UNIVERSITY OF WASHINGTON

Human Subjects Division
Box 359470

HUMAN SUBJECTS REVIEW COMMITTEE APPLICATION

BOX FOR COMMITTEE USE ONLY
MASTER ☐ COMM. ☐ INVESTIGATOR ☒
APPLICATION NO. 43181 EB
RECEIVED Human Subjects Division JUN 11 2012 UW

Send three one-sided copies of this form (including one copy with original inked signatures) and three one-sided copies of all relevant materials (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statement, advertisements, etc.) to the Human Subjects Division, Box 359470. Do not leave blanks. Attach one one-sided copy of each research proposal, grant or contract, and/or one one-sided copy of the protocol and investigator's brochure for clinical trials. Students should attach one one-sided copy of thesis or dissertation proposals. For information and assistance, visit our web site at http://www.washington.edu/research/hsd/index.php or call (206) 543-0098. We will not accept handwritten forms, incomplete forms, or forms printed on both sides of the paper. Use 10 point type or larger throughout application. The contents of this application and attachments will be kept confidential within the limits of the law.

☒ **Check this box if your project falls into one or more of the minimal risk ("expedited") categories of research (see web site for listing of categories) and send us only two copies of all your materials.**

I. PRINCIPAL INVESTIGATOR (Provide all the information requested. Correspondence will be directed to this person. You may designate a contact person other than yourself in section II., below.)

Name Zoran Popović Title Professor Position Faculty
Department Computer Science & Engineering Division
Mail box or address Box 352350
Telephone 206-543-4226 Fax 206-543-2969 e-mail zoran@cs.washington.edu

II. CONTACT PERSON (Provide all the information requested. This person does NOT have signatory authority with regard to this application.)

Name Beatrice Marx Title Program Manager Position Staff
Mail box or address Box 352350
Telephone 206-616-2660 Fax 206-543-2969 e-mail beamarx@cs.washington.edu

III. TITLE OF PROJECT:

A Game Based Expert Development for Code Verification Tasks Using Large-Scale Data Mining

IV. SIGNATURES: The undersigned acknowledge that: 1. this application is an accurate and complete description of the proposed research; 2. the research will be conducted in compliance with the recommendations of and only after approval has been received from the Human Subjects Review Committee (HSRC). The lead research is responsible for all aspects of this research, including: reporting any serious adverse events or problems to the HSRC, requesting prior HSRC approval for modifications, and requesting continuing review and approval.

A. Investigator: Zoran Popović 6/1/2012
TYPED NAME PLUS SIGNATURE DATE

B. Faculty sponsor (for student):
TYPED NAME PLUS SIGNATURE DATE

C. The Chair, Dean, or Director acknowledges the researcher is qualified to do the research, sufficient resources will be available, and (if no external funding review occurred) there was an internal review of scientific merit.

Ed Lazowska 6/4/12
TYPED NAME PLUS SIGNATURE DATE

6/25/12 APPROVE ☒ DISAPPROVE ☐
HUMAN SUBJECTS REVIEW COMMITTEE SIGNATURE DATE

Subject to the following conditions: Expedited, Category 7
Current application + approval covers the game PipeJam only

Period of approval is one year, from 6/25/12 through 6/14/13

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

V. CO-INVESTIGATORS (Provide all the information requested for each co-investigator. Add sheets if necessary.)

Name Michael D. Ernst Title Associate Professor Position Faculty
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Mail box or address Box 352350
Telephone 206-221-0965 Fax 206-543-2969 e-mail mernst@cs.washington.edu

Name Werner Dietl Title Research Associate Position Faculty
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Name Seth Cooper Title Creative Director Position Professional Staff
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VI. SECTION 1 - LIST EACH PROPOSED AND FUNDED GRANT OR CONTRACT RELEVANT TO THIS APPLICATION, AND ATTACH A COMPLETE COPY OF EACH GRANT OR CONTRACT. THIS SHOULD INCLUDE GRANTS THAT SUPPORT FACULTY TIME FOR DATA ANALYSIS AND MANUSCRIPT PREPARATION, (I.E. SALARY SUPPORT). **IF NONE, CHECK HERE ☐. FOR CENTER OR PROGRAM PROJECT GRANTS LIST P.I. AND TITLE FOR EACH SEPARATE PROJECT OR CORE. ADD SHEETS IF NECESSARY.**

A. Type of proposal: ☒ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other, specify

B. Name of principal investigator: Zoran Popović

C. Name of funding agency: DARPA

D. Agency's number (if assigned):

E. Title of proposal: Verification Games: Crowd-sourced Formal Verification

F. Inclusive dates: from 4/1/2012 through 3/31/2015

G. Status: ☒ New ☐ Competing renewal ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

VI. SECTION 2 - TRAINING VERIFICATION & REPORT

A. Certification of training in the protection of human research subjects should be attached to this application if:

1. Funding was indicated in VI. Section 1 from any of the following sources:
   a. the National Institutes of Health (NIH);
   b. the Department of Defense (DoD) or a DoD component (e.g. Department of the Navy (DoN), Air Force, etc.); *[NOTE – Complete the Supplement: Department of Defense Involvement.]*
   c. a sponsor for which completion of training in the protection of human research subjects is a requirement to receive funding.

OR

2. The study is being conducted in collaboration with a non-UW institution/organization, including DoD involvement, that requires the completion of training in the protection of human research subjects (e.g., FHCRC, VA, DoD, etc.).

