Once complete, upload this form as a Word document to the IRB Protocol Management System: https://secure.research.vt.edu/irb

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 WILL THIS RESEARCH INVOLVE COLLABORATION WITH ANOTHER INSTITUTION?

☒ **No,** go to question 1.3
☐ **Yes,** answer questions within table →

IF YES
Provide the name of the institution [for institutions located overseas, please also provide name of country]**:**
Indicate the status of this research project with the other institution's IRB: ☐ Pending approval ☐ Approved ☐ Other institution does not have a human subject protections review board ☐ Other, explain:
Will the collaborating institution(s) be engaged in the research? (http://www.hhs.gov/ohrp/policy/engage08.html) ☐ No ☐ Yes
Will Virginia Tech's IRB review all human subject research activities involved with this project? ☐ No, provide the name of the primary institution: ☐ Yes *Note: primary institution = primary recipient of the grant or main coordinating center*

1.3 IS THIS RESEARCH FUNDED?

☐ **No,** go to question 1.4
☒ **Yes,** answer questions within table →

IF YES
Provide the name of the sponsor [if NIH, specify department]: US Department of Agriculture-National Institute of Food and Agriculture (USDA-NIFA) and Virginia Cooperative Extension
Is this project receiving federal funds? ☐ 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 <u>not</u> 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:
- ☐ 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

1.4 DOES THIS STUDY INVOLVE CONFIDENTIAL OR PROPRIETARY INFORMATION (OTHER THAN HUMAN SUBJECT CONFIDENTIAL INFORMATION), OR INFORMATION RESTRICTED FOR NATIONAL SECURITY OR OTHER REASONS BY A U.S. GOVERNMENT AGENCY?

For example – government / industry proprietary or confidential trade secret information

- ☒ **No**
- ☐ **Yes,** describe:

1.5 DOES THIS STUDY INVOLVE SHIPPING ANY TANGIBLE ITEM, BIOLOGICAL OR SELECT AGENT OUTSIDE THE U.S?

- ☒ **No**
- ☐ **Yes**

Section 2: Justification

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

About 1.7 million Virginians rely on wells, springs, and cisterns for their household water supply. Unlike in homes served by regulated municipal water supplies, maintenance and monitoring of these systems is solely the homeowner's responsibility. Not surprisingly, water quality can deteriorate if these systems are not maintained properly or new sources of contamination emerge. The objective of the Virginia Household Water Quality Program (VAHWQP) is to provide Virginia families with access to an educational program designed to improve household water quality and reduce associated health risks. In addition, the study will provide information to researchers, extension agents, and participants regarding the prevalence of drinking water quality issues in private systems, potential associations between the presence of contaminants and demographic, health or environmental factors, and the effect of this type of programming on maintenance of private water supplies.

In 2007, Dr. Brian Benham, in the Biological Systems Engineering (BSE) Department at Virginia Tech, received a USDA grant to revive an extension program which had been discontinued following the retirement of Dr. Blake Ross. The VAHWQP aims to provide relatively low cost household water quality testing for Virginia families reliant on private supply systems, and to provide education on system maintenance and typical water quality problems to participants. The program is coordinated by Ms. Erin Ling, also in the BSE department. The program received an IRB exemption in April 2007 ("Household Water Quality Program", IRB# 07-192). In late 2011, the group received a Rural Health and Safety Education (RHSE) grant (PI: Leigh-Anne Krometis, BSE) from USDA-NIFA which aimed to continue the program in specific target regions of the state. After receiving IRB approval for this study, we wish to continue

operating the Virginia Household Water Quality Program using the same approach moving forward.

1. We will occasionally conduct "follow-up" phone surveys with past participants of the program. Depending on funding, up to 100-200 interviewed per year when surveys take place. The objective of the survey is to determine whether or not the previous VAHWQP participants took any action or altered their water supply system maintenance following participation in the program.

2. Conducting focus groups - Focus groups will be conducted occaisionally to determine the level of awareness about VAHWQP drinking water clinics, and to gather input from groups and individuals that we would like to be more engaged with our efforts (doctors, nurses, public health officials, rural community group leaders).

3. Conducting "drinking water clinics" - Drinking water clinics providing confidential drinking water sample analysis and system maintenance education will be offered in about 40-60 Virginia counties each year. Participants will attend two (optional) educational meetings and complete a short questionnaire that is contained in the sample kit. The questionnaire covers questions about water system age and construction, characteristics of the water (e.g., smell, off color, or taste), potential nearby sources of pollution, and basic demographic and health information.

