Corporate Opportunities

Please encourage your customers to participate in the NASS Spine Registry!

Registry Support
Corporate and other entities are invited to support the NASS registry in the form of unrestricted grants in exchange for recognition. Supporters will receive recognition through traditional means related to registry promotion, at NASS events and through NASS publications. Please contact NASS at registry@spine.org for details on support and recognition.

Data Access and Use
Aggregate data may be requested for use by third parties with the permission of NASS. Permissions are granted at the discretion of NASS on a case-by-case basis. Requests for aggregate data will be considered after data for 1,000 patients with a particular diagnosis have been collected. All requests are approved by the NASS Board of Directors following a recommendation from the Research Council. Requests may be made by completing a permissions form found at www.spine.org/Registry. Requests should include:

- A description of the requesting party(ies), intended use and purpose;
- Any conflicts of interest relevant to the project and NASS;
- Description of the data sought and timeframe in which it is needed.

Pricing is dependent on the nature of the request. NASS will provide assistance in

Overview

Consecutive patients in the United States presenting for treatment to a variety of spine care providers including surgical and medical specialists.

Patients presenting at the start of an episode of care (and its later corresponding follow-ups). An episode of care begins when the first intervention of any kind occurs up to one year of care later. It includes care since the intervention whether related or not. Each patient will generate one episode of care.

Inclusion Criteria:
Patients age 18 and older with the below diagnoses and any related treatments associated to the lumbar spine. The cervical and thoracic spine are not included at this time (but are planned for later inclusion).

- Low back pain (724.2) (M54.5)
- Lumbar disc herniation (722.10) (M51.26, M51.27)
- Lumbar radiculopathy (724.4) (M54.14, M54.15, M54.17)
- Lumbar facet syndrome (724.8) (M54.08)
- Lumbar instability (724.6) (M53.2X7, M43.27, M43.28, M53.3)
- Lumbar spondylolisthesis (738.4) (M43.10, M43.00)
- Lumbar stenosis (724.02) (M48.06)
- Lumbar scoliosis (737.30) (M41.20)
- At this time, the registry is particularly interested in entry of patients with lumbar spondylolisthesis.

Exclusion Criteria: Extra-spinal conditions (ie, visceral, vascular, genitourinary)
developing report parameters (if needed) to obtain information.

All reports or data sets will be based on de-identified, aggregate data. The aggregate data included in all reports is considered NASS intellectual property and may not be reproduced, further disseminated or otherwise used except as noted or permitted by NASS.

Any publication that is the result of use of NASS aggregate data should be reviewed by the Registry Research Committee in advance of publication to assure appropriate representation of the data.

**Platform Use-Year 3 (Tentative)**

Beginning tentatively in June 2020, NASS may allow industry applications to conduct research using the registry platform (not access to participants). Approval of platform use is at NASS’ discretion on a case-by-case basis. Cost and logistics of platform use are determined on a case-by-case basis. All industry research data will be firewalled from the aggregate data pool. Industry data can be restricted for use only by the industry research sponsor if so desired. All research must conform to the registry format of only accepting de-identified data. If data is used in treatment/device research, FDA medical device reporting requirements are the responsibility of the entity conducting the research. Any approved research project would require a separate IRB.

**Collaborative Research**

Proposals for research collaboration with the NASS organization using the registry may be considered by NASS. Requests will be evaluated using NASS’ Criteria for Research Collaboration with Outside Entities. Any approved research project will require a separate IRB. Proposals for collaborative projects along with the information required in the criteria checklist may be sent to:

North American Spine Society
NASS Staff
nassregistry@spine.org

**Extended Services-Adding Elements to the Platform**

Extended services include, but are not limited to, addition of measures, calculations or services to the platform that NASS may not wish to subsidize or develop. Should a Participant wish to work with Ortech, the platform vendor, on an extended service offering, they may do so at their own expense. Any extended service offerings must not materially risk Ortech’s requirement to ensure that the Participant Data is fully de-identified, will require the prior written approval of NASS, and will require a separate agreement between a Participant and Ortech. Requests for written approval by NASS need to include identification of the entity requesting an extended service offering and a description of that offering including what data will be collected. Any additions to the registry achieved through extended service offerings become the property of NASS.