The Certification of Training is available on the HSD website (http://www.washington.edu/research/hsd/verify/). The Principal Investigator/Lead Researcher and all who are considered to be "senior/key personnel" by NIH, or who are required to complete training under DoD or another sponsor's requirements, should be listed on the same Certification. Search first by the PI's last name and select by clicking on the correct record. List subsequent individuals in the same order they are listed on the grant application. Click on "View Report" to generate a PDF of the Certificate of Training; print the report; and include it with the IRB application.

B. If the sponsor or collaborating institution/organization requires "refresher/renewal" training in the protection of human research subjects, attach documentation of the frequency that this training is required.

VII. SUMMARY OF ACTIVITY. Answer in spaces provided (add numbered, referenced, single-sided sheets when necessary). Do not refer to an accompanying grant or contract proposal.

A. BACKGROUND AND PURPOSE OF RESEARCH. Provide relevant background information and explain **in lay language** why this research is important and what question(s) or hypotheses this activity is designed to answer.

This research involves collecting data on player pathways through UW Center for Game Science created web-based online game and using the analysis of that data to inform the iterative design of this game so that they provide players with optimal performance improving pathways. Additionally, we are interested in the social dynamics of players as they collectively work on game solutions. The research questions involved are:

- RQ1: Where in the game are players progressing and not progressing?
- RQ2: How long do players stay in particular game states or levels and can we redesign those states to make them more or less challenging so that we retain as many players as possible towards a goal of game completion?
- RQ3: What is the improvement rate of players on the ability to solve hard software verification problems through the game interface? How much can their problem solving skills be improved over time?
- RQ4: How do external social interactions through a web forum affect player retention rates?

The game is developed for the purpose of solving a hard problem: software verification. By playing an extended period of time players who knew nothing about the game or these types of problems gradually improve their performance. The key question of this work is whether individually or collectively game players can reach the level of expertise where they are capable to efficiently solve problems that cannot be solved by any other means. The game that maps software verification into a game is already developed (PipeJam), and we expect it to evolve in order to optimize human skill improvement (see Figure 1). To be visible by the widest possible audience, the game will be distributed on free public gaming portal sites such as Kongregate.com, and work-unit sites like Mechanical Turk through which the player can earn money by completing work units. The actual variation of PipeJam in our experiments is currently unknown as the iterative process of log analysis leads to new variations of the game, often automatically produced by the game itself. It is instrumental to our project that we present players with variation of the game, because we are optimizing for best performing game towards greatest player retention and greatest productivity. Some examples of conditions we will be varying within each game include different game levels, varying cognitive difficulty, a game with and without audio, a game with and without animations, a game with multiple players jointly solving problems vs individual play, etc. **The overall research agenda we are targeting with this research is how much certain aspects of the game or social layer around the game affect general player engagement and retention and ultimately player learning.** PipeJam will be released in the similar distribution platforms (online gaming portal on a web page) and collect similar data logs. This is in many ways similar to looking at the web access logs from a particular web page, it's just that our web page actually has interactive game content, and thus logs are slightly more detailed to include full interaction with the game.

For crowdsourcing sites like Mechanical Turk, or Flash Game License we will be paying users money to play our games on their websites. On these sites, users complete tasks posted by other people (in a bulletin board or web forum format; see Recruitment section below) in exchange for small amounts of money. Common tasks on these sites include solving CAPTCHAs, filling out surveys, playing games, annotating images, or filtering websites—in short, things that a computer might have difficulty doing whereas a human can do easily.

Besides asking users to play portions or prototypes of our games, we will ask them to fill out basic survey questions or basic, non-identifying demographic information. Survey questions depend on what specific part of the game we ask people to do, but would generally be designed to measure engagement, affect, and usability: for example, "Please rate how much fun you had on a scale of 1-7," or "If you could change one thing about this user interface to make it clearer, what would it be?" Demographic questions would be simple things, such as age, sex, education level, occupation, and videogame playing background.

These users are assigned meaningless user ids by the websites that then get passed to us. We will not have access to any personal information besides non-identifiable basic demographic questions we collect through surveys. We will only use sites, like Mechanical Turk, that require users to be 18 or over. Due to our inability to identify participants and the age requirement, we are asking for waiver of consent.
There are two reasons for use of crowdsourcing sites: one, we often want to control the number of users who see a particular new or experimental version of our games; releasing these to an online game portal available to all means we

lose control over the number of users who see them. Two, by paying users a certain amount for their participation, we can ask users to play for a particular length of time or complete a certain task and also request them to provide us with detailed feedback by administering a simple survey. This is generally not possible on free flash game websites, where there is no incentive for users to do anything besides what they already want to do.

