

**SYRACUSE UNIVERSITY**

**INSTITUTIONAL REVIEW BOARD**

**Full Board Review or Expedited Review Application**

Check which type of review is requested:

[ ]  Expedited Review- One signed copy of my application for **expedited** review.

Expedited review covers research that involves only minimal risk procedures. See Standard Operating Procedure 012. <http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-012-Expedited.pdf> for guidance.

[ ]  Full Board Review- One signed copy of my application for **full board** review.

Includes research that cannot be reviewed using the expedited process involving more than minimal risk to the participant and requires review by the full IRB. See Standard Operating Procedure 013. <http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-013-Full-Board.pdf> for guidance.

Application Checklist:

[ ] [ ]  All questions on the application have been answered.

[ ] [ ]  The application has been signed by the investigator/faculty advisor and when appropriate, the student.

[ ] [ ]  Copies of all appropriate, consent and/or assent documents (written, electronic, or oral consent script) are included.

 [ ] [ ]  Copies of any research instruments (surveys, questionnaires, interview questions, etc.) are included.

[ ] [ ]  Copies of all recruitment tools (flyers, emails, posters, newspaper ads, etc.) are included.

[ ] [ ]  All required appendices, including a list of references are included.

[ ] [ ]  Copies of other IRB approvals or letters of cooperation are included. When the investigation is to be carried out in cooperation with another institution or with an investigator at another institution, a letter indicating the willingness of the institution to cooperate in the study must be included with the proposal.

[ ]  The principal investigator/faculty member and student/research staff have completed the appropriate [**C**ollaborative **I**nstitutional **T**raining **I**nitiative (CITI) Web-based Training Program](http://www.citiprogram.org) for Human Subjects required by SU.\*

[ ]  All students/research staff or any other individuals listed in the application who will have direct contact with participants and/or identifiable human participant data have completed the appropriate [**C**ollaborative **I**nstitutional **T**raining **I**nitiative (CITI) Web-based Training Program](http://www.citiprogram.org) for Human Subjects required by SU.\*

\* Submission of CITI Training Certificate is required **only** if CITI training was completed at another institution.

**I/We assure the IRB that the following statements are true:** All information provided in this form is correct. I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as appropriately trained staff, necessary facilities and equipment. I will seek and obtain prior written approval from the IRB for ***any modifications*** including changes in procedures, investigators/research staff, consent forms, questionnaires, surveys, etc. I will promptly report any unanticipated problems that may occur in the course of this study. I will report any significant findings which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of my study. I will maintain records of this research according to IRB standards. If any of the above conditions are not met, I understand that approval of this research may be suspended or terminated.

**Faculty Member/Principal Investigator**

Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

Name (typed):

**Student/Research Staff**

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

Name (typed):

**This application must be typewritten and all questions must be answered. To complete form, tab to each field. Incomplete forms will be returned to the investigator for additional information. Outdated applications will not be accepted for review.**

**To edit the content of the form/unprotect the document as follows:**

 Microsoft Office Users

 Unlock Document:

* Open the Document, Click the ***Enable Editing*** box and/or select the ***View*** Tab and select ***Edit***, on the Ribbon across the top choose the ***Review*** Tab**>**Click on ***Restrict Editing*** (Image of Paper/Lock)**>**Select box for ***Stop Protection*** (at the very bottom of the page).Leave the side bar open until you have completed your edits.

 Protect Document:

* Once your edits to the document have been completed, to protect or re-lock the document

please ensure the following boxes arecheckedon the right hand side:

***1. Formatting restrictions [Limit formatting to a selection of styles],***

***2. Editing restrictions [Allow only this type of editing in the document:],*** drop down to second option ***Filling in Forms***

***3. Start enforcement click the box Yes, Start Enforcing Protection***.

*Click* ***OK*** with no password entered at the prompt.

1. **Protocol Information**

 **Title of Protocol:**

Principal Investigator Eligibility: Faculty at the assistant, associate, or full professor level, academic, research, or professor-of-practice faculty, department chair/dean, or administrative staff with the position of director or higher may serve as the Principal Investigator (PI) or Co-Investigator (Co-PI). If you have any questions regarding this Syracuse University institutional policy, call the IRB office at 315.443.3013 for guidance.