Our program is continuing beyond the original grant proposal (funded through August 2012) with funding from Virginia Cooperative Extension and other sources. Focus groups will be used occasionally to help us adapt or improve our messaging and advertising and to identify and successfully engage new audiences. We would like to conduct phone surveys every few years with people who participated in our drinking water clinics in the past year to 18 months to gauge impact and resulting behavior change from participation, again, with the intent of improving our programming and impact.

4. Contacting participants to see if they are interested in participating in further research studies. Based on data gathered, research opportunities, and funding, additional research studies may be pursued. IRB approval will be obtained for any study prior to our contacting participants.

5. Using components from collected data, development of an groundwater arsenic risk model for Virginia. Working with Jebson and Schreiber in Geosciences, a relative risk of exposure to arsenic from groundwater will be developed. Incidence of arsenic in groundwater in Virginia is not well understood to date, and VAHWQP data will provide a better understanding of this geologically occurring contaminant, which is potentially dangerous to human health.

6. Youth VAHWQP project. Working through STEM, agriculture, or science middle and high school teachers, or 4H Extension agents, we will offer water testing to the families of students and 4H members. Families will receive a consent letter explaining the program, and asking for voluntary participation from students whose household water comes from private wells or springs. For 2015, we have a small donation to completely cover the cost of sample analysis ($50 per kit) so there will be no charge to the students' families. Students interested in participating will receive a water sample test kit, follow directions to collect a sample from their household water tap, and bring the sample to school. When possible, the class will travel to Virginia Tech with the water samples on a field trip to tour our lab in the Human and Agricultural Biosciences Building 1 (HABB1), and participate in discussions about well construction and protection, contaminants of concern, and addressing water problems. Sample results will be shared with the classes in a general way (% exceeding recommended levels for certain contaminants, sources of contaminants, and ways to address problems through treatment or improving well construction. Actual results from water sample analysis will be returned to parents directly during a meeting that explains results and addressing problems. Students will assist in presenting this information to their parents, and VAHWQP faculty will be available for questions if needed. If parents are not able to attend this meeting, results will be mailed with interpretation information and contact information for the VAHWQP coordinator, so the parents may follow up with any questions or concerns. Our hope is to reach more famliies reliant on wells and springs across the state with information about the safety of their water, and solutions to problems, if they exist. When available, we will use grant funding to cover the cost ($50 per sample kit). If grant funding is not available, the cost will be $50 per sample kit.

7. PCPP's in Virginia's Private Well Water Research Study: This study is based on the discovery of pharmaceuticals and personal care products (PPCPs) and pesticides in natural streams and drinking water throughout the US and worldwide. Previous investigations on the occurrence of these compounds have been focused on wastewater treatment effluent, surface water resources, and groundwater resources with

little emphasis on private well water. The purpose of the study is to test whether these compounds are present in Virginia private well water supplies and at what concentrations. This study will analyze the impact of well characteristics (age, depth, and type), land usage practices (septic, animal feeding operation, field crops/nursery, and streams), and environmental factors (geology and soil type) on the occurrence and concentrations of PPCPs and pesticides.

2.2 EXPLAIN WHAT THE RESEARCH TEAM PLANS TO DO WITH THE STUDY RESULTS:

For example - publish or use for dissertation

Study results will be used to develop extension and peer-reviewed publications, and to inform future related programming. Results will only be publicly reported on a "lumped" basis, i.e. water quality or survey results may be reported on a county or clinic group level (e.g. x% of participants in Y county provided water samples with a concentration of Z or greater), but never on an individual (household) level (e.g. participants from a household at Y address had a concentration of Z).

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

For the retrospective survey of past VAHWQP participants, subjects may include anyone who participated in VAHWQP drinking water clinics between 2008 up to the year before the survey is administered. This is intended to capture participants that participated at least a year ago, to give them time to perform behaviors such as having a well driller examine their well cap for cracks or damage, or having a septic system pumped. Participants will never be surveyed more than once.

For the drinking water clinics, participation is open to anyone who is over 18 years of age, uses a private drinking water supply system (well, spring, or cistern) and lives in or adjacent to a Virginia county offering a drinking water clinic. Participation in drinking water clinics is completely voluntary.

