CONCISE SUMMARY
Endoscopic versus Shunt Treatment of Hydrocephalus in Infants (ESTHI)
Hydrocephalus Clinical Research Network

Your child is being asked to join a research study. The research is for children who have Hydrocephalus. Before you consider having your child be a part of the research, you should be aware of the following information:

• Research is voluntary. Your child does not have to be in this study.
• Your child will get the standard medical care for their Hydrocephalus even if you decide not to have your child join the study.
• This study is being conducted to see if there is a difference between Endoscopic Third Ventriculostomy with Choroid Plexus Cauterization (ETV+CPC) and Ventriculoperitoneal Shunt (VPS) on brain function.
• To confirm that your child is a good candidate for this study, we will send your child’s medical information to a group of Hydrocephalus experts. They will confirm if your child could be in this study.
• This study uses randomization. This means neither you nor the surgeon will not pick which of the two surgeries your child receives. There is a 50/50 chance of getting ETV+CPC and a 50/50 chance of getting VPS.
• During surgeries, it’s typical to drain a small amount of Cerebrospinal Fluid (CSF) and discard it. Instead of discarding it, we will send it to another hospital to analyze the proteins in it.
• Everyone in the study gets standard medical treatment for Hydrocephalus.
• This study includes visits to a Neuropsychologist. The Neuropsychologist will assess your child’s mental development.
• The study lasts about 5 years. If you choose to enroll your child now, you can still choose to remove them from the study at any time.
• Your child might benefit from being in the study, but there is no guarantee of benefit.
• This study has some risks, such as loss of confidentiality. The risks are explained later in this document.
• Please be sure all your questions are answered before you decide to let your child be in the study.
• If you think you want your child to be in the study, you should read the rest of this document and discuss it with the study team. The document explains what will happen to people in the study.

____________________
Parent/Guardian’s initials confirming discussion
Parental Permission and Authorization Document
Primary Children’s Hospital

Study Title: Endoscopic versus Shunt Treatment of Hydrocephalus in Infants (ESTHI)

Principal Investigator: John Kestle, MD

Study Sponsor: National Institute of Health (NIH)

Source of Support: National Institute of Health (NIH)

Multicenter: Hydrocephalus Clinical Research Network (HCRN)

Study Investigators: John Kestle, MD

BACKGROUND
Why is this research being done?

Your child is being asked to participate in a research study at Primary Children’s Hospital because he/she is having a surgical procedure for the treatment of hydrocephalus. Hydrocephalus occurs when excess fluid (known as cerebrospinal fluid or “CSF”) builds up in the brain (in the fluid-filled chambers called “ventricles”). This puts pressure on the brain, which can lead to problems in normal growth and development.

A common treatment of hydrocephalus is the placement of a shunt. A shunt is a small plastic tube that is placed through incisions on the scalp into the ventricles. The tube is then tunneled under the skin to the abdomen. The excess fluid flows through the tubing and is absorbed. This is the most common way to treat hydrocephalus and has been in use for many years.

Another treatment for hydrocephalus is endoscopic third ventriculostomy with choroid plexus cauterization (ETV+CPC). ETV is a procedure where a small camera is inserted into the ventricles and is used to make a hole in the floor of the third ventricle, allowing CSF to flow out of the brain. CPC is a procedure that reduces the production of CSF. Combining ETV with CPC (“ETV+CPC”) has been in use in North America for about 10 years.

Surgeons have to decide which of these procedures to use when treating infants with hydrocephalus. Currently, there is no clear evidence that one procedure is superior to the other. Both procedures can fail, requiring repeat surgeries. The chance of the procedure...
failing early (within 6 months) is higher with ETV+CPC compared to shunt, but the chance of the procedure failing later (after 6 months) might be less with ETV+CPC compared to shunt. Shunts drain more CSF, usually resulting in ventricles that are closer to normal-size compared to ETV+CPC. We do not know, however, if this makes any difference to brain function.