**Principal Investigator/Faculty Member Information**

|  |  |  |
| --- | --- | --- |
| First Name:       | Middle Initial:       | Last Name:       |
| Title:       |
| Department:       | College:       |
| Campus Address:       |
| Campus Phone :       | Fax :       |
| Email:       | Cell Phone (optional):       |

**Student/Research Staff Information [ ]  [ ] NA**

|  |  |
| --- | --- |
| First Name:       | Last Name:       |
| [ ]  Graduate Student [ ]  Undergraduate Student [ ]  Other:       |
| Department:       | College:       |
| Local/Campus Address:       |
| Local/Campus Phone:  | Fax:       |
| Email:       | Cell Phone (optional):       |

1. **Funding Information**
	1. **Will/has the research been submitted as a grant or contract proposal? [ ]  No [ ]  Yes**

 **Will/has the research been submitted through OSP? [ ]  No [ ]  Yes**

 **If yes, who is the proposed sponsor and what is the title of the proposal submitted to OSP?**

 **Sponsor:**

 **Title:**

* 1. **Is this research currently being funded in part or in whole? [ ]  No [ ]  Yes (indicate below)**

 **[ ]  Internal Funding (check all that apply):**

|  |  |  |
| --- | --- | --- |
| [ ] [ ]  **Departmental Funds**  | [ ]  [ ]  **No cost study** | [ ] [ ]  **Personal Funds** |
| [ ]  **Gifts** |  [ ]  **Other, specify:**       |

[ ]  **External Funding (list all that apply and insert additional rows if needed):**

|  |  |
| --- | --- |
| **Agency/Sponsor** | **Funding Mechanisms** |
|       | **[ ]  Grant**  | **[ ]  Contract** |
|       | **[ ]  Grant**  | **[ ]  Contract** |

* 1. **Is this research to be performed:**

 **for faculty research [ ]  No [ ]  Yes**

 **for a masters thesis [ ]  No [ ]  Yes**

 **for a doctoral dissertation [ ]  No [ ]  Yes**

 **for an honors thesis [ ]  No [ ]  Yes**

 **for undergraduate research [ ]  No [ ]  Yes If Yes, please choose one of the options below:**

 **This research will be conducted as part of a course requirement:**

**[ ]  It is a student project designed as a systematic investigation that will lead to generalizable knowledge (i.e.-Capstone /Honor’s /SOURCE Thesis, or other student work generated as a result of this research that will be displayed on the SU website, shared at workshop/conference, or shared outside of the classroom and/or Syracuse University community at a conference/workshop, etc.).**

***OR***

 **[ ]  It is a student project designed solely to fulfill a course requirement.**

***Student projects involving human participants that are conducted* solely *to fulfill course requirements and to receive a course grade and will not be shared outside the classroom and/or the Syracuse University community do not require IRB review. For additional information please consult:*** [**Student-Projects**](https://researchintegrity.syr.edu/wp-content/uploads/2016/10/Policy-For-Student-Projects.doc)

**[ ]  None of the above. Other purpose (explain):**

**NOTE REGARDING APPLICATON PREPARATION:** **When there is more than one researcher listed in the protocol as part of the research team, please avoid the use of pronouns or references to “the research team/member/s of the research team” or the use of similar terminology. Instead, all such references should include the names of the members of the research team listed in either Sections 1 or 6 of the protocol application as appropriate.**

1. **Study Rationale**
	1. **Using non-technical language, describe the objective of this proposed research including purpose, research**

**question, hypothesis, etc.****From your description, the IRB should be able to determine how this proposed study adds to the knowledge on the research topic in order to judge the risks and benefits to the research participants. NOTE: A reference list citing relevant background information must be provided as an appendix with this application.**

1. **Methods**
	1. **Provide a detailed description of what participants will be required to do; including any technical terms**

 **or procedures.**

* 1. **Describe how you will have sufficient time to conduct and complete the research?**

* 1. **Surveys, interviews, questionnaires will be conducted:**

 **[ ]  No (Skip to 4.4)**

**[ ]  Yes Include all research instruments including surveys, questionnaires, sample interview questions,**

 **etc. as separate appendices. If the survey instrument is commonly used in your discipline, only**

 **provide a citation to the instrument.**

* 1. **Community Based Participatory Research (CBPR) is described as** [**research**](http://en.wikipedia.org/wiki/Research) **that is conducted as an equal partnership between traditionally trained "experts" and members of a** [**community**](http://en.wikipedia.org/wiki/Community)**. Is this research categorized as CBPR?**