For the youth VAHWQP programs, participation is open to students enrolled in classes interested in collaborating with us who have wells or springs for their household water and obtain parental consent to test their water, and if applicable, attend the field trip. These classes are identified through existing connections with local Extension offices. Alternatively, we will work with interested 4H agents to reach club members and their families in the same way. Students with wells or springs will have the option to participate and will get consent from parents. Parents will participate by giving consent for children to collect water sample, receiving sample results at a meeting or in the mail. All results are kept confidential and only discussed with the students or public in an aggregation. For 2015, we have an estimate of 54 students across two schools scheduled to participate. For 2016, we will plan to offer this program in 4-5 more schools and/or 4H clubs, reaching an estimated 100-150 students total.

For PPCP's in Virginia's Private Well Water Research Study: The subject pool is comprised of individuals that are 18 years or older that use a well and have participated in the Virginia Tech's Well Water Testing: Drinking Water Clinics (http://www.wellwater.bse.vt.edu/clinics.php) before. Participation in this study is completely voluntary. Participants will be recruited with a letter emailed to the address provided during the drinking water clinic. The letter will be emailed by the coordinator of VAHWQP.

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, visit the following link for further information: http://www.policies.vt.edu/index.php (policy no. 2010)

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

Participation will be voluntary. The program will be advertised through newspaper and radio advertisements, fliers, local civic and church groups, and through county extension mailings.

For Youth VAHWQP, teachers of agriculture, STEM, or science classes will be identified through connections with local Extension offices. Alternatively, we will work with interested 4H agents to reach club members and their families in the same way. Students with wells or springs will have the option to participate and will get consent from parents.

PPCP's in Virginia's Private Well Water Research Study: The pool of households was chosen through pre-selection of two counties of focus from the sampling history of the drinking water clinics. Specific households will be chosen based on parameters (geology, well age, well depth, and well type) that will accomplish the research goals of this project. Once household has been chosen from the pool of past drinking water clinic participants in a county of focus, a letter will be sent via email to the household asking for their volunteer participation in the study; which will include obtaining water samples from their well and being interviewed by a graduate student conducting this project.

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.

Retrospective survey - Participants in VAHWQP programming between the year two years prior and the year before the present year will be selected because: a) they will be familiar with the most recent VAHWQP programming initiated by Dr. Benham and Ms. Ling; and b) at least one year will have elapsed since their initial participation, providing them time to potentially improve their water quality system if their participation identified potential areas of concern.

Focus groups - Potential participants (health workers, state agency employees, Soil and Water Conservation District employees, community leaders) will be identified through existing relationships and recommendation by other key individuals in the identified counties. The focus groups are intended to gather information from people who deal with our target rural population of well and spring users on a regular basis, but are not currently actively engaged in our programs.

Drinking water clinics - Extension agents trained through the Virginia Master Well Owner Network may conduct drinking water clinics in their home counties. Voluntary participation in drinking water clinics is open to anyone over the age of 18 years who relies on a well, spring or cistern for their water supply.

Additional research studies - Based on data gathered, research opportunities, and funding, additional research studies may be pursued. IRB approval will be obtained for any study prior to our contacting participants.

Development of arsenic risk model for Virginia - components of all participant data from 2012 onward will be included in this study (address of sample, metals data and pH from flushed sample).

For Youth VAHWQP, teachers of agriculture, STEM, or science classes will be identified through connections with local Extension offices. Alternatively, we will work with interested 4H agents to reach club members and their families in the same way. Students with wells or springs will have the option to participate and will get consent from parents to participate.

PPCP's in Virginia's Private Well Water Research Study: The population was chosen based on the two counties of focus. First, the counties of focus were selected based on the county having an adequate sampling history from the drinking water clinics (>100 samples). Study investigators are interested in differing well types so we looked for a good distribution of well types and then selected the county of focus based on the geology it is located (crystalline or carbonate bedrock), which is a driver of water quality and contaminant mobility.

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
- ☒ Written/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:

Retrospective phone survey - The surveyor will initially explain the purpose of the call and ask "May I ask you a few questions?"

Focus groups - participants will be told that their participation is completely voluntary, and that nothing they say during the focus group will be attributed to them specifically. A consent to participate form will explain the objective of the study, time will be given to answer any questions, and participants will sign form.

