Evaluation of the Research to Policy Collaboration Model

NCT03671434

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1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

This mixed-methods study will evaluate the impact of the Research-to-Policy Collaboration (RPC) model on the use of scientific research in federal policymaking. Human Subjects research will be carried out to assess the RPC effects on participating researchers who are trained and coached by the model to respond to current policy opportunities and translate scientific research to public officials.

A survey will be used to assess researchers reported policy competencies and motivation for conducting policy-relevant research. This study will also examine whether these outcomes vary as a function of collaborative experiences with public officials and hypothesizes that more productive and satisfying collaborations will improve researchers' ongoing policy engagement and increases in policy-relevant research. These surveys will be supplemented by qualitative interviews to discuss researchers' experiences translating research and working with public officials. This includes discussion of (1) barriers and facilitators of participating in researcher-public official partnerships, (2) the types of interactions between researchers and public officials facilitated by the RPC, and (3) how the RPC affects researchers' assumptions about and interactions with public officials.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study. Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

This study will measure changes in participants' policy knowledge and skills, policy engagement, and the extent to which research activities are informed by public officials' needs.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

Experiences collaborating with public official will be assessed among participants in the RPC intervention (experimental) condition. Aspects of these collaboration experiences that will be measured include satisfaction, perceived value and impact, and trust and respect.

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

The persistent gap between research and policymaking is a multifaceted challenge borne in part out of limited interaction between researchers and public officials. Yet, interaction without adequate preparation for policy engagement (i.e., training and supports) may thwart researchers' efforts to support public officials' use of empirical evidence. Although varied policy training approaches for researchers exist, little empirical work has explored their effectiveness in improving policy knowledge and skills or supporting researchers' enduring policy engagement. Furthermore, scant research has considered the extent to which facilitating policy experiences among researchers may shift researchers' perspectives on how research evidence is produced, communicated, and disseminated.

2.2 Previous Data

Describe any relevant preliminary data.

N/A

2.3 Study Rationale

Provide the scientific rationale for the research.

The RPC model is based on a growing literature around the use of scientific evidence in policymaking, which emphasizes the need to cultivate positive interactions and collaborations between researchers and public officials. A prominent facilitator for public officials' use of research is the translation of relevant scientific findings in the context of trusting relationships with researchers. Public officials often turn to "experts" when addressing issues that are part of a political agenda. Therefore, connecting researchers to current policy opportunities and priorities in ways that engender trusting relationships aligns with known facilitators of public officials' use of research evidence. However, such connections must be made tactfully, and enhancing researchers' policy competencies can strengthen the success of their policy outreach.

The success of connections between public officials and researchers may be improved by strengthening researchers' policy knowledge and skills. Much more research is needed to evaluate training approaches and enhance their effectiveness. Specifically, research is needed that evaluates the impact of training approaches by longitudinally tracking researchers' reported confidence and skills, participation in policy efforts, and interactions with public officials. Efforts are also needed to explore the extent to which researchers' policy competencies translate into public officials' increased utilization of research findings.

In addition to supporting public officials' use of research evidence, researcher-public official partnerships may have the potential to improve the usefulness of research activities for public officials. Few supports are in place to help researchers proactively consider policy and practice implications prior to study development, even though research that is responsive to public officials' needs may be more likely to be used by public officials in the future. Policy-informed research adjusts to prevailing policy priorities, shaping the questions that are investigated and how results are interpreted and communicated. A cultural shift toward more policy-informed research is needed, including the way it is produced, interpreted, and communicated—and opportunities for researcher-public official collaboration may support this shift. Some studies have shown that co-creation of research knowledge can strengthen the utility of findings for policymaking and implementation. However, the majority of partnerships applying research in a decision-making context focus on producing generating timely and actionable research, whereas there is a need to complement this knowledge base by investigating subtler partnerships in which research is distilled for co-interpretation of policy implications.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.). Indicate specifically whether you will include any of the following vulnerable populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.) Review the corresponding checklists to ensure that you have provided the necessary information.