**[ ]  No. (Skip to 4.5)**

**[ ]  Yes. Please explain:**

* + 1. **In CBPR research studies, the community participates fully in all aspects of the research process including conception, design, and analysis.**

**With this in mind, describe how you plan to engage community members in your research study:**

* + 1. **Describe how you plan to provide community members with appropriate training for human subjects research? Include in your description what training will be provided.**

* + 1. **Describe your plan to disseminate research findings with members of the community throughout the course of your study.**

* 1. **Will this research be conducted by SU investigators in foreign countries?**

**[ ]  No. (Skip to 4.6)**

**[ ]  Yes. An International Research Form must be completed and submitted with this application.** [**http://researchintegrity.syr.edu/wp-content/uploads/2016/10/International-Research-Form-2013.doc**](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/International-Research-Form-2013.doc)

* 1. **Will this research involve genetic testing?**

**[ ]  No. (Skip to Section 5)**

**[ ]  Yes. A Genetic Research Form must be completed and submitted with this application.** [**http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Genetics.doc**](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Genetics.doc)

1. **Performance Site Information**
	1. **Describe how you will have adequate facilities to conduct your research. Please describe where the**

 **researchers will conduct the research and data analysis. Will these activities be conducted on campus using**

 **campus facilities, classrooms, laboratories, offices, etc.? Will they be conducted off campus at the**

 **researcher(s) home/private office, using agency/organization space, in public spaces, etc. ? A combination?**

* 1. **List all Performance Sites Other than SU** *(insert additional rows if needed)*.

(*This may apply when a SU investigator collaborates with a non-SU investigator or institution or an agency/organization will provide space to perform the research. Please check all that apply and add additional sites. Each will require a letter of cooperation and/or IRB approval*.)

|  |  |  |
| --- | --- | --- |
| Check all that apply | Name of Performance Site (list all participating sites below) | IRB Approval and/or Letter of Cooperation |
| [ ]  | SUNY Upstate Medical University  | [ ] [ ]  Attached[ ]  Pending |
| [ ]  | \*Syracuse City Schools | [ ] [ ]  Attached[ ] [ ]  Pending |
| [ ]  | \*Other, specify site:       | [ ]  Attached[ ]  Pending |

*\*The following additional information is required: contact information for the site, if the site has an IRB, and whether the IRB has approved the research, or plans to defer review to SU’s IRB:*

* 1. **Will this research be conducted in a school or is it funded by the US Department of Education?**

**[ ]  No (Skip to 5.4)**

**[ ]  Yes. If yes, complete the form found at:**

[**http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Department-of-Education-Schools-Form.doc**](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Department-of-Education-Schools-Form.doc)

* 1. **Is this a multi-center research project in which Syracuse University will function as the coordinating**

 **center/lead institution?** (*A multi-center study is one where different PIs at different institutions are*

*conducting the same study*.)

[ ]  **[ ]  [ ]  No**

 **[ ]  Yes. If yes, describe the plans to manage information obtained in multi-site research that may**

 **be relevant to the protection of research participants such as: unanticipated problems**

 **involving risks to participants or others, interim results, and protocol modifications:**

1. **Research Qualifications**

**CITI training is required for the faculty member listed below and all researchers and research staff who have direct contact with participants and/or identifiable human participant data.**  **NOTE: If training is not completed at the time of submission, approval of your application will be delayed.**

* 1. **List the names and research qualifications of the primary investigator/faculty advisor listed in Section 1 of**

**this application. Briefly describe the qualifications of the person listed including: Professional Experience, Education (earned degrees only), Licensure (when applicable), Research Experience, CITI Human Research Training modules. Please do not copy and paste your resume or C.V. qualifications. Qualifications should be appropriate to the type of research being conducted and the targeted population/s involved in the research.**

* 1. **List the names and research qualifications of the student/research staff listed in Section 1 of this application. Qualifications should be appropriate to the type of research being conducted and the targeted population/s involved in the research. This might include any pertinent coursework and/or involvement in other research projects. Please add CITI training certification information.**

* 1. **List the name(s) and research qualifications of all other individuals who will be involved in this research and will have direct contact with participants and/or identifiable human participant data. Qualifications should be appropriate to the type of research being conducted and the targeted population/s involved in the research. This might include any pertinent coursework and/or involvement in other research projects. Please add CITI training certification information.**

* 1. **How will you ensure that all persons listed in Section 6 will remain informed about the protocol and their research related duties and functions (e.g.-weekly meetings, via email, phone, etc.)?**

