R·I·T

Rochester Institute of Technology

INSTITUTIONAL REVIEW BOARD

585-475-2167 ~ www.research.rit.edu/hsro ~ hsro@rit.edu

FORM A: Request for IRB Review of Research Involving Human Subjects

- **To be completed by the investigator** after reading the RIT Policy for the Protection of Human Subjects in Research, found in the *Institute Policies and Procedures Manual*, Section C5.0, and on the Office of Human Subjects Research website, http://www.rit.edu/research/hsro/process_geninfo.php.
- Submit an **electronic version** of the completed form and ALL attachments (consents, instruments, tasks, etc.) **along with a signed hard copy** to **Dawn Severson**, Engineering Hall, Room #2115 hsro@rit.edu

Project Title: An Insider Threat Activity in an Engineering of Secure Software Engineering Course		
Investigator's Name: Daniel E. Krutz, PhD	Investigator's Phone: 585 475 2896	Investigator's Email: dxkvse@rit.edu
Investigator's College and Department: Golisano, Software Engineering		
Project Start Date: 12/15/2014	Date of IRB Request: 10/1/2014	
If Student, Name of Faculty Supervisor:	Faculty's Phone:	Faculty's Email:
If Not Employed or a Student at RIT, List Name, College & Dept. of RIT Collaborator:	RIT Collaborator's Phone:	RIT Collaborator's Email:
Will this project be funded externally? ☐ Yes ☒ No	Is the Investigator a student? ☐ Yes ☒ No	
If yes, name of funding agency:		
Status of project: ☐ Submitted on	☐ Funding pending	☐ Funding confirmed
Do you have a personal financial relationship with the sponsor? ☐ Yes ☐ No If yes, please read RIT policy C4.0 – Conflict of Interest Policy Pertaining to Externally Funded Projects. Complete the **Investigator's Financial Disclosure Form** and attach it to this Form A. *All information will be kept confidential.*		

BY MY SIGNATURE BELOW, I ATTEST TO AN UNDERSTANDING OF AND AGREE TO FOLLOW ALL APPLICABLE RIT, SPONSOR, NEW YORK STATE, AND FEDERAL POLICIES AND LAWS RELATED TO CONDUCTING RESEARCH WITH HUMAN SUBJECTS. If significant changes in investigative procedures are needed during the course of this project, I agree to seek approval from the IRB prior to their implementation. I further agree to immediately report to the IRB any adverse incidents with respect to human subjects that occur in connection with this project.

Signature of Investigator — Date: 10/1/14

Signature of Faculty Advisor (for Student) or RIT Collaborator (for External Investigator) — Date

James R Vallino — Date: 10/1/14

Signature of Department Chair or Supervisor

Complete the attached Research Protocol Outline and attach to this cover form with other required attachments.

Attachments required for all projects:

- ☒ Project Abstract
- ☒ Investigator Responsibilities and Informed Consent Training Certificate(s) from OHRP (see http://ohrp-ed.od.nih.gov/)

Attachments required where applicable:

- ☐ Informed Consent Materials
- ☐ Questionnaire or survey
- ☐ Relevant Grant Application(s)
- ☐ Letter of Support from School Principal
- ☐ Cover letter to subjects and/or parents or guardians
- ☐ External site IRB approval
- ☐ Other

6) **Describe the data collection process.**

a) **Will the data collected from human subjects be anonymous?** ☒ Yes ☐ No

b) **Will the data collected from human subjects be kept confidential?** ☒ Yes ☐ No

c) **Describe your procedures for ensuring anonymity and/or confidentiality:**
Clipboard survey will not ask for, or record who filled out the survey response.

d) **How much time is required of each subject?** Approximately 5 minutes.

e) **If subjects are students, will their participation involve class time?** No

f) **What methods, instruments, techniques, and/or other sources of material will you use to gather data from human subjects?**
RIT's clipboard system

