TOURO UNIVERSITY
COLLEGE OF OSTEOPATHIC MEDICINE
IRB REVIEW FORM

Application number:

Application Title:

Applicant:

IRB Reviewer: ______________________________________________

Date of Review: _____________________________________________

Recommendation

Approve ____________  Disapprove ____________  Modify _________

The Applicable laws and regulations for students and normal volunteers

45 CFR 46  {DHHS: Protection of human subjects}
21 CFR 50  {FDA: Informed consent}
21 CFR 56  {FDA: IRB review and approval}

Principal investigator

1. Does the principal investigator have the appropriate qualifications, experience, and facilities to insure that all aspects of the project and follow-up will be conducted rigorously and with due regard for the safety and well being of the subjects?

2. Are adequate procedures in place through which the researcher will monitor the project and report problems to the IRB?

3. What is the investigator past record with regard to approved research?

Risks and benefit analysis

1. Are both risks and anticipated benefits accurately identified, evaluated, and described?
2. Do the potential benefits outweigh potential risks to the study subjects? Explain.

3. Is there any vulnerability among prospective subjects that might be relevant to evaluating the risks of participation?

4. Are there adequate provisions for a continuing reassessment of the balance between the risks and benefits?

**Informed consent**

*Considering the fact that the study involves normal volunteers,*

1. Do the proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits?

2. Are the subjects given sufficient information with regard to Procedure Purpose Risks Anticipated benefits

3. Is the possibility (or improbability) of direct benefit to the subjects fairly and clearly described?

4. Is the language and presentation of the information to be conveyed appropriate to the subjects’ population (in this case the student volunteer?)

5. Who will be explaining the research to potential subjects? Should someone in addition to or other than the investigator be present?

6. Should subjects be reeducated and their consent required periodically? Are there any incentives offered for participation?

7. Should we (the IRB committee) monitor the incoming data to determine whether new information should be conveyed to participating subjects? If yes, how often should this occur? Who is responsible for bringing new information to the attention of the IRB committee between scheduled reviews?

8. Should there be a data and safety monitoring committee?
9. Any suggestions for improving the consent form?

Protection of human subjects

1. Does the nature of the research require or justify using the proposed subject population?

2. Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate?

3. Will any special psychological, physiological, or social characteristics of the subjects group pose special risks for them?

Privacy and confidentiality

1. Is the privacy of subjects invaded?

2. Will the subject be collecting sensitive information about individuals?

3. Any reservations concerning subject solicitations, recruitment, or enrollment?

Briefly justify the reason(s) for your overall recommendation.