* 1. **Explain why you do not need additional qualified staff, other than those listed in Sections 1 and 6, to conduct your study.**

1. **Characteristics of Participants**
	1. **Approximate Number of Participants to be recruited:**

* 1. **Age Range of Participants:**
	2. **If your age range includes an upper limit, justification must be provided:**

**If not, please indicate [ ]  No.**

* 1. **Does this study target a vulnerable population such as children, those with decisional impairments, or prisoners? Does the study target a specific population, gender, social, or ethnic group?**

 **[ ]  No. (Skip to 7.5)**

 **[ ] [ ]  Yes. If yes, answer 7.4.1. and 7.4.2. below.**

* + 1. **If yes, check all that are targeted/vulnerable populations and when appropriate provide a copy of the required form. \*The forms can be found on the IRB Website under Special Populations:** [**http://researchintegrity.syr.edu/human-research/forms/**](http://researchintegrity.syr.edu/human-research/forms/)

**[ ]  Children/minors - \*Requires additional form\***

 **[ ]  Decisionally impaired - \*Requires additional form\***

**[ ]  Prisoners - \* Requires additional form\***

**[ ]  Pregnant women - \*Requires additional form\***

**[ ]  Legally restricted, non-prisoner**

**[ ]  Educationally disadvantaged**

**[ ]  Economically disadvantaged**

**[ ]  Elderly/aged**

**[ ]  Other, specify:**

 \***NOTE\*: These additional forms can be found on the IRB Website (under Special Populations):**

[**http://researchintegrity.syr.edu/human-research/forms/**](http://researchintegrity.syr.edu/human-research/forms/)

* + 1. **Explain the rationale for using this particular group(s):**
	1. **List all study specific inclusion/eligibility criteria (e.g.-gender, age range, population characteristics, location, etc.):**

* 1. **List all study specific the exclusion/ineligibility criteria. The exclusion criteria must parallel the inclusion criteria:**

* 1. **Does this research involve participants likely to be vulnerable to coercion or undue influence?**

**[ ]  No. (Skip to 7.8)**

**[ ]  Yes. If yes, describe the additional protections included in the protocol to protect their rights and**

 **welfare.**

* 1. **General state of Health: ("Unknown"- *unless you will obtain health data on participants prior to beginning the study.*)**

1. **Recruitment of Participants**
	1. **Describe in detail how participants will be identified and recruited. Include in your description how you**

**will have access to a population that will allow recruitment for the number of participants required for your research. Do not merely state “Volunteers”.**

* 1. **Describe who will recruit participants.**

* 1. **Identify all applicable recruitment methods that apply: NOTE:Copies of all advertising materials including flyers, posters, ads, letters, scripts or detailed descriptions; including graphics MUST be provided with your application.** ([See SOP 036 for Recruitment/Advertising](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-036-Recruitment-Advertising.pdf)).

**[ ]  Flyers [ ]  E-mail [ ]  SU Today News Service**

**[ ]  Internet Posting[ ] [ ]  [ ]  Posters [ ]  Television**

**[ ]  Letter[ ]** **[ ]** **[ ]  Newspaper** **[ ]  Departmental Research Boards**

**[ ]  Telephone** **[ ]  Radio** **[ ]  Social Media**

**[ ]  Other (describe):**

* 1. **Will participants be compensated?**

**[ ]  No. (Skip to Section 9)**

**[ ]  Yes. If yes, answer 8.4.1. and 8.4.2. below.**

**Note: All information regarding compensation must be included in consent/assent documents.**

* + 1. **If Yes, specify the method of compensation (e.g. monetary, course credit, gift card, toy, etc.), the**

 **amount of compensation, and how the compensation will be awarded (per task, per session, etc.).**

 **8.4.2.** **Describe how compensation will be awarded if the participant withdraws after beginning the**

 **study. Compensation cannot be contingent upon full participation and must be pro-rated in a**

 **manner that recognizes the time and effort of the participant prior to withdrawal. Provide a**

 **copy of the pro-rating schedule.**

1. **Informed Consent Procedures**

**Consent is required for all human subject participants. Final copies of ALL consent/assent documents (including electronic or oral scripts) must be provided for IRB approval and date stamping. Informed consent/assent documents must be on *official SU departmental letterhead.***

**Must use NEW consent form templates as indicated for the type of consent you plan to use.**

* 1. **How many consent documents are included with this application?**
	2. **How many assent documents are included with this application?**
	3. **Is more than one consent/assent document included with this application?**