- **Adults unable to consent**
  - Review "CHECKLIST: Cognitively Impaired Adults (HRP-417)" to ensure that you have provided sufficient information. HRP-417 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Individuals who are not yet adults (infants, children, teenagers)**

- If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research ("children"), review the "CHECKLIST: Children (HRP-416)" to ensure that you have provided sufficient information. HRP-416 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

- **Pregnant women**
  - Review "CHECKLIST: Pregnant Women (HRP-412)" to ensure that you have provided sufficient information. HRP-412 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Prisoners**
  - Review "CHECKLIST: Prisoners (HRP-415)" to ensure that you have provided sufficient information. HRP-415 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).
- **Neonates of uncertain viability or non-viable neonates**
  - Review "CHECKLIST: Neonates (HRP-413)" or "CHECKLIST: Neonates of Uncertain Viability (HRP-414)" to ensure that you have provide sufficient information. HRP-413 and HRP-414 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3.1 Inclusion Criteria

List the criteria that define who will be included in your study.

Researchers who voluntarily enlist in the RPC will be asked to participate in the trial. All participants will be over 18 years old.

3.2 Exclusion Criteria

List the criteria that define who will be excluded in your study.

None.

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

Researchers who choose to stop participating in the study or the RPC itself. All study participants can choose to opt-out of the study at any time.

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

No follow-up will be conducted with withdrawn subjects.

4.0 Recruitment Methods

4.1 Identification of subjects

Describe the methods that will be used to identify potential subjects or the source of the subjects. If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.
StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, please indicate this in section 4.1 along with any other methods for identifying subjects. Note that information provided in this protocol should be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Hershey submissions using Enterprise Information Management (EIM) for recruitment, attach your EIM Design Specification form on the Basic Information page in CATS IRB (http://irb.psu.edu). See HRP-103 Investigator Manual, "What is appropriate for study recruitment?" for additional information.

Researchers voluntarily enlist to participate in the Research-to-Policy Collaboration (RPC), which recruits researchers from professional societies, committees or work groups, listservs, word-of-mouth, and referrals from other researchers. All those enlisted in the RPC are then invited to participate in the study. Those who agree to participate in the study are randomly assigned to an intervention group that receives the RPC or to a control group that receives a "light touch" policy engagement intervention. Those who do not agree to participate in the study will not be placed in the control group, but will be part of the RPC group alongside study participants who were randomly assigned to receive the RPC.

4.2 Recruitment process

Describe how, where and when potential subjects will be recruited (e.g., approaching or providing information to potential subjects for participation in this research study).

All researchers who voluntarily sign-up to participate in the RPC will be invited to participate in this study. Researchers enlist themselves in the intervention by completing an information form about their areas of expertise, an essential part of RPC implementation. Subsequent to the standard implementation intake form, research participants will be asked to participate in the study. Researchers can participate in the RPC even if they opt out of participating in the study.

4.3 Recruitment materials

List the materials that will be used to recruit subjects. Add recruitment documents to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. For advertisements, upload the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, you do not need to upload a separate recruitment document for information placed on the StudyFinder site to your study in CATS IRB. Necessary information will be captured on the StudyFinder page in your CATS IRB study.

RPC participants are recruited primarily via emails that are sent to individual researchers or via listservs for groups or organizations in which many members are researchers, and thus are eligible to participate in the RPC. Recruitment emails are adapted based on context and a standard flier will be attached to recruitment emails. The flier mentions the voluntary nature of the associated study. RPC participants may choose to participate in the study or they may decline study participation without that affecting their ability to participate in the RPC.

4.4 Eligibility/screening of subjects

If potential subjects will be asked eligibility questions before obtaining informed consent, describe the process. Add the script documents and a list of the eligibility questions that will be used to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page.

StudyFinder: If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, any scripts (phone, email, or other) used when contacting StudyFinder participants as well as any eligibility screening questions must be added to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page.

N/A

5.0 Consent Process and Documentation

Refer to "SOP: Informed Consent Process for Research (HRP-090)", for information about the process of obtaining informed consent from subjects. HRP-090 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

Describe where and when the consent process will take place.

The study consent form is provided online immediately subsequent to a researcher enlisting in the RPC (which also occurs online) and prior to entering the online survey. RPC participants will then be asked to agree or decline participation in the study.

5.1.1.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

The consent form notes that study participation is voluntary and there is an option to decline participating in the study such that researchers may participate in the RPC without participating in the study.