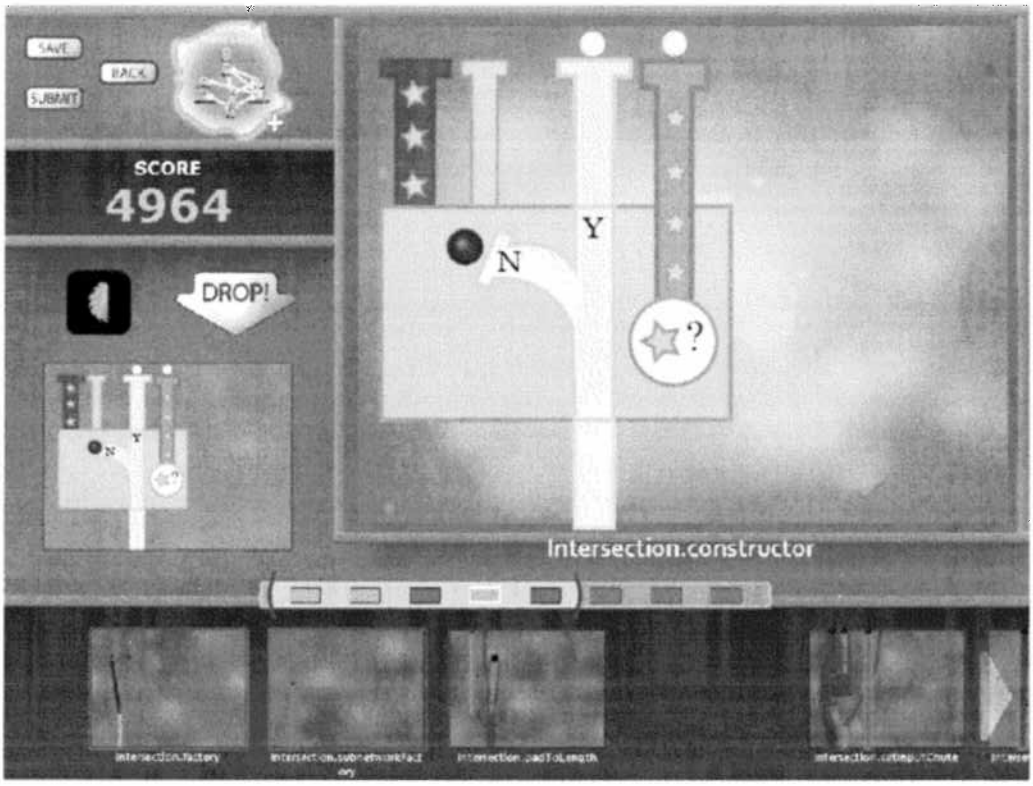


Figure 1. Example of the PipeJam game screen. The software verification problem is mapped into a visual problem where balls are traversing the network of pipes.

B. RESEARCH PROCEDURES INVOLVED.

1. Provide a complete description of: a. the study design, and b. sequence and timing of all study procedures that will be performed, e.g., volume of blood, size of biopsy, drug administration, questionnaire, name of psychological test. Provide this information for each phase of the study (pilot, screening, intervention and follow-up). **Use lay language.** Attach study flow sheet, if available.

   To answer our research questions, we will collect:

   - Logs of player clicks and movements or traces through the game (see Figure 2). The game being designed keep a record of the pathways players take while playing. We can use this to look at moments of player frustration or triumph and help us refine future iterations of the game to maximize player retention and player learning.

   - unique usernames that players create for themselves and use to sign in the game. These usernames will be used to track whether and how often players return to previously played game and may be used to provide specific types of players with individualized versions of the game. As part of the account creation process, we will be asking for email addresses. After account creation, we will never use the email addresses, and they will not be associated with user data. Additionally, only usernames are visible to researchers. Any contact made to our participants will be done through emails sent by our computer software that makes the individual addresses invisible to researchers. The usernames are only used for our game and their related forums. We will not collect player data with game that UW does not design.

- any public online forum discussions players engage in, using the same usernames as the ones they registered with to play the game. We are interested in whether engaging with other players outside of the game leads to higher engagement with the game. Players will only be interacting with other players.

We will never collect real names of players nor ask them to do anything they wouldn't normally do as online game players.

The game will keep a log of player behavior including which decisions were made in the game and how long players stay at certain game states before making a decision. Other data will include player discussions in public online forums. These will be linked to usernames but (1) it is public data and (2) players will have consented to our collection of their forum data prior to creating a username.

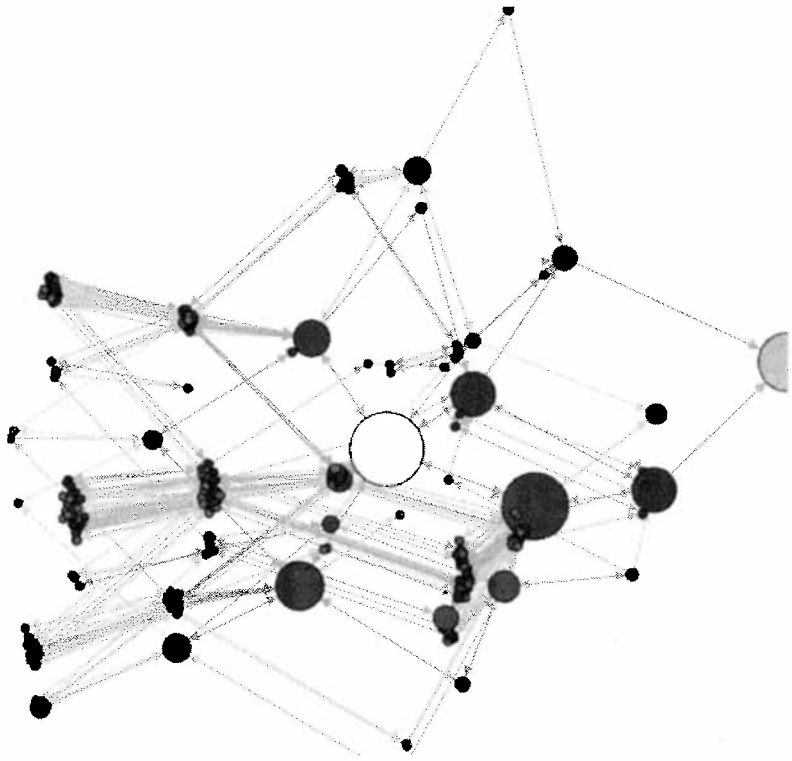


Figure 2. An example of our data visualization of player pathways (AKA play trace). Each node represents a decision point or game screen with the size of the circle showing how often players visit that game condition. Each arrow represents the choices players make.