**[ ]  No. (Skip to 9.4.)**

**[ ]  Yes. If yes, follow instructions below (9.3.1 and 9.3.2).**

* + 1. **Assign form numbers to each individual document and add it to the footer of the document-e.g.**

 **Consent form 1, Consent form 2, Assent form 1, etc.**

* + 1. **Create a separate log as an appendices identifying each document-e.g. Consent form 1-**

 **parental consent, Consent form 2-adult participant consent; Assent form 1-child assent, etc.)**

* 1. **Using the guidance below, indicate the type of consent you will obtain for your study (check all that apply).**
		1. **Written Consent [ ]  (ATTACH COPY**)

Written Consent is signed documentation of consent. Written consent is required for all research conducted in-person. Researchers should retain signed copies of all consent documents for three years after the research is complete, after which they can be destroyed.

**NEW Template:** [**http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent- TemplateWritten.docx**](http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-%20%20TemplateWritten.docx)

**Provide a brief statement of what will be said when the consent process is initiated. For example, how will consent be introduced/explained to participants.**

* + 1. **Electronic Consent** [ ]  **(ATTACH SCRIPT)**

Electronic Consent is only appropriate for research when there is no direct contact with the participant; either in-person or remotely (i.e., via electronic surveys, etc.).

**NEW Template:** [**http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-Template-Electronic.docx**](http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-Template-Electronic.docx)

* + 1. **Oral Consent** [ ]  **(ATTACH SCRIPT)**

Oral Consent is a request for the waiver of documentation of signed consent (written consent). Oral consent is most conducive for research conducted in situations when the collection of signatures is not practicable. Oral consent should be used for research conducted remotely using video conferencing platforms via the Internet, for phone interviews, in sensitive situations where the collection of signature is the only thing that connects the participants to the research and places them at risk of a breach of confidentiality, and/or for distinct cultural groups/communities in which signing forms is not the norm. Oral consent may also apply if participants have a low literacy level and forms must be read to them and when research is conducted in a field and the transporting of signed documents is not practicable and presents additional risk. Oral consent should be documented in the researchers’ field notes.

**NEW Template:** [**http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-Template-Oral.docx**](http://researchintegrity.syr.edu/wp-content/uploads/2019/04/New-Consent-Template-Oral.docx)

**Provide the justification for the waiver of written consent:**

**Provide a brief statement of what will be said when the consent process is initiated. For example, how will consent be introduced/explained to participants.**

* + 1. **N/A** **[ ]  Data Analysis Only, no consent form required.**
	1. **Provide the name/s of the members of the research team listed in Sections 1 and/or 6 who will conduct the consent interview?**

* 1. **How will you ensure that prospective participants have sufficient opportunity to consider whether or not to participate in your study?**

* 1. **What steps will be taken to minimize the possibility of coercion or undue influence?**

* 1. **An ASSENT statement is required for participants who cannot legally give consent themselves. Assent statement:**

**[ ]  No (Skip to 9.9)**

**[ ] [ ]  Yes (ATTACH COPY)**

* + 1. **From whom will consent be obtained and by what means for minors or the individuals considered to be cognitively impaired in their decision making ability?** **[ ]  N/A**

* + 1. **If subjects are minors, will they still be involved in the study when they reach the age of majority (18)?**

**[ ]  No**

**[ ]  Yes. If yes, outline your plan to re-consent these participants when they reach the age of**

 **majority.**

**[ ]  N/A**

* 1. **Will non-English speaking individuals be participants in the research?**

**[ ]  No (skip to Section 10)**

**[ ] [ ]  Yes If yes, indicate how consent will be documented from non-English speaking participants?**

 [ ]  **A translated written informed consent document in a language understandable to the participant. This should be an accurate translation of the full informed consent. (ATTACH COPY)**

**Identify the name of the individual or translation service that provided the translation of the consent document.**

**List the qualifications of the individual or translation service that provided the translation of the consent document.**

 [ ]  **Orally, using a qualified translator to translate the English informed consent document**

 **to the participant, and a translated short form in a language understandable to the participant (ATTACH COPY)**

**Identify the name of the individual or translation service that will provide translation for the consent process and during the conduct of the research.**

**List the qualifications of the individual or translation service that will provide translation for the consent process and during the conduct of the research.**

 [ ]  **A signed confidentiality statement is required (link to form:** [**http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Confidentiality-Agreement-Template-SAMPLE.doc**](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/Confidentiality-Agreement-Template-SAMPLE.doc) **)**

1. **Potential Financial Conflict of Interest**

A conflict of interest exists when any investigator or personnel listed in this research protocol’s financial interests may

reasonably be affected by research, scholarship, educational or other externally funded activity. Or, when the immediate

family\* of anyone in such a role, have significant financial interests that may compromise, or have the appearance of compromising, an investigator’s professional judgment that could directly and significantly affect the design, conduct, or reporting of the research, proposed, or funded.

