## FOR OFFICE USE ONLY: IRB Protocol # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Application Received: \_\_\_\_\_\_\_\_\_\_\_\_\_

## Routed: \_\_\_\_\_\_\_\_\_ Training Complete: ­­­\_­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Non-Research Class Project - Request for Clearance Form**

This form is designed to document **class projects** that **do not** constitute research involving human subjects. The IRB is required by federal law (45 CFR 46) to review activities that involve human subjects in research. The regulations define research as: “*A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purpose of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes”.* The key phrase is “to develop or contribute to generalizable knowledge.”

If your class project does not constitute research in accordance with the federal definition above, you may use this simplified form - **appropriate for non-research class projects only** - to document your activity. To qualify as non-research under the federal definition, the data collected **cannot be “generalized”** (publications, presentations or disseminated outside the classroom in any fashion, including seminars, conferences, weblogs, social networks, etc). If you need clarification or have questions about how to complete this application, please call the Research Compliance Office at 532-3224, or e-mail us at [comply@ksu.edu](mailto:comply@ksu.edu).

**Class Project Request:**

Yes No

I have reviewed and understand the federal definition for research involving human subjects

provided in the above paragraph: (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>)

Yes No

I conclude that the class project described does not constitute research under the federal

definition.

Yes No

I agree that the information or data gathered in this activity will not be “generalized or

disseminated” in any way outside of the classroom.

Yes No

I understand that if activities in my class do constitute research under the federal definition

above, the Application for Approval Form must be submitted to the IRB and approved prior to initiation of the activity involving research with human subjects.

The items listed below are categories/topics that may be considered high risk. If selected as project topics you should proceed with caution. If these topics are involved, a full application to the IRB should be considered. Problematic activities might include but are not limited to:

* more than minimal risk encountered by subjects on a daily basis
* persons under 18 years of age (these subjects require parental or guardian consent)
* use of video taping or auto recording
* persons who are physically or mentally disabled
* subjects in institutions (e.g., prisons, nursing homes, halfway houses)
* pregnant females as target population
* persons 65 years and older as a target population
* ethnic or racial populations as a target population
* victims
* questions about any kind of illegal or illicit activity
* sexually explicit materials or questions about sexual orientation, sexual experience or sexual abuse
* any procedure that might be viewed as invasion of privacy
* deception of subjects
* any form of potential abuse; i.e., psychological, physical, sexual
* administration of substances (food, drugs, etc.) to subjects
* handling of money or other valuable commodities
* extraction or use of blood, other bodily fluids, or tissues

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| --- | --- | --- | --- |
| **Instructor:** (must be a KSU faculty member) | | | |
| **Name:** |  | **Degree/Title:** |  |
| **Department:** |  | **Campus Phone:** |  |
| **Campus Address:** |  | **Fax #:** |  |
| **E-mail Address:** |  | **Class Reference Number:** |  |
| **Class Number:** |  | | |
| **Class Title:** |  | | |

|  |  |
| --- | --- |
| **Class Roster and email addresses:** (may be entered here or attached as a separate document to this form) | |
| **Students Names and email addresses:** |  |

**PROJECT DESCRIPTION** (please provide a concise narrative, 100 words or less, description of the proposed activity in terms that will allow the URCO or other interested parties to clearly understand what

it is that you propose to do that might involve project participants):

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**PROCEDURE** (briefly state how the data for this project is to be collected)**:**

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Assurances:

* I assure that this project will not result in data that will be “generalized” in accordance with the federal definition of research in 45 CFR 46.
* I assure the protection of participants involved in the class project in accordance with 45 CFR 46 and Kansas State University Policy.
* The URCO strongly recommends all personnel involved complete the online training (<http://www.k-state.edu/comply/irb/training/>). I assure that students will complete training as deemed necessary.
* I assure that the information herein provided to the URCO is to the best of my knowledge complete and accurate. I also assure that no modifications or changes will be made to the activity that would change the project’s Non-Research status, without notification to the URCO.
* I assure that I will promptly report to the URCO any unanticipated problems involving participants in the activity as described.

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Instructors Signature Date

**\*\*Upon receipt, you will receive an email confirmation and be issued a tracking number. Following URCO review, a clearance letter will be sent via campus mail. Remember that the project should not begin until you have received the clearance letter.**

**\*\*If you have questions, please call the University Research Compliance Office (URCO) at 532-3224, or email us at comply@ksu.edu**