5.1.2 Waiver or alteration of the informed consent requirement

If you are requesting a waiver or alteration of consent (consent will not be obtained, required information will not be disclosed, or the research involves deception), describe the rationale for the request in this section. If the alteration is because of deception or incomplete disclosure, explain whether and how subjects will be debriefed. Add any debriefing materials or document(s) to your study in CATS IRB (http://irb.psu.edu) on the "Supporting Documents" page. NOTE: Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations. HRP-410 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Study participation involves deception regarding the extent of a professional development and policy engagement opportunity. Deception is necessary for internal validity because awareness of one's condition in the experiment could lead to social desirability biases in survey responses.

The risk of deception is minimal because the intervention received by the control group is greater than that received in normal practice (i.e., no intervention, training, or engagement). Furthermore, it is not unusual for the intervention subjects (i.e., researchers) to be recruited for voluntary commitments that result in limited engagement due to limited organizational capacity (e.g., involvement in a policy committee that becomes inactive). The experience of control group participants is expected to be greater than or comparable to other experiences for which they might be recruited outside of the current study context; therefore, participation in the study will not adversely affect the rights and welfare of study participants.

Survey participation involves little risk for participants, which involves the loss of confidentiality of their responses to the survey or interview. Confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties. To minimize this risk, data files will be encrypted and direct identifiers will be removed from the data prior to storage and analysis. Furthermore, the questions asked are not of a sensitive nature, and data protection plans minimize threats to confidentiality; therefore, participation in the survey will not adversely affect the rights or welfare of participants. Because research participants will be recruited online, the majority of the intervention takes place online, and participants will be located across the United states, it is not viable to complete a written consent. Therefore, survey participants will be consented via an online survey. Consent is therefore implied. Participants are presented with consent information and must click "I agree" prior to entering the web-based survey. An option for "I do not agree" would end the survey and indicate that the RPC participant does not agree to participate in the study.

Observation participation involves minimal risk because the probability of harm or discomfort from the collection of observational data from public meetings is not greater than participating in the public meeting with no observation. Meeting attendees voluntarily elect to participate in these meetings, and meeting participants have complete control regarding with whom or the extent to which they share personal information. A waiver will not adversely affect the rights or welfare of subjects because meeting participants have the right to end participation in the observed meeting at any time, and the observer will be present as a passive participant who does not interfere with naturally occurring phenomenon. The observation is unobtrusive, as the observer will join the meeting in a similar manner as the meeting participants. Most meetings are expected to last around 30 minutes; therefore, a written consent procedure would detract time available for the meeting itself. Furthermore, written consent procedures would disrupt the nature of interactions that are of focus in the observation. No pertinent information of value to meeting participants will be gleaned from the observation. Observational field notes reflect process data regarding natural processes and interactions that occur during the intervention. No information will be obtained that is relevant to the welfare of observed participants.

All study participants will be debriefed via email regarding their status as part of the RPC group or control group subsequent to the conclusion of the study, approximately one year following the baseline survey.

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

Refer to "SOP: Written Documentation of Consent (HRP-091)" for information about the process to document the informed consent process in writing. HRP-091 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If you will document consent in writing, describe how consent of the subject will be documented in writing. Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. Links to Penn State's consent templates are available in the same location where they are uploaded and their use is required.

N/A.

5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)

If you will obtain consent (verbal or implied), but not document consent in writing, describe how consent will be obtained. Add the consent script(s) and/or information sheet(s) to your study in CATS IRB (http://irb.psu.edu) on the "Consent Forms and Recruitment Materials" page. Links to Penn State's consent templates are available in the same location where they are uploaded and their use is required. Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. HRP-411 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.

Survey participation consent will be implied. Participants are presented with consent information and must click "I agree" prior to entering the web-based survey. An option for "I disagree" would end the survey and indicate that the RPC participant does not agree to participate in the study.
Public meetings will be observed, involve minimal risk, no threats to the welfare of observation subjects, and informed consent procedures would interfere with naturally-occurring meeting processes that are the subject of study; therefore, observations of public meetings involve subjects who are exempt from written, verbal, or implied consent.

