MEMORANDUM

DATE: September 7, 2016

TO: Kris Wernstedt, Maria Jimena Pinzon, Patrick S Roberts, Sarah Christian Steller

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: Local Government Attitudes & Flood Risk

IRB NUMBER: 16-542

Effective September 7, 2016, the Virginia Tech Institution Review Board (IRB) Chair, David M Moore, approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at: http://www.irb.vt.edu/pages/responsibilities.htm

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As: Exempt, under 45 CFR 46.110 category(ies) 2,4
Protocol Approval Date: September 7, 2016
Protocol Expiration Date: N/A
Continuing Review Due Date*: N/A

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.
<table>
<thead>
<tr>
<th>Date*</th>
<th>OSP Number</th>
<th>Sponsor</th>
<th>Grant Comparison Conducted?</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/31/2016</td>
<td>11188603</td>
<td>National Science Foundation</td>
<td>Not required (Exempt approval)</td>
</tr>
</tbody>
</table>

* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irbadmin@vt.edu) immediately.
Section 1: General Information

1.1 DO ANY OF THE INVESTIGATORS OF THIS PROJECT HAVE A REPORTABLE CONFLICT OF INTEREST? (http://www.irb.vt.edu/pages/researchers.htm#conflict)

☐ No
☐ Yes, explain:

1.2 IS THIS RESEARCH SPONSORED OR SEEKING SPONSORED FUNDS?

☐ No, go to question 2.1
☐ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
<th>Provide the name of the sponsor [if NIH, specify department]: National Science Foundation &amp; National Oceanic and Atmospheric Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this project receiving or seeking federal funds?</td>
<td></td>
</tr>
</tbody>
</table>
| ☐ No  
| ☑ Yes |
| If yes, |
| Does the grant application, OSP proposal, or “statement of work” related to this project include activities involving human subjects that are not covered within this IRB application? |
| ☐ No, all human subject activities are covered in this IRB application |
| ☐ Yes, however these activities will be covered in future VT IRB applications, these activities include: |
| ☑ Yes, however these activities have been covered in past VT IRB applications, the IRB number(s) are as follows: IRB11-181 (See Attachment 1) |
| ☐ Yes, however these activities have been or will be reviewed by another institution’s IRB, the name of this institution is as follows: |
| ☐ Other, explain: |
| Is Virginia Tech the primary awardee or the coordinating center of this grant? |
| ☐ No, provide the name of the primary institution: |
| ☑ Yes |

Section 2: Justification

2.1 DESCRIBE THE BACKGROUND, PURPOSE, AND ANTICIPATED FINDINGS OF THIS STUDY:

Our project examines the obstacles to and opportunities for the use of seasonal climate forecasts in flood planning and management in the U.S.. In this portion of the study, we are implementing a second national survey to examine the behavior of and perspective on flood risk among local government agencies. The
Chief intellectual merit in this portion of our study is to enhance understanding of the tradeoffs among different aspects of flood mitigation. As such, it amplifies our earlier work on the project in which we advanced approaches to capture and measure preferences of local government officials related to characteristics of uncertain information.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:
For example - publish or use for dissertation

We plan to publish the results in peer reviewed journals and professional publications, as well as through presentations at academic and professional meetings.

Section 3: Recruitment

3.1 DESCRIBE THE SUBJECT POOL, INCLUDING INCLUSION AND EXCLUSION CRITERIA AND NUMBER OF SUBJECTS:
Examples of inclusion/exclusion criteria - gender, age, health status, ethnicity

The subject pool will include high-level government officials (e.g. emergency managers, planners, public works directors, chief administrative officers, elected officials, and fire chiefs) involved in disaster management. Participants will be adults (over the age of 18) and may be of any race, health status, and ethnicity. The approximate number of participants is 8,710.

3.2 WILL EXISTING RECORDS BE USED TO IDENTIFY AND CONTACT / RECRUIT SUBJECTS?
Examples of existing records - directories, class roster, university records, educational records

☐ No, go to question 3.3
☒ Yes, answer questions within table

IF YES

Are these records private or public?
☒ Public
☐ Private, describe the researcher’s privilege to the records:

Will student, faculty, and/or staff records or contact information be requested from the University?
☒ No
☐ Yes, provide a description under Section 14 (Research Involving Existing Data) below.

3.3 DESCRIBE RECRUITMENT METHODS, INCLUDING HOW THE STUDY WILL BE ADVERTISED OR INTRODUCED TO SUBJECTS:

The researchers will contact prospective participants via mail and email invitations (see Attachment 2 and 3). Each invitation will include an access code to the survey. Prospective participants will be identified using ICMA’s database of local government staff, obtained from MGI Lists. Surveys will be conducted online using Qualtrics. Consent information will be included at the beginning of the survey. A project website will be created (See Attachment 4). No advertising will be used.