2. Would subjects undergo these or similar procedures (medical, psychological, educational, etc.) if they were not taking part in this research? ☐ No ☒ Yes If "Yes," describe how the study procedures differ from what subjects would otherwise undergo.

Our game is just like those that participants might play on public websites, and our data collection is invisible to the participant.

3. Check all of the boxes below that apply to your research:

Drug administration

☐ Administration of a drug (either FDA-approved or investigational) for research purposes to a subject-patient during general or regional anesthesia.

☐ Administration of a drug (either FDA-approved or investigational) for research purposes to a subject-patient during the 1.5 hours preceding general or regional anesthesia.

Blood lines

☐ Inserting an intravenous (central or peripheral) or intra-arterial line for research purposes in a subject-patient **during** general or regional anesthesia.

Sample collection

☐ Obtaining samples of blood, urine, or cerebrospinal fluid for research purposes while a subject-patient is under general or regional anesthesia.

☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery, while the subject-patient is under general or regional anesthesia.

Radio-isotopes

☐ Administration of a radio-isotope for research purposes during the 3 hours prior to anesthesia or while a subject-patient is under general or regional anesthesia.

If you checked this box, you are responsible for informing **in advance** all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.

Experimental devices

☐ Implantation of an experimental device while a subject-patient is under general or regional anesthesia.

Other experimental manipulations or procedures

☐ Other manipulations or procedures performed solely for research purposes while a subject-patient is under general or regional anesthesia (e.g., experimental liver dialysis, experimental brain stimulation)

None of the above

☒ None of the above apply to my research

4. If you checked any box in question #3 except "none of the above", answer the following questions:

a. Provide the name and institutional affiliation of the physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

b. If you have not yet consulted with an appropriately qualified person about this issue, describe in detail your plans to do so. The IRB will not approve your application without this consultation. If UW Department of Anesthesiology approval has been obtained, please provide the Department's letter of support.

C. DECEPTION: If any deception or withholding of complete information is required for this activity, explain why this is necessary and attach a protocol explaining if, how, when, and by whom subjects will be debriefed.

The research does not involve deception.

D. SUBJECTS

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. If your research is approved for a specific number of subjects, the data from any "extra" subjects cannot be described as having been obtained with IRB approval.

See the HSD website for the definition of "human subject" http://www.washington.edu/research/hsd/docs/1253. Before answering the questions below, be sure that you are familiar with the definition.

1. **Subject groups/categories and numbers.** Complete this table by listing:

- Your groups or categories of subjects. "Group" should be defined as appropriate for your research.
  - "Units" within a group. For most research, a group will consist of individuals, such as children aged 8-12, or individuals with high blood pressure. However, this will not be true for all research. Examples of groups with "units" that are not individuals:
    - Dyads such as Alzheimer's-patient-and-caregiver, with one group of the dyads assigned to one intervention (e.g., behavioral modification) and another group of the dyads assigned to a comparison intervention(e.g., drug treatment).
    - Families. For example, a study of mental health interventions for homeless families might have one group of 30 families assigned to one intervention and another group of 30 families assigned to a different intervention.
    - Other. For example, the "units" in autism research might be an autistic individual and all his/her living blood relatives. The units in an academic excellence study might be a student-parents-teacher unit.
  - Types of groups. There are many ways in which subjects might be grouped. Examples:
    - By intervention. Example: research comparing two different drugs for high blood pressure.
    - By subject population. Example: research comparing the incidence of domestic violence in families living in urban settings versus families living in rural settings.
    - If you have only one group, fill in only one line in the table. Add more lines if needed.
- The age range of each group.
- The upper limit/number of **completed** subjects you need for each group. ***Completed*** *means that all research procedures involving the subjects or the obtaining of specimens/records/data have been completed as far as is possible for each subject, including any follow-up (such as follow-up access to medical records.) In some cases, such as an online survey, it is not possible to predict the number of subjects who will complete the research. If you cannot predict or describe the maximum number of subjects you need in each group, check the appropriate box and provide your rationale in the space provided below the table.*

Group name/description	**Age range of subjects**	**Maximum desired number of individuals (or other group unit, such as families) who will complete the research.***	**Cannot provide a number.****
Crowdsourcing population (Mechanical Turk members)	18 and up	Max 100,000	☒**
Web-based free game play	13 and up	Max 2,000,000	☐**
			☐**
			☐**

We have no control of the number of people accessing the web-based game. The same is the case for Mechanical Turk sites. The numbers are simply maximum estimates.

***This is the number of subjects (individuals, dyads, families, etc., as appropriate) in each group that will be considered for approval by the IRB.**

****If you cannot predict or describe the maximum number of subjects you need in each group:**

Provide your rationale and description of research scope here. *Include any information or estimates you might have about the number of subjects, so that the IRB has a sense of the scope of your research. For example, your research might be a small pilot study of all patients presenting with a rare disease at UW Medicine in the next year. Or, it might involve a survey posted on Craig's List for two weeks that could result in thousands of responses.*

NOTE: In your annual Status Report, you will be asked to complete the table below with your subject numbers. While developing your research protocol, please plan ahead so that you will have an accurate record of the subject numbers above.

This is for illustration only. Do not complete this table.