Federal Guidelines emphasize the importance of assuring there are no conflicts of interest in research projects that could affect the welfare of human participants. If this study involves or presents a potential conflict of interest, additional information will need to be provided to the Vice President for Research.

The following significant financial interests must be disclosed if interest is in the sponsor of the research, or the product being tested:

*Significant Financial Interest* – Anything of monetary value – aggregated for the Investigator and the Investigator’s spouse, domestic partner, and dependent children – that reasonably appears to be related to the Investigator’s institutional responsibilities including but not limited to the following:

1. Salary or other payment for services (e.g. consulting fees) that exceeded in the previous twelve months or is reasonably expected to exceed in the next twelve months $5,000
2. Equity interests (e.g. stocks, stock options or other ownership interests) that meet the following tests:
	1. exceeds $5,000 in value as determined through reference to public prices or other reasonable measures of fair market value (e.g. most recent sales price recognized by the company), or
	2. constitutes more than a 5% ownership interest in any single entity.
3. Intellectual property rights (e.g. patents, copyrights and royalties from such rights) upon receipt of income related to such rights and interests.
4. Services as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service.
5. Reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and is not reimbursed).

Syracuse University Policy on Conflict of Interest for Research Investigators:

[**http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-032-Institutional-Conflict-of-Interest.pdf**](http://researchintegrity.syr.edu/wp-content/uploads/2016/10/SOP-032-Institutional-Conflict-of-Interest.pdf) *\*Immediate family means a spouse, domestic partner or dependent children.*

* 1. **Do any of the investigators or personnel listed in this research protocol, or members of the immediate**

 **family of the investigators or personnel, have a financial interest associated with this study that requires**

 **disclosure?**

**[ ]  No (Skip to question 10.3)**

**[ ]  Yes; If yes, identify the individual(s):**

* 1. **Has this financial interest been disclosed and managed?**

**[ ]  Yes. The Office of Research Integrity and Protections will verify that a management plan is in place with the Vice President for Research.**

**[ ]  No. Action is required. Please contact the Office of Research Integrity and Protections for further information and guidance at** **orip@syr.edu** **.**

**10.3 To your knowledge, did the University, or your School/Department receive a gift or equipment donation, or promises thereof, from commercial sponsors of this research project?**

**[ ]  No**

**[ ]  Yes; If yes, identify the sponsor:**

***Final IRB approval cannot be granted until all potential conflict matters are settled. The IRB requires a recommendation from the Vice President for Research regarding disclosure to participants and management of the conflict.***

1. **Data Collection, Storage of Data and/or Confidentiality**

**Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission***.*

* 1. **PRIOR TO CODING: Simply list the individually identifiable data you will obtain, use or disclose others**

 **(e.g.-participant names, email/home addresses, phone numbers, audio/video recording, photographs, IP**

 **addresses, or any other identifiable data that can link the participant to the data being collected).**

* 1. **Describe: a) How data will be maintained (e.g., paper or electronic spreadsheet, desktop computer,**

 **laptop or other portable device); b) How you will maintain the confidentiality and data security, (e.g.,**

 **password protected computer, encrypted files, locked cabinet and office); and c) Who will have access to**

 **the data (e.g., research team, sponsors, consultants). Provide the names of the members of the research**

 **team listed in either Sections 1 or 6 of the protocol application and/or any other persons outside of the**

 **research team who will have access to the data (e.g., sponsors, consultants, etc.).**

* 1. **If you will be sharing data between members of the research team and/or with others, describe how data**

 **will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email).**

 **Please provide the names of the members of the research team listed in either Sections 1 or 6 of the**

 **protocol application or any other persons outside of the research team with whom you will share data. If**

 **transmitted via electronic networks, describe how you will secure the data while in transit. Specify**

 **whether the data you will share is identifiable.**

* 1. **If you plan to code the data linking to the participant, describe the method in which it will be coded.**