Drinking water clinics - Participation in the drinking water clinics will be wholly voluntary. Return of the questionnaire with the drinking water sample will be assumed to imply consent. The water sample will still be analyzed and results returned to the participants even if s/he chooses not to answer some or all of the questionnaire.

Additional research study - participation in further research study is completely voluntary. IRB approval will be obtained by the PI prior to contacting participants. If participant is interested, they will contact the PI for the specific study directly. If not interested, they can ignore the request for participation.

Youth VAHWQP - Students with wells or springs will have the option to participate and will get consent from parents to participate. Consent form has been uploaded in documents section. Questionnaire will also be completed by participating families.

PPCP's in Virginia's Private Well Water Research Study: Participation in this study is completely voluntary. The participants will be contacted through an emailed letter explaining the study and the letter states to contact investigators if they are interested in participating. A consent form will be reviewed at the time of sampling and interviewing at the well owner's household, and the homeowner's signature obtained at that point.

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

Retrospective phone survey - The surveyor (project co-PI with assistance from graduate student).

Focus groups - PI and Co-PI

Drinking water clinics - The co-PIs and possibly graduate students will collect the questionnaires (hard copy) upon return of the water samples. Hard copy questionnaires will be saved in a locked file cabinet.

Youth VAHWQP - Teachers or 4H agents will distribute consent forms and collect returned consent forms. VAWHQP coordinator will be available to answer any questions about participation. These forms will be copied, and one copy will be returned to teachers or 4H agents, and another copy will be kept in a locked filing cabinet by the VAHWQP coordinator. Participating famlies will also complete the standard drinking water clinic questionnaire and return it with water samples.

PPCP's in Virginia's Private Well Water Research Study: Drs. Kang Xia (CSES, VT), Brian Benham (BSE, VT), and Ms. Erin Ling (BSE, VT) will be overseeing the project and will be guiding Mr. Will Vesely (MS degree graduate student, CSES, VT). Mr. Vesely will be obtaining consent from subjects.

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

Retrospective phone survey - verbally over the phone

Focus group - if possible, via email signature prior to the focus group meeting. If this is not possible, a hard copy of the consent to participate form will be signed the day of the focus group.

Drinking water clinics - when questionnaire and/or waiver (if applicable) is completed by participant.

Youth VAHWQP - Teachers or 4H agents will distribute consent forms and collect returned consent forms. VAWHQP coordinator will be available to answer any questions about participation. These forms will be copied, and one copy will be returned to teachers or 4H agents, and another copy will be kept in a locked filing cabinet by the VAHWQP coordinator on the VT campus. Participating families will also complete the standard drinking water clinic questionnaire and return it with water samples.

PPCP's in Virginia's Private Well Water Research Study: When the participant signs the consent waiver at the time of the scheduled site visit.

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.

Retrospective phone survey - After initial introduction on the phone

Focus groups - prior to focus group meeting by email and/or at the beginning of the focus group meeting

Drinking water clinics - After distribution of sample collection kits, prior to return of kits for analysis

Additional research study - participants interested in volunteering for an additional study, and selected to participate, will complete a consent form to be provided by the PI.

Youth VAHWQP - consent forms will be sent home the week prior to sample collection, and returned prior to students receiving water sample collection kits. Questionnaire will be completed the evening before or morning of sample collection and returned with sample bottles.

PPCP's in Virginia's Private Well Water Research Study: When the participant signs the consent waiver at the time of the scheduled site visit.

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.

Youth VAWHQP - consent forms will be sent home for parents to review several days prior to sample collection. Parents may contact VAHWQP coordinator if there are any questions.

PPCP's in Virginia's Private Well Water Research Study: Letters will be sent out to the past three years of drinking water clinic participants and no sampling will occur until the consent documents are signed.

☐ 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:

Retrospective phone survey - Past VAHWQP drinking water clinic participants will be called (using phone number provided during participation) and asked if they would mind answering a few questions about their management of their water supply. If the participant agrees, the interview should take roughly five minutes.

Focus groups - Participants will be asked to attend a half-hour to hour long meeting at a time and location determined to be convenient for all participants. Facilitators will provide an overview of the VAHWQP program, and then ask 4-5 open ended discussion questions regarding the program, perceptions of private water supplies and associated testing and maintenance requirements, perceptions of connections between human health and private water supplies, and ideas for messaging. Focus group participants will be asked to agree to participate by signing an informed consent form at the beginning of the meeting.

