IRB Limited Protocol Form for Extramural Grant Development

Texas A&M University-Commerce Institutional Review Board (IRB)

[Texas A&M University-Commerce IRB Website](http://www.tamuc.edu/research/humanSubjectsIRB.aspx)

Where human subjects, human data, or human specimens will be used in research, **awards will not be made and accounts will not be established prior to IRB review and approval.** This procedure is necessary to comply with 45 CFR 46.103, which states, “Under no condition shall research using human subjects be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB.”

One exception to this mandate exists in the federal regulations (45 CFR 46.118). Where definite plans for involvement of human subjects are not available at the time of funding, *developmental approval* may be sought. Whether a project receives developmental approvalis at the discretion of the IRB.

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| Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency. |

The Principal Investigator (PI) may submit this application by e-mail to Mona Gilley ([ResearchCompliance@tamuc.edu](mailto:ResearchCompliance@tamuc.edu)) to qualify the application as a signed electronic submission. Alternatively, the application may be delivered in paper form with an original signature to the Office of Sponsored Programs, P. O. Box 3011, Commerce, TX 75429-3011. Any questions regarding this policy should be directed to the ORSP at 903-886-5143 or by e-mail Mona Gilley ([ResearcCompliance@tamuc.edu](mailto:ResearcCompliance@tamuc.edu)).

Developmental Approval Form

Texas A&M University-Commerce Institutional Review Board (IRB)

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| For office use only Protocol Number: | | |
| Date: | ► | Developmental Approval Expiration date: |
|  | ► |  |
| Comments: | | |

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| --- | --- |
| ►Research Title (This title should match the title of your grant application. You may use a subtitle to denote a specific research protocol.) |  |
| ►Submitted as: |  |
| ►Proposed Start date of research | Anticipated start date for funding:  Anticipated end date for funding:  Anticipated start date for research activities involving human subjects:  Anticipated end date for research activities involving human subjects: |
| ►Source of funding |  |

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| --- | --- | --- |
| ►Principal Investigator | Name: | Phone: |
|  | Department: | E-mail: |
|  | Campus Address: |  |
|  | Signature: Date: | Fax: |

**To be completed by the applicant**

Name of Applicant:

E-mail address:

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of this research protocol. I have carefully read all the instructions and information included with the Submission and Protocol Forms.

Signature of applicant:

Date:

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| ►Co-Investigator | Name: | Phone: |
|  | Campus Address: | E-mail: |
|  | Fax: |

|  |  |  |
| --- | --- | --- |
| ►Co-Investigator | Name: | Phone: |
|  | Campus Address: | E-mail: |
|  | Fax: |

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| 1. | Describe the purpose and potential benefit of the research study. Describe how it involves human subjects.  **Description:** |
| 2. | Answer if data collection is planned:  *Describe the means you will use to obtain the data. Describe all procedures in which participants will participate.*  **Description:** |
| 3. | Answer if existing data use is planned:  a. *What are the types of data or specimens?*    b. *What is the source of the data or specimens?* |
| 4. | Provide a timeline regarding when human subjects components will be planned, developed and implemented. |