Both procedures are commonly used by pediatric neurosurgeons. It is unclear whether one procedure or the other has a worse long term outcome; they may be the same. This study is being conducted to see if there is a difference between shunt and ETV+CPC on brain function. If you think you might be interested in this study, our first step is to get an opinion from a panel of hydrocephalus experts. If you agree, we would send your child’s medical information and brain images to the panel. We will ask them if they think that both procedures (shunt and ETV+CPC) are good options for your child. The information we share with the panel will not include your child’s name, and will be the minimum amount of information necessary for them to determine if both procedures are good options. We will then share the panel’s opinion with you. If they feel that one of the options (ETV+CPC or shunt) is a poor choice for your child, we will let you know and we will not discuss this study any further. If the panel of hydrocephalus experts feels that both procedures are appropriate options for your child then we will discuss the randomized trial with you and you can decide whether or not to have your child participate in the study. Your signature here is to allow us to share your child’s medical details with the panel of hydrocephalus experts, and is not at this time to provide consent for your child’s participation in this study.
CONSENT to share medical information with a panel of hydrocephalus experts:
I confirm that I have read and understand this consent and authorization document up to this point, and have had the opportunity to ask questions. I understand that sections of any of my child’s medical notes may be looked at by responsible individuals from Primary Children’s Hospital, from the international group of hydrocephalus experts, and from regulatory authorities where it is relevant to my child taking part in research. I give permission for these individuals to have access to my child’s records. I understand that my child’s participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child’s medical care or legal rights being affected. I will be given a signed copy of the consent and authorization form to keep.

I understand that once the panel of hydrocephalus experts provides their opinion, this will be shared with me and that by signing below I am not providing consent for my child to be enrolled into this study. Rather, once the panel of hydrocephalus experts has provided their opinion I will then be given the opportunity to consider whether or not I will provide consent for my child to participate in this study, as will be explained in the remainder of this document.

___________________ ________________________ _________________________
Child’s Name Parent/Guardian’s Name Relationship to Child

____________________ _________________________
Parent/Guardian’s Signature Date

________________________________________
Name of Person Obtaining Authorization and Consent

________________________________________
Signature of Person Obtaining Authorization and Consent

__________________________
Date
CONSENT to participate in Randomized Trial:

Randomized Trial: Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. The best way to make a fair comparison is to do a randomized trial. In a randomized trial your child will have a 50/50 chance (similar to the flip of a coin) of having ETV+CPC or shunt to treat their hydrocephalus.

This study is being conducted under the direction of the Hydrocephalus Clinical Research Network by John Kestle, MD at Primary Children’s Hospital. You have a right to know about the procedures, risks, hazards, discomforts, and possible benefits of this study to assist you in making an informed decision about whether or not you want your child to participate. Before deciding, it is important that you read and understand this form. If there is anything you do not understand about the study after reading this information, please ask your study doctor or any study staff member.

This document is called an “informed consent form” and it explains:

- The purpose of this research study
- What will happen during this study, such as procedures that will occur, data being collected, and what your child’s participation will require
- What the risks are to your child due to being in this study
- The potential benefits, if any, of being in this research study
- The answers to any questions you may have

If all of your questions have been answered to your satisfaction, and you decide to allow your child to take part, you will be asked to sign this consent form. You will be given a copy of this consent form after it has been signed and dated by you and the investigator, to keep for your records, if you wish.

Who is being asked to take part in this research study?

Your child is being invited to take part in this research study because your child is having a procedure for the treatment of hydrocephalus. Patients invited to participate in this study must be 12 months of age (corrected) or under and able to have either a shunt or ETV+CPC, based on their pre-operative MRI.

What procedures will be performed for research purposes?

If you decide to have your child take part in this research study, your child will undergo the following procedures:
Surgical Procedure:
The preparation that your child receives prior to surgery (e.g. doctor evaluations, laboratory tests, imaging) is the same whether your child participates in the study or not. For those patients in the study, the decision to perform a shunt or ETV+CPC surgery will be made through a computer generated randomization program (similar to flipping a coin) once the child is in the operating room. The incision for either surgery is made at the top of the head.

Both of these surgical procedures are standard and are commonly performed by pediatric neurosurgeons; neither one is experimental.

Patients are usually in the hospital for one to two days after surgery for hydrocephalus, but other issues and complications can keep them in the hospital longer. We don’t anticipate any complications arising as a result of the selected surgical procedure, but your child will be closely watched and data will be collected to document any issues that your child may experience whether or not they are associated with the choice of surgical procedure.

During your child’s surgery, as per usual care, we typically drain some CSF from the brain and at the end of the surgery it is discarded. Instead of discarding it we would like to keep a small sample and send it to a CSF Repository at Washington University in St. Louis, Missouri. This will allow us to test the CSF for specific proteins to see if we can learn more about hydrocephalus or brain function. Your child’s CSF sample collected for this research study will not include whole genome or whole exome sequencing. This means that the researchers have no plans to look at or try to “read” the protein information that makes up your child’s genes (DNA) in the sample. Your child’s CSF sample will only be used for this study.

