**Application for Institutional Review of Research**

**Involving Human Subjects**

**Note:** Please complete this form thoroughly keeping in mind that the primary concern is the **potential risk** (economic, ethical, legal, physical, political, psychological/emotional, social, breach of confidentiality, or other) to the participants. Include **attachments** of all materials to be used in the investigation (PDF preferred). The Institutional Review Board (IRB) must have enough information about the transactions with the participants to evaluate the risks of participation.

**Names and employee IDs for all investigators (Z-IDs for students)**

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| Z1839739, A1887077 |

**Status (select all that apply):**  Faculty  Graduate Student  Undergraduate Student  Non-NIU Affiliate

**Department (main PI):**

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| --- |
| Computer Science |

**Phone (main PI):**

|  |
| --- |
| (312)-856-5765 |
|  |

**E-mail address (for all investigators):**

All communications will occur via **NIU email** accounts (for all NIU affiliates).

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**Project Title:**

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| Human activity recognition framework to detect the intensity of activities using wrist-worn wearables |

**Note:** All projects involving human subjects research must receive formal written clearance from the IRB **prior** to the start of data collection.

**Type of Project** (Check one)

Departmental Research (faculty/student projects not externally funded and not indicated below)

Graduate Thesis/Dissertation (IRB application should be submitted AFTER proposal defense)

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| **Advisor/Committee Chair** (& e-mail):      Dr. Pratool Bharti (pbharti@niu.edu) |

DNP Project (Doctor of Nursing Practice)

Undergraduate Project (Senior thesis/capstone, research rookies, independent study)

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| **Advisor/Committee Chair** (& e-mail): |

Externally Sponsored Research

A complete copy of the grant proposal or contract must accompany this application form for IRB review to take place.

Source of Funding:

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Title of grant proposal (if different from IRB protocol):

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* Name of principal investigator on grant proposal:

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* Sponsored Programs Administration file number (or grant number if awarded):

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| SPA# |

Other

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| Specify: |

## **Part I. Purpose and Procedures:**

1. 1) Describe the purpose of your study and the reason(s) this study is needed. Include any necessary background information and a description of your hypothesis or your research question.

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| To understand the effectiveness of physical exercises/ activities, it is very important to not only detect the category of exercise but also the intensity at which it is performed. Current state-of-the-art solutions for human activity / exercise recognition captures the category of exercise (running, walking etc.) but ignores the intensity. In this study, we aim to design the algorithm/ framework to detect the intensity of human activities using wrist-worn wearables. We will collect the accelerometer and gyroscope data from wearables tied on subject’s wrist while performing the relevant exercises/ activities. The end goal of this study is to design an algorithm that can take these sensory data from subject’s wearable and predict the intensity of those activities. |

2) The following items will help the IRB reviewers understand the step-by-step procedures of your study:

2A) Explain the participant **eligibility** and **exclusion** criteria that will be used.

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| Any participants who are 18 years or older and actively involved in regular exercise can participate in this study. Participants should be physically fit and very comfortable to walk and jog intermittently for almost 20 minutes. Participant will start the experiment with walking on treadmill at 3 mph for a 45 seconds session. After 45 seconds, participant can take rest or withdraw from the study. Participants will keep walking/ jogging in each 45 seconds long session. Speed will be increased by 0.5 mph every new session. Maximum allowed speed is 7 mph. They can take a break any time they want and withdraw from this study anytime. |

2B) Explain the **recruitment** procedures (how will participants learn about the study?). If using the snowball technique, please explain who contacts potential participants (other participants or the researcher). *Please attach recruitment scripts, flyers, or postings.*

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| Recruitment script is attached with this application. PI will send the recruitment script to his friends and fellow students in his classroom and explain the study and data collection process. We are looking for 15-20 participants in this study. |

2C) Explain the **consent process** (verbal and/or written procedures for informing participants of the nature of the study and what they will do).