**Measures**

Demographics
Previous Back Problems and Treatment
Current Back Problem and Treatment
Diagnosis (Symptoms, Structural and Compressive Pathology)
Co-morbidities
Interventions*
- Non-procedural Interventions
- Medications
- Physical Therapy
- Procedural Interventions
- Surgical Procedures
- Injections

*Where applicable “Other” option is available to allow input of Other Treatment not already available in the list

Complications
Patient Follow-up
- Oswestry Disability Index
- EQ-5D-5L
Policy Statements

Commercial Statements. NASS does not participate in or allow commercial statements or endorsements.

Funding. Support does not confer influence over policy, decision-making or topic selection.

Use of NASS Name or Logo. The NASS name, logo or registry name should only be used in the methodology description of any study or project as providing access to the data. NASS maintains strict control over the use of the NASS name and logo and has prior approval on all uses, except for inclusion in the methodology description. Any reference to the NASS registry in publications, education, presentations or other formats or publicity resulting from the data should use the following verbiage/reference to the registry. “NASS Spine Registry, North American Spine Society, Burr Ridge, IL, (www.spine.org/Registry).

Registry Participant Lists. NASS will not sell, share or use participant names or contact information, with the following exceptions:

- If the Participant signs a release for promotional/marketing use by NASS;
- NASS will include all Participants in a registry directory, which may be available to registry Participants and the public.
- Participants may promote their participation in the registry using verbiage provided by NASS for promotional purposes.

The NASS platform vendor, Ortech, may not use Participant information to identify customers for promotional purposes.

Adverse Event Reporting. NASS may report, at its discretion, to its membership, federal agencies or other relevant bodies adverse events it determines to be important to share with the field relative to patient care and safety, as identified through its aggregate, de-identified data. NASS is not able to share specific adverse events tied to participants and their patients due to the de-identified nature of the data.

Aggregate Data. Aggregate registry data is the property of NASS. Aggregate data may not be used without first obtaining the express written consent of NASS, with the exception that a participant may use aggregate data previously released to the public by NASS (i.e., in published reports and slide sets). Written permission may be obtained by completing a permissions form found at www.spine.org/Registry. If data is used in treatment/device research, FDA medical device reporting requirements are the responsibility of the entity conducting the research.

Data Ownership. Participants own their own data. NASS owns the de-identified, aggregate data. If a participant chooses to leave the registry, all de-identified aggregate data provided by the participant remains the property of NASS and the registry.

Publications. Any publication that is the result of use of NASS aggregate data should be reviewed by the Registry Research Committee in advance of publication to assure appropriate representation of the data.
Abstract
The spine field lacks sufficient evidence on the treatment of spine disorders and injuries. Investigation needs to continue to help clarify the comparative effectiveness of various spine treatments as well as their value. The NASS Spine Registry aims to collect data to enhance understanding of spine care treatments and their resulting patient outcomes, as well as examine the natural history of spine disorders. In this registry, NASS will track patient care and outcomes, with the long-term goals of potentially using the data for quality improvement purposes or best practices, to begin closing the gaps in the medical evidence for spine care and for advocacy purposes. Participating providers will receive confidential feedback on their care based on their data; NASS will only have access to de-identified aggregate data. Patients will receive immediate feedback on their progress. Because spine care is delivered by a diverse group of providers, the registry will be applicable for use by a multidisciplinary audience (both relative to specialty, surgical/medical orientation, and practice setting).

Purpose
- Quality improvement for spine care.
- To collect de-identified data on spine care from diverse sites relative to specialty and practice setting to enhance understanding of spine care treatments and their resulting patient outcomes, as well as examine the natural history of spine disorders.

Registry Type
Diagnosis-based observational registry for longitudinal analysis.

Primary Sponsor
North American Spine Society. The North American Spine Society (NASS) is a 501(c)3 multidisciplinary medical organization dedicated to fostering the highest quality, ethical, value-based and evidence-based spine care through education, research and advocacy. NASS is comprised of members from multiple disciplines related to spine care including orthopedic surgery, neurosurgery, physiatry, neurology, radiology, anesthesiology, research, physical therapy and other spine care professionals. NASS engages in continuing medical education, research, health policy and advocacy activities on behalf of its members in the spine field. More information about NASS can be found on the NASS website at: [www.spine.org](http://www.spine.org).
Funding
The registry is funded by NASS and through registry subscriber fees, data access fees, platform use fees.

Contacts
NASS:
NASS Staff
North American Spine Society
7075 Veterans Blvd
Burr Ridge, IL 60525
nassregistry@spine.org

Registry Vendor:
Ortech Systems, Inc.
300 Wellington Street, Ste. 104
London, Ontario, Canada N6B 2L5
(see Ortech procedures for specific technical contacts)

Clinical Leads
Daniel K. Resnick, MD, MS
Zoher Ghogawala, MD

Start Date
The registry is anticipated to be open to sites June 2018.

