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/humansubjects/guidance/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]:
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:

The purpose of this study is to collect data from various individuals who use technologies related to the locating of underground utility assets in order to compile a centralized database of the information. This information will then be used in a web-based decision support tool to help engineers, designers, constractors, etc. choose an appropriate technology for their specific project. The decision support tool is being developed because 1) no current record of all technologies and their limitations/use exists, 2) the standardized collection of data will lead to the ability to compare multiple technologies based on project needs and limitations through pre-defined parameters, 3) help reduce costs associated with using an innappropriate method and 4) increase project safety by accurately determining the location of underground utility assets.

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

For example - publish or use for dissertation

The data collected from vendors/consultants will be used to compile a standard database within the computer program being developed to use for selecting which technology is appropriate for a certain project.

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 be practicing engineers, state transportation officials, geophysicists, and any personnel directly involved with the daily use of current locating technologies or someone within the company who has sufficient knowledge of the devices to accurately answer the questions relating to its use.

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:

Existing relationships with persons in the industry will be used and references provided by them for further participants. Certain companies or organizations (such as the Virginia DOT) who would benefit from the development of this support tool will be contacted directly to request their participation.

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.

This population was chosen because of their regular use of locating technologies. These individuals are also typically involved in research to improve technologies and are involved in major utility relocation, rehabilitation, or repair projects where multiple utilities and project conditions may exist. These companies and organizations are heavily involved in projects that directly impact the public around the world and are considered the best in subsurface utitlity engineering.

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: **Confirmation through emails sent in response to a letter/email describing the study, its' purposes, and the desired outcome of the project.**

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?

The PI, Sunil Sinha, and the Co-investigator Lewis Hutchins

4.4 WHERE WILL THE CONSENT PROCESS TAKE PLACE?

Online, through an email response from the participants stating their desire to voluntarily participate in the study, OR through participants voluntarily returning the questionnaire.

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.

At the beginning, when potential participants are initially contacted and introduced to the study.

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:

Upon accepting the invitation to participate, participants will be asked to complete a 9 page questionnaire comprised of multiple choice and fill in the blank questions (approximately 90% multiple choice). The anticipated amount of time to complete the questionnaire is 30 - 45 minutes and will be done at the location chosen by the participant on his/her own time and accord - there will be no involvement by the research team unless participants have a question regarding filling out the forms, in which case a phone call or email response will be sent.

5.2 DESCRIBE HOW DATA WILL BE COLLECTED AND RECORDED:

Data will be collected on the Microsoft Excel-based questionnaires and returned to the research team. The data will then be entered into an Excel program and stored as a database within the decision support tool program.

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?

No risks regarding the catergories listed have been found to exist.

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

Not applicable - no risks have been found to exist.

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

Upon completion of the support tool and compilation of the information gathered into a standardized database, participants will have access to the study results (which will have no information linking participants) and the program to use as needed to decrease risks on a project involving undergound utilities and lessen the economic burden of completing these projects through the proper use of technology.

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: Upon receipt of completed questionnaires, the participants will be given an individual ID in lieu of using their names.
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 document will be stored on the computer of Dr. Sunil Sinha, in his faculty office on the VT campus. The desktop computer remains in**

Patton Hall, locked in his office, further locked within the confines of the VCEMP office, and is password protected. No one other than Dr. Sinha uses or has rights to this computer. Upon completion of the study and thesis, the may be destroyed. Participants may be acknowledged in the final report but their roles or what data they provided will not be disclosed.

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

Excel questionnaires will be stored on the personal computer of Lewis Hutchins with password restricted access.

8.4 WHO WILL HAVE ACCESS TO STUDY DATA?

Only the research team will have access to the data, and only Lewis Hutchins will have direct access to the files.

8.5 DESCRIBE THE PLANS FOR RETAINING OR DESTROYING THE STUDY DATA

Upon successful publication of the Thesis leading to the Masters Degree in Civil Engineering, all files will be handed over to Dr. Sunil Sinha for retainment for a period of time while the thesis is reviewed and until it is determined that future work in this field will not need the data collected.

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?
Will compensation be prorated? ☐ Yes, please describe: ☐ No, explain why and clarify whether subjects will receive full compensation if they withdraw from the study? *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:
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?
Who will have access to the recordings?
Who will transcribe the recordings?
When will the recordings be erased / destroyed?

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: *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?
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----------