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

- Submit an electronic version of the completed form along with a hard copy to Marsha Konieczny, RIT IRB Administrator, 2000 Louise Slaughter Building, marshak@mail.rit.edu.

Project Title: Wheelchair Tray Senior Design Project

Investigator’s Name: Investigator’s Phone: Investigator’s Email:

Investigator’s College and Department:

Project Start Date: Date of IRB Request:

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

If yes, name of funding agency: NSF

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

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

Signature of Department Chair or Supervisor Date

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

Attachments required for all projects:
☒ Project Abstract
☒ IRB Training Certificate(s) from OHRP (see http://ohrp-ed.od.nih.gov/)

Attachments required where applicable:
☒ Informed Consent Materials ☐ Cover letter to subjects and/or parents or guardians
☒ Questionnaire or survey ☐ External site IRB approval
☒ Relevant Grant Application(s) ☐ Other
Form A (continued): Research Protocol Outline

- The RIT Institutional Review Board (IRB) categorizes Human Subjects Research into five Risk Types (Exempt, or Type I-IV, defined at the end of this form). As the investigator, you should determine which type best categorizes your project. The IRB will make the final determination of risk type, and will consider your ranking at the time of their review.

- Please complete this entire form (1 through 10 below). ENTER A RESPONSE FOR EVERY QUESTION. If a question does not apply to your project, please enter "N/A". Leaving questions blank may result in the form being returned to you for completion before it is reviewed by the IRB.

- Underlined terms are defined at the end of this form.

FOR ALL PROJECTS, please complete 1-10 below.

1) If you believe your project qualifies for Exemption, which exemption number(s) apply? Which Risk Type (Type I-IV) do you believe applies to your project? Type II Minimal Risk (Note: The IRB makes the final determination of Exemption or Risk Type).

2) Describe the research problem(s) your project addresses.
This senior design project goal is to design a wheelchair tray for two members of Arc of Monroe County homes. The tray or trays will replace the wheelchair trays the consumers currently use. See attached abstract for more details.

3) Describe expected benefits to subjects and/or knowledge to be gained from your project.
Benefits to subjects may change as the project develops and as specific needs of the consumers are identified and prioritized, but they may include: ability to see the ground in front of them while tray is in place; elimination of under-tray brackets used by the current design, reducing the risk of leg injury due to involuntary convulsions; reduced chance of knocking tray off wheelchair due to accidental collisions; reduced chance of a loose tray sliding into the pumps used to control involuntary convulsions, a problem with the current wheelchair trays; reduced chance of writing implements rolling off tray during motion; increased independence if the consumers no longer need assistance in retrieving lost objects or reattaching a dislodged tray.

4) Describe the population sample for your project.
   a) How many subjects will participate in this project?
      2
   b) How will these subjects be identified and selected for participation?
      Subjects were identified entirely by the Arc of Monroe County. They learned of the RIT NSF project and approached us with a list of needs that they had for specific consumers or specific Arc facilities. Projects are being selected from this list based on a combination of (1) the Arc's level of need for the device, (2) the degree to which the need fits the definition of projects provided by NSF for this project, and (3) the likelihood that the project is at a level of difficulty that it can be completed in 20 weeks by a team of students.
   c) Describe the rationale for inclusion or exclusion of any subpopulation.
      All subjects are people with disabilities, and we have not had reason to exclude anyone fitting this description. This was specified by NSF in the proposal guidelines.
   d) How will you recruit subjects?
      Subjects are not being recruited. See 4b above.
   e) Describe any incentives for participation you plan to use.
      None
5) Will you include any of the following vulnerable populations in your research? (Check any that apply)

- [ ] Children
- [x] Mentally Ill
- [ ] Prisoners
- [x] Mentally Handicapped/Retarded
- [ ] Pregnant Women
- [ ] Fetuses

If any of these populations are to be included, please address the following:

a) Rationale for selecting or excluding a specific population:
   We are excluding people who do not have disabilities. See 4c above.

b) Description of the expertise of project personnel for dealing with vulnerable populations:
   Project personnel will only work with human subjects under the direct supervision of Arc occupational therapists or house managers.

c) Description of the suitability of the facilities for the special needs of subjects:
   The only facilities being used by the subjects are the Arc facilities. The subjects already live there, and these facilities are already suitable.

d) Inclusion of sufficient numbers of subjects to generate meaningful data:
   No data are being collected.

6) Describe the data collection process.
   a) Will the data collected from human subjects be anonymous? [x] Yes [ ] No
   b) Will the data collected from human subjects be kept confidential? [x] Yes [ ] No
   c) Describe your procedures for ensuring anonymity and/or confidentiality:
      The consumers' names will not be used in association with any personal information collected. Photographs will only be taken where the consumer or their advocate consents. The information will not be anonymous, as some measurements and questions can only be obtained by direct interaction with the consumers.
   d) How much time is required of each subject? ~4 hours
   e) If subjects are students, will their participation involve class time? N/A
   f) What methods, instruments, techniques, and/or other sources of material will you use to gather data from human subjects?
      Tape measures, photographs, interviews

7) Will this research be conducted at another university or site other than RIT? [x] Yes [ ] No