[*Please attach all documents (assent, consent, parent permission) that are appropriate for each group of subjects participating in the study. Consent forms should be prepared for adult participants (age 18 or over). Assent forms should be prepared for minor subjects appropriate to their ages, and permission form(s) for parents or legally authorized representatives should also be prepared. For children too young to comprehend a simple explanation of participation, parental permission is sufficient only if the research will provide direct benefit to the subject, a member of the subject's family, or other children with the same condition as the subject.]*

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| Consent form is attached with the application |

2D) Describe the **data collection** procedures including what data will be collected, how it will be collected (include a description of any interventions to be used), the duration of participation in the study session(s), and how the session(s) will end.

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| A wrist-worn device will be tied on the wrist of participant. This device is very similar to Apple and Samsung smartwatch embedded with accelerometer and gyroscope sensors. These sensors are widely used in academia and industry to study for human activity recognition. These sensors capture the acceleration and angular speed of the human body part where sensor is tied. PI will conduct this experiment at NIU recreation center where he will ask the participant to walk/ jog for a session longing 30-45 seconds at a particular speed that is comfortable for them. He will change the speed by 0.5 mph in each passing session in the range of 3mph to 6mph. Participants are encouraged to take 5 minutes break after each session. Participant can decline to participate in the study any time they want. They can withdraw from study after of within any session. |

2E) If applicable, explain the procedures for providing **compensation**.

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| NA |

2F) If applicable, explain the procedures for **debriefing** participants. *Please attach a debriefing script or sheet*

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| NA |

**Reminder:** Include copies of all questionnaires, surveys, interview questions, listing of all information/data to be collected, etc. with this application. It is the responsibility of the researcher to obtain any relevant permission for copyrighted materials. If the research involves an oral interview or focus group discussion that could evolve as it progresses, include a list of discussion topics and any “starter” questions for each topic that can reasonably be expected to be covered. If a *draft* of a written questionnaire or survey is attached, it should be clearly labeled as such and a final version must be submitted *before* data collection begins.

**Part II: Research Participants**

3) Participant demographics:

 Gender: All  M  F  Trans M  Trans F  Nonconforming

 Estimated age(s):

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| 20-30 |

 Are any subjects under age 18? Yes  No 

 **Potentially** vulnerable populations (please indicate if any of the following groups are the **target population of the study**)

Pregnant women & fetuses

Prisoners

Decisionally impaired/mentally disabled

Specific racial or ethnic group(s) (list in box):

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If any potentially “vulnerable populations” will be the target of the study, be sure to include a response to 2A above explaining eligibility criteria.

 Target number of participants in the **entire study** (including controls) from start to finish (keep in mind that this is just an **estimate of the total**):

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| 15 |

4) Please explain any outside institutional (e.g., schools, hospitals) approval you will need to obtain and how approval will be sought. Provide scripts, letters, or emails providing any information that will be used to obtain needed approvals/permission. It is the responsibility of the researcher to follow all applicable policies of any outside institution(s).

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| NA |

**Part III: Risk/Benefit assessment**

1. What knowledge/benefit(s) to the field will be gained from the study?

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| This study is looking to design an algorithm which can detect the user’s exercise intensity using smartwatch and without use of GPS. This will be a significant improvement in the current state-of-the-art. |

1. What direct benefit(s) are there to the participant(s) (if any) from the proposed research? *[For example, learning a new skill, psychological insight, teaching experience]**[Please note that compensation is* ***NOT*** *considered a direct benefit.]*

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| NA |

1. Describe any potential risks (breach of confidentiality, economic, ethical, legal, physical, political, psychological/emotional, social, etc.) to the subjects posed by the proposed research. (Note: Some studies may have “no reasonably foreseeable risks.”) Investigators are required to report all unexpected and/or adverse events to the IRB. Therefore, it is important that you list all reasonably anticipated risks because unanticipated adverse events may need to be reported by NIU to OHRP.

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| The participant may trip from the treadmill due to fatigue or overspeed. PI will be there to help in any these kind of unlikely events. |

1. Federal regulations require that researchers use procedures that minimize any risks to participants. What procedures will be used to minimize each risk and/or deal with the challenge(s) stated in “7” above?