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review the "SOP: Written Documentation of Consent (HRP-091)" and the "Investigator Manual (HRP-103)" to ensure that you have provided sufficient information. HRP-091 and HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

It is anticipated that all RPC participants will speak English fluently due to the nature of their engagement in U.S. domestic public policy. Therefore, we anticipate no study participants to be non-English speaking.

5.3.2 Cognitively Impaired Adults

Refer to "CHECKLIST: Cognitively Impaired Adults (HRP-417)" for information about research involving cognitively impaired adults as subjects. HRP-417 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

5.3.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

RPC participants, and consequently study participants, include high-functioning research faculty, professors, evaluators, and other skilled professionals who will have the capacity to provide consent.

5.3.2.2 Adults Unable To Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state, review "SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative". HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

N/A

5.3.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate whether assent will be required of all, some or none of the subjects. If some, indicate which subjects will be required to assent and which will not.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

N/A

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state, review "SOP: Legally Authorized Representatives, Children and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children". HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." HRP-013 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

N/A. All RPC participants, and consequently study participants, will be over age 18.

5.3.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

N/A

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See the "Investigator Manual (HRP-103)" for a list of the 18 identifiers. HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

N/A

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

N/A

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

N/A

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

N/A

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. If the section is not applicable, remove the statement and indicate as not applicable.

N/A

7.0 Study Design and Procedures

7.1 Study Design

Describe and explain the study design.

This human subjects research involves a longitudinal randomized controlled trial and depth interviews of researchers who participate in the Research-to-Policy Collaboration (RPC). Researchers are recruited to participate in the RPC. When a researcher voluntarily enlists in the RPC, they provide information about themselves and their expertise as part of RPC implementation. Subsequently, RPC participants are invited to participate in the study. Those who agree to participate are randomly assigned to either the RPC intervention group or a blinded control group that receives a "light touch" intervention. The next step of RPC implementation involves creating a discussion forum for engaging researchers in training or policy efforts. Different discussion forums will be used for each group: the RPC group (including those in the study who were assigned the intervention as well as those who refused to participate in the study) and the control group. The control group will receive information sheets regarding how to engage in policy, whereas the RPC group will be actively engaged in a series of six voluntary one-hour webinars preparing researchers for policy engagement, and will receive solicitations for contributing to policy efforts via the discussion forum. These activities are designed to build researchers' capacity for successful collaborative interactions with congressional staff around *current policy priorities* and *specific, time-sensitive needs* of congressional offices.

Those in the RPC group who have expertise related to current congressional priorities and needs may be invited to participate in a Rapid Response Event, which brings researchers and congressional staff together face-to-face to meet in congressional offices (Washington, DC) and plan a collaborative response to a current policy issue. To clarify expectations for involvement and minimize the threat of disappointing those who are not invited to the Rapid Response Event, all RPC participants are repeatedly informed throughout the capacity-building stage (via trainings and the discussion forum) that this selection process will occur based on their participation in trainings, web-based engagement, and a match between their expertise and congressional needs. Subsequent to these meetings, RPC participants work collaboratively with one another and the congressional office to respond to the current policy issue.

Participation in the study is voluntary among those enlisting in the RPC; opting out of the survey will not impact their ability to participate in the intervention. Study participants are asked to complete the survey approximately every three months for about one year: (1) Baseline, (2) Subsequent to training, (3) Subsequent to policy engagement, and (4) Follow-up. Twenty-two study participants in the intervention group will be asked to complete in-depth qualitative interviews regarding their experiences: 11 will participate prior to RPC involvement and 11 will participate subsequent to their RPC involvement. Qualitative interviews will be recorded and transcribed.

Observations of public meetings may involve three types of participants: (1) public officials, (2) researchers who have consented to study participation, and/or (3) researchers who are involved in the intervention but did not consent to study participation. Public meetings include: (1) those that occur in

public officials' offices, which are located in congressional office buildings that are open to the public (i.e., any member of the public may visit any office at any time), and (2) online trainings that are open to the public, accessible through a URL on a publicly available website.

7.2 Study Procedures

Provide a description of all research procedures being performed and when they are being performed (broken out by visit, if applicable), including procedures being performed to monitor subjects for safety or minimize risks. Include any long-term follow-up procedures and data collection, if applicable.