Drinking water clinics - Programs are launched through local evening meetings (more than one evening meeting may be necessary if several county programs are conducted at one time) and are usually held in a centrally located meeting hall. Attendees of these initial meetings are presented with information on local geology characteristics in relation to groundwater pollution, the nature of household water quality problems, and specifics of the water testing program to follow. Attendees are invited to sign up to participate in the testing program. Each participant will pay $50 for a sampling kit. These sampling kits will consist of a questionnaire, sample collection instructions, and four pre-sterilized bottles: one 125 mL bottle for bacterial analysis (E. coli, coliform), one 250 mL bottle for microbial source tracking analysis, one 125 mL "first draw" bottle for initial metals (arsenic, lead) analysis, and one 250 mL "flushed" sample bottle for other analyses (arsenic, lead, iron, manganese, hardness, sulfate, chloride, fluoride, total dissolved solids, pH, copper, sodium, and nitrate). The accompanying questionnaire asks about water system characteristics, homeowners perceived water quality, basic household demographics (age, income, education level), and incidence of gastointestinal illness in the past month. Instructions with the sampling bottles explain how to collect the samples (collect "first draw" sample after water has spent 6 hours+ in the distribution system, allow tap to run five minutes, collect water in following three bottles).

Shortly after the initial program meeting, water samples are received over a three hour period from participants at a designated local drop-off point (usually the Extension office). The samples are packed in ice and immediately delivered to the Water Quality Lab in the Biological Systems Engineering Department at Virginia Tech for analysis. Water quality analyses will be performed immediately by the BSE Water Quality Lab Manager and project graduate students using standard USEPA or APHA procedures.

After the analysis is complete (three to four week period), participants are encouraged to attend a final program meeting (typically held at the same location as the initial meeting) to obtain their confidential test results (provided in a sealed envelope) and discuss management practices to reduce or prevent water contamination or address problems, if any were identified. Results are provided to each participant in a sealed envelope. In addition to the extension agent giving the presentation, other representatives from Virginia Department of Health or Virginia Water Well Association may be available to discuss potential ways

to address potential water quality problems.

Additional research studies - Based on data gathered, research opportunities, and funding, additional research studies may be pursued. IRB approval will be obtained for any study prior to our contacting participants.

Optional data sharing - Occasionally, another entity, such as a county or groundwater management entity wishes access to water quality data stripped of identifying information. In this case, we will include a letter in the sample kit for these clinics explaining what will be done with the data and that identifying information will be excluded from what is shared (name, address, phone number, email). Participants will have the option to opt in or out of sharing the information. Letters of consent for data sharing will be submitted to IRB for approval prior to use.

Development of arsenic risk model for Virginia. Jebson and Schreiber will put arsenic and pH data from flushed household water samples (2012 and onward) in a logistic regression model with other existing data to determine, if any, correlations between geology, soil data, and other groundwater chemical data (obtained from Virginia Department of Enviromental Quality (DEQ)). Chemical parameters other than arsenic will be used as explanatory variables. Arsenic and pH data will be put into a GIS with other data, collected by DEQ, and will be included on a statewide map of Virginia Specific arsenic concentrations will not be identified, nor will specific addresses or points on a map, but relative risk for arsenic exposure will be identified as high, medium or low.

Youth VAHWQP project. Working through STEM, agriculture, or science middle and high school teachers, or 4H Extension agents, we will offer water testing to the families of students and 4H members. Families will receive a consent letter explaining the program, and asking for voluntary participation from students whose household water comes from private wells or springs. Students interested in participating will receive a water sample test kit, follow directions to collect a sample from their household water tap, and bring the sample to school. When possible, the class will travel to Virginia Tech with the water samples on a field trip to tour our lab in the Human and Agricultural Biosciences Building 1 (HABB1), and participate in discussions about well construction and protection, contaminants of concern, and addressing water problems. Sample results will be shared with the classes in a general way (% exceeding recommended levels for certain contaminants, sources of contaminants, and ways to address problems through treatment or improving well construction. Actual results from water sample analysis will be returned to parents directly during a meeting that explains results and addressing problems. Students will assist in presenting this information to their parents, and VAHWQP faculty will be available for questions if needed. If parents are not able to attend this meeting, results will be mailed with interpretation information and contact information for the VAHWQP coordinator, so the parents may follow up with any questions or concerns. Our hope is to reach more famliies reliant on wells and springs across the state with information about the safety of their water, and solutions to problems, if they exist. When available, we will use grant funding to cover the cost ($50 per sample kit). If grant funding is not available, the cost will be $50 per sample kit. All details of the program delivery regarding water testing and interpretation will be the same as described under "Drinking water clinics" above.

