THE COMMITTEE ON TRAUMA | QUALITY PROGRAMS of the AMERICAN COLLEGE OF SURGEONS

ACS COT Firearm Study
Frequently Asked Questions

General Administrative

1. **Who are the Principal Investigators for this study?**
   The Principal Investigators are Avery Nathens, MD, PhD, MPH, FACS, FRCPSC, and Deborah Kuhls, MD, FACS, FCCM. The study Co-Investigators are Frederick Rivara, MD, MPH, and Ashley Hink, MD, MPH.

2. **Is our center required to use an Institutional Review Board (IRB) for participation in this study?**
   While the ACS does not require participating centers to seek IRB approval, we encourage you to investigate your local requirements. We have provided an example IRB application for institutions on the TQP Account Center. As the grantee, the American College of Surgeons (ACS) is required to secure IRB approval. The CIRBI Advarra, a third-party central IRB, has granted us exemption for the study. We will provide this letter to centers to help with any institutional IRB efforts or requirements. We do not have any expectations for individual centers to use CIRBI.

3. **Is the TQIP Business Associate Agreement (BAA)/Data Use Agreement (DUA) sufficient for our center's participation in this study or will we need an additional agreement?**
   The existing TQIP BAA/DUA is sufficient for TQIP center participation in the study.

4. **When logging onto the TQP Data Center, a "Data Use and License Agreement" notice pops up and I cannot get past it unless I sign "agree." Why am I receiving this? Does this need to be signed for me to access the Data Center?**
   This is the agreement to access all platforms on the Data Center and was agreed to previously by your center if you access the Trauma platform to submit or view your TQIP/NTDB data. We still encourage you to read the Data Use Agreement and take any other additional steps needed on your side. You will not be able to access the new COT Research Initiative platform to participate in the Firearm Study until agreeing to this form.

5. **What will be the opportunities for authorship on manuscripts?**
   For the large study that comes out of the aggregate data, the lead at the participating centers will be listed as a *collaborator.* The "lead" is determined by your center. The National Library of Medicine includes *collaborators* as a category of authors in PubMed and is searchable by your name. If there is interest in developing your own studies out of the data, the national de-identified data set will be available to participating centers. There will also be the opportunity to write manuscripts utilizing your own local data. This would create additional opportunities for research that is coming directly out of your center.

6. **Who should be receiving study updates and information?**
   Study leaders at participating institutions and any other staff participating in the study at the institution should inform our team of their contact information. Updates and communications from the ACS will be distributed to these individuals and we want to make sure we have accurate contact information at each participating center. Please provide contact information to us at ACSFirearmStudy@facs.org.

7. **Will there be support throughout the study to answer technical and data questions?**
   Yes, ACS staff will offer dedicated support throughout the duration of the study. Your center may contact ACSFirearmStudy@facs.org with questions.

Data Collection and Submission

1. **What is the study period?**
   Although our grant period is through July 2022, the data collection period of the study is shorter. The data collection period is anticipated to last up to 12 months, beginning in March 2021.

2. **Is there training provided on the data elements, abstraction, and other details regarding technical support?**
   Yes, the Data Collection Training is available for on-demand viewing and can be accessed via this link or on the TQP Account Center under the "Resources" tab.

3. **How is our center expected to obtain the additional data elements?**
   There is not a uniform method on obtaining the additional data, and this will depend on your center. Many of these data elements are either already available via the trauma registry or are within the electronic medical/health record given many of these are assessed and documented as a part of routine patient care. *We are not asking centers to perform a separate interview of patients during or after their hospital encounter to gather this information outside of their regular care as many of these data elements are pertinent aspects of patients' histories and relevant to informing their risk of repeat injury and what services they need.*

   This includes information that might be ascertained in a follow-up phone call or visit related to the injury and treatment up to a week after discharge. Identifying and collecting this information may involve new approaches to data collection or documentation within the medical record. This may include creating a separate note or template for patients in the electronic medical record in which elements of the social history in addition to specific risks and social determinants of health are collated together, which will also help with ease of abstraction. In all cases, the ACS relies on participating centers to make informed decisions about how they will identify or obtain the necessary information, either in collaboration with other departments (e.g. Social Work, case management) or independently.

4. **Does my center need to add the firearm study data elements to our registry?**
   We do not require you to add these data elements to your registry for the firearm study. Instead we provide participants, free of a charge, with a data collection and submission platform accessed from the TQP Data Center and is designed specifically to support the data needs of this project. You are *required* to use this platform to collect and submit data to participate in this study, however you are welcome to also add these elements to your registry for your own purposes though you would need to work with your registry vendor to make that possible.

5. **Who at my center is responsible for collecting and submitting these data elements?**
   We do not have requirements for data collection assignment and, as such, you are welcome to assign whomever you deem appropriate at your center. This may be an existing trauma registry staff person or team, a resident or fellow committed to supporting this study, or an alternative solution that works for your center.