Group Name / Description	# Completions				# Ongoing (subjects still involved)	# Withdrawals, drops, lost		
	Total approved by IRB	A At time of last Status Report	B Since last Status Report	A + B Total to date		C At time of last Status Report	D Since last Status Report	C + D Total to date

2. Explain how you will achieve equitable subject representation in the following categories. If not applicable, justify exclusions.

   a. Age (minors, elderly): On public web sites, the players ages will be completely unknown. To register for an account on Kongregate.com, and other web portals, players must have confirmed that they were 13 years old or older. Minors over 13 years old may play our game with parental consent. Crowdsourcing web sites like Mechanical Turk, only allow players who are 18 and over.

   b. Gender: The gender breakdown of our players will be unknown.

   c. Ethnic and racial minority populations: The race/ethnicity of our players will be unknown.

3. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)

   They must be willing to register a unique username, which requires a legitimate email address and agreement to our disclaimer, to play the game. This is so we can track people as they return to the game multiple times and from different machines.

4. What characteristics (exclusion criteria) would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)

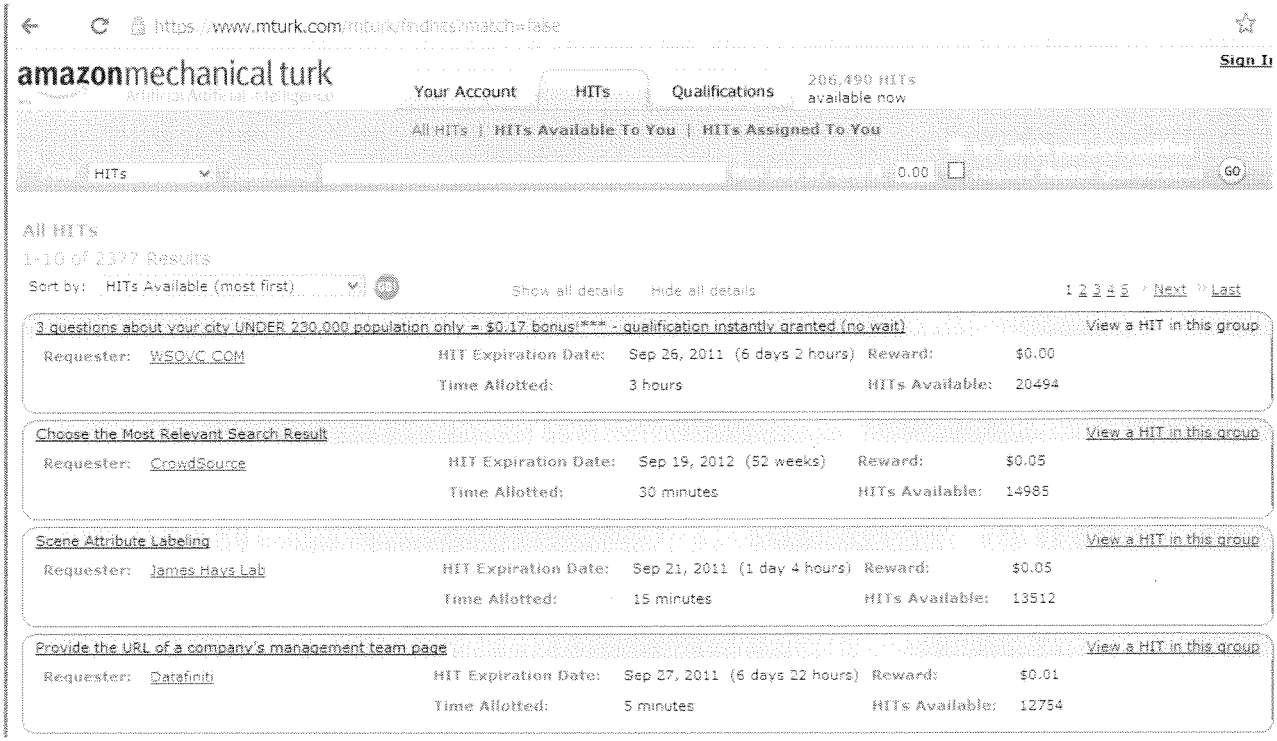
   None

5. Describe the subject recruitment strategies you will use for each group of subjects. (Attach advertisements, flyers, contact letters, telephone contact protocols, Health Sciences recruitment web site template, etc.)

   On public game sites, playing our game is entirely voluntary; there is no active recruitment process.

   The game will be distributed through a variety of online gaming portals such as Kongregate.com, newgrounds.com etc. Existing gamers who frequent these sites will see the game in the listing of game that these sites provide and may then opt to play one of our games.

   Our recruitment on crowdsourcing sites such as Mechanical Turk will be via a post to the websites' systems that looks similar to a web forum or bulletin board. An example screenshot from Mechanical Turk:



Each entry describes the work unit the reward (often under $0.05) and time allotted.

6. Explain who will approach subjects to take part in the study and how this will be done to protect subjects' privacy. (Attach letters of cooperation from agencies, institutions or others involved in subject recruitment.)

   The game will be publicly available for general consumption. Players who go to existing gaming portals will either opt to play one of our game or not, registering a username if they choose to opt in. During the registration process we will provide information about how we collect data and that it will be used for research but none of the data is identifiable and it all becomes part of a larger set of aggregate data.

   On crowdsourcing sites, the only people who can see the game challenge are those who are already part of the crowdsourcing site, thus doing what they would be ordinarily on that site.

7. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.

   Playing our game is entirely voluntary, including the crowdsourcing sites.

8. Will you give subjects gifts, payments, services without charge, or extra course credit? ☐ No ☒ Yes If yes, explain:

As shown in the previous image, each unit of game play will be rewarded by a small monetary reward. Each user will receive $0.10 to $5 upon completion of testing out our game prototypes. Most of the pay will be in the low, under $0.50 amount, but if we end up needing many participants in a very short time, we can raise the payment.