Neurocognitive Testing:
The main question this study is trying to answer is whether there is a difference between ETV+CPC and shunt in terms of patients’ brain function later on. In order to measure this, your child will have neurocognitive testing before (or shortly after) surgery, and 12 months later. In addition we would like to do the testing again when your child is 3 and 5 years old. The time for neurocognitive testing can vary from patient to patient, but is expected to take anywhere from 1 to 2 hours for this study.

Questionnaires
You will be asked to complete a brief survey to assess your child’s progress. The questions vary based on your child’s age and will be taken around the time of surgery, at hospital discharge, 1 year after surgery and at 3 and 5 years of age. This questionnaire will take about 30 minutes to complete.
**Diffusion Tensor Imaging:**
Your child will receive imaging such as MRI, CT, or ultrasound as a normal part of their treatment for hydrocephalus, whether you decide to participate in the study or not. If you do decide to participate in the study, your child’s MRI will include DTI (diffusion tensor imaging). This type of imaging is used to see if the parts of the brain which relay information (white matter) appear normal or have damage. Many hospitals include DTI as part of routine MRI. If yours doesn’t, it will be added for this study and will add 1 to 2 minutes to the usual MRI length. This MRI will be done 12 months after your child’s surgery and will be sent, along with the MRI done before your child’s surgery, to Penn State University. They will measure the size of your child’s ventricles and brain tissue.

**Monitoring and Follow-up:**
If your child qualifies to take part in this research study, your child will have data collected that will indicate how well they are doing at their regular follow up visits. All patients will be followed as per the routine recommendations of their surgeon; no additional visits or tests will be required other than the neurocognitive testing and MR DTI described above. In general, the first follow-up visit is in the first 12 weeks after surgery and then will occur at least yearly (some surgeons may prefer to see patients more often). An imaging study of the brain is usually done within 3 months of shunt surgery to check the status of the shunt or ETV+CPC and to re-evaluate the size of the ventricles. For those patients who have consented to be in the study information from these images and any done at later visits will be collected. We will follow and collect follow-up information on all children who participate in the study until the study ends. Enrolled patients will be followed for at least 12 months. We also want to monitor how your child is doing when they reach school age. We will repeat the neurocognitive testing and DT MRI when your child is 3 years old, and again at 5 years old. These MRIs will also be sent to Penn State University.

While your child is enrolled in this research, we will contact you occasionally to keep in touch, help schedule neurocognitive testing, and make sure we have your current phone number and any back-up contact information.

If your child’s shunt or ETV+CPC stops working or has any other problems we will collect data about what happened, which will include data about the hospitalization, imaging, and surgery required to repair or replace it. If this does happen and another surgery is required, we will again collect a small sample of CSF from his/her head at the time of surgery. This small sample will also be shipped to the CSF Repository at Washington University for evaluation.
What are the possible risks, side effects, and discomforts of this research study?

Both surgical procedures are part of the standard of care delivered to children with hydrocephalus needing fluid diversion. All ETV+CPC and shunt procedures are associated with low incidences of: incisional pain after surgery, the risk of infection and bleeding, new seizures or changes in seizures, CSF leak, new neurologic problems, injury to abdominal organs (only associated with shunt), and low sodium in the body (hyponatremia). Your doctor will discuss these risks with you. All MRI imaging done while your child is enrolled in this research will be standard of care. Because medical imaging is being done, some children may experience claustrophobia in the MRI scanner and might need sedation. This may occur whether your child is participating in this study or not. There are no additional medical or surgical risks that are expected to occur from participating in this trial. It is possible in all research and medical care that your child may experience a previously unknown risk or side effect.

As in most research, there is a risk that your child’s personal information could be accessed by an unauthorized individual; however, great care will be taken by the research staff to prevent such attempts. Any information about your child obtained from this research will be kept as confidential (private) as possible. All records related to your child’s involvement in this research study will be stored in locked filing cabinets or on computers protected with passwords. Your child’s identity on these records will be indicated by a case number rather than by name, and the information linking these case numbers with your child’s identity will be kept separate from the research records. Your child will not be identified by name in any publication of the research results.

What are possible benefits from taking part in this study?

There are no direct benefits to your child from participating in this study. The information we get from this study may help us treat future patients by knowing if one hydrocephalus treatment surgery is better than the other in terms of later brain function.

What treatments or procedures are available if I decide not to have my child take part in this research study?

You may choose not to have your child participate in this study and your child will receive the same level of care they require without any penalty.

Will the results of this study be available to me?

During this study, we may learn something about hydrocephalus that could help you and your child’s doctor make decisions about their healthcare. When the study is finished, the results will be publically available at http://www.ClinicalTrials.gov.
PERSON TO CONTACT

Whom should I contact if I have questions or if my child experiences any side effects, adverse events, or injury?

