INSTITUTIONAL REVIEW BOARD

APPLICATION FOR REVIEW OF PROJECTS INVOLVING HUMAN SUBJECTS

FOR INTERNAL USE ONLY **TU IRB APPLICATION NUMBER:_____**

Please note: Handwritten applications will *not be* accepted.

SUBMISSION REQUIREMENT: The Thomas University Institutional Review Board **(IRB)** requires that ***students***, faculty and researchers **submitting an IRB application to conduct research involving humans as subjects complete the appropriate online Collaborative Institutional Training Initiative (CITI) certification courses available at https://www.citiprogram.org/index.cfm?pageID=14&languagePreference=English&region=1 Please be sure to select Thomas University as the affiliate institution on the CITI website to see the list of required courses per research area.**

Application Type: ___NEW ___ RESUBMISSION Date Application Submitted to IRB: _____
___FOR ACADEMIC TEACHING PURPOSES ONLY *(FACULTY ONLY)*

Title of Project: _____

This proposal is submitted as:
____a. Exempt from full review, explain _____

____b. Expedited review, explain _____

____c. Full committee review

Name of Principal Investigator: _____
Department:
Address:
Phone:
Fax:
Email:

Co-Investigator(s): List the full names, titles and departments of all Co-Investigator(s) – Cite ***both your and their experience*** with this kind of research – include your name within the co-investigator(s) group to distinguish your experience among the group as the principal investigator. (If no one but you will be collecting data, state that fact.)

Faculty Sponsor: _____
Department:
Phone:
Email:

IRB Submission: Have you submitted this study to any other IRB? **No____Yes____**

A. What IRB(s)? List name of Institution(s)_____

B. What category of review was the project submitted as?_____

C. Status of review (i.e. approved, not approved, pending). If the project was approved, please attach a copy of the approval letter.

Joint Institutional Research: Describe how permission has been obtained from cooperating institution(s) – i.e., school, hospital, prison, or other relevant organization. *(Attach letters of permission and approval.)*

Does this cooperative research require additional IRB permission from another institution?
_____YES _____NO

Estimated date to begin data collection: (pending IRB approval)_____

Duration of project: (Please remember you may not begin data collection without IRB approval)
Start Date:_____ ***Ending Date:***_____

Drug/Device Usage: (check all that apply)

____Project ***does not use any*** drug/device for research

____Project uses an approved drug for a **new application**
____Project uses an **unapproved drug** – IND#_____
____Project uses an approved device for a **new application**
____Project uses an investigational device – IDE#_____
____Letter of **indemnification** attached (letter should include person/firm and date of filing)
____Letter of indemnification **not applicable**

Sponsorship:

____Project **does not require funding** from an outside source or a commercial sponsor

____Project **requires funding** from an outside source or a commercial sponsor
a. Commercial sponsor clinical contact name_____
b. Commercial sponsor clinical contact telephone number_____
c. Funding source:_____
____Funding obtained
____Funding application pending
____Funding application to be submitted, deadline_____

Please explain the *scientific merit* of the study:

General Outline of Proposed Study:

A. Describe the research design – include objectives, procedures *(include number of times observations, examinations, tests, etc. will be conducted)* and expected results.

B. Describe the involvement of human subjects - you may use a flow chart to illustrate exactly what will happen to the subjects.

1. **Are subjects deliberately deceived in any way? _____Yes _____ No**
   a. ***If YES*, what is the nature of the deception?** *(Explain)*

   b. **Why is it essential to the research?** *(Explain)*

2. **If subject deception occurs, what explanation do you give to subjects following their participation?**

3. **Do subjects risk any harm – physical, psychological, legal social or otherwise by participating in the research? _____Yes _____ No *If Yes, are the risks necessary?*** *(Explain)*

4. **What safeguards do you use to minimize risk to subjects?**

C. Does this project utilize materials of human origin (e.g. blood, tissues)?
_____No ____Yes- *Explain how:*

D. In this section, please summarize the complete proposed project within a *maximum of two*, concise paragraphs *in lay or non-technical terms*:

Description of Your Subject Population:

A1. Target Population/Incidental Population *(check all that apply)*

- Pregnant Women _____
- Children or Minors _____
- Human Fetuses _____
- Human Neonates _____
- Prisoners _____
- Mentally Disabled Persons _____
- Wards of the State _____
- Economically Disadvantaged Persons
- Educationally Disadvantaged Persons
- Detainee (*Held in Penal Institution*)_____

A2. Does your target population include any of the following "Special Class Subject Groups," which may be considered a vulnerable population? *(Check all that apply.)*