Describe where or how you will be obtaining information about subjects (e.g., medical records, school records, surveys, interview questions, focus group topics, audio or video recordings, data collection forms, and collection of specimens through invasive or non-invasive procedures to include the amount to be collected and how often). Add any data collection instruments that will be seen by subjects to your study in CATS IRB (http://irb.psu.edu) in the "Supporting Documents" page.

7.2.1 EXAMPLE: Visit 1 or Day 1 or Pre-test, etc. (format accordingly)

Provide a description as defined above and format accordingly.

Online surveys using Qualtrics will be administered at the time when researchers sign-up to participate in the RPC. Survey instruments are provided as a supporting document. The survey asks for demographic information and about prior policy experiences, recent policy engagement, policy-informed research activities, perceptions about engaging public officials, perceived self-efficacy engaging with public officials, reported policy knowledge and training needs, satisfaction in collaborating with public officials, value and impact of partnering with public officials, and trust and respect within researcher-public official partnerships.

Qualitative interviews will occur prior to RPC implementation at the time of study enrollment. Interviews will occur by web-chat or phone, and will ask:

- What are your experiences of working with policymakers? What worked well? What were some of the challenges?
- What do you think the most useful kinds of evidence are for policymakers? Can you give examples?
- What types of interactions or initiatives do you think would be most helpful to link researchers and policymakers?

7.2.2 EXAMPLE: Visit 2 or Day 2 or Post-test, etc. (format accordingly)

Provide a description as defined above and format accordingly.

The same survey protocol as used in the pre-test will be administered approximately every three months for about one year: (2) Subsequent to training, (3) Subsequent to policy engagement, and (4) Follow-up. Efforts to minimize survey attrition will include tracking non-responses to follow-up surveys and requesting survey participation via individual emails twice per week until survey completion or until the 3-week window for survey participation ends or until the participant opts-out of participating in the survey. In the last week of the survey window, survey participants who have not yet participated or opted-out of participation will be contacted by phone to request their participation and to complete the survey over the phone if needed.

Qualitative interviews will occur subsequent to the RPC implementation, approximately 9 months following study enrollment, using web-chat or phone. These interviews will ask:

- How did you become involved in the RPC? Is this your first involvement with policy? With legislation? If no, what are your previous experiences?

- What were your expectations and aspirations from involvement in the RPC?
- Can you describe the interactions you've had with policymakers through the RPC? (e.g. informal coffees, phone calls, formal meetings, etc). How does this compare to interactions outside the RPC?
- What kinds of evidence have you seen and used as part of the RPC? How? Did this reflect your expectations?
- What has worked well? What could have gone better? (Risks of interaction, perceptions and stereotypes)

This study also involves non-human research data, drawing from public information regarding public officials' use of research evidence, which will be obtained from legislators' sponsored bills, public statements, and reported research use by public officials. Non-human research data will also support the interpretation of key findings from the current investigation that involve human subjects.

This study also involves human research data that are exempt from consent processes. This involves observations of public meetings occurring through the RPC, including researcher trainings and meetings between researchers and public officials' offices. Observations involve minimal risk to subjects because the probability of harm or discomfort from the collection of observational data from public meetings is not greater than participating in the public meeting with no observation. Meeting attendees voluntarily elect to participate in these meetings, and meeting participants have complete control regarding with whom or the extent to which they share personal information. Meeting participants have the right to end participation in the observed meeting at any time. The observation of public meetings is unobtrusive, as the observer will join the meeting in a similar manner as the meeting participants. Meeting durations are expected to last around 30 minutes; therefore, a written consent procedure would detract time from the meeting itself. Furthermore, written consent procedures would disrupt the nature of interactions that are of focus in the observation. No pertinent information of value to meeting participants will be gleaned from the observation. Observational data involve unstructured, qualitative field notes regarding natural processes and interactions that occur during the intervention. These public research data are process-oriented to enable internal evaluation and inform improvements to the RPC.

7.3 Duration of Participation

Describe the duration of an individual subject's participation in the study.

Study participation lasts for up to two years or until the participant opts-out of the study.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

Indicate the total number of subjects to be accrued. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures.)

We aim to enroll a maximum of 300 researchers in the baseline period of this study. The target number of study participants in the full study is 80, including 40 researchers in the intervention and 40

researchers in the control group. This level of oversampling is required because not all researchers will complete all phases of the intervention and oversampling will combat attrition from study participation.