3.4 PROVIDE AN EXPLANATION FOR CHOOSING THIS POPULATION:
Note: the IRB must ensure that the risks and benefits of participating in a study are distributed equitably among the general population and that a specific population is not targeted because of ease of recruitment.

The intended interviewees are high-level government officials in charge of making decisions related to emergency management.
Section 4: Consent Process

For more information about consent process and consent forms visit the following link: http://www.irb.vt.edu/pages/consent.htm

If feasible, researchers are advised and may be required to obtain signed consent from each participant unless obtaining signatures leads to an increase of risk (e.g., the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting in a breach of confidentiality). Signed consent is typically not required for low risk questionnaires (consent is implied) unless audio/video recording or an in-person interview is involved. If researchers will not be obtaining signed consent, participants must, in most cases, be supplied with consent information in a different format (e.g., in recruitment document, at the beginning of survey instrument, read to participant over the phone, information sheet physically or verbally provided to participant).

4.1 CHECK ALL OF THE FOLLOWING THAT APPLY TO THIS STUDY’S CONSENT PROCESS:

☐ Verbal consent will be obtained from participants
☐ Signed consent will be obtained from participants
☒ Consent will be implied from the return of completed questionnaire. Note: The IRB recommends providing consent information in a recruitment document or at the beginning of the questionnaire (if the study only involves implied consent, skip to Section 5 below)
☐ Other, describe:

4.2 PROVIDE A GENERAL DESCRIPTION OF THE PROCESS THE RESEARCH TEAM WILL USE TO OBTAIN AND MAINTAIN INFORMED CONSENT:


4.3 WHO, FROM THE RESEARCH TEAM, WILL BE OVERSEEING THE PROCESS AND OBTAINING CONSENT FROM SUBJECTS?


4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?


4.5 DURING WHAT POINT IN THE STUDY PROCESS WILL CONSENTING OCCUR?

Note: unless waived by the IRB, participants must be consented before completing any study procedure, including screening questionnaires.


4.6 IF APPLICABLE, DESCRIBE HOW THE RESEARCHERS WILL GIVE SUBJECTS AMPLE TIME TO REVIEW THE CONSENT DOCUMENT BEFORE SIGNING:

Note: typically applicable for complex studies, studies involving more than one session, or studies involving more of a risk to subjects.

☐ Not applicable

Section 5: Procedures
5.1 PROVIDE A STEP-BY-STEP THOROUGH EXPLANATION OF ALL STUDY PROCEDURES EXPECTED FROM STUDY PARTICIPANTS, INCLUDING TIME COMMITMENT & LOCATION:

Prospective survey participants will require 1-2 minutes to read the recruitment postcard (see Attachment 2) and subsequent email (see Attachment 3) and accept or decline participation. Those who choose to participate are expected to take 15 minutes to complete the survey. Attachment 5 provides a copy of the PDF survey. Subjects will use an individual access code to access the online survey at the time and location of their choice. Non-response follow-up will be conducted via email with each recruitment wave two weeks after the initial invitation.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Data will be collected using Qualtrics online survey software platform. Survey responses will be automatically recorded upon submission and available to the research team for download. We anticipate using CSV download formats, and will clean and prepare the data for analysis in the statistical software package Stata. The results of the survey may be published.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITIES (INCLUDES ENROLLMENT, RECRUITMENT, SURVEYS)?

View the “Policy for Online Research Data Collection Activities Involving Human Subjects” at http://www.irb.vt.edu/documents/onlinepolicy.pdf

☐ No, go to question 6.1
☒ Yes, answer questions within table

IF YES

Identify the service / program that will be used:

☐ www.survey.vt.edu, go to question 6.1
☐ SONA, go to question 6.1
☒ Qualtrics, go to question 6.1
☐ Center for Survey Research, go to question 6.1
☐ Other

IF OTHER:

Name of service / program:

URL:

This service is…

☐ Included on the list found at: http://www.irb.vt.edu/pages/validated.htm
☐ Approved by VT IT Security
☐ An external service with proper SSL or similar encryption (https://) on the login (if applicable) and all other data collection pages.
☐ None of the above (note: only permissible if this is a collaborative project in which VT individuals are only responsible for data analysis, consulting, or recruitment)

Section 6: Risks and Benefits

6.1 WHAT ARE THE POTENTIAL RISKS (E.G., EMOTIONAL, PHYSICAL, SOCIAL, LEGAL, ECONOMIC, OR DIGNITY) TO STUDY PARTICIPANTS?

No potential risks are expected to study participants.