If you have any questions about this research study (including information about medical treatment and compensation), or if your child experiences any side effects, adverse events or injury during participation in this research study, you should contact John Kestle, MD at 801-662-5362 or Lynette Holman at 801-662-5352 Monday through Friday from 9:00am to 4:00pm MST.

In the event of a medical emergency, you can contact Primary Children’s Hospital 24 hours a day at 801-662-1000, and ask for the on call neurosurgeon.

INSTITUTIONAL REVIEW BOARD

If you have questions regarding your child’s rights as a study subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board Office at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

COMPENSATION IF INJURY OCCURS

Who will pay if my child is injured as a result of taking part in this study?

If your child is injured from being in this study, medical care is available at Primary Children’s Hospital, as it is to all sick or injured people. The University of Utah and Primary Children's Hospital has not set aside any money to pay the costs for such care. The University and Primary Children's Hospital will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care your child receives. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If your child is injured in this study, and you want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.
VOLUNTARY PARTICIPATION

Is my child's participation in this research study voluntary?

It is up to you to decide whether or not your child will take part. If you do decide that your child will take part you will be asked to sign this consent form. If you decide your child will take part you are still free to withdraw your child at any time and without giving a reason. This will not affect the relationship you have with your doctors or staff nor standard of care your child receives. It will also not affect your child’s current or future medical care at the hospital or affiliated health care providers or your current or future relationship with a health care insurance provider.

Your child’s doctor is involved as an investigator in this research study. As both your doctor and a research investigator, they are interested both in your child’s medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your child’s study participation, you may discuss your child’s care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your child’s doctor.

RIGHT OF INVESTIGATOR TO WITHDRAW

You may withdraw your child from the study at any time without penalty. Dr. John Kestle or the study sponsor can withdraw your child without your approval. Effective medical care is the primary concern of your child’s physician and the investigator.

Circumstances may arise that may warrant discontinuation of this study according to their judgment without regard to your consent.

COSTS TO SUBJECTS AND COMPENSATION

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Any costs that may be incurred as a part of the study (i.e., the administration of the neurocognitive testing or the addition of DTI to imaging) will not be your responsibility, or your insurance provider’s responsibility. You will, however, continue to be responsible for costs incurred whether or not you participate in this study, such as your child’s hospital stay and any standard of care (routine) services, including costs not covered by your insurance, such as any applicable co-pays, coinsurances, and deductibles. You will be billed in the standard fashion for your child’s routine care (not study-related).
**Will I be paid if my child takes part in this research study?**

To cover any costs incurred for time away from work and/or travel for your child to undergo the neuropsychological assessments, you will receive $500 following the successful completion of your child’s neuropsychological assessments.

**NEW INFORMATION**

*If I agree to have my child take part in this research study, will I be told of any new risks that may be found during the course of the study?*

You will be promptly notified if, during this research study, any new information develops which may cause you to change your mind about allowing your child to continue to participate.

**NUMBER OF SUBJECTS**

We expect about 176 children from 14 children’s hospitals will be in this study and about 25 from Primary Children’s Hospital. The sites participating in this study are in a network consisting of pediatric neurosurgeons at hospitals in the United States and Canada. The study is expected to last 5 years, with an additional 2 year follow up study for monitoring school age children.

**APPROVAL TO USE YOUR CHILD’S PROTECTED HEALTH INFORMATION**

*Will this research study involve the use or disclosure of my child’s identifiable medical information?*

This research study will involve the recording of current and/or future identifiable medical information from your child’s hospital and/or other (e.g., physician office) records. The information that will be recorded will be the minimum necessary to study the differences between shunt and ETV+CPC. The medical record data will include baseline and demographic data, prior functional status, information about the surgery such as the length of time it took and the type of surgery performed, signs and symptoms of treatment failure, findings from radiographic images, and the occurrence of any complications.

Radiographic images obtained as part of this study will be stored using assigned code numbers. The information linking these code numbers to each child’s identity will be kept in a separate, secure location.
How we will protect and share your child’s information:

We will take every precaution we can to keep your child’s information private. However, as mentioned in the potential risks section above, it is possible that unauthorized access to your child’s information could occur. To protect your child’s confidentiality, study information will be kept in a secured manner and electronic records will be password protected. Data for all sites will be maintained at the HCRN Data Coordinating Center (DCC), located at the University of Utah in Salt Lake City, Utah. Your child will be assigned a unique study identification number, and the data stored at the DCC will not include your child’s name or hospital medical record number. The DCC has dedicated security experts who ensure data is entered into secure database systems and who monitor the data closely, including monitoring regular scans for any suspicious outside attempts to access the data.