Completion Date
The registry is anticipated to be an on-going, long-term project with the anticipated future inclusion of additional spine measures.

Methods
Background
Patients presenting to spine care providers will be treated according to their individual complaints, anatomy, and preferences. Differences between patients who select different treatment modalities will exist and can be used to describe the relative value of different interventions for different patient populations. When similar groups of patients choose different treatment modalities, a comparison of relative effectiveness can be performed.

Design
The project will use a measure set intended to capture demographic, treatment and complications data, and patient-reported outcomes. Patients and physicians will enter data into a centralized,
HIPAA compliant database that meets industry norms. The registry data will be de-identified in an automated fashion upon entry and only de-identified registry data will be available for analysis.

Subjects/Eligibility

- Consecutive patients in the United States presenting for treatment to a variety of spine care providers including surgical and medical specialists.
- Patients presenting at the start of an episode of care (and its later corresponding follow-ups). An episode of care begins when the first intervention of any kind occurs up to one year of care later. It includes care since the intervention whether related or not. Each patient will generate one episode of care.
- Inclusion Criteria:
  - Patients age 18 and older with the below diagnoses and any related treatments associated to the lumbar spine. The cervical and thoracic spine are not included at this time (but are planned for later inclusion).
    - Low back pain (724.2) (M54.5)
    - Lumbar disc herniation (722.10) (M51.26, M51.27)
    - Lumbar radiculopathy (724.4) (M54.16, M54.14, M54.15, M54.17)
    - Lumbar facet syndrome (724.8) (M54.08)
    - Lumbar instability (724.6) (M53.2X7, M43.27, M43.28, M53.3)
    - Lumbar spondylolisthesis (738.4) (M43.10, M43.00)
    - Lumbar stenosis (724.02) (M48.06)
    - Lumbar scoliosis (737.30) (M41.20)
  - At this time, the registry is particularly interested in entry of patients with lumbar spondylolisthesis.
- Exclusion Criteria:
  - Extra-spinal conditions (ie, visceral, vascular, genitourinary)

Measures to Minimize Bias

Patients will be entered consecutively in order to avoid bias in enrollment.

Participation in the study is voluntary and patients are free to choose not to participate. If a patient chooses to participate, he or she is free to withdraw from the study at any time during its course. If a patient withdraws from the study, it will not involve penalty or loss of benefits to which the patient is otherwise entitled. Any new findings developed during the course of the study which may relate to a patient’s willingness to continue participation will be provided to the patient.

This project is multi-center in collaboration with the North American Spine Society. Centers will represent a variety practice settings and specialties.

Informed Consent/Institutional Review Boards (IRBs)

The registry received IRB exemption from a central IRB entity, Western Institutional Review Board (WIRB). This exemption determination can apply to multiple sites, but it does not apply to any institution that has an institutional policy of requiring an entity other than WIRB (such as an internal IRB) to make exemption determinations. WIRB cannot provide an exemption that overrides the jurisdiction of a local IRB or other institutional mechanism for determining exemptions. Please ensure that your site can and will accept WIRB’s exemption decision.

If local IRB approval is required in addition to WIRB, a waiver of informed consent should be requested based upon the fact that only de-identified patient data is being collected centrally for
analysis. Site-specific data will only be used for local quality improvement efforts. A letter discussing clarification and guidance on application of the Common Rule relative to registry participation resulting from communications with government officials is available. The correspondence discusses application of consent waivers for individual sites participating in registry data collection for quality improvement purposes and the use of a centralized IRB for a registry.

Confidentiality and Data Ownership
Participating providers will receive confidential performance feedback. NASS will only have access to de-identified aggregate data. NASS will own the de-identified aggregate data. Participating providers will own their submitted data. Registry vendor will not own any project data.

The results of this project, derived from analysis of de-identified data, may be published in a medical book, journal or other publication or used for teaching purposes, quality improvement or advocacy. When results are published, used or discussed in conferences, no information will be included that would reveal a patient’s identity unless specific consent for this activity is obtained.

All efforts will be made to keep all identifiable medical information confidential by participating providers (NASS and the registry will not be in possession of identifiable information). The information provided on any questionnaires may subsequently become part of a patient’s office record if it adds to the patient’s care. If so, it must be kept confidential. Patient information held at each site must be placed under a code for the purpose of analyzing the data at the site level. Patient names and other identifying information will be removed from questionnaires at the site level. Reasonable efforts will be made to protect each patient’s privacy and the confidentiality of medical information. Representatives from an IRB, an oversight committee that reviews projects to protect rights of participants, may inspect records during internal auditing procedures. However, these individuals are required to keep all information confidential.