Twenty-two researchers from the intervention group will be selected to participate in depth-interviews (11 at pre-test and 11 at post-test). Researchers will be sampled purposively such that the sample is representative of those with or without prior policy experience and range in their attitudes toward policy engagement (e.g., skeptical or positive), which will be determined by survey data from the first time point.

8.2 Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 – to include reflections on, or calculations of, the power of the study.

Statistical analyses are all powered at least at a 90% level to detect effect sizes of 0.2 or greater (power analysis conducted with *Optimal Design plus Empirical Evidence*).

8.3 Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Surveys data will be analysed longitudinally by modelling change across 4 time points—including repeated measures and multilevel growth curve models (MLM) using *MPlus*. Missing data will be handled with multiple imputation.

Qualitative interview data will be analyzed using a thematic process followed by an intensive discourse analysis. Data will be interpreted alongside observational data using an interpretive policy analysis to develop a data-driven theoretical framework for describing evidence use in the RPC.

9.0 Confidentiality, Privacy and Data Management

For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, the research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form Application Supplement", which is available in the Library in CATS IRB (http://irb.psu.edu). Refer to Penn State College of Medicine IRB's "Standard Operating Procedure Addendum: Security and Integrity of Human Research Data", which is available on the IRB's website. **In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" in section 9.0 if you are conducting Penn State Hershey research and move on to section 10.**

For all other research, in the sections below, describe the steps that will be taken to secure the data during storage, use and transmission.

9.1 Confidentiality

9.1.1 Identifiers associated with data and/or specimens

List the identifiers that will be included or associated with the data and/or specimens in any way (e.g., names, addresses, telephone/fax numbers, email addresses, dates (date of birth, admission/discharge dates, etc.), medical record numbers, social security numbers, health plan beneficiary numbers, etc.).

If no identifiers will be included or associated with the data in any way, whether directly or indirectly, please indicate this instead.

Study participants will be assigned a unique ID that allows data to be connected longitudinally. Surveys and interviews will not be directly identifiable as ID codes will be used that are only identifiable by the research team. A key for ID codes will be kept in a separate file, which will include names, phone number, email address, and institutional affiliation. No other identifiable data will be collected in this study.

9.1.1.1 Use of Codes, Master List

If identifiers will be associated with the data and/or specimens (as indicated in section 9.1.1 above), describe whether a master record or list containing a code (i.e., code number, pseudonyms) will be used to separate the data collected from identifiable information, where that master code list will be stored, who will have access to the master code list, and when it will be destroyed.

If identifiers are included or associated with the data as described in section 9.1.1 above, but no master record or list containing a code will be used, it will be assumed by the IRB that the investigator plans to directly link the identifiers with the data.

Identifiable information obtained through the Qualtrics study will be stripped from the data file prior to storage on the server. Only the research team will have access to the master list of ID codes. The master list of ID codes will be destroyed within three years of the end of the project.

9.1.2 Storage of Data and/or Specimens

Describe where, how and for how long the data (hardcopy (paper) and/or electronic data) and/or specimens will be stored. NOTE: Data can include paper files, data on the internet or websites, computer files, audio/video files, photographs, etc. and should be considered in the responses. Refer to the "Investigator Manual (HRP-103)" for information about how long research records must be stored following the completion of the research prior to completing this section. HRP-103 can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

Please review Penn State's Data Categorization Project for detailed information regarding the appropriate and allowable storage of research data collected according to Penn State Policy AD71. Although the IRB can impose greater confidentiality/security requirements (particularly for sensitive data), the IRB cannot approve storage of research data in any way or using any service that is not permissible by Penn State Policy AD71.

All data collected as part of this proposal will be stored on password-protected servers or in locked filing cabinets and accessed only by the interviewer and project investigators. Personal identifying information will be stored separately from the study data, and data will be stored in an encrypted format. Interviews will be digitally recoded, transcribed, and stored in password-protected servers to which only the research team will have access.

9.1.3 Access to Data and/or Specimens

Identify who will have access to the data and/or specimens. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

Max Crowley, Taylor Scott, and the research team will have access to study data.