- Pediatric/Minor Patients _____
- Juvenile or Minor Prisoners _____
- Women of Childbearing Age _____
- Psychiatric Patients _____
- Mentally Disabled Patients _____
- Institutionalized Persons _____
- Human in vitro fertilization
- Traumatized and Comatose Patients_____
- Terminally Ill Patients_____
- International Research
- Institutionalized Persons _____
- Persons with Diminished Capacity /Cognitively Impaired Persons_____
- HIV/AIDS Patients _____
- *Thomas University Adult Students* _____
- Adult Students (*Other Institutions*)_____
- Minorities _____
- Volunteers _____
- Elderly and aged persons
- Thomas University Students who are Minors _____
- Thomas University Employees
- Other (*I.e., Within NIH Category of Suicidality*)_____

B. Gender of Focus: ____*Both*, Male and Female Genders ____ Males Only ____ Females Only

C. Age Range: _____ to _____ ***(Years of Age)***

D. *Estimated* Total Number of Subjects *(where applicable):* Experimental_____ Controls_____

E. Describe the results of the *(Priori) power analysis* which determined the adequacy of your sample size, *(where applicable in accordance with the nature of the proposed research)*:

F. Criteria for *inclusion* of subjects:

G. Criteria for *exclusion* of subjects:

H. If *you are associated* with the subjects (e.g. students, employees, patients), please explain the nature of the association:

I. How are subjects recruited? What inducement is offered? *(Attach a copy of letter or advertisement or poster, digital advertisement on DVD or CD, if any is used.)*

J. Will someone receive payment for recruiting subjects? ____No ____Yes *If YES,* *Explain:*

K. How are confidentiality and/or anonymity assured? Is identifying information removed from the data? If so, at what stage? *Explain:*

L. Will research data, written or otherwise recorded, be destroyed at the end of this study? ____Yes ____No

1. ***If NO,* where and in what format and for how long will the data be stored?**

2. **To what uses might it be applied in the future** *(i.e., research demonstration, public performance, archiving)?*

3. **How will subjects' permission for further use of their data be obtained?** ***(NOTE:*** *It is usually required to archive data for a minimum of three years.)*

Informed Consent:

____Please attach a copy of informed consent form, which should include HIPAA requirements if the research falls within the bounds of the Standards for Privacy of Individually Identifiable Health Information or Privacy Rule. If HIPAA elements are **not included**, please provide a copy of HIPPA authorization form along with the informed consent.

Complete A-C below.

NOTE: **Compound Authorization under the Privacy Rule:**

A HIPAA authorization is different than a subject's informed consent. A HIPAA authorization, when executed, is the subject's permission for his/her identifiable health information to be used and/or disclosed for a research purpose. An informed consent document, on the other hand, apprises potential research subjects of the possible risks and benefits associated with participating in the clinical investigation and, when executed, indicates their willingness to participate. ***See 45 C.F.R. 164.508(b)(3).***

____Informed consent ***not applicable*** (Expedited or Exempt study)
Do not complete A-C below. S*kip to Number #15*

A. Describe how people are identified as potential study subjects (physician referral, record review etc):

A1. Who will perform the screening of patients to determine eligibility?

A2. When does screening occur in relation to the signing of the consent?

A3. Describe how potential subjects will be approached and by whom:

B. Indicate the approximate length of time that potential subjects will be given to consider participation in this study (length of time between study explanation and signing of the consent form):

C. Please describe subject payment information:

C1. Subjects will *not be* paid_____

C2. Subjects will be paid (describe as follows)

a. Total compensation_____

b. Payments will be dispersed as follows:
b.1. One time payment _____

b.2. Multiple payments (please list the frequency and amount of each payment_____

b.3. Other (describe)_____

b.4. Subjects will be provided with other compensation, such as gifts or services without charge (please describe)_____

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15. Waiver of Informed Consent:

Are you requesting a waiver of informed consent?

NO_____ *If NO skip to #16* **YES_____ If Yes, complete 15A-15F below**

ALL of the following conditions must be TRUE in order for a waiver to be granted. Please discuss and provide rationale for each condition below:

15A. The research involves *no more than minimal risk* to the subjects?
TRUE_____
Please explain:

FALSE_____ *If false, does not meet criteria for waiver*

15B. The waiver will not adversely affect the rights and welfare of the subjects?
TRUE_____ *Please explain:*

FALSE_____ *If false, does not meet criteria for waiver*

15C. The research could not be practicably carried out without the waiver?
TRUE_____ *Please explain:*

FALSE_____ *If false, does not meet criteria for waiver*

15D. Whenever appropriate the subjects will be provided the additional pertinent information after participation.
TRUE_____ *Please explain:*

FALSE_____ *If false, does not meet criteria for waiver*

15E. 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.)*
TRUE_____ *Please explain:*

FALSE_____ *If false, does not meet criteria for waiver*

15F. The research presents no more than minimal risk *and* involves no procedures for which written consent is normally required outside of the research context.
TRUE_____ *Please explain:*