Benefits and Risks to Participants
Clinical Risks to Patients
There is no clinical risk to patients.

Informational Risks to Patients or Provider Participants
There are no additional informational risks to patients or provider participants as the registry is HIPAA compliant and only the de-identified data is shared.

Benefits to Patients/Providers
Patients will not be compensated for participation by NASS, nor are there any costs to patient participants. Patients will also receive feedback on their health condition in the form of Oswestry Disability scores each time they complete the Oswestry instrument in follow-up to care. Links to patient education will also be available to patients via the registry.

Provider participants will receive confidential feedback on their care in order to assist them in quality improvement activities.
Registry Procedures

*Registry platform use and technical information can be found in the Ortech specifications and instructions.

Resources Needed
- Access to onsite tablets or computers with internet access for provider, staff and patient use.
- Staff assistance for any patients who may not be familiar with computers to complete forms.

Recruitment
- Patients will be recruited without regard to gender, race, age (as long as they are 18+ years), locale, language preference, insurance type or status, or socioeconomic status.
- No specific advertising; registry may be listed on the participating institution’s clinical research web page.

Patient Selection
- All potentially eligible patients in the United States will be screened for potential enrollment. Include, consecutively, U.S. patients presenting to spine care providers who will be treated according to their individual complaints, anatomy and preferences. There will be an emphasis on enrolling all patients with the diagnosis of lumbar spondylolisthesis.
- Patients age 18 and older with the below diagnoses and any related treatments or complications of the lumbar spine. The cervical and thoracic spine are not included in registry at this time.
  - Low back pain (724.2) (M54.5)
  - Lumbar disc herniation (722.10) (M51.26, M51.27)
  - Lumbar radiculopathy (724.4) (M54.16, M54.14, M54.15, M54.17)
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- Patients presenting at the start of an episode of care (and its later corresponding follow-ups). An episode of care begins when the first intervention of any kind occurs up to one year of care later. It includes care since the intervention whether related or not. Each patient will be considered one episode of care.

Patient Enrollment/Manual Data Entry
Data must be entered at the time of patient encounter. It may not be retrieved from the medical record. Do not add identifiable patient health information in any of the registry free text boxes.

First Visit
- Eligible patients will be enrolled consecutively to avoid enrollment bias. In order to link physician and patient forms to the appropriate patient at each entry, the physician/site will need the patient’s last name, last four digits of the social security number (SSN), and year of birth.
- When a patient makes an appointment for a first visit, office staff will create a new patient record in the registry and record the patient ID number. **This ID number should be noted.** This number is used by the clinician at the first patient encounter to link patient
diagnosis, the diagnostic matrix, and details regarding treatment to the demographic and outcome measures entered by the patient. If the clinician anticipates the need to refer back to an individual patient record, the number should be stored at the site in a HIPAA compliant database as it can be used to link the de-identified registry data to an individual patient. Staff will then obtain the patient email and trigger an email to the patient in advance of the office visit (a minimum one week in advance, if possible) with a link to the New Patient Universal registry forms for the patient to complete online in advance of the appointment. Staff should check to see if forms are completed in advance of the appointment and print the patient summary for provider review prior to the initial patient exam.

- If the patient does not have email or is not familiar with computers, they may complete the New Patient Universal forms online at the time of appointment via a clinic kiosk/computer. Once completed, these forms should also be printed for provider review prior to initial patient exam. Clinic staff will need to start up and log into the onsite kiosk/computer each morning to make it available for patient use daily.
- For patients who are not familiar with computers, assistance may need to be provided to the patients in completing the forms at an onsite computer.

During the patient visit, the provider completes New Patient Physician form online via the registry software. In order to link this form to the appropriate patient, the physician will need the patient’s last name, last four digits of the SSN, and year of birth.

- The information provided on the questionnaires may subsequently become part of a patient’s office record if adds to the patient’s care. If so, it should be kept confidential. Patient names and other identifying information should be removed from questionnaires.

Interventions and Follow-up

- Any time during the same episode of care an intervention is performed, the provider should complete either a Procedure Intervention Form or Nonprocedure Intervention Form via the registry platform depending on the type of intervention.