9. Will any of the subjects or their third-party payers be charged for any study procedures? ☒ No ☐ Yes If yes, explain:

10. Where will the study procedures be carried out? (Attach copies of IRB approvals or letters of cooperation from non-UW research sites, if necessary.)

    They will be all performed online.

E. RISKS AND BENEFITS

1. Describe nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks of withholding standard care or procedures if this is the case. Do not reference the consent form.

   Possible feelings of invasion of privacy and breach of confidentiality.

2. Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare. (If you will include protected groups of subjects (minors, fetuses in utero, prisoners, pregnant women, decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group. Please also complete the Supplement: Protected and Vulnerable Populations.)

   Our terms of service agreement includes information that attempts to make clear that the data we collect is anonymous and relatively standard practice for online game. No players will be treated any differently than other players and we will not be able to tell any recognizable features from their playtraces.

3. Is it possible that you will discover a subject's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of study procedures? ☒ No ☐ Yes If yes, explain how you will handle this situation.

4. Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."

   The game can solve the problem of security bugs in software and aid towards reducing the ability of viruses to infect software.

5. Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

   This research has the potential to deepen our understanding of player engagement through game design principles and the social benefits to a gaming community with regard to player engagement. Additionally, our game will discover a new pathway of finding security issues in software.

F. ADVERSE EVENTS OR EFFECTS

1. Who will handle adverse events? ☒ Investigator ☐ Referral ☐ Other, explain:

   N/A

2. Are your facilities and equipment adequate to handle possible adverse events? ☐ Yes ☐ No, explain:

   N/A

3. Who will be financially responsible for treatment of **physical injuries** resulting from study procedures?

   ☐ Study sponsor ☐ Subject or subject's insurer ☐ UW compensation plan ☐ Veterans Affairs ☐ Other, explain:

   No physical injuries are expected to occur.

G. CONFIDENTIALITY OF RESEARCH DATA

1. Will you record any direct subject identifiers (names, Social Security numbers, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.) ☐ No ☒ Yes If yes, explain why this is necessary and describe the coding system you will use to protect against disclosure.

   We will ask players to create a unique username to log into our game with. This will only be used to match return visits to each other so we know when a player has returned to a game multiple times over weeks / months. We will never know the real identities of our players nor have any identifiable information.

2. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? ☐ No ☐ Yes If yes, explain why this is necessary and for how long you will keep this link.

   N/A

3. Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g., sponsors, advisers, government agencies, etc.).

During and after data collection, we will store all data on password-protected computers and/or in a locked file cabinet that only members of the research team can access. All study data will be kept for up to 7 years after the study start date. We will provide data to DARPA.

4. Will you place a copy of the consent form or other study information in the subject's medical or other personal record?
☒ No ☐ Yes. If yes, explain why this is necessary.

5. Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future? ☒ No ☐ Yes
If "Yes," explain and include this information in the consent form.

H. ADDITIONAL INFORMATION

1. If the study will involve radiation exposure to subjects, e.g., X-rays, radioisotopes, what is status of review by the UW Radiation Safety Committee (RSC): ☐ Pending ☐ Approved (Attach one copy of approval.) ☒ NA

2. Protected Health Information (PHI). Will you or any member of your research team obtain, access, or use a subject's protected health information by any method, and for any purpose including "pre-screening"?

"Methods" may include but are not limited to: directly looking at a medical record (electronic or paper), requesting medical record information from a service such as the UW Center for Health Excellence, or viewing surgery schedules, clinic records, appointment books, etc.

Examples of where PHI may be located include: medical records, dental records, clinical lab tests that you will have performed on subject samples, pharmacy records, medical billing records, clinical databases, etc.

☒ No ☐ Yes. If "yes":

a. Describe the type of records/data, location and how you will obtain the information:

b. Will you obtain any of the information without HIPAA authorization from each subject?

☐ No ☐ Yes. If "yes": Complete and attach the Waiver Request: HIPAA Authorization, and the Waiver Request: Consent or Consent Requirements. If the records are owned by the University of Washington or a state agency, complete and attach a UW Confidentiality Agreement.

c. Will you obtain HIPAA authorization from subjects for any of the information?

☐ No ☐ Yes. If "yes", attach the HIPAA Authorization form you propose to use

d. Will you be obtaining any of the data as a Limited Data Set?

☐ No ☐ Yes

3. Other Records. Will you or any member of your research team obtain, access, or use academic, employment, or any other type of records about subjects, by any method, and for any purpose including "pre-screening"?

"Methods" may include but are not limited to: directly looking at a record (electronic or paper), requesting records from offices such as Payroll or the UW Registrar's Office, obtaining records from the state Department of Health, etc.

☒ No ☐ Yes. If "yes":

a. Describe the type of records/data, location, and how you will obtain the information.

b. Will you obtain any of the information without the subject's consent?

☐ No ☐ Yes.

If the records are owned by the University of Washington or a state agency, complete and attach a UW Confidentiality Agreement.

4. Will you use the Clinical Research Center (CRC) at the UW or Seattle Children's for any of your research activities?

☒ No ☐ Yes.

If you answered "yes":

A medical record will be created for your subjects at UW Medicine and CRC staff may need to access those medical records for you. This may be because they are performing procedures or collecting data for you. It may also be required if an event happens on the CRC that requires treatment (such as fainting during a blood draw). This means that you must obtain a signed HIPAA Authorization form from each subject and give a copy of it to the CRC. ***Complete and attach the UW research HIPAA Authorization template, available on the HSD Forms webpage. There is guidance in the template about how to describe the information that the CRC staff may access and disclose to you.***

5. Will you make audio-visual or tape recordings or photographs of subjects? ☒ No ☐ Yes. If yes, explain what type of recordings you will make, how long you will keep them, and if anyone other than the members of the research team will be able to see them.