FALSE_____ *If false, does not meet criteria for waiver*

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16. Confidentiality and Privacy Procedures:

16A. Does the project involve **protected health information** as defined by HIPAA?
_____ YES _____ NO *If NO, skip to # 17; otherwise, continue to question B.*

16B. IF YES to A (above) Are you requesting a waiver of authorization to use or disclose protected health information? (i.e., using patient protected health information without obtaining patient consent).
_____ YES _____ NO *If YES, skip to question D.*

16C. IF *NO* to 16.B (above)--*Please attach an authorization form for review**, if** HIPAA requirements are **not addressed in the submitted informed consent**. **Do not complete items 1-11 below. Skip to #18.***

D. IF *YES* TO 16.B (above) Please complete items D1-D11 below:

D1. If requesting a waiver of authorization to disclose personal protected health information, please explain why the waiver is needed?

D2. Will you record any direct identifiers (names, social security numbers, patient, hospital, laboratory numbers, addresses, telephone numbers, email addresses, locator information etc.)?
_____ YES _____ NO

D3. Please explain why it is necessary to record findings using these identifiers.

D4. Will the data be reported in such a manner that the subjects are not identified directly? *(Explain):*

D5. Describe the coding system you will use to protect confidentiality of these subject identifiers.

D6. Describe how subject identifiers will be maintained and destroyed after the study is completed.

D7. Will you retain a link between the study numbers and direct identifiers after the data collection is complete? **_____ YES _____ NO**
If yes, explain why this is necessary and state how long you will keep this link?

D8. Will you provide a link or identifier to anyone outside the research team?
_____ YES _____ NO ***If YES,*** *please explain why and to whom?*

D9. How long, where, and in what form (such as paper, digital or electronic media, etc) will data be kept? In addition, describe what security provisions will be taken to protect the data (password protection, locked file etc).

D10. Indicate the length of time research records will be kept before EITHER all identifiers/codes are removed OR the records are destroyed. Please describe the procedures used for destruction.

D11. If multi-site projects, how will confidentiality be maintained?
***Please note: Signature of this application form by the primary investigators provides written assurance that the identifiable individual patient information will not be reused or disclosed improperly**.

Cross-Cultural Research:

17. Will this research be conducted with subjects who reside in another country or live in a cultural context different from mainstream US society? _____ YES _____ NO

If yes, will there be corresponding complications in your ability to minimize risks to subjects, maintain their confidentiality, and/or assure their right to voluntary informed consent as individuals?
_____ YES _____ NO ***If YES***, explain how you will resolve them.

Restrictions: Research Purposes Only

18. Procedures for RESEARCH PURPOSES ONLY:

18A. List procedures, which are being performed for RESEARCH PURPOSES ONLY

- **NOTE:** These procedures would not normally be done in the absence of this research protocol ***(IF None,*** *Skip to #19):*

18B. Describe rationale for using each noted procedure:

18C. How will the procedures that are for RESEARCH PURPOSES ONLY be paid for?

- Who will be responsible for these costs if the patient's insurance will not cover it?

- Will the subjects incur additional cost as a result of participation in this study? If yes, explain:)

19A.Will the utilization of hospital/medical facility fiscal resources be needed for research purposes?
Such as:
- Manpower
- Medical record retrieval **please note medical records 3 years or older incur a retrieval, delivery and filing cost*
- Nursing time for documentation

____No - *if No, skip to #20*
____Yes - *if Yes, continue to #19B*

19B. If the hospital/medical facility will be reimbursed, please describe the procedures that will be used to reimburse the hospital/medical facility:

20. Describe any ALTERNATE TREATMENTS (as opposed to those for research purposes only) **and their relative advantages and disadvantages:**
NONE_____ *Skip to # 21*
YES _____ *Please describe below:*

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21. RISK VS BENEFITS ANALYSIS:

21A. Describe the anticipated benefits of this research to individual subjects:

21B. Describe the likelihood of the risk of harm (including stress, discomfort, invasion of privacy, potential loss of confidentiality, etc.) from study procedures, drugs, devices etc.

21C. **How do the anticipated benefits of this research outweigh the risks**?

D. Please indicate projected incidence, severity and duration of side effects. (If the study compares an experimental drug to a marketed drug, include information on side effects of marketed drug also. If there is a washout period or a placebo-only period during this study, indicate any potential risks to subjects without medication during this time. Include physical, psychological, social, economic or other risks or discomforts.)

E. Other Potential Risks:

F. Precautionary measures to be taken to eliminate or reduce the risks and/or discomforts:

22. Conflict of Interest:

22A. _____ YES _____ NO Have you or will you or a member of you immediate family receive from the sponsor of the research financial or other forms of compensation?