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| We will provide breaks (5-10 minutes) after every 45 seconds session and the participant is free to take longer and multiple breaks as they desire to avoid fatigue or tireness. In order to prevent risk of over speeding, the maximum speed that a participant may walk/jog/run will be 1mph lesser than their usual comfortable pace. |

9) If support services are required to minimize risk of harm, explain what will be provided (list of services available).

[***DeKalb area*** *resource list:*

*https://www.niu.edu/divresearch/compliance/resources/files/Counseling-Resource-DeKalb.pdf*

*If using this, please include with your application.]*

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| NA |

1. How do the potential benefits of the study *justify* the potential risks to the participants?

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| NA |

**Part IV: Consent Document Variations**

11) Will audio, video, or film recording be used? Yes  No

If **yes**, specify the recording format to be used.

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Please keep in mind that specific consent must be sought in the informed consent document(s) by including a **separate signature/date line giving consent** for recording. This is in addition to the signature/date line giving consent to participate in the research project.

12) Will this project require the use of consent/assent documents written in a language other than English?

Yes  No

**Reminder**: If non-English documents will be used, please have the document translator **provide documentation** (email or written) that the translation is equivalent to the English version. [*This can be done after the protocol is approved in order to minimize the number of changes needed.]*

13) Are you requesting a **waiver of a** **signature** on the informed consent document? Yes  No

Please indicate the justification for requesting this waiver:

The only record linking the subject to the research would be the signed consent document

and the principal risk of the research would be breach of confidentiality.

The research involves minimal risk to the subjects and involves no procedures for which

written consent is normally required outside of the research context (e.g., online surveys).

14) Are you requesting a **waiver/alteration** of some other aspect of the informed consent document?

*[This section is particularly relevant for studies involving* ***deception****.]*

Yes  No

14a) Please explain which aspects of informed consent will be missing or altered along with a justification for the change.

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14b) Please explain how the project meets all of the following criteria:

1) The research presents no more than minimal risk of harm to the participants.

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2) The waiver/alteration will not adversely affect the rights or welfare of the participants.

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3) The research could not practicably be carried out without the waiver or alteration.

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4) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

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15) Will any HIPAA protected health information be collected as part of the data? Yes  No

If **yes**, describe the procedures for protecting the information.

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*[Please provide a copy of your HIPAA disclosure form to be given to participants.]*

16) Will any protected school records be collected as part of the data? Yes  No

If **yes**, describe the procedures for protecting the information.

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**Part V: Confidentiality and Anonymity**

17) Will identifying information be connected to the data, or is there a way to re-identify the data through pseudonyms or a code that is kept separate from the data? Yes  (**confidential** data) No  (**anonymous** data)

**QUALTRICS USERS**: You may want to keep your survey anonymous by allowing student participants to access a second Qualtrics survey where they enter their name and student ID if needed. This would require clear instructions in the original survey along with a link to the second survey where they enter the identifiers for course credit or entry into a drawing.

18) If you answered **yes to question #17**, describe precautions to insure the privacy of the subjects, and the confidentiality of the data, both in your possession and in reports and publications.

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| No identifiable information will be collected from the participants. |

19) If you are collecting your data through an on-line survey tool, will the survey instrument collect email and/or IP addresses with the data?

No  **The survey will be set so that email/IP addresses are NOT collected**

(in Qualtrics: within a survey select “survey options” then “anonymize responses” toward the bottom)

Yes  **IP and/or email addresses WILL be collected** **with the data**

N/A   **I am not using an online survey tool.**

**Please Note:** Some electronic survey items may not be accessible to people who use screen readers as a way of accommodating their visual impairments. We recommend that you follow the link below to check the accessibility of your Qualtrics survey items: <https://www.qualtrics.com/support/survey-platform/survey-module/survey-tools/check-survey-accessibility/>)

20) How will the records (data, recordings, and consent forms) be stored? **Also** indicate how long records will be kept and how and when they will be disposed of.

*[Note: Signed informed consent documents must be maintained for 3 years following completion of the study.]*

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| Data will be stored into the secured account of PI’s cloud server. Records will be stored for 3 years. |

**Part VI: Projects Involving Deception *[complete only if your study includes deception]***

21) Describe the deception being used. Be sure to clarify whether this is deception by **omission** (an important aspect of the study is withheld from the participants) or **commission** (the participant is misled about some aspect of the study) or both. *[Complete* ***item 14*** *if aspects of consent are missing.]*

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| NA |

22) Why is deception a necessary and unavoidable component of the experimental design?