PPCP's in Virginia's Private Well Water Research Study: An interest letter will be emailed to the 2014-2016 drinking water clinic participants from Montgomery and Spotsylvania counties that have been selected based on the criteria described above. Households that will be sampled will be determined based on the responses and being able to sufficiently analyze the project variables. In the letter requesting participation, the participants will be informed about the detailed contents of the questionnaire. During the scheduled visit to the household, after the consent form has been signed, the participants will be verbally given a questionnaire asking about the medications they take, medications they give to their pets and livestock, septic tank history if applicable, and the pesticides they apply to their fields or lawn. We will discuss with the participants the purpose of the study and what the sampling process is as well as answer any questions they have. Participants will allow us to use their drinking water supply system to collect 500 mL of water sample for this study from the faucet of the drinking water supply. As an incentive for participation, participants will be given a free water analysis identical to what they received through the drinking water clinic (value $55).

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Retrospective survey - Data will be collected in an Access database by the surveyor as the partcipant

answers questions.

Focus groups - data will be collected by an audio digital recording device, and transcribed.

Drinking water clinics - Data will be collected on laboratory bench sheets signed by the analyst and then entered into an Access Database with accompanying questionnaire data. The database will be used to generate participant summary reports, and to analyze data for future publication.

All data will be stored on password-protected Virginia Tech servers only accessible by the Co-PIs. All data reported publicly will be stripped of participant identifying information such as name, address, etc.

PPCP's in Virginia's Private Well Water Research Study: Questionnaire data, water quality analysis data, and original consent forms will be recorded on a laboratory notebook and then the data will be manually entered into an electronic database stored on a password-protected. All paper documents (e.g., signed consent forms and paper surveys) with identifying information will be stored in locked filing cabinets inside a locked office for 5 years.

5.3 DOES THE PROJECT INVOLVE ONLINE RESEARCH ACTIVITES (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 ☐ Blackboard, 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?

Retrospective survey - Participation is voluntary. Risks are minimal and not greater than those ordinarily encountered in daily activities.
Focus groups - Participation is voluntary. Risks are minimal and not greater than those ordinarily encountered in daily activities.
Drinking water clinics - Participation is voluntary. Risks are minimal and not greater than those ordinarily encountered in daily activities. Analysis data is confidential unless the participant chooses to discuss results with program investigators.
Additional research studies- Participation is voluntary. Risks are minimal and not greater than those

ordinarily encountered in daily activities. Potential risks to participation will be covered in an additional IRB protocol. All data reported publicly will be stripped of participant identifying information such as name, address, etc.
Youth VAHWQP - same as Drinking water clinics above.

PPCP's in Virginia's Private Well Water Research Study: All confidential information will be stored on a password-protected server. Data will be restricted to the PIs/co-PIs and participating graduate student. Any data reported will not allow identification of the individual participants. Participation is voluntary. Risks are minimal and not greater than those ordinarily encountered in daily activities.

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

Retrospective survey - All data will be confidentially stored on password protected Virginia Tech servers. No one but study PIs and associated graduate students will have access to the data, and any data reported will be on a level at which it will be impossible to identify individual participants.

Focus groups - All data will be confidentially stored on password protected Virginia Tech servers. No one but study PIs and associated graduate students will have access to the data, and any data reported will be on a level at which it will be impossible to identify individual participants.

Drinking water clinics - All data will be confidentially stored on password protected Virginia Tech servers. No one but study PIs and associated graduate students will have access to the data, and any data reported will be on a level at which it will be impossible to identify individual participants.

Additional research studies - Potential risks to participation will be covered in an additional IRB protocol.

Youth VAHWQP - same as Drinking water clinics above. Extra steps will be taken to ensure that students don't receive sensitive information about their water quality at school to avoid embarrassment or stigma - parents will receive this information directly during the meeting or via mail to the home.

