Human Subjects Research Application

Instructions
Please complete this form for all new human subjects research. All the questions, including the bullet-point questions, must be addressed in order to provide the Institutional Review Board with the necessary information to review your proposed research study. IRB approval **must** be obtained prior to beginning any human subjects research, including recruitment of study participants.

Submission
Submit this form and all required documents listed in section nine and any other section as needed **here**. Researchers are also required to take the Collaborative Institutional Training Initiative (CITI) online training through Pratt Institute's subscription. Completion of CITI training is a required step of PI certification and initiation of grant award. **If a member of the team completed the CITI at another institution, then please include a copy of their certificate in the appendix of this application.**

1 General Information

Protocol Title

Date

Research is being conducted for:
○ Research project
○ Individual or Group Student Assignment/ Thesis/DR/Capstone
○ Other

Which category of approval are you requesting?
○ Exempt to the Office of Human Research Protections
○ Expedited review
○ Full IRB committee review

If you are requesting an exemption or an expedited review, please use the "Reason for Exempt/Expedited Review Request" below to provide a rationale for the request. Please refer to the specific categories of exemptions and expedited reviews outlined by the U.S. government. The descriptions of exempt categories appear on the Pratt IRB website, and the descriptions of expedited categories can be found on the Office for Human Research Protections website.

Reason for exempt/expedited review request:

Please use this space to provide a rationale for why this research study should be considered exempt or receive an expedited review. Selection of category is subject to review.

Why does your study fall under exemption or expedited review?

150 word limit

2 Principal Investigator

CITI Certification is required. Delay in completion of CITI training can delay application review and approval.

Name | School/Department | Email | ○ Faculty ○ Staff ○ Student | CITI Certified? ○ Yes ○ No ○ Pending

3 Co-Investigator

CITI Certification is required. If more space is required, please add on a separate page.

Name | School/Department | Email | ○ Faculty ○ Staff ○ Student | CITI Certified? ○ Yes ○ No ○ Pending

4 Faculty Advisor

CITI Certification is required. If more space is required, please add on a separate page.

Name | Rank | Email | CITI Certified? ○ Yes ○ No ○ Pending

5 Research Staff

Name _____ **Currently CITI Certified?** ○ Yes ○ No ○ Pending

Name _____ **Currently CITI Certified?** ○ Yes ○ No ○ Pending

Name _____ **Currently CITI Certified?** ○ Yes ○ No ○ Pending

6 Collaborators

If you will be conducting this study in collaboration with non-Pratt investigators or in non-Pratt facilities, please complete this section.
Only one institution's IRB should review and approve research studies, not multiple institutions.
CITI Certification (or acceptable alternative training) is required. Delay in completion of CITI training can delay application review and approval.

Name	Affiliated Institution	IRB Approval	CITI/RCR Certified
		○ Yes ○ No ○ Pending	○ Yes ○ No ○ Pending
		○ Yes ○ No ○ Pending	○ Yes ○ No ○ Pending

7 Funding Sources

If the study is funded, please provide a copy of the full grant, proposal and/or award. ☐ N/A

☐ External Federal Fund **Agency** _____

☐ External Non-Federal Fund **Source** _____

8 Introduction

Please provide a brief summary of the following:

Provide relevant background information on your study:

Why do you need to utilize human subjects to meet your study objectives?

What are the aims of your study?

How will your study develop or contribute to generalizable knowledge?

Duration

From: Date of IRB Approval

To:

Study Site(s):

Generalizable Knowledge: Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), or inform policy. For conclusions to be generalizable, they must actually be disseminated for research purposes (or be part of a program of investigation that will be disseminated).

A useful definition of dissemination is that the material will be shared beyond Pratt Institute. Obvious examples of dissemination are publication in a scholarly journal, presentation at a professional conference, sharing results with a newspaper reporter, or presentation to an outside client for a capstone course.

Thesis or dissertation projects conducted to meet the requirement of a graduate degree are usually considered generalizable, and require IRB review and approval.

9 Study Population

Total Number of Subjects

Age Range

Characteristics of Study Population

Please check all that apply. These categories refer to your **targeted sample**, not individuals who may coincidentally become part of your study. Some protected populations may require an addendum form to be completed and attached to the protocol documents, as additional considerations are required.

☐ Senior (≥ 65)
☐ Children (< 18)
Must complete and attach **consent form for youth**
☐ Pratt Students/Staff
If yes, refer to survey protocols in Office for Institutional Research
☐ Prisoners
☐ Non-English Speaking
☐ Ethnic Minorities
☐ Individuals with Impaired Decision-Making Capacity
☐ Pregnant Women
Must complete and attach **consent form for adults**
☐ Other:

10 Selection of Subjects

Discuss the following topics below.

Describe the inclusion/exclusion criteria.
Why are you using certain subjects, and/or excluding others?

11 Recruitment Tools

Include sample recruitment tools (e-mails, phone/in-person scripts, Facebook posts, etc) as a separate document when e-mailing your application to IRB@pratt.edu.

12 Recruitment Process

Discuss the following topics below.

How will potential subjects be identified as candidates for this study?

What is the method for initial contact, and why?
Please list each recruitment tactic (email, text, social media, in person soliciting, etc).

13 Informed Consent Procedures

Include copies for all selections below as separate documents when e-mailing your application to IRB@pratt.edu. **NOTE:** If you are requesting a waiver of documentation of informed consent, you still need to provide the informed consent language that will be given to, and discussed with, human subjects as a separate e-mailed document. Please see the informed consent template here.

☐ **Written Informed Consent will be obtained** use appropriate form
☐ **Oral Informed Consent will be obtained** use appropriate form

14 Informed Consent/Assent Process

Discuss the following topics below.

What consent/assent procedures will be followed?