- Patient follow-up for data should occur at 3 months, 6 months and 12 months, plus any other visit outside these timeframes. Any time a patient follow-up visit occurs:
  - The provider should complete the Physician Procedure Follow-up Form(s), if applicable using the registry software. **NOTE:** You will need the patient ID number from registration in order to access the follow-up forms.
  - The patient should complete the Patient Follow-Up Form via either a triggered email or at the onsite computer in the office.

- Staff should check to see if forms are completed in advance of any appointment and print the completed forms for provider review prior to patient exam.
  - The information provided on the questionnaires may subsequently become part of a patient’s office record if adds to the patient’s care. If so, it should be kept confidential. Patient names and other identifying information should be removed from questionnaires.

Feedback to Sites and Patients

- Patients. Each time a patient completes a follow-up form, they will automatically be shown and able to print a comparison of their Oswestry Disability Score relative to their previous visits indicating their status of health change.

- Patient Enrollment. Sites and NASS will be able to see how many patients have been enrolled from each site as information and an incentive for further enrollment.
• Confidential Site Feedback. Each site will have the option to pull reports from the registry providing confidential feedback on the care given patients entered in the system from their site and relative to the aggregate for specific diagnoses.
• Link to Patient Education. Patients will be able to link to the NASS Knowyourback.org patient education website as part of the data entry process.

FAQs
• **What do I tell patients about what we are doing?** Patients should be told that this is a project to better understand spine care treatments and disorders that offers patients and spine care providers an important opportunity to work together and to contribute to the study of spine care.
• **Who can see PHI?** The registry data will be de-identified in an automated fashion upon entry and only de-identified data will be available for analysis. Only the site entering data will have access to their own PHI. Neither NASS nor Ortech will have access to PHI.
• **Who do I contact if I have a questions about how to use the registry software?** Danica Parsons, Application Support Representative, Ortech Systems, Inc. Danica.Parsons@ortechsystems.com, 226.663.5399 x101.
• **Who do I contact if I have other questions about the project?** NASS Staff, North American Spine Society, nassregistry@spine.org.

6.21.18
## Benefits/Uses

### For Providers

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Description</th>
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<tbody>
<tr>
<td>Any spine care provider can use the NASS Spine Registry</td>
<td>Any physician or allied health care provider who treats the spine can use the registry. It is not necessary to be a NASS member. There are no restrictions on provider type, specialty, or medical/surgical orientation.</td>
</tr>
<tr>
<td>Broad tracking of patient treatments</td>
<td>Tracks patient diagnosis and treatment (both medical and surgical) across the spectrum of patient care and does not focus on a single procedure or treatment type.</td>
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<tr>
<td>Affordable</td>
<td>Affordable for all practice types and sizes—from the largest health systems to solo practitioners.</td>
</tr>
<tr>
<td>Confidential, de-identified data</td>
<td>Data is de-identified at the point of entry. Only you see your site's personal health information (PHI). PHI never reaches NASS or the platform vendor. NASS sees the de-identified, aggregate data pool.</td>
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<tr>
<td>No need to purchase software</td>
<td>Web-based—You just need access to the internet.</td>
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<td>No dedicated coordinator required</td>
<td>Does not require a dedicated coordinator. If you choose to collect data where you would like to have a coordinator, that's up to you. However, a coordinator is not required or necessary to participate in the registry.</td>
</tr>
<tr>
<td>Own your own data</td>
<td>You own your data; NASS owns the de-identified aggregate data.</td>
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<tr>
<td>Confidential feedback on your care and outcomes with benchmarking against peers</td>
<td>Pull real-time reports at your convenience to see your results with benchmarking against other registry participants (aggregate, de-identified data)</td>
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<tr>
<td>Central IRB</td>
<td>A central IRB exemption determination eliminates the need for IRB approval (unless your local institution requires it)</td>
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<td>Minimized burden</td>
<td>Designed to keep administrative burden at a minimum through:</td>
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<td></td>
<td>-use of the central IRB</td>
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<td>-patient assistance through in-office and remote data entry</td>
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<td>-optimized measure set</td>
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<td></td>
<td>-ability to allow staff to assist in data entry</td>
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<td>Provide patients with information about their care and provide patient education</td>
<td>After entering their data, patients have access to their up-to-date ODI score and a link to the NASS patient education website, KnowYourBack.org.</td>
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<td></td>
<td>Use ODI scores to discuss progress with patients</td>
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<td>Enhance your reputation as a leader and concerned practitioner in spine</td>
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<td>Contribute to evidence-development for spine care</td>
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<tr>
<td>Quality improvement</td>
<td>Use personal and comparison data to review care</td>
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<td></td>
<td>Inspire quality improvement projects driven by registry data</td>
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<td></td>
<td>Identify variations in care</td>
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<td>Identify high and low risk patients to help predict outcomes</td>
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<tr>
<td>Leverage your data to demonstrate the value of your care in a value-conscious system</td>
<td>Share results with payers, accreditors and others to demonstrate the quality of your care and negotiate incentives</td>
</tr>
<tr>
<td>Promote your participation in the registry</td>
<td>Demonstrate your commitment to quality of care and market your practice</td>
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<tr>
<td>Use registry participation/data to support maintenance of certification, accreditation or licensing</td>
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<tr>
<td>Identify knowledge gaps</td>
<td>Use data to pinpoint knowledge gaps and select appropriate education opportunities</td>
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<tr>
<td>Expand your network by connecting with other registry participants</td>
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For NASS