9.1.4 Transferring Data and/or Specimens

If the data and/or specimens will be transferred to and/or from outside collaborators, identify the collaborator to whom the data and/or specimens will be transferred and how the data and/or specimens will be transferred. This information should not conflict with information provided in section 9.1.1.1 regarding who has access to identifiable information, if applicable.

N/A

9.2 Subject Privacy

This section must address subject privacy and NOT data confidentiality.

Indicate how the research team is permitted to access any sources of information about the subjects.

Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact with or to whom they provide personal information.

Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

All personal information is self-reported and the sensitivity of information requested is minimal. Interaction among study participants occurs as a function of their voluntary participation in the RPC, not the study; thus, all interactions are voluntary. Therefore, study participants have complete control regarding with whom or the extent that they provide personal information.

10.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects. As defined in "SOP: Definitions (HRP-001)", available in the Library in CATS IRB (http://irb.psu.edu), Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that 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. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. **Please complete the sections below if the research involves more than minimal risk to subjects OR indicate as not applicable.**

10.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

N/A. This study involves Minimal Risk to participants.

10.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

N/A. This study involves Minimal Risk to participants.

10.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

N/A. This study involves Minimal Risk to participants.

10.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

N/A. This study involves Minimal Risk to participants.

10.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

N/A. This study involves Minimal Risk to participants.

10.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

N/A. This study involves Minimal Risk to participants.

10.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

N/A. This study involves Minimal Risk to participants.

10.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

N/A. This study involves Minimal Risk to participants.

11.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. For each potential risk, describe the probability, magnitude, duration, and reversibility. Consider all types of risk including physical, psychological, social, legal, and economic risks. If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant. If applicable, describe risks to others who are not subjects.

Please keep in mind that loss of confidentiality is a potential risk when conducting human subject research and should be addressed as such.

This study involves little risk for participants, which involve the loss of confidentiality of their responses to the survey or interview and deception regarding the extent of a professional development and policy engagement opportunity. Confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by any third parties. To minimize this risk, data files will be encrypted and direct identifiers will be removed from the data prior to

storage and analysis. Survey questions asked are not of a sensitive nature, and data protection plans minimize threats to confidentiality. The risk of deception is also minimal because the intervention received by the control group is greater than that received in normal practice (i.e., no intervention, training, or engagement). Furthermore, it is not unusual for the intervention subjects (i.e., researchers) to be recruited for voluntary commitments that result in limited engagement due to limited organizational capacity (e.g., involvement in a policy committee that becomes inactive). Therefore, the experience of control group participants is expected to be greater than or comparable to other experiences for which they might be recruited outside of the current study context.

12.0 Potential Benefits to Subjects and Others

12.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 14.0.

There are no direct benefits of participating in this study.

12.2 Potential Benefits to Others

Include benefits to society or others.

This work has the potential to strengthen efforts to improve the use of research evidence in policymaking processes, as well as to inform how researchers are trained and prepared for policy engagement. Moreover, insights gleaned will inform the academic literature regarding how research is used in policymaking processes at the federal legislative level of governance.

13.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.

N/A. There are no individual results of value to study participants.

14.0 Subject Stipend (Compensation) and/or Travel Reimbursements

Describe the amount and timing of any subject stipend/payment or travel reimbursement here. If there is no subject stipend/payment or travel reimbursement, indicate as not applicable.

If course credit or extra credit is offered to subjects, describe the amount of credit and the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered.

If an existing, approved student subject pool will be used to enroll subjects, please indicate as such and indicate that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Survey participants will be compensated $10 for completion of each survey time point (maximum of $40). Compensation will be made with an electronic Amazon gift card emailed to the provided email address. Study participants reflect a relatively elite group for which monetary incentives are not commiserate with fair-market

consultation rates (approximately $50-100 per hour); therefore, $10 per 20-minute survey (or a rate of $30 per hour) is not an unduly influence for participation.

15.0 Economic Burden to Subjects

15.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

Participants will not be affected by direct costs for participation in this study; however, indirect costs include participants' time for participation. Participation in the survey is expected to require approximately 20 minutes, or a total of one hour of researchers' time participating in all four of the surveys. Twenty-two participants who voluntarily agree to participate in depth qualitative interviews will spend an additional hour participating.