   If yes, describe location: Arc of Monroe County Rush House

   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? N/A - minimal risk only
   b) Assess their likelihood and seriousness to subjects:
      N/A - minimal risk only
   c) Discuss the potential benefits of the research to the population from which your subjects are drawn:
      The intent of the project is to benefit the individual person(s) with disabilities involved with this project, as outlined in the NSF proposal guidelines. See 3 above. If there are benefits to the population from which the subjects are drawn, it will be through coincidence that they have the same exact needs. In that case, the other individuals may see the same benefits as described in 3.
   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:
      The risks to the consumers are no greater than the risks they face every day with their current wheelchair trays. The current trays are insufficient and, in some cases, actually cause injury to the consumers with
whom we will work. The new trays are being designed specifically to eliminate these problems. If, for some reason, the project results in a wheelchair tray that is determined to have the potential to cause more or more serious injuries, then the consumers are free to return to the use of the original wheelchair trays.

e) Describe the planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness:
The subjects names will not be recorded with any personal information. All information recorded by the team will be maintained by the team leader and given directly to the faculty advisor at the end of the project, to be kept in locked storage.

f) Where appropriate, describe plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects:
The wheelchair trays will be used under supervision of Arc occupational therapists or house managers until the consumers are comfortable using them safely.

9) Will you be seeking informed consent? ☒ Yes ☐ No
   If yes, describe:
   a) What information will be provided to prospective subjects?
The activities in which they will be involved, a list of potential benefits, a list of potential risks, a contact person at RIT who will answer any questions they may have, the length of time the subject will be asked to give, an approximate completion date for the project, an explanation of how their personal information will be kept confidential, and a statement that the subjects' participation is voluntary and can be stopped at any time.

   b) What (if any) information will be concealed prior to participation, and why?
      None

   c) How will you ensure consent is obtained without real or implied coercion?
The consumers involved requested this device

   d) How will you obtain and document consent?
      Consent form. See attached.

   e) Who will be obtaining consent? Provide names of specific individuals, where available, and detail the nature of their preparation and instructions for obtaining consent.
The student senior design team will obtain consent. All have completed the informed consent online "training". Caseyann Sarli, Jaclyn Capeci, and Owen Dublin

   f) Attach a copy of your consent materials (forms, protocol, script, etc.) to this application.

10) Please attach a copy of your project description or proposal abstract.
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.

Type I: No risk of injury to subjects; informed consent is not required, but may be recommended.

Type II: Minimal risk to subjects; informed consent is needed.

Type III: Potential exists for harming the subject or violating their rights. Informed consent and assurance of minimization of risk is required.

Type IV: Significant possibility of injury to the subject exists. In this instance:
- Risk must be outweighed by the potential benefit to the subject and the knowledge to be gained,
- Informed consent and assurance of minimization of risk are needed,
- The IRB must meet to discuss the proposed project, and
- The provost must approve.

Human Subjects Research - Definitions
Anonymity – Anonymity offers the best insurance that disclosure of subjects’ responses will not occur. Research data that is anonymous contains no information that would link the data to the individual who provided the information.

Confidentiality – Confidentiality refers to (a) identifiable data (some information about a person that would permit others to identify the specific person, such as a non-anonymous survey, notes or a videotape of the person) and (b) agreements about how those data are to be handled in keeping with respondents’ interest in controlling the access of others to information about themselves. The two critical elements of this definition of confidentiality indicate the critical role of informed consent, which states how the researcher will control access to the data and secures the respondent’s agreement to participate under these conditions.

Child (Definition of) and Use of Children in Research - 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. In New York State, a person age 18 is considered an adult and can provide consent without parental permission. However, some students at RIT are under age 18. To use children (individuals under the age of 18 years) in research, you must first obtain the permission of the parent(s) and then obtain assent from the child.

Human Subjects - The regulations define human subject as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (1) If an activity involves obtaining information about a living person by manipulating that person or that person’s environment, as might occur when a new instructional technique is tested, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met. (2) If an activity involves obtaining private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information), the definition of human subject is met. [Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a school health record).]

Informed Consent – Informed consent is a process by which individuals learn about a study – the substantive issue investigated, participation demands (including time expenditure, types of activities), participant rights (voluntariness, confidentiality), risks, benefits, costs/compensation, contacts if further questions arise, etc. There are multiple ways to convey these elements of consent: by written document, oral presentation with script, oral presentation without script. In addition, there are various ways to document consent: written signature of the participant, written indication of participant’s study identification number, oral recording of consent, oral consent documented by the investigator. In addition, sometimes it is important to obtain separate consent for the use of photographs or videotaped images. The different ways to obtain consent include:

1. Written consent with written documentation by participant.
   a. formal style (for study involving mothers and children)
   b. informal style
   c. formal style for at-risk population
2. Written consent with written indication of participant’s study identification number.
3. Written consent without documentation (for no/minimal risk survey studies).
4. Oral presentation with script with oral consent documented by the investigator.
5. Oral presentation with script without documentation (includes contact card).
6. Oral presentation without script without documentation (provides rationale for request for waiver of written documentation and indicates what will be said).
7. Written consent with written documentation by participant for use of photos.
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.