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| NA |

23) Debriefing of participants will be:

Immediate (directly following the research session)

Delayed

Full (all aspects of deception will be revealed)

Partial (some aspects of deception will remain unexplained)

a) If debriefing is delayed, why is the delay necessary, and when will it occur?

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b) If debriefing is not full, why is partial debriefing necessary? Would the participant be harmed in any way by full debriefing?

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c) If debriefing is partial, will full debriefing occur later?

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d) Does the presence of deception increase risk of harm to the participants?

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e) Is the respondent free to withdraw his/her data after being fully debriefed?

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24) Who will provide the debriefing?

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| NA |

**Reminder**: Please include a copy of your debriefing script/sheet with this application.

**Part VII: Credit and Compensation**

25) If participants will receive course credit for participation, please describe it below.

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| NA |

26) If participants will receive some other form of compensation for participation, please describe it below.

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| NA |

27) Describe any alternative tasks that will be available for participants to earn the credit or compensation.

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| NA |

**Part VIII: Conflict of interest**

28) Do any of the researchers conducting this study have any potential conflicts of interest?

*[Conflicts of interest may include financial or personal interest, or any condition in which the investigator’s judgment regarding a primary interest may be biased by a secondary interest.]*  Yes  No

29) If **yes** to the above question, please describe the nature of the conflict of interest.

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**Part IX: Researcher Qualifications**

30) In addition to listing the investigators’ names, indicate their qualifications to carry out the research described in

this application.

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| Computer Science graduate student. He completed the CITI training and have some prior experience of conducting these kind of experiments. |

31) State the date of completion of the **CITI Human Subjects Protection** training program(s) for the individuals

listed in the question above. The required course is “**Social & Behavioral Research - Basic/Refresher, Basic**

**Course.** The required CITI training is accessible from the ORCIS website at

https://www.niu.edu/divresearch/compliance/human/training/index.shtml

If you have comparable training elsewhere, please include the certification with this application.

[*Note: NIU policy requires that research investigators must complete appropriate training before conducting human subjects research*.]

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| 10/16/2019 |

**To be completed by investigator and confirmed by advisor (if student project) and departmental reviewer.**

**Check the items that are accompanying this completed application form:**

1.  Subject recruitment/introductory materials

2. ­­­­Informed consent documents (select at least one):

Consent form for adults (if participants are age 18 or over)

Assent form for minors (if participants are under age 18)

Parental permission form (if participants are under age 18)

3.  All surveys, questionnaires, interview questions, or other instruments to be used

4.  grant proposal SPA# included on front of application (for **externally funded** projects)

**REQUIRED SIGNATURES: ALL PROJECTS**

CERTIFICATION

I certify that I have read and understand the policies and procedures for research projects that involve human subjects and that I intend to comply with Northern Illinois University Policy. Any changes in the approved protocol will be submitted to the IRB for approval prior to those changes being put into practice unless it involves an immediate safety issue for a subject during a procedure. (In such instances, the researcher is required to promptly notify the IRB after the fact.) I also understand that all non‑exempt projects require review at least annually.

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\* Investigator(s) Signature(s) Date

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\* Signature of Faculty Advisor Date

(Student Projects Only)

\* Signature of Authorized Departmental Reviewer Printed name Date

**\* PIs (both faculty and students), faculty advisors, and ADRs may choose to send an email statement (or email thread) indicating acknowledgement of the certification statement above in lieu of signatures.**

Return this form, together with necessary documentation, to the Office of Research Compliance, Integrity, and Safety at [researchcompliance@niu.edu](mailto:researchcompliance@niu.edu) (a single PDF is preferred, but we can work with multiple files and Word documents). For information or additional assistance with the approval process, please call our office at (815) 753‑8588 (Lowden Hall, 301) or access the ORCIS web page at <https://www.niu.edu/divresearch/compliance/index.shtml>