6. Will your study involve use of equipment involving energy input to the subjects (EMG, EKG, MRI, ultrasound, etc.)? ☒ No ☐ Yes. If yes, attach documentation that all equipment will be tested regularly by the Scientific Instrument Division (call (206) 543-5580 for information) or describe safety testing procedures you will use.

7. Have all Investigators (i.e., all UW personnel responsible for the design, conduct or reporting of the proposed research) read and complied with GIM 10, the University's policy governing the disclosure of Significant Financial Interests? ☐ No ☒ Yes. (Note: This application can not be considered unless all Investigators have read and complied with GIM 10, which may be accessed at http://www.washington.edu/research/osp/gim/gim10.html.)

8. Does any Investigator have a Significant Financial Interest related to the proposed research that must be disclosed as provided in GIM 10? ☒ No ☐ Yes. If yes, each Investigator having a Significant Financial Interest must comply with GIM 10, including submission of a Significant Financial Interest Disclosure Form. Final review of this application cannot occur until the GIM 10 review is complete. Delays in complying with GIM 10 will result in delays in completing the final review of this application. Please list the name of each Investigator having a Significant Financial Interest below:

I. CONSENT FORMS

Check all that apply:

☒ **Written** *Attach copies of all consent forms for each subject group. Include a footer identifying the version date of each form and a header or title that identifies each different form. If you propose to delete one or more of the required elements of consent from a consent form, attach and complete the form called Waiver Request: Consent or Consent Requirements.*

☐ **Waiver of written documentation of consent** *This means that you are requesting a waiver of the requirement to obtain written documentation of consent. Complete and attach the form called Waiver Request: Consent or Consent Requirements. Also, attach the Information Statement, oral consent or assent protocol and script, or other materials you will use to communicate the necessary elements of consent to the subjects.*

☐ **Waiver of consent** *This means that you are requesting a waiver of the requirement to obtain consent. Complete and attach the form called Waiver Request: Consent or Consent Requirements.*

☐ **Assent** *Attach copies of any written materials or scripts you will use with minor subjects (individuals under the age of 18) to obtain their assent to being in your research.*

☐ **Parental permission** *Attach copies of any written materials or scripts you will use with parents, to obtain their permission to enroll their minor children in your research. See also Supplement: Protected and/or Vulnerable Populations for waivers or alterations of consent requirements.*

☐ **"Short Form" consent** *Attach copies of all materials you will use for the consent process. Complete and attach the form called Waiver Request: Consent or Consent Requirements.*

J. DRUGS, SUBSTANCES, AND DEVICES

1. List **all** non-investigational drugs or other substances used to conduct this research (analgesics, anesthetics, drugs used to treat side effects, etc.). Include products used for standard clinical care if they are used in this study for research purposes.

Name	Source	Dose	How administered

2. List **all** investigational new drugs or other investigational substances to be used in the study. Include marketed products used "off-label" (different formulation, dose, route of administration, or indication). Provide:

   - **three** copies of a concise summary of information about the drug prepared by the investigator (including animal and human toxicity data, studies done in animals and humans to date);
   - **one** copy of the Investigator's Brochure;
   - **one** copy of the study protocol.

   Important note: You must register an IND with the appropriate institutional pharmacy (**UWMC: 598-6054; HMC: 731-5448, VA: 764-2142**) before using the drug in research.

Name	Source	Dose	How administered	IND Number	Phase of testing

3. List all investigational devices you will use. Provide the information requested below and attach one copy of the company protocol. If there is no Investigational Device Exemption (IDE), explain why. Include a statement as to why the device qualifies as non-significant risk. Provide a copy of the FDA letter(s) which states the device classification (PMA, 510K, Class I, II, or II, or custom device) and categorization (Category A or B). "Category A" means that Medicare may **not** be billed for the device or for services related to its use. "Category B" means that Medicare may be billed for services related to its use **if** the U.S. Health Care Finance Administration (HCFA) grants authorization. **Important Note:** Register IDE devices with the UWMC Manager of Surgical Support Services (598-6538) or the HMC Business Manager of Surgical Services (731-8094) to obtain authorization for use.

   a. Name of the device:

   b. Name of the manufacturer:

   c. Description of its purpose and how you will use it in this study:

   d. Descriptions of previous studies in humans and animals:

   e. Investigational Device Exemption (IDE) number or FDA status:

Tia N. White

From: Zoran Popovic [zoran@cs.washington.edu]
Sent: Monday, June 25, 2012 2:48 PM
To: Tia N. White
Cc: Beatrice Marx
Subject: Re: Human Subjects Review Application, HSd Study #43181

Hi Tia, as i mentioned this application is identical to the IRB approval we already have for other games. The key difference is in the REMOVAL of the children younger than 13 because this needs to be approved by AFRL surgeon general and we know from the experience that that is a non-starter there. The specific answers are below:

1. Is PipeJam the only game you are currently seeking approval for under this application? If not, please provide a list and description of the other games subjects participating in the current study will play.

This is the only game that we will be sending for AFRL approval, so this IRB will only have one game on it.

2. Please provide a brief description of PipeJam (i.e. what's the overall goal of the game, at what level are subjects asked to participate).