6. **What is an acceptable time frame that the data should be submitted for each patient?**
   We expect data to be submitted quarterly in accordance with the current TQIP Call for Data schedule, though patients may be submitted at any time throughout the study period.

7. **Who at my center has access to the data collection and submission platform?**
   Your center can assign access to whomever is responsible for data collection and submission for this study at your center, either an existing contact with access to the TQP Data Center or a new contact. For more information on contact management, please refer to the "Navigating the Account Center" Resource Guide or tutorial, located in the Educational Resources section of the TQP Participant Hub.

8. **Will my center have access to the data we collect and submit?**
   Yes, your center will have access to the data you collect and submit for the duration of the study. Those data can be exported from the platform at any point during your participation. You will also have access to additional study data that will be de-identified and can be used for other research investigations.

Additional Data Elements and Patient Inclusion

1. **What patients qualify for this study?**
   All firearm injury patients treated by your center during the duration of this study, including patients of all ages and patients treated and discharged from the ED. Patients treated for an index firearm or gun injury sustained March 1, 2021 or after presenting for treatment at participating trauma center can be included. Patients meeting criteria for NTDS are included, and those treated in the ED and released that would otherwise meet the criteria can be included. There are some circumstances with nuances for consideration. For instance, if a patient presents for care after already being treated at your center (for instance for a post-operative complication or further surgeries), they should not be included again in the study if they were already included or if they were injured prior to 3/1/21. If a patient presents for initial care in a delayed fashion within the NTDS time frame - for instance if they were injured 4 days prior but are now presenting for care at the trauma center, they can be included.

2. **What data does my center need to collect on patients treated and discharged from the ED?**
   As patients treated and discharged from the ED do not meet NTDS inclusion criteria and as such are not included in your data submissions to TQP, you will be required to collect and submit 30-40 NTDS elements for these patients beyond the data elements defined in the Data Dictionary for this study. The subset of NTDS elements required is listed in the Data Dictionary for this study and defined

in the NTDS Data Dictionary, and those elements will also be collected and submitted using the platform provided by the ACS.

3. **How should my center handle missing data on certain patients or data elements?**
   We expect participants to submit as much of the study data on as many appropriate patients as possible, however, we understand that, as with the NTDS, data are not always known or available for all patients. We encourage you to submit regardless of missing data. We acknowledge that data captured in the patient population discharged from the ED might be challenging but expect an attempt to do so whenever possible.

4. **Are there additional data privacy concerns for my center beyond those associated with conventional data submission to the TQP?**
   We understand the data collected and submitted for this study are covered under your existing agreements with the ACS and, as the data for this study will be collected and submitted using a platform on the website your center already uses to submit data to the ACS, we do not expect any additional privacy concerns. Note, however, that this study involves free text data and we expect participants to be mindful of the information they submit to adhere to appropriate privacy rules and regulations – e.g. do not submit patient name, SSN, etc.

5. **We do not currently collect Adverse Childhood Experience's (ACE's) data. Is the expectation that the parents fill out the ACE's or the minor?**
   We have no expectations for centers to have parents or patients fill out a questionnaire, but are hoping that information from social work notes, H&Ps, pediatric notes, child abuse evaluations, psych consultations etc. would provide insight into if children have experienced Adverse Childhood Experiences. Perhaps not all of them are regularly assessed in clinical care, but many of these are detected in collecting patient histories, even if not in a formal manner that specifically calls them ACE's. For instance, if it is documented that a child experienced physical or sexual abuse, lived in the home with a caregiver that had a substance abuse disorder or was incarcerated, etc., those would qualify. If you want to capture this in a more formal way, it is up to your team at your center, but we do not have that expectation.

6. **When can we expect to enter the study's supplemental data on those patients whose initial data is already collected through the NTDS registry? For those eligible patients who are admitted from the ED, at what point do you expect those supplemental (social hx, criminal hx, other additional variables provided via study) to be uploaded into your EDC?**
   Patient data collected through the NCGVR tool will be linked to NTDS data (if NTDS eligible) based on the submitted patient ID. As long as the patient ID you submit within the NCGVR tool matches the ID submitted through our NTDS channels (via TQIP), the NCGVR data can be submitted prior to NTDS data. The dependence for the NCGVR would be knowing the patient ID in your registry to input into the tool. For the ED-only patients, they can be submitted as soon as their record is completed as there is no linkage to NTDS data.

7. **For patients who are not included in the trauma registry, are we supposed to randomly assign a patient ID number? If not, what are you expecting to see in this field?**
   If the firearm injury patient meets NTDS inclusion criteria and therefore will be included in TQP submission(s), please ensure you are using the same patient ID across your TQP upload(s) and the Research Initiatives platform. If the firearm injury patient does not meet NTDS inclusion criteria, you are welcome to submit a numerical patient ID that is determined by your center as those patients will not be linked with NTDS datasets. However, please confirm that any patient IDs submitted for these patients do not overlap with any other IDs submitted via TQP or the Research Initiatives Platform.