6.2 EXPLAIN THE STUDY’S EFFORTS TO REDUCE POTENTIAL RISKS TO SUBJECTS:

Not applicable. However, we will inform subjects of the purposes and progress of our study
6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

Results will benefit local public officials structure better coordination strategies for disaster mitigation and preparation. The study also will provide insights to the policy and academic communities the relative importance that local public officials place on disaster mitigation benefits.

Section 7: Full Board Assessment

7.1 DOES THE RESEARCH INVOLVE MICROWAVES/X-RAYS, OR GENERAL ANESTHESIA OR SEDATION?

☑ No
☐ Yes

7.2 DO RESEARCH ACTIVITIES INVOLVE PRISONERS, PREGNANT WOMEN, FETUSES, HUMAN IN VITRO FERTILIZATION, OR INDIVIDUALS WITH MENTAL DISORDERS?

☑ No, go to question 7.3
☐ Yes, answer questions within table

If Yes

This research involves:
☐ Prisoners
☐ Pregnant women  ☐ Fetuses  ☐ Human in vitro fertilization
☐ Individuals with a mental disorder

7.3 DOES THIS STUDY INVOLVE MORE THAN MINIMAL RISK TO STUDY PARTICIPANTS?

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily activities or during the performance of routine physical or psychological examinations or tests. Examples of research involving greater than minimal risk include collecting data about abuse or illegal activities. Note: if the project qualifies for Exempt review (http://www.irb.vt.edu/pages/categories.htm), it will not need to go to the Full Board.

☑ No
☐ Yes

If you answered “Yes” to any one of the above questions, 7.1, 7.2, or 7.3, the board may review the project’s application materials at its monthly meeting. View the following link for deadlines and additional information: http://www.irb.vt.edu/pages/deadlines.htm

Section 8: Confidentiality / Anonymity

For more information about confidentiality and anonymity visit the following link: http://www.irb.vt.edu/pages/confidentiality.htm

8.1 WILL PERSONALLY IDENTIFYING STUDY RESULTS OR DATA BE RELEASED TO ANYONE OUTSIDE OF THE RESEARCH TEAM?

For example – to the funding agency or outside data analyst, or participants identified in publications with individual consent

☑ No
Yes, to whom will identifying data be released?

8.2 WILL THE RESEARCH TEAM COLLECT AND/OR RECORD PARTICIPANT IDENTIFYING INFORMATION (E.G., NAME, CONTACT INFORMATION, VIDEO/AUDIO RECORDINGS)?

Note: if collecting signatures on a consent form, select “Yes.”

☐ No, go to question 8.3
☒ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
</tr>
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<tbody>
<tr>
<td>Describe if/how the study will utilize study codes: Our study will use codes, which will be linked to participant identifying information, to control access to the survey. These codes will be separated from responses in all data analysis.</td>
</tr>
</tbody>
</table>

If applicable, where will the key [i.e., linked code and identifying information document (for instance, John Doe = study ID 001)] be stored and who will have access? The access codes will be stored in a password protected file available only to the PI, with a secondary code containing no identifying information linking to survey response data.

Note: the key should be stored separately from subjects’ completed data documents and accessibility should be limited.

The IRB strongly suggests and may require that all data documents (e.g., questionnaire responses, interview responses, etc.) do not include or request identifying information (e.g., name, contact information, etc.) from participants. If you need to link subjects’ identifying information to subjects’ data documents, use a study ID/code on all data documents.

8.3 HOW WILL DATA BE STORED TO ENSURE SECURITY (E.G., PASSWORD PROTECTED COMPUTERS, ENCRYPTION) AND LIMITED ACCESS?

Examples of data - questionnaire, interview responses, downloaded online survey data, observation recordings, biological samples

Results, which will have secondary codes with no participant identifying information, will be kept in Stata files. Access codes will be kept in a password protected file stored on the PI's hard disk in a locked office.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

All principal investigators will have access to the anonymized survey data. This data will contain no identifying information. The study also will share this anonymized data with the research community, per sponsor guidelines.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING STUDY DATA:

We will retain the data in password-protected (for identifying information) and other Stata files (for anonymized information) for a period of five years before destroying it.

