# Penn State Mark

# HRP-509 Study Team Member Qualifications

Template Version 11/2/2021

## Instructions

**DO NOT ENABLE TRACK CHANGES WHEN MODIFYING THIS DOCUMENT.** Effective 09/01/2021, the PSU HRPP no longer requires completion of this form for all study team members. Examples of when this form may be required include but are not limited to:

* Those study team members who will perform research procedures requiring special expertise or credentials above and beyond what is typically expected in the course of research conduct and/or clinical care;
* Individuals conducting biomedical procedures in a non-clinical setting;
* Student and faculty advisor for those projects that designate the student as Principal Investigator;
* Individuals participating in the research via execution of an Individual Investigator Agreement.

Note, all study team members will still need to be listed in Question #1 on the Study Team Member page of CATS. The Principal Investigator (PI) should be listed on the Basic Information page of CATS.

Please note: If you will be listing more than four (4) Study Team Members, duplicate the questions below and extend the template to provide the information for each additional member. Likewise, if you will be listing fewer than four (4) Study Team Members, remove the additional un-needed questions below.

## Instructions for Individuals Using Visual Assistive Technology (e.g., JAWS)

* There are form fields and instructional text that are outside of the form fields, so the best way to navigate through this document is to use the down arrow key.
* To navigate through the checkbox options, after hearing “select all that apply,” down arrow once for the list of options. When reaching an individual checkbox, use the Home button to move to the front of the line and right arrow once to hear the properties of the form field. Use the spacebar to check or uncheck the box. You may need to down arrow and then up arrow again for confirmation on whether the checkbox is checked.
* This document includes entry fields for the PI and up to four study team members. If you are using visual assistive technology (i.e., a screen reader) and more than four team members need to be added, email [ORP@psu.edu](mailto:ORP@psu.edu) to request a new version of this document. Do not complete this document until the new version is provided. If you are not using a screen reader, you may simply copy and paste any additional fields needed.

## Principal Investigator

### Full Name (First Name followed by Last Name).

Enter full name of PI here.

### Provide the individual’s responsibilities for this research study (e.g., recruitment, protocol development, data analysis/management, performing tests/procedures). Check all boxes that apply.

Involved in consent

Recruitment activities, including identification of potential subjects/records

Protocol development

Data analysis/management at any time in the course of the study

IRB submissions

Data collection, e.g., survey, interviews, focus group, at study visits

Collection of biological specimens by non-invasive means, e.g., urine without a Foley catheter, hair/nail clippings, uncannulated saliva, mucosal and skin cells collected by buccal scrapping or swab, etc.

Research laboratory testing

Procedures/tests requiring clinical degree, certification, licensure, or demonstrated competency such as ECG, EEG, physical exams/assessments, venipuncture, etc.

Procedures/tests not requiring clinical degree, certification, or licensure

Review/assessment (severity, attribution, etc.) of data collected as part of the study, e.g., adverse event data, ECGs, laboratory test results, radiographic scans, etc. (check only for appropriately qualified study team members). Note: Final review must be completed by Principal Investigator.

Oversight of student investigator

Other responsibilities: If other, please specify:

Specify PI’s other responsibilities here.

### Describe the individual’s qualifications related to this individual’s responsibilities (e.g., years of education, certification, license, degrees, etc.).

Describe PI’s qualifications here.

### Describe the individual’s research experience or training related to this individual’s responsibilities.

Describe PI’s research experience here.

## Study Team Member #1

### Full Name (First Name followed by Last Name).

Enter full name of team member 1 here.

### Provide the individual’s responsibilities for this research study (e.g., recruitment, protocol development, data analysis/management, performing tests/procedures). Check all boxes that apply.

Recruitment activities, including identification of potential subjects/records

Protocol development

Data analysis/management at any time in the course of the study

IRB submissions

Data collection, e.g., survey, interviews, focus group, at study visits

Collection of biological specimens by non-invasive means, e.g., urine without a Foley catheter, hair/nail clippings, uncannulated saliva, mucosal and skin cells collected by buccal scrapping or swab, etc.

Research laboratory testing

Procedures/tests requiring clinical degree, certification, licensure, or demonstrated competency such as ECG, EEG, physical exams/assessments, venipuncture, etc.

Procedures/tests not requiring clinical degree, certification, or licensure

Review/assessment (severity, attribution, etc.) of data collected as part of the study, e.g., adverse event data, ECGs, laboratory test results, radiographic scans, etc. (check only for appropriately qualified study team members). Note: Final review must be completed by Principal Investigator.

Oversight of student investigator

Other responsibilities: If other, please specify:

Specify other responsibilities for team member 1 here.

### Describe the individual’s qualifications related to this individual’s responsibilities (e.g., years of education, certification, license, degrees, etc.).