22B. _____ YES _____ NO Do or will you or a member of your immediate family have a vested interest in the company/agency/firm that is to sponsor the research (answer no if there is no sponsor for the research)

22C. _____ YES _____ NO Are you submitting FDA form 3454 or 3455 (Conflict of Interest)? **If yes**, please attach a copy.
If yes to either 22.A. or 22.B. Complete 1 and 2 below:

1. Describe the relationship between you or a member or your immediate family and the sponsor of the research.

2. Include a statement in the consent form addressing potential conflicts of interest or state below why you believe such a statement is not necessary for the protection of human subjects.

23. Additional Attachments *(Checklist)***:**

____Copy of Human Subjects Education Training Certificate; *or* the **Collaborative IRB Training Initiative (CITI) Training Certificate;** or the current form of documented proof issued *by the training authorities* regarding the completion of the respective training. **(The application will *not* be reviewed without this documentation.)**

____Copy of principal investigator(s)' curriculum vitae attached *(See the following CV Waiver Statement)*
____*CV Attached Waiver Principal Investigator:* A copy of CV as an attachment can be waived if the principal investigator has previously submitted a copy of their CV within the last two years and that CV resides on file with the IRB, or the investigator is a student who is under the guidance of a faculty sponsor.

____Copy of all other investigator(s)' curriculum vitae attached *(See the following CV Waiver Statement)*
____*CV Attached Waiver All Other Investigators:* A copy of CV as an attachment can be waived if all other additional investigators have previously submitted a copy of their CV within the last two years and that CV(s) reside on file with the IRB, or the investigators are students who are under the guidance of a faculty sponsor.

____Copy of Data Collection Form attached
____Copy of Survey

Assurance of Principal Investigator:

I will promptly report **proposed changes in the activity** or **unanticipated problems** involving risk to subjects or others including adverse reactions to biologicals, drugs, radioisotope labeled drugs, or to medical devices to the IRB and, in case of Department of Health, Education and Welfare supported activities*(where applicable*), to the Department of Health, Education and Welfare.

As the Principal Investigator on this project, I certify by my signature below that the information provided in this application is accurate and fully describes any and all procedures regarding human subjects under, which I will conduct this research.

I, the undersigned, agree to accept responsibility for my co-investigator(s) and other personnel involved on this project, in regards to their compliance with the above stated policies.

I will retain the documentary evidence of informed consent, documentation of the experiment, experimental data, reports and all procedures performed for ***at least three years after*** the proposed activity has been completed or discontinued.

The IRB is obligated to continually review this activity. Therefore, I agree to furnish progress reports to the committee when requested.

I, the undersigned, understand and agree that ***upon approval of this application***, should complaint of a *violation of any procedures* as proposed within this document occur, as deemed through investigation by the Thomas University IRB or bodies employed by Thomas University, this application *will be reversed and denied continuation of approval, and the termination of the research under this proposal will be so ordered and enforced to the fullest extent of the law.*

Please note: Signature of this application form by the primary investigator provides written assurance that the identifiable individual patient information will not be reused or disclosed improperly. A signature further attests that they have read and understand all abovementioned statements concerning Thomas University policy for research or similar activities involving humans as subjects; federal, state and county regulations and laws where applicable; and certify that they will uphold all regulations and policies as required and prescribed by law, along with the principles set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research's report, The Ethical Principles and Guidelines for the Protection of Human Subjects of Research (commonly known as the "Belmont Report") and Title 45 – Public Welfare Section 46, "Protection of Human Subjects" of the U.S. Code of the Department of Health and Human Services.

_____ _____

Principal Investigator's Signature (SEAL) ***Date***

For faculty supervisor approval:

I believe that the research can be safely completed without endangering human subjects and within the bounds of the principles set forth by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 's report, The Ethical Principles and Guidelines for the Protection of Human Subjects of Research (commonly known as the "Belmont Report") and Title 45 – Public Welfare Section 46, "Protection of Human Subjects" of the U.S. Code of the Department of Health and Human Services. Furthermore, I have read the enclosed proposal, and I am willing to supervise the investigator(s).

_____ _____

Faculty Sponsor's Signature (SEAL) ***Date***

RESPONSE TO APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

All responses to research will be provided to the ***principal investigator*** in writing from the Thomas University Institutional Review Board. According to the complexity of the research, a response from the board (full review of application) may take up to, ***but not exceed,*** three weeks. Should further, appropriate review by officials of the institution be deemed necessary, it could delay a response from the Institutional Review Board for an additional two week period beyond the initial three week period. In addition, the request for an expedited review by the principal researcher ***does not exclude*** the possibility of a determination of a ***full committee review***. This is held at the discretion of the Institutional Review Board and its Chairperson. When at all possible and should the research request exhibit those criteria that merit an expedited review that option ***will be exercised*** by the Institutional Review Board.

For questions, please contact the Thomas University IRB at irb@thomasu.edu.