- Evaluate comparative effectiveness of various treatments
- Monitor for safety issues
- Longitudinal analysis of care
- Quality improvement projects and identification of best practices
- Help to close the gaps in the medical evidence for spine
- Measure development
- Investigate ability to act as a Qualified Clinical Data Registry for the Medicare Quality Payment Program
- Use of the de-identified, aggregate data pool for possible future research (data access services or NASS use for specific questions).
- Policy or reimbursement advocacy
NASS CRITERIA FOR RESEARCH COLLABORATION WITH OUTSIDE ENTITIES

NASS is regularly approached by researchers, industry and other entities to collaborate in a variety of research projects. In the past these requests have been handled on a case-by-case basis by the Board, Research Council Director and staff without a standardized set of criteria by which to make decisions. The NASS Research Council believes that, in the interests of fairness and objectivity, these requests for research collaboration should be evaluated based on a standard set of criteria. The research department then can evaluate requests based on this criteria checklist, decline those that do not meet NASS' requirements and forward to the Board of Directors those that meet NASS requirements and bear consideration. These standards also provide a basis for explanation when collaboration opportunities are declined. The NASS research department and Research Council Director will be responsible for enforcement of the criteria once a collaborative project has begun.

Criteria for NASS Research Collaboration:

- Yes  No  Topic is relevant to NASS mission and research goals as outlined by the Board of Directors and Research Council, and/or of high priority to the Board of Directors.

- Yes  No  Topic is of scientific value to the spine care field, either improving or adding to the existing knowledge base.

- Yes  No  Subjects’ interests and rights are protected. There are no significant risks to study subjects, NASS or NASS members in terms of participating in the study and/or providing data (privacy issues are paramount).

- Yes  No  No ethical or legal risks are identifiable. There is no adverse impact on NASS in terms of credibility or prejudice. Requesting party is unquestionably ethical, and association would likely add to NASS’ scientific standing. There is no conflict of interest for involved parties, and all involved parties, including investigators, will disclose any relevant relationships prior to a final decision being made by NASS regarding collaboration or at anytime thereafter as requested by either collaborating party (see below). There are no issues related to real and perceived product endorsement or what might otherwise be perceived as undue industry influence.

- Yes  No  NASS plays a crucial and well-defined role in the study. The study is unable to proceed without NASS’ involvement, either due to logistics or NASS’ approval. NASS reserves the right to withdraw from the study at
any time, if it (Research Council or Board of Directors) believes the study is not in NASS' best interest.

- Yes  - No  Participation would bring a significant source of revenue or funding to NASS, and minimal or acceptable (at the discretion of the Board of Directors) NASS resources are required to accomplish the research at issue – resources include funding and/or staff time.

**Conflict of Interest Standards**

- Yes  - No  At the discretion of NASS, and keeping in mind investigators’ disclosures, investigators *may* have no role in deliberations or voting if the study is supported by or includes NASS cooperation.

- Yes  - No  NASS maintains strict control over the use of the NASS name and logo in association with the study, and has prior approval on all its uses.

- Yes  - No  Ownership of data is determined before the study begins.

- Yes  - No  NASS’ role in the project and credit/recognition are determined in detail, prior to the start of the project. This would address collaboration (institutions cannot be a principal investigator or co-principal investigator on government grants), authorship, publication rights and financial support, both received by and provided by NASS.

- Yes  - No  If industry monies are to be used in the funding of the research, it must be submitted as an unrestricted grant, with NASS or NASS and/or the principal investigators determining its use.