

Institution Review Board
Continuing Review – Use of Human Subjects

Project Title: _____

Principal Investigator: _____

Office Phone: _____

Department: _____

Location of Activity: _____

Tarleton State University’s policy of Protection of Human Subjects provides for continuing review of all projects at least annually or whenever material changes are made in project design. The following requested information will provide the basis for continuing review. Please answer all questions; if not applicable mark N/A.

Please return form by _____

1. Date activity was first approved: _____

A. Is activity still being conducted? YES _____ NO _____

B. If response is “NO” indicate if TEMPORARY _____ or PERMANENT _____

C. Indicate whether abandonment is due to:

PROJECT COMPLETION _____ (if so, attach final summary)

COMPLICATIONS _____ RISKS OF SUBJECT _____ OTHER _____ (explain)

2. Has your activity involved sites other than Tarleton State University? YES _____ NO _____

Name site(s) _____

3. Total number of subjects involved in project to Date: _____

A. How many have been enrolled since last review? _____

B. Of current enrollment how many were

- Healthy Volunteers: University employees, Minors (< 18 yrs), Men, Women, Proband, Proband’s family
Patients: Outpatients, Inpatients, Minors (<18 yrs), Men, Women, Proband, Proband’s family
Vulnerable Subjects: Pregnant Women, Cognitively impaired, Comatose, Traumatized, Terminally ill, Fetus (viable), Fetus (non-viable)
Other: Other class: (explain below)

RACE: African-American _____ Asian _____ Caucasian _____ Hispanic _____ Other _____

4. Was informed consent obtained from all subjects? YES _____ NO _____

If "NO," explain _____

A. Executed consent forms are maintained at _____

B. Is current consent procedure adequate? YES _____ NO _____

If "NO," explain _____

C. Briefly describe any problems encountered in obtaining consent: _____

5. Did any unanticipated complications/reactions occur during subject's participation? YES _____ NO _____ If

"YES," has IRB been previously notified? YES _____ NO _____

If applicable, the FDA? YES _____ NO _____ Please include copy of FDA report.

Describe any adverse experiences not previously reported to the IRB in the project summary and indicate if they were directly or indirectly study related.

6. Did any death occur? YES _____ NO _____ If "YES," state number _____

Cause of death _____ Reported to IRB _____ To Sponsor _____ To FDA _____

Please enclose completed IRB Form # 5 report of death for event not previously reported.

7. Specify all conditions for removal from study:

Medical condition unchanged

Medical condition worse

Complications intolerable

Subject's voluntary withdrawal

Investigator's decision

Subject's failure to follow study procedures

Completion of all study activities

Closure of the study by the sponsor/FDA

8. If protocol described safeguards to avoid risks or detect complications, were these measures adequate? YES _____ NO _____

If "NO," explain _____

9. Has the previously approved protocol/consent form been altered in any way? YES _____ NO _____

Any study modifications must be reviewed/approved by the IRB per Federal regulations.

If "YES," detail in progress report.

10. If radiation is involved in the continuing review, the Radiation Safety Committee must review and approve.

11. Attach progress report: describe subject experiences (benefits/reactions/withdrawals; current assessment of risks/benefit based on results to date, and any new information including publications).

12. Attach a clean current consent form to be updated. If modified, changes must be highlighted.

13. For research involving the cooperating institutions, send appropriate forms (IRB # 8) to the facilities as described in this packet.

PRINCIPAL INVESTIGATOR SIGNATURE

DEPARTMENT CHAIR SIGNATURE

DATE

DATE

TSU IRB Form # 3
Revised 3/00

CERTIFICATES OF CONFIDENTIALITY

Investigators authorized by a Certificate of Confidentiality to protect the identity of research subjects may not be compelled to identify research subjects (by name or other identifying characteristics) in any civil, criminal, administrative, legislative, or other proceedings. Research involving sensitive issues may benefit from special protection to assure the privacy of subjects. "Sensitive" research includes the collection and study of any of the following information:

- sexual attitudes, preferences, practices
- use of alcohol, drugs, or other addictive products
- illegal conduct

Sensitive research includes studies resulting in potential psychological, economic, or social harm such as the following:

- financial disadvantages
- difficulty in gaining employment or promotion
- damage to reputation within the community
- social stigmatization or discrimination
- adverse effects on psychological well-being or mental health

Certificates of Confidentiality are available through the following Federal agencies:

National Institute of Mental Health
National Institute on Alcohol Abuse and Alcoholism
National Institute on Drug Abuse
Centers for Disease Control and Prevention
Agency for Toxic Substances and Disease Registry
Food and Drug Administration (IND)
Health Resources and Services Administration
Indian Health Service
National Institute of Allergy and Infectious Disease
National Cancer Institute
National Institute of Environmental Health Sciences
National Institute of Heart Lung and Blood
Substance Abuse and Mental Health Administration

Primary Contact: Olga Boikess
National Institute of Mental Health
17-C-02 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3877