7) **Will this research be conducted at another university or site other than RIT?** ☐ Yes ☒ No
If yes, describe location:

Note: If you will be conducting human subjects research at another university or college, you will also need to obtain IRB approval from that institution. **Attach a copy of that approval to this application.**

8) **Describe potential risks (beyond minimal risk) to subjects:**

a) **Are the risks physical, psychological, social, legal or other?**
No

b) **Assess their likelihood and seriousness to subjects:**
n/a

c) **Discuss the potential benefits of the research to the population from which your subjects are drawn:**
Some self-reflection and the discoveries from this paper will be made to assist for future research.

d) **Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others, or in relation to the importance of the knowledge to be gained as a result of the proposed research:**
n/a

e) **Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness:**
An anonymous clipboard survey will be used to gather results. The results will not be made available to the instructors of the course until after grades have been submitted.

f) **Where appropriate, describe plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects:**
n/a

9) **Will you be seeking informed consent?** ☐ Yes ☒ No
If yes, describe:

a) **What information will be provided to prospective subjects?**
n/a

b) **What (if any) information will be concealed prior to participation, and why?**
n/a

c) **How will you ensure consent is obtained without real or implied coercion?**
n/a

d) **How will you obtain and document consent?**
n/a

RIT IRB Risk Type Classification

Exempt

Research activities in which the only involvement of human subjects will be in one or more of the following six categories of **exemptions** are not covered by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. ***If the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*** [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

No Greater than Minimal Risk – The probability and magnitude of harm or discomfort anticipated in the research *is no greater than* those ordinarily encountered in daily life or in the performance of routine physical and psychological examinations or tests.

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Population Sample

- Describe the proposed involvement of human subjects in your project.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects.

Research Activity - The ED Regulations for the Projection of Human Subjects, Title 34, Code of Federal Regulations, Part 97, define research as "a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge." *If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study of the collection of data to test a hypothesis, it is research.* Activities which meet this definition constitute research whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Risks in Research – As with any activity, there is potential for harm in the social and behavioral sciences – from inconvenience or embarrassment to stigma or legal or economic consequences. Typically, however, in these sciences both the potential harms and the risks of them are minimal and not of the type routinely being assessed in biomedical research. Much of the risk relates to disclosure of the identity of human subjects or the information they provide; thus, considerable effort in these sciences is devoted to safeguarding subjects' privacy and the confidentiality of the data they provide even when the information has no or minimal potential for harm.

Minimal risk means that the probability and magnitude of *harm* or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. "Risk" refers to a probability that some harm will occur. "Harm" refers to a specific outcome(s) or event(s) – and can be inconvenience, physical, psychological, social, economic, or legal in nature. If human subjects are exposed to a degree of harm roughly equivalent to what one would expect in the course of daily life or in the course of routine tests and examinations, then "minimal risk" applies.

Sources of Materials

- Identify the sources of research material to be obtained from individually identifiable living human subjects in the form of specimens, records, or data.
- Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Project Abstract

Title: "An Insider Threat Activity in an Engineering of Secure Software Engineering Course"

We will be conducting an in class activity where students are asked to work in small teams designing a secure software system. Students will be unknowingly placed into project teams who will act as "moles", posing an insider threat to the software team. At the conclusion of the modeling activity, the moles will be exposed and a discussion will ensue regarding:

- What malicious activities the moles were able to achieve.
- How the teams did designing a system that was protected against these insider threats.
- What teams could do in the future to protect against these insider threats.

This certifies that Dan Krutz has completed the Human Subject Assurance online training, Module 1.

Sunday, August 04, 2013

(Use your browser's "Print" button to print this certificate.)

This certifies that Dan Krutz has completed the Human Subject Assurance online training, Module 2.

Sunday, August 04, 2013

(Use your browser's "Print" button to print this certificate.)

This certifies that Dan Krutz has completed the Human Subject Assurance online training, Module 3.

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