6.3 WHAT ARE THE DIRECT OR INDIRECT ANTICIPATED BENEFITS TO STUDY PARTICIPANTS AND/OR SOCIETY?

Retrospective study - the surveyor will offer information on any similar nearby programs if the participant is interested. The results of this study will be used to adapt and improve messaging for future programming.

Focus groups - knowledge of our programming and materials to assist them in helping clientele with private water supplies.

Drinking water clinics - Participants will receive affordable analysis of their home drinking water quality and basic information on home water system maintenance. They will learn about potential health and nuisance effects associated with contaminated water, and be offered educational advice about maintaining their system, routine testing and interpretatio, and addressing water problems.

Additional research study - opportunity to volunteer to participate in additional study. Benefits to be determined based on specifics of study.

Youth VAHWQP - same as Drinking water clinics above. In addition, students will learn this information first hand, which will be linked to specific standards of learning.

PPCP's in Virginia's Private Well Water Research Study: The anticipated societal benefit of this investigation is improved knowledge of the extent and type of PPCPs and pesticides that are present and their concentrations in Virginia private well water supplies. This information would be useful to policy and decision makers and informative to the concerned citizens including the participants.

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 MENTALLY DISABLED PERSONS?

☒ **No,** go to question 7.3
☐ **Yes,** answer questions within table →

IF YES
This research involves: ☐ Prisoners ☐ Pregnant women ☐ Fetuses ☐ Human in vitro fertilization ☐ Mentally disabled persons

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 ANY STUDY FILES CONTAIN 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 →

IF YES
Describe if/how the study will utilize study codes: Retrospective survey - The surveyor (asking the

questions) will have access to the partcipants' name and phone number; however, the surveyor will not have any information about the participants' water quality (i.e. whether the sample they provided during the VAHWQP clinic was positive for any contaminants, etc.). This data will be available to the researchers for analysis through a code that will allow the survey questions and prior observed water quality to be linked.

Drinking water clinics - New clinic participant provided drinking water samples will be issued an alpha-numerical code upon arrival in the lab, which will be written on the accompanying household questionnaire. Laboratory analysts will use this alpha-numeric code to label and report water quality results.

Development of arsenic exposure risk model: Specific arsenic concentrations will not be identified, nor will specific addresses or points on a map, but relative risk for arsenic exposure will be identified as high, medium or low.

PPCP's in Virginia's Private Well Water Research Study: Yes. The pre-visit inquiry letter, consent forms, and the onsite questionnaires will contain confidential information such as name, addresses, phone number and email. Only the PIs/co-PIs and graduate student will have access to this information, which will be stored on a password protected server in the BSE department at VT.

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? Retrospective survey - The codes will be available in a separate file. The PIs and the research team (graduate students) will have access.**

Drinking water clinics - The questionnaires (with the codes written on them) will be stored in a locked filing cabinet. Ultimately, the questionnaire and water quality data will be entered into an Access database, which will be stored on password protected VT server.

Development of arsenic risk model: All data will be stored on password protected Virginia Tech servers.

Youth VAHWQP - all signed consent forms and completed questionaires will be stored as explained under "Drinking water clinics" above.

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 WHERE WILL DATA BE STORED?

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

Hard copy data (laboratory bench reports, questionnaires) will be stored in a locked cabinet. Access databases of the collected data will be stored on a passowrd-protected server in the BSE department.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

The PIs, co-PIs, and participating graduate students will have access to the "raw" data. All data will be stored on Virginia Tech password-protected servers with limited access (only research team).

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

Access databases will be retained indefinitely. All data will be stored on Virginia Tech password-protected

servers with limited access (only research team). Hard copy questionnaires will be shredded in five years.

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

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

IF YES
Does the study plan to obtain a Certificate of Confidentiality? ☐ No ☐ Yes (Note: participants must be fully informed of the conditions of the Certificate of Confidentiality within the consent process and form) *For more information about Certificates of Confidentiality, visit the following link:* *http://www.irb.vt.edu/pages/coc.htm*

