$50.00 additional from each participating physician. If you have more than one project you wish reviewed and you submit them at the same time, no additional fees are required.
  
5. Within six weeks after the meeting, you will receive written notification of the IRB decision.
  
6. A brief update on the progress of your study is due annually unless otherwise stated. Forms for this purpose will be provided by the IRB. The annual fee of \$100, payable to ACAM, is due at this time.
  
7. Any correspondence or questions should be directed to Kim Mossburg in Dr. Stephen Elsassers office, 205 South Engelwood Drive, Metamora, Illinois 61548, Ph. (309) 367-2321, FAX (309) 367-2324.
  
8. The contact for ACAM membership information is Grace Claus, Membership Services Coordinator, 23121 Verdugo Drive, Suite 204, Laguna Hills, CA 92653, Ph. (714) 583-7666, FAX (714) 455-9679.