In addition to the investigators listed on the first page of this form and the research staff, the following individuals will or may have access to identifiable information (such as date of birth and date of surgery) related to your child’s participation in this research study:

- Radiological images obtained for this study will be sent to Penn State University for brain volumetrics. The shared images will limit the amount of your child’s personal information to the amount needed to verify your child and your child’s name will be replaced by an assigned study ID.

- CSF samples obtained at your child’s initial surgery and subsequent surgeries will be sent to Washington University in St. Louis for protein analysis. These samples will limit the amount of your child’s personal information to the amount needed to verify your child and your child’s name will be replaced by an assigned study ID.

- Authorized representatives of the University’s Institutional Review Board (the committee that oversees research studying people) and authorized members of the University’s workforce may review your child’s research information (which may include identifiable medical information such as date of birth) for the purpose of monitoring the appropriate conduct of this research study.

- A Data Safety Monitoring Board (DSMB) comprised of a group of pediatric surgeons and biostatistics specialists selected for this study will be ensuring patient safety and monitoring study results.

- Representatives from the NIH (National Institutes of Health), who is funding this study, may desire to access some data for quality assurance.

- In unusual cases, the investigators may be required to release identifiable information related to participation in this research study in response to an order.
from a court of law. If the investigators learn that your child or someone with whom your child is involved is in serious danger or potential harm, they will need to inform, as required by state law, the appropriate agencies.

If we share your child’s identifying information with groups outside of Primary Children’s Hospital they may not be required to follow the same federal privacy laws that we follow. They may also share your child’s information again with others not described in this form. The DCC will follow the same federal privacy laws that we follow.

A description of this clinical trial is available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**For how long will the investigators be permitted to use and disclose identifiable information related to my child’s participation in this research study?**

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include identifiable medical information) related to participation in this research study for as long as it may take to complete this research study. The study is expected to take 7 years to complete; 5 years for the initial study including 12 month follow up, with an additional 2 year follow up study for monitoring school age children. Records relating to the research conducted shall be retained for at least 3 years after completion of the research.

You have a right to information used to make decisions about your child’s health care. However, your child’s information from this study will not be available during the study; it will be available after the study is finished. This authorization does not have an expiration date.

**What if I decide to NOT have my child participate after I sign the Consent and Authorization form?**

You may cancel this approval to use your child’s health information. **This must be done in writing.** You must either give your cancellation in person to the Principal Investigator or the Principal Investigator’s staff, or mail it to John Kestle, MD, 100 North Mario Capecchi Drive, Suite 3850, Salt Lake City, UT 84113. If you cancel this approval, we will not be able to collect new information about your child, and your child will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.
REQUIRED CLINICALTRIALS.GOV REGISTRATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
CONSENT
I confirm that I have read and understand this consent and authorization document and have had the opportunity to ask questions. I understand that my child’s participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child’s medical care or legal rights being affected. I understand that sections of any of my child’s medical notes may be looked at by responsible individuals from the University of Utah or from regulatory authorities where it is relevant to my child taking part in research. I give permission for these individuals to have access to my child’s records. I will be given a signed copy of the consent and authorization form to keep.

I agree to allow my child to participate in this research study and permit you to use and disclose health information about my child for this study, as you have explained in this document.

__________________________  ____________________________  
Child’s Name  

__________________________  ____________________________  
First Parent/Guardian’s Name  

__________________________  Date  
First Parent/Guardian’s Signature  

__________________________  
Relationship to Child  

__________________________  ____________________________  
Second Parent/Guardian’s Name  

__________________________  Date  
Second Parent/Guardian’s Signature  

__________________________  
Relationship to Child  

__________________________  
Name of Person Obtaining Authorization and Consent  

__________________________  Date  
Signature of Person Obtaining Authorization and Consent
## NATIONAL INSTITUTES OF HEALTH
### Reporting Race and Ethnicity Data

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<tr>
<th>Date of Birth</th>
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### Ethnicity
Do you consider yourself to be Hispanic or Latino? (See definition below.) Select one.

- **Hispanic or Latino.** A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, “Spanish origin,” can be used in addition to “Hispanic or Latino.”
  - o Hispanic or Latino
  - o Not Hispanic or Latino

### Race
What race do you consider yourself to be? Select one or more of the following.

- o **American Indian or Alaska Native.** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.
- o **Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)
- o **Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as “Haitian” or “Negro” can be used in addition to “Black” or “African American.”
- o **Native Hawaiian or other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- o **White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

- o Check here if you do not wish to provide some or all of the above information.