How will consent/assent be sought and obtained?

Will researchers go over the consent language and answer any questions from subjects? ○ Yes ○ No

If children are subjects, how will their assent be obtained, and the permission of their parent(s)/guardian(s)?

15 Surveys or Questionnaires (e.g. online surveys, mailed surveys, personal or medical history)

Provide a sample list of survey, questionnaire or interview questions.

Interviews ☐ In Person ☐ Phone ☐ Video ☐ Other: _____ Recorded: ☐ Audio ☐ Video

Focus Groups ☐ In Person ☐ Phone ☐ Video ☐ Other: _____ Recorded: ☐ Audio ☐ Video

16 Research Procedures

Discuss the following topics below.

What study procedures should a subject expect during this study?

How many times will subjects be engaged in research? How long is each research session (approx.)?

Which procedures are experimental, and/or which procedures are routine?

If deception is used, how will subjects be deceived and/or debriefed?

18 Compensation

Compensation can only be offered if allowed by grant guidelines. The office of research and strategic partnerships does not offer or administer compensation for IRB participants outside of grant funded research. If compensation is offered, connect with ORSP to discuss compensation method.

Amount/value of total compensation?

19 Risks

Discuss the following topics below.

Describe any potential risks and/or discomforts (physical, emotional, psychological, social, legal, or other).
All potential risks should be mentioned here, even minor risks.

NOTE: Please do not say that there are no risks. There are always risks involved with human subjects research, even if they are minimal. Also, be sure to include all risks noted here in the Risks section of the consent/assent/permission document(s).

Assess the likelihood, seriousness, and potential reversibility of each risk mentioned above. Describe procedures for protecting against these risks, and assess their likely effectiveness.

Describe any alternative procedures, including the choice not to participate.

20 Benefits

Discuss the following topics below.

Describe any potential benefits to subjects and/or to society in general that may be expected from this research.

Describe the importance of knowledge that may reasonably be expected to result from this research.

If no direct benefits to subjects are anticipated, please state so.

21 Research Data

Will personally identifiable information be recorded? ☐ Yes ☐ No If yes, please check all that apply:

☐ Name ☐ Email Address ☐ Street Address, city, five-digit zip code, county ☐ Date of Birth ☐ SSN ☐ Internet IP Address

22 Sharing Research Data

Will you be sharing any research data with anyone outside of Pratt? ☐ Yes ☐ No If yes, please describe:

Will the research data be assigned a unique ID? ☐ Yes ☐ No

If yes, will a link between the unique ID and person's identifiable information be retained? ☐ Yes ☐ No If yes, for how long and how:

23 Privacy and Confidentiality

Discuss the following topics below.

To what extent will subjects be identifiable? Will subjects and their information be anonymous or confidential (see definition)? If some will be anonymous, and some will be confidential, provide an explanation.

Anonymous: Individuals cannot be identified by anyone, including the research team

Confidential: Individuals can be identified directly or through identifiers, but the research team promises not to divulge that information, and takes steps to protect their information

What procedures are in place to protect subjects' privacy and maintain their confidentiality? Include procedures for data collection, storage, and future use of data.

Describe whether codes will substitute names and/or identifiable records.

If there is a focus group setting, how will researchers try to protect the privacy of subjects from having their information shared outside of the research setting? What will participants be told as far as not sharing information heard during the focus group?

Who will have access to the research data?

How will the database/system storing the data be protected? Will it be password-protected, or encrypted for online data collection?

If audio and/or video will be recorded, please include why this needs to be recorded, and how this data will be stored.

How long will records and other materials be maintained? By whom?

When will the records be destroyed? This should be no sooner than three years after the completion of the study, possibly longer depending on the funding source.

If research is being conducted outside of the United States, who will be verifying that data will be collected and protected within the country's data protection laws (for example, the EU's General Data Protection Regulation (GDPR))? Is there a collaborator who will be ensuring this compliance?

24 Further Information

Is there other information that would help the IRB better understand your proposal?

25a Principal Investigator's Signature (Faculty/Staff PIs only)

By submitting this form, I acknowledge and accept my responsibility for protecting the rights and welfare of human research participants as discussed in the Common Rule (45 CFR 46) and Belmont Report. I certify that I will comply with all applicable regulations and directions of the Institutional Review Board, which may include:

1. Conducting this research study as approved by the IRB
2. Submitting any changes to the protocol to the IRB for review and approval prior to implementation
3. Monitoring and supervising investigators and research staff in the conduct of the research
4. Maintaining accurate, current and complete records of all study materials including all IRB correspondence
5. Complying with all local, state, federal, and (if applicable) foreign laws, as well as Pratt's institutional policies regarding the conduct of research with human subjects

Principal Investigator's Name

25b Principal Investigator's Signature (Student PIs/Faculty Advisors only)

Student Principal Investigator (Student PI)

By submitting this form, I acknowledge and accept my responsibility for protecting the rights and welfare of human research participants as discussed in the Common Rule (45 CFR 46) and Belmont Report. I certify that I will comply with all applicable regulations and directions of the Institutional Review Board, which may include:

1. Conducting this research study as approved by the IRB
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4. Maintaining accurate, current and complete records of all study materials including all IRB correspondence
5. Complying with all local, state, federal, and (if applicable) foreign laws, as well as Pratt's institutional policies regarding the conduct of research with human subjects

Principal Investigator's Name

Faculty Advisor

By typing my name, I acknowledge and accept my responsibility as the Faculty Advisor to the Student Principal Investigator:

- I am a member of Pratt Institute's faculty.
- I have read and understand the oversight and guidance expected of me, as noted on the Student Project Guidelines website.
- I understand that I am responsible for the overall management of this research study in conjunction with the student PI, as approved by the IRB.

Faculty Advisor's Name