 **Coding in this instance refers to the use of pseudonyms or the assignment of ID#’s that links identifiable**

 **data to the participant. Please provide the names of the members of the research team listed in Sections 1**

 **or 6 of the protocol application that will have access to the key to the code.**

* 1. **How have Principal Investigator (P.I.) and research team members listed in Sections 1 and 6 worked**

 **together to ensure appropriate measures are in place to protect the privacy interests of the participants**

 **and the confidentiality of data collected in the research design? How will the P.I. and research team**

 **members continue to do so while the research is being conducted.**

**Privacy can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.**

* 1. **Describe what provisions are in place to protect the privacy interests of participants, where “privacy**

**interest of participants” refers to the participant’s desire to limit interventions or interactions with others and to limit access of others to their private information. The description should include: a) the location of data collection (i.e.-private location vs. public location, a private space with a closed door, the use of headphones for remote interviews conducted via the Internet etc.), b) the method of data collection (focus groups, one-on-one interviews, questionnaires/surveys, via telephone, via identified remote Internet platforms, via email/posted mail communications, etc.), and c) the type of data that will be that will be collected (i.e.-written, oral, recorded, etc.). All locations of data collection must be specified. For example, if the research will be conducted on campus, specify the location of the campus facilities/classrooms/offices. If the research will be conducted off-campus, specify the location (i.e.-home office, public spaces, community/agency spaces, etc.).**

* 1. **Will participants be recorded in any manner (i.e.-audio, video, film, still photographs, via Zoom or other**

 **internet platform)?**

 **[ ]  No. (Skip to Section 12)**

**[ ]  Yes. If yes, specify the medium you will use:**

* + 1. **Describe how and where the recordings/photographs will be stored.**

* + 1. **Describe the purpose for the recordings and how they will be used. Will they be used for data**

 **analysis only or will they be shared in presentations, at professional conferences/workshops or**

 **in any other manner?**

* + 1. **Name the persons listed in either Sections 1 or 6 of the application who will have access to the**

 **recordings.**

* + 1. **How long will the recordings be kept and what is the disposition of the recordings once the**

 **research is complete?**

**NOTE: *Specific permission for each type of recording must be sought in the consent form and should be indicated at the end of the document using checkboxes (I agree to be audio recorded \_Yes \_No; I agree to be videotaped \_Yes \_No, etc.)***

1. **Risk to Participants**
	1. **Describe in detail any possible physical, psychological, social, political, legal, economic, or other risks to**

 **the participants, either immediate or long range. Risk may be minimal but never totally absent. Do not**

 **say “No Risk”.**

* 1. **Describe what procedures will be used to minimize each risk you have stated above. Also, include in**

 **your description the availability of medical or psychological resources that participants might require as**

 **a consequence of the research, if applicable. If participants need to be debriefed at the end of the study, a**

 **copy of the debriefing statement must be attached.**

* 1. **Does this research involve more than minimal risks to participants?**

**[ ]  No. (Skip to Section 13)**

**[ ]  Yes. If yes, please provide plan for monitoring the data collected to ensure the safety of participants. (Your data safety monitoring plan must include the following: Description of who will monitor the data, what data will be monitored, how frequently will it be monitored, what analysis will be performed on the data, what decision rules (e.g. stopping rules) will be considered, if unexpected harms will be detected promptly, if an increased frequency or severity of unexpected harms will be detected promptly, if the protocol will be stopped once harms are proven to outweigh benefits.).**

1. **Benefits**
	1. **Describe any benefits to the** **participants in general. Incentives, such as course credit, payment, gift cards, entry into a raffle, etc. are considered an inducement to participate in the research and should NOT be described as a benefit.**

* 1. **Society at large****.**

* 1. **Explain how the benefits outweigh the risks involved.**

**A number will be assigned to your protocol. Please refer to it whenever calling or writing for information.**

* **All supporting documentation including list of references, consent and/or assent form(s), survey instruments, interview questions, recruitment materials, letters of support, IRB approvals from other institutions, etc. must be included with the application.**
* **Applications can be submitted as an attachment to an email sent to** **orip@syr.edu****.**
* **All correspondence will be directed to the Principal Investigator listed in the protocol. Other persons listed in Section 1 will be cc’d only on email correspondence.**

**Office of Research Integrity and Protections**

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**Syracuse, NY 13244**

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