Describe qualifications for team member 1 here.

### Describe the individual’s research experience or training related to this individual’s responsibilities.

Describe research experience for team member 1 here.

## Study Team Member #2

### Full Name (First Name followed by Last Name).

Enter full name of team member 2 here.

### Provide the individual’s responsibilities for this research study (e.g., recruitment, protocol development, data analysis/management, performing tests/procedures). Check all boxes that apply.

Recruitment activities, including identification of potential subjects/records

Protocol development

Data analysis/management at any time in the course of the study

IRB submissions

Data collection, e.g., survey, interviews, focus group, at study visits

Collection of biological specimens by non-invasive means, e.g., urine without a Foley catheter, hair/nail clippings, uncannulated saliva, mucosal and skin cells collected by buccal scrapping or swab, etc.

Research laboratory testing

Procedures/tests requiring clinical degree, certification, licensure, or demonstrated competency such as ECG, EEG, physical exams/assessments, venipuncture, etc.

Procedures/tests not requiring clinical degree, certification, or licensure

Review/assessment (severity, attribution, etc.) of data collected as part of the study, e.g., adverse event data, ECGs, laboratory test results, radiographic scans, etc. (check only for appropriately qualified study team members). Note: Final review must be completed by Principal Investigator.

Oversight of student investigator

Other responsibilities: If other, please specify:

Specify other responsibilities for team member 2 here.

### Describe the individual’s qualifications related to this individual’s responsibilities (e.g., years of education, certification, license, degrees, etc.).

Describe qualifications for team member 2 here.

### Describe the individual’s research experience or training related to this individual’s responsibilities.

Describe research experience for team member 2 here.

## Study Team Member #3

### Full Name (First Name followed by Last Name).

Enter full name of team member 3 here.

### Provide the individual’s responsibilities for this research study (e.g., recruitment, protocol development, data analysis/management, performing tests/procedures). Check all boxes that apply.

Recruitment activities, including identification of potential subjects/records

Protocol development

Data analysis/management at any time in the course of the study

IRB submissions

Data collection, e.g., survey, interviews, focus group, at study visits

Collection of biological specimens by non-invasive means, e.g., urine without a Foley catheter, hair/nail clippings, uncannulated saliva, mucosal and skin cells collected by buccal scrapping or swab, etc.

Research laboratory testing

Procedures/tests requiring clinical degree, certification, licensure, or demonstrated competency such as ECG, EEG, physical exams/assessments, venipuncture, etc.

Procedures/tests not requiring clinical degree, certification, or licensure

Review/assessment (severity, attribution, etc.) of data collected as part of the study, e.g., adverse event data, ECGs, laboratory test results, radiographic scans, etc. (check only for appropriately qualified study team members). Note: Final review must be completed by Principal Investigator.

Oversight of student investigator

Other responsibilities: If other, please specify:

Specify other responsibilities for team member 3 here.

### Describe the individual’s qualifications related to this individual’s responsibilities (e.g., years of education, certification, license, degrees, etc.).

Describe qualifications for team member 3 here.

### Describe the individual’s research experience or training related to this individual’s responsibilities.

Describe research experience for team member 3 here.

## Study Team Member #4

### Full Name (First Name followed by Last Name).

Enter full name of team member 4 here.

### Provide the individual’s responsibilities for this research study (e.g., recruitment, protocol development, data analysis/management, performing tests/procedures). Check all boxes that apply.

Recruitment activities, including identification of potential subjects/records

Protocol development

Data analysis/management at any time in the course of the study

IRB submissions

Data collection, e.g., survey, interviews, focus group, at study visits

Collection of biological specimens by non-invasive means, e.g., urine without a Foley catheter, hair/nail clippings, uncannulated saliva, mucosal and skin cells collected by buccal scrapping or swab, etc.

Research laboratory testing

Procedures/tests requiring clinical degree, certification, licensure, or demonstrated competency such as ECG, EEG, physical exams/assessments, venipuncture, etc.

Procedures/tests not requiring clinical degree, certification, or licensure

Review/assessment (severity, attribution, etc.) of data collected as part of the study, e.g., adverse event data, ECGs, laboratory test results, radiographic scans, etc. (check only for appropriately qualified study team members). Note: Final review must be completed by Principal Investigator.

Oversight of student investigator

Other responsibilities: If other, please specify:

Specify other responsibilities for team member 4 here.

### Describe the individual’s qualifications related to this individual’s responsibilities (e.g. years of education, certification, license, degrees, etc.)

Describe qualifications for team member 4 here.

### Describe the individual’s research experience or training related to this individual’s responsibilities.

Describe research experience for team member 4 here.

At the completion of this document, please attach document to Question #2 on the Study Team Member page in CATS IRB.