WARNING
If you wish to SAVE completed document, SAVE it to your computer BEFORE completing it.

IRB File #

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 NIA.

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

Approved: _____ _____ Expires: _____ _____
MM DD YEAR MM DD YEAR

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 complicationsIreactions 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**

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