HRP-594 Protocol for
Not Human Subjects Research Determination

Protocol Title:

Provide the full title of the study as listed in item 1 on the basic information page in CATS IRB (http://irb.psu.edu).

Evaluation of the Family Advocacy Program's Outreach Campaigns through Feedback Sessions with FAP Staff

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Version Date:

Provide the version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

02/08/2023

Important Instructions for using this protocol template:

1. All human subject research must be reviewed by the IRB prior to initiation. If you have questions about whether an activity is human research, contact the appropriate IRB office for guidance.
2. To request a written determination that an activity is not human research, add this completed protocol template to your study in CATS IRB (http://irb.psu.edu) in the "Basic Information" page. Links to Penn State's protocol templates are available in the same location where they are uploaded and their use is required.
3. The IRB uses "HRP-310 – WORKSHEET - Human Research Determination" to determine whether an activity is research and if so, uses "HRP-311 – WORKSHEET - Engagement Determination" to determine if the research engages PSU. These worksheets can be found in the IRB Library in CATS IRB (http://irb.psu.edu). You may use these worksheets to guide the information you provide in your description below.
4. This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to make a not human research determination.
5. Information should be written in lay language. Do **NOT** copy and paste grant proposal information into the protocol.

If you need help…

All locations:
Human Research Protection Program
Office for Research Protections
101 Technology Center
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu
https://www.research.psu.edu/irb

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1.0 Review of select activities that generally do not meet the definition of human subjects research

Review the select activities below. These activities generally do not meet the definition of research. **If you are conducting any of these activities, you do not need to submit anything to the IRB unless you need a written determination that an activity is not human subjects research.**

1.1 Program Evaluation/Quality Improvement or Quality Assurance Activities

The activities to be conducted are designed specifically to assess or improve performance within a particular classroom, clinical setting, business, or department. The intention of the project and outcome are not intended to contribute to generalizable knowledge and are designed specifically to be used within the environment in which the activities are conducted. See https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/ for OHRP information regarding such activities.

1.2 Case Reports

Clinical

Generally, the activities to be conducted consist of case reports of 3 or fewer patients (persons) that describe a particular treatment, presentation or outcome. Most importantly, nothing was done with the patient(s) with prior intent of conducting research.

Other

Report about experiences or observations associated with three or less individuals.

1.3 Student Course Assignments/Projects

The activities to be conducted are done so with the intent to satisfy the curriculum requirements of a course, are not intended for use outside of the classroom, and are typically concluded at the end of the relevant semester. The activities are not intended to create new knowledge or contribute to generalizable knowledge.

Some student course assignments and projects may meet the definition of human participant research. For example, a student may be conducting the activities with the intent to conduct further investigation or analyses in order to contribute to generalizable knowledge. If this is the case, IRB review and approval or determination is required prior to the conduct of such activities.

Studies intended to result in a dissertation or thesis are considered to be research and do not fall under this description of student course assignments/projects.

1.4 The following have been deemed to not to be research in the 2018 Common Rule:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.

- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

2.0 Determining if activities meet the definition of human subjects research

If the activities to be carried out do not fall into one of the conditions listed in Section 1 above, review this section carefully to determine if your proposed activities meet the definition of human subjects research.

IRB review or exemption determination is required only if the proposed activities meet the federal definitions of research AND human subject. If, after reviewing the information in this section, the proposed activities meet the federal definitions of research **AND** human subject, then:

- This template should not be used
- Access CATS IRB (http://irb.psu.edu)
- Navigate to the Library
- Choose an appropriate protocol template to complete and follow the instructions in the template

If, after reviewing the information in this section, the proposed activities do ***not*** meet the federal definition of either research **OR** human subject, then:

- You are not required to submit anything, unless you need a written determination that an activity is not human research to meet the requirements of a sponsor or other entity.
- Contact the HRPP if you need assistance – see contact information above on first page.

2.1 Definitions of Research

2.1.1 DHHS Definition of Research

According to The Department of Health and Human Services (DHHS) regulations, research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

- If **ALL** of the boxes below are checked "YES" the activities meet the DHHS definition of research.

- If **ANY** of the boxes below are checked "NO" the activities do not meet the DHHS definition of research.

☒Yes ☐No	Is the activity an investigation? (*Investigation*: a searching inquiry for ascertaining facts; detailed or careful examination)
☒Yes ☐ No	Is the investigation systematic? (*Systematic*: having or involving a system, method, or plan)?
☒Yes ☐ No	Is the systematic investigation designed to develop or contribute to knowledge? (*Designed*: done with purpose and intent. *Develop*: to elaborate or expand in detail. *Contribute*: to be an important factor in; help to cause. *Knowledge*: truths, facts, information.)
☒Yes ☐No	Is the knowledge generalizable? (*Generalizable*: universally applicable)

2.1.2 FDA Definition of Research

According to the Food and Drug Administration (FDA) regulations, a clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administraiton under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be sumitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

- If **Box 1 AND one or more of the second, third or fourth boxes** below are checked "YES", the activities meet the FDA definition of clinical investigation.