8.6 DOES THIS STUDY REQUEST INFORMATION FROM PARTICIPANTS REGARDING ILLEGAL BEHAVIOR?

☒ No, go to question 9.1
☐ Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the study plan to obtain a Certificate of Confidentiality?</td>
</tr>
</tbody>
</table>
Section 9: Compensation

For more information about compensating subjects, visit the following link: http://www.irb.vt.edu/pages/compensation.htm

9.1 WILL SUBJECTS BE COMPENSATED FOR THEIR PARTICIPATION?

☐ No, go to question 10.1
☐ Yes, answer questions within table

### IF YES

<table>
<thead>
<tr>
<th>What is the amount of compensation?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will compensation be prorated?</td>
</tr>
<tr>
<td>☐ Yes, please describe:</td>
</tr>
<tr>
<td>☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study?</td>
</tr>
</tbody>
</table>

Unless justified by the researcher, compensation should be prorated based on duration of study participation. Payment must not be contingent upon completion of study procedures. In other words, even if the subject decides to withdraw from the study, he/she should be compensated, at least partially, based on what study procedures he/she has completed.

Section 10: Audio / Video Recording

For more information about audio/video recording participants, visit the following link: http://www.irb.vt.edu/pages/recordings.htm

10.1 WILL YOUR STUDY INVOLVE VIDEO AND/OR AUDIO RECORDING?

☐ No, go to question 11.1
☐ Yes, answer questions within table

### IF YES

<table>
<thead>
<tr>
<th>This project involves:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Audio recordings only</td>
</tr>
<tr>
<td>☐ Video recordings only</td>
</tr>
<tr>
<td>☐ Both video and audio recordings</td>
</tr>
</tbody>
</table>

Provide compelling justification for the use of audio/video recording:

How will data within the recordings be retrieved / transcribed?

How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security?
Section 11: Research Involving Students

11.1 DOES THIS PROJECT INCLUDE STUDENTS AS PARTICIPANTS?

☒ No, go to question 12.1  ☑ Yes, answer questions within table

IF YES

Does this study involve conducting research with students of the researcher?

☐ No
☐ Yes, describe safeguards the study will implement to protect against coercion or undue influence for participation:

Note: if it is feasible to use students from a class of students not under the instruction of the researcher, the IRB recommends and may require doing so.

Will the study need to access student records (e.g., SAT, GPA, or GRE scores)?

☐ No
☐ Yes

11.2 DOES THIS PROJECT INCLUDE ELEMENTARY, JUNIOR, OR HIGH SCHOOL STUDENTS?

☐ No, go to question 11.3  ☑ Yes, answer questions within table

IF YES

Will study procedures be completed during school hours?

☐ No
☐ Yes

If yes,

Students not included in the study may view other students’ involvement with the research during school time as unfair. Address this issue and how the study will reduce this outcome:

Missing out on regular class time or seeing other students participate may influence a student’s decision to participate. Address how the study will reduce this outcome:

Is the school’s approval letter(s) attached to this submission?

☐ Yes
☐ No, project involves Montgomery County Public Schools (MCPS)
☐ No, explain why:
### 11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

- [ ] No, go to question 12.1
- [ ] Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded:</td>
</tr>
<tr>
<td>[ ] Included</td>
</tr>
<tr>
<td>[ ] Actively excluded, describe how the study will ensure that minors will not be included:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Will extra credit be offered to subjects?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] No</td>
</tr>
<tr>
<td>[ ] Yes</td>
</tr>
</tbody>
</table>

If yes,

- What will be offered to subjects as an equal alternative to receiving extra credit without participating in this study?
- Include a description of the extra credit (e.g., amount) to be provided within question 9.1 (“IF YES” table)

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### Section 12: Research Involving Minors

#### 12.1 DOES THIS PROJECT INVOLVE MINORS (UNDER THE AGE OF 18 IN VIRGINIA)?

Note: age constituting a minor may differ in other States.

- [x] No, go to question 13.1
- [ ] Yes, answer questions within table

<table>
<thead>
<tr>
<th>IF YES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide?</td>
</tr>
<tr>
<td>[ ] No</td>
</tr>
<tr>
<td>[ ] Yes, thoroughly explain how the study will react to such reports:</td>
</tr>
</tbody>
</table>

Note: subjects and parents must be fully informed of the fact that researchers must report threats of suicide or suspected/reported abuse to the appropriate authorities within the Confidentiality section of the Consent, Assent, and/or Permission documents.