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
What is the amount of compensation? Drinking water sample analysis valued at $50+ provided for free when possible. In 2015 we received a donation from Southeast Rural Community Assistance Program to support private well education and testing. We are using this funding to pay for sample analysis for the youth VAHWQP. We will update the protocol if the funding situation changes in 2016. **PPCP's in Virginia's Private Well Water Research Study: Virginia Tech will pay the $25 per water sample for the materials and supplies and the analytical cost for the determination of PPCPs and pesticides. As compensation for their participation in this study each participating household will receive a complementary water test identical to the test they received through the drinking water clinic (value: $55). All the travel expenses related to the site visits will be paid by Virginia Tech.**
Will compensation be prorated? ☐ Yes, please describe: ☒ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study? **Participants either provide sample and receive analysis or do not** *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
This project involves: ☒ Audio recordings only ☐ Video recordings only ☐ Both video and audio recordings
Provide compelling justification for the use of audio/video recording: **To document discussions in focus groups only.**
How will data within the recordings be retrieved / transcribed? **Audio recordings will be transcribed by research assistants into Microsoft Word.**
How and where will recordings (e.g., tapes, digital data, data backups) be stored to ensure security? **The audio-tapes will be stored in locked files before and after being transcribed**
Who will have access to the recordings? **The project investigators and graduate students**
Who will transcribe the recordings? **The project investigators; graduate students; hourly paid research assistants. Transcribers will sign a form stating that they will not discuss any item on the tape with anyone other than the researchers.**
When will the recordings be erased / destroyed? **Tapes will be destroyed within 2 weeks of completing the transcriptions and the transcriptions will be destroyed 3 years after the completion of this evaluation.**

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: All students in selected classes will be invited to participate in classroom activities associated with this project, whether their own water samples are tested or not.** **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: This issue will be addressed by teachers at participating schools. We are aware that some students will not be able to participate due to not wanting to miss class during the field trip.**
Is the school's approval letter(s) attached to this submission? ☐ Yes ☐ No, project involves Montgomery County Public Schools (MCPS) ☒ No, explain why: **Have not received yet.** *You will need to obtain school approval (if involving MCPS, click here: http://www.irb.vt.edu/pages/mcps.htm). Approval is typically granted by the superintendent, principal, and classroom teacher (in that order). Approval by an individual teacher is insufficient. School approval, in the form of a letter or a memorandum should accompany the approval request to the IRB.*

11.3 DOES THIS PROJECT INCLUDE COLLEGE STUDENTS?

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

IF YES
Some college students might be minors. Indicate whether these minors will be included in the research or actively excluded: ☐ Included ☐ Actively excluded, describe how the study will ensure that minors will not be included:
Will extra credit be offered to subjects? ☐ No ☐ Yes **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)

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.

☐ **No,** go to question 13.1
☒ **Yes,** answer questions within table

IF YES
Does the project reasonably pose a risk of reports of current threats of abuse and/or suicide? ☒ No ☐ Yes, thoroughly explain how the study will react to such reports: *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.*
Are you requesting a waiver of parental permission (i.e., parent uninformed of child's involvement)? ☐ No, **both** parents/guardians will provide their permission, if possible. ☒ No, **only one** parent/guardian will provide permission. ☐ Yes, describe below how your research meets **all** of the following criteria (A-D): Criteria A - The research involves no more than minimal risk to the subjects: Criteria B - The waiver will not adversely affect the rights and welfare of the subjects: 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:
Is it possible that minor research participants will reach the legal age of consent (18 in Virginia) while enrolled in this study? ☒ No ☐ 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: *For more information about minors reaching legal age during enrollment, visit the following link:* *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.*

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

13.1 DOES THIS PROJECT INVOLVE DECEPTION?

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

IF YES
Describe the deception:
Why is the use of deception necessary for this project?
Describe the debriefing process:
Provide an explanation of how the study meets <u>all</u> 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? Originally from participant water samples, now stored in Access databases on password protected servers. Participation in drinking water clinics is voluntary and written consent is obtained when participants complete the questionnaire and submit their water samples.
Provide a detailed description of the existing data that will be collected or studied/analyzed: Initially, addresses will be included in the data, but this information will be stripped out of anything shared outside the group of co-PIs. Data shared publicly will not contain any identifying participant information, and data will be generalized to create a gradated risk model. Metals data from flushed water samples collected from January 2012 onward will be used to determine any correlations with locations and metals concentrations to develop an arsenic risk model for the state of Virginia. **PPCP's in Virginia's Private Well Water Research Study: Information collected previously as part of the drinking water clinic survey (well age, depth and proximity to contamination sources) will be reviewed with the participant and used in this study.**
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? Yes, signed consent will be obtained

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----------