Pipe Jam is a game that takes in software programs and turns them into a game that can be played by anyone. The goal of the game is to resolve all the resource conflicts (jams). if successful, the game solution can be directly mapped into new software program that can be guaranteed to not have any bugs, or security issues. Therefore, since the game can be played by thousands of people worldwide, the world can eventually have more robust software without bugs, and without security holes that makes them susceptible to attacks by viruses. Instead of only highly skilled programmers doing software verfication, we can hopefully turn this into a million people worldwide doing the same task.

The game play entails redirecting traffic by switches, widening pipes or roads, narrowing them down, or doing road reconstruction. each problem is phrased in terms of sequence puzzles that need to be solved together. When the solution is found the entire traffic jam situation resolved. Each player is directly involved in solving these puzzles either in teams or individually.

3. In Section D.2. of the application, you indicated that minors over 13 years of age can play the game with parental permission. Please describe how parental permission would be obtained or documented.

The consent forms contains the specific language (identical to our previous irb application). I think Beatrice may have pointed at this already. if a person is a minor and older than 13 then they need to have their parrents click through approve play of the game.

When registering for an account the first time:

[NAME OF GAME]
TERMS OF SERVICE AND CONSENT

By registering an account and signing in to play this and other UW Center for Game Science games you acknowledge that:

a) **We are recording logs of player decisions and player scores.** As you play this game, you are participating in a research study, and it is keeping a record of your decisions and pathways through the game so that the game's creators, researchers at the University of Washington*, can improve the game for future players, as well as see whether our games improve your abilities with in-game tasks over time. Your mouse clicks and key presses are being recorded. This is used to help us determine where players get stuck, so we can identify if it is a problem with the game design or with learning goals. We also use this information to personalize the game experience to each player. Your play log will be added to a massive dataset that shows us trends in player behavior. This data will be kept for 7 years. This logging is no different than the standard practice in the game industry aimed at improving player's experience.

b) **For some games, we are also asking for basic demographic information: Age, Gender, and Education Level.**

c) **The username you create can also be used in public forums, and your posts there are naturally publically available.** We may study the public forum posts to understand how players who interact with each other also engage with our games.

d) **The data will be shared with DARPA** who are working with us on this project.

e) **This data may be published or shared with the academic community** for the purposes of presenting research findings and furthering the advancement of improving games and learning through games. The log data will be in the aggregate and collected form, (not per individual) without the possibility for anyone to determine any personably identifiable information or even personably identifiable game play information. Forum data will be coded and analyzed and will not be linked to your forum profiles.

f) **Game administrators reserve the right to disable game accounts at any time.**

g) **We may contact a small number of you to solicit additional information on your experience with a game, which you are free to decline.** This will be done through a message sent to the email address you use to register a username. We will not know what your email address is, since the email service will be automated through a computer system. You will never get spam nor will we share your email address with anyone.

If at any time you do not want to participate in our research, simply stop playing and delete your account.

If you have any questions or concerns about the research or game, please feel free to contact us at cgs-feedback@cs.washington.edu or at (206) 616-2660. If you have questions about your rights as a research participant, you may contact a member of UW's Human Subjects Division at (206) 543-0098 Please note that emails are considered insecure and privacy is not guaranteed.

[ ] Agree [ ] Disagree

desired username: _____

valid email address: _____

desired password: _____

retype desired password: _____

*This study is part of a research project entitled A Game Based expert development for code verification with researchers: Zoran Popović, Seth Cooper, Erik Andersen, Yun-En Liu, Michael Ernst, Werner Dietl – Computer Science & Engineering, University of Washington;

When playing a game during a condition that does not require players to register usernames:

[NAME OF GAME]
TERMS OF SERVICE AND CONSENT

By registering an account and signing in to play this and other UW Center for Game Science games you acknowledge that:

a) **We are recording logs of player decisions and player scores.** As you play this game, you are participating in a research study, and it is keeping a record of your decisions and pathways through the game so that the game's creators, researchers at the University of Washington*, can improve the game for future players, as well as see whether our games improve your abilities with in-game tasks over time. Your mouse clicks and key presses are being recorded. This is used to help us determine where players get stuck, so we can identify if it is a problem with the game design or with learning goals. We also use this information to personalize the game experience to each player. Your play log will be added to a massive dataset that shows us trends in player behavior. This data will be kept for 7 years. This logging is no different than the standard practice in the game industry aimed at improving player's experience.

b) **In some cases, we are also asking for basic demographic information: Age, Gender, and Education Level.**

c) **The data will be shared with DARPA** who are working with us on this project.

d) **This data may be published or shared with the academic community** for the purposes of presenting research findings and furthering the advancement of improving games and learning through games. The log data will be in the aggregate and collected form, (not per individual) without the possibility for anyone to determine any personably identifiable information or even personably identifiable game play information.

If at any time you do not want to participate in our research, simply stop playing.

Please contact us if you do not want any of your previously recorded data to be used in our research or if you have any questions or concerns. We can be reached at cgs-feedback@cs.washington.edu or at (206) 616-2660. If you have questions about your rights as a research participant, you may contact a member of UW's Human Subjects Division at (206) 543-0098. Please note that emails are considered insecure and privacy is not guaranteed.

By checking *Agree* below, you agree that you are 13 years or older, have read the above terms and give your consent to conduct research on your game playing. If you are under 18, you agree that a parent or guardian has read the above terms and gives their consent for research.

[ ] Agree [ ] Disagree

*This study is part of a research project entitled A Game Based Learning and Problem Solving Framework Using Large-Scale Data Mining with researchers: Zoran Popović, Seth Cooper, Erik Anderson, Yun-En Liu, Michael Ernst, Werner Dietl – Computer Science & Engineering, University of Washington