<table>
<thead>
<tr>
<th>Are you requesting a waiver of parental permission (i.e., parent uninformed of child’s involvement)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] No, both parents/guardians will provide their permission, if possible.</td>
</tr>
<tr>
<td>[ ] No, only one parent/guardian will provide permission.</td>
</tr>
<tr>
<td>[ ] Yes, describe below how your research meets all of the following criteria (A-D):</td>
</tr>
<tr>
<td>Criteria A - The research involves no more than minimal risk to the subjects:</td>
</tr>
<tr>
<td>Criteria B - The waiver will not adversely affect the rights and welfare of the subjects:</td>
</tr>
</tbody>
</table>
Criteria C - The research could not practicably be carried out without the waiver:
Criteria D - (Optional) Parents will be provided with additional pertinent information after participation:

<table>
<thead>
<tr>
<th>Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ No</td>
</tr>
<tr>
<td>☐ Yes, will the investigators seek and obtain the legally effective informed consent (in place of the minors’ previously provided assent and parents’ permission) for the now-adult subjects for any ongoing interactions with the subjects, or analysis of subjects’ data? If yes, explain how:</td>
</tr>
</tbody>
</table>

For more information about minors reaching legal age during enrollment, visit the following link: [http://www.irb.vt.edu/pages/assent.htm](http://www.irb.vt.edu/pages/assent.htm)

The procedure for obtaining assent from minors and permission from the minor’s guardian(s) must be described in Section 4 (Consent Process) of this form.

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**Section 13: Research Involving Deception**

For more information about involving deception in research and for assistance with developing your debriefing form, visit our website at [http://www.irb.vt.edu/pages/deception.htm](http://www.irb.vt.edu/pages/deception.htm)

**13.1 DOES THIS PROJECT INVOLVE DECEPTION?**

- ☒ No, go to question 14.1
- ☐ Yes, answer questions within table

**IF YES**

<table>
<thead>
<tr>
<th>Describe the deception:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Why is the use of deception necessary for this project?</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Describe the debriefing process:</th>
</tr>
</thead>
</table>

Provide an explanation of how the study meets all the following criteria (A-D) for an alteration of consent:

Criteria A - The research involves no more than minimal risk to the subjects:
Criteria B - The alteration will not adversely affect the rights and welfare of the subjects:
Criteria C - The research could not practicably be carried out without the alteration:
Criteria D - (Optional) Subjects will be provided with additional pertinent information after participation (i.e., debriefing for studies involving deception):

By nature, studies involving deception cannot provide subjects with a complete description of the study during the consent process; therefore, the IRB must allow (by granting an alteration of consent) a consent process which does not include, or which alters, some or all of the elements of informed consent.

*The IRB requests that the researcher use the title “Information Sheet” instead of “Consent Form” on the document used to obtain subjects’ signatures to participate in the research. This will adequately reflect the fact that the subject cannot fully consent to the research without the researcher fully disclosing the true intent of the research.*
Section 14: Research Involving Existing Data

14.1 WILL THIS PROJECT INVOLVE THE COLLECTION OR STUDY/ANALYSIS OF EXISTING DATA DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS, OR DIAGNOSTIC SPECIMENS?

Please note: it is not considered existing data if a researcher transfers to Virginia Tech from another institution and will be conducting data analysis of an on-going study.

☐ No, you are finished with the application
☐ Yes, answer questions within table

**IF YES**

From where does the existing data originate?

Provide a detailed description of the existing data that will be collected or studied/analyzed:

Is the source of the data public?

☐ No, continue with the next question
☐ Yes, you are finished with this application

Will any individual associated with this project (internal or external) have access to or be provided with existing data containing information which would enable the identification of subjects:

- Directly (e.g., by name, phone number, address, email address, social security number, student ID number), or
- Indirectly through study codes even if the researcher or research team does not have access to the master list linking study codes to identifiable information such as name, student ID number, etc or
- Indirectly through the use of information that could reasonably be used in combination to identify an individual (e.g., demographics)

☐ No, collected/analyzed data will be completely de-identified
☐ Yes,

If yes,

*Research will not qualify for exempt review; therefore, if feasible, written consent must be obtained from individuals whose data will be collected/analyzed, unless this requirement is waived by the IRB.*

Will written/signed or verbal consent be obtained from participants prior to the analysis of collected data? - select one -

This research protocol represents a contract between all research personnel associated with the project, the University, and federal government; therefore, must be followed accordingly and kept current.
Proposed modifications must be approved by the IRB prior to implementation except where necessary to eliminate apparent immediate hazards to the human subjects.

Do not begin human subjects activities until you receive an IRB approval letter via email.

It is the Principal Investigator's responsibility to ensure all members of the research team who interact with research subjects, or collect or handle human subjects data have completed human subjects protection training prior to interacting with subjects, or handling or collecting the data.

---------END---------