1	☐Yes ☒No	Is the activity an experiment that involves a test article (drug, device or biologic) and one or more human subjects? AND
2	☐Yes ☒ No	Must the activity meet the requirements for prior submission to the FDA under section 505(i) of the Federal Food, Drug and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice? OR
3	☐Yes ☒ No	Must the activity meet the requirements for prior submission to the FDA under section 520(g) of the Federal Food, Drug and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device? OR
4	☐Yes ☒No	Are the results of this activity intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit?

2.2 Definitions of Human Subject

2.2.1 DHHS Definition of Human Subject (Updated with 2018 Common Rule revisions)

According to DHHS regulations, human subject is defined as "a living individual, about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."

- If **ALL** of the boxes below are checked "YES" the activity involves human subjects.

- If **BOXES 1 and 2** below are checked "YES" the activity involves human subjects.

- If **BOXES 1, 3, and 4** below are checked "YES" the activity involves human subjects.

1	☐Yes ☐No	The investigator is gathering information or biospecimens about *living* individuals.
2	☐Yes ☐No	The investigator will use, study, or analyze information or biospecimens obtained through either of the following mechanisms: • Physical procedures or manipulations of those individuals or their environment for research purposes ("intervention"). • Communication or interpersonal contact with the individuals ("interaction").
3	☐Yes ☐No	The investigator will gather data that is either: • Data about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e., "private information").

		• Data individuals have provided for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e., "Private information").
4	☐ Yes ☐ No	Individuals' identities can be readily ascertained or associated with the information by the investigator (i.e., "identifiable information") and/or with the biospecimens by the investigator (i.e., "identifiable biospecimen").

2.2.2 FDA Definition of Human Subject

According to FDA regulations, human subject is defined as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control."

- If **EITHER** is checked "YES" the activities meet the FDA definition of human subject.

☐ Yes ☐ No	An individual will be a recipient of any test article (i.e., drug, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act) or as a control.
☐ Yes ☐ No	An individual on whose specimen, whether identifiable or not, an investigational medical device will be used.

2.2.3 Coded Data and/or Biospecimens

According to DHHS guidance, coded means that (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens. DHHS considers coded data to be identifiable.

☐ Yes ☐ No	The provider of the data and/or biospecimens will remove the code before sending the data and/or biospecimens to the researcher (therefore no link exists between data received and the identifiable information); **OR**
☐ Yes ☐ No	The holder of the key and investigator enter into an agreement prohibiting the release of the key to the investigator under any circumstances, until the individuals are deceased; **OR**
☐ Yes ☐ No	The investigator has documentation of written policies and operating procedures from a repository or data management center that prohibits the release of the key to the investigators under any circumstances, until the individuals are deceased; **OR**
☐ Yes ☐ No	There are other legal requirements prohibiting the release of the key to the investigator, until the individuals are deceased.

Once you have reviewed the definition questions in Sections 2.1 and 2.2, please re-review the instructional text provided in Section 2.0 to determine if a submission to the HRPP is necessary before proceeding with the remainder of this form.

3.0 Description of Study Activities

Provide a brief description of the activities to be conducted by answering the questions below. The information should supplement and not contradict the answers provided in section 2 above.

3.1 Purpose

Describe the purpose, specific aims or objectives of the study or activities to be conducted. If activities do not meet the definition of research according to sections 1 and/or 2.1 above, please clearly outline the purpose of the activities.

The purpose of this project is to conduct program evaluation for the Department of Defense (DoD) by evaluating the Family Advocacy Program's (FAP) Domestic Violence Awareness (DVA) and Child Abuse Prevention (CAP) campaigns. This project will evaluate the implementation of the campaigns by conducting program improvement feedback sessions with FAP staff.

3.2 Procedures

Describe the procedures used to obtain information (e.g., communication or interpersonal contact with individuals, manipulation of individual's environment, or physical procedures).

Clearinghouse staff will conduct 60-minute online feedback sessions with FAP staff involved in the implementation of the campaigns with the purpose of program improvement. Feedback sessions will occur online using Zoom or Microsoft Teams. These sessions will be recorded to aid in the coding process.

3.3 Data and/or specimens

Describe the data and/or biospecimens that will be gathered or used about individuals without interaction or intervention with subjects including any names and sources of datasets, links to provider websites, etc.

N/A

3.3.1 Data Collection and Analysis

Describe the data and/or biospecimens that will be collected or used and how and by whom the data and/or biospecimens will be analyzed.

Information collected during the feedback sessions will include a description of campaign activities, strengths and challenges experienced with implementation, and lessons learned.

3.3.2 Method of Collection

Describe how the data and/or biospecimens were originally gathered from individuals (e.g., obtained as part of another IRB approved protocol at this institution/another institution or as a part of routine clinical practice).

N/A

3.3.3 Identifiability of Data and/or Biospecimens

Indicate whether the collected data and/or biospecimens can be directly or indirectly associated/link with individual identities by you, or by others if you are receiving coded data.

N/A