15.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

This study involves Minimal Risk to participants.

16.0 Resources Available

16.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

All recruitment is virtual using email. The RPC is primarily implemented remotely, including web-based trainings, engaging researchers' responses to policy efforts via emails and a discussion forum, and working collaboratively on responses to legislative requests. Most meetings occur via phone or webchat except for the meetings that occur as part of the Rapid Response Event, which brings researchers and

congressional staff together face-to-face to plan a response to current policy efforts. Those meetings are held in congressional offices in Washington, DC. Observations will occur during web-based trainings as well as on-site during the Rapid Response Event. Surveys with researchers will occur online, or occasionally by phone as part of attrition-reduction efforts.

16.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

It is anticipated that around 300 researchers will be recruited for the RPC. We believe that at least ¾ (*n* = 225) of those may participate in the study at baseline, and approximately half of those individuals may complete the study (*n* = 112), which would over-sample for the current study.

16.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

The Primary Investigator, Max Crowley, is supported for 15% of FTE to work on this project, which will ensure that research and compliance activities are completed as specified by the sponsored research and as dictated by the IRB protocol.

16.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subject might need as a result of their participation in the study, if applicable.

This study involves Minimal Risk for participants.

16.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

All research team members must complete the mandatory CITI training in human subjects research. The IRB protocol will be reviewed by all team members, and compliance will be monitored by the Primary Investigator.

17.0 Other Approvals

17.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from cooperating institutions, community leaders, schools, external sites, funding agencies).

N/A

17.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of HRP-902 - Human Tissue For Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – Hershey only – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes, but are no longer needed for clinical use. Upload a copy of HRP-901 - Human Body Fluids for Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Clinical Research Center (CRC) Advisory Committee – All campuses – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of HRP-903 - Radiation Review Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/investigator

18.0 Multi-Site Research

If this is a multi-site study (i.e., the study will be conducted at other institutions each with its own principal investigator) and you are the lead investigator, describe the processes to ensure communication among sites in the sections below.

18.1 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

N/A

18.2 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

N/A

18.3 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

N/A

18.4 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

N/A

18.5 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

N/A

19.0 Adverse Event Reporting

19.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

20.0 Study Monitoring, Auditing and Inspecting

20.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

21.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting identifiable data and/or specimens that will be banked for future undetermined research, please describe this process in the sections below. This information should not conflict with information provided in section 9.1.1 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly).

21.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

All data will be handled in accordance with the consent procedures and IRB protocol. Identifiers will be stripped from the data files for archival storage. Identifying information will be destroyed within three years of the end of the project.

21.2 Location of storage

Identify the location where the data and/or specimens will be stored.

Archival data will be stored on SharePoint, PSU's secure cloud file transfer server.

21.3 Duration of storage

Identify how long the data and/or specimens will be stored.

De-identified study data will be archived indefinitely. Identifying info will be destroyed within three years of the end of the project.

21.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

Only the research team will have access to archival data.

21.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

Identifying information will not be released. Only members of the research team will have access to archival data.

21.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

N/A

22.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

Crowley, M.D. Scott, J.T. & Fishbein, D. (2017). Translating prevention research for evidence-based policymaking: Results from the Research-to-Policy Collaboration pilot. *Prevention Science.*

Dumont K. (2015). Leveraging knowledge: Taking stock of the William T. *Grant Found Use Res Evid Grants Portf N Y NY William T Grant Found*.

Oliver, K., Innvar, S., Lorenc, T., Woodman, J., & Thomas, J. (2014). A systematic review of barriers to and facilitators of the use of evidence by policymakers. *BMC Health Services Research, 14*, 1-12.

Scott, T., Larson, J., Buckingham, S., Maton, K., & Crowley, M. (in press). Bridging the research-policy divide: Pathways to engagement and skill development. *American Journal of Orthopsychiatry.*

Singh, G. G., Tam, J., Sisk, T. D., Klain, S. C., Mach, M. E., Martone, R. G., & Chan, K. (2014). A more social science: barriers and incentives for scientists engaging in policy. *Frontiers in Ecology and the Environment*, *12*, 161–166.

Tseng V. (2013). Forging common ground: fostering the conditions for evidence use. *J Leis Res,* 46, 6.