**DYSTONIA COALITION DATA & MATERIALS REQUEST FORM**

This form is to be used to request data, video, and/or biosamples from the Dystonia Coalition. For information about the Dystonia Coalition and details of data available through the Dystonia Coalition, refer to: [www.dystoniacoalition.org](http://www.dystoniacoalition.org). Please email completed form to the Dystonia Coalition Program Manager at [dystoniacoalition@emory.edu](mailto:dystoniacoalition@emory.edu). Once submitted, the form will be reviewed by the Dystonia Coalition Executive Committee. Data cannot be released until the Executive Committee approves the request, and local IRB approval is obtained by the requestor.

**Project Title:** Click here to enter text.

**Principal Investigator Information**

|  |  |
| --- | --- |
| Name: Click here to enter text. | Position Title: Click here to enter text. |
| Department: Click here to enter text. | Institution: Click here to enter text. |
| Street Address: Click here to enter text. | *City & State: Click here to enter text.* |
| Zip Code: Click here to enter text. | Country: Click here to enter text. |
| Telephone: Click here to enter text. | Email: Click here to enter text. |

**Co-Principal Investigator/s Information** (Please include all co-investigators, if applicable)

|  |  |
| --- | --- |
| Name: Click here to enter text. | Position Title: Click here to enter text. |
| Department: Click here to enter text. | Institution: Click here to enter text. |
| Street Address: Click here to enter text. | City & State: Click here to enter text. |
| Zip Code: Click here to enter text. | Country: Click here to enter text. |
| Telephone: Click here to enter text. | Email: Click here to enter text. |

**Study coordinator or contact information** (if different from PI)

|  |  |
| --- | --- |
| Name: Click here to enter text. | Position Title: Click here to enter text. |
| Email: Click here to enter text. | Telephone: Click here to enter text. |

Does the project have IRB/ethics board approval?  Yes (please attach approval)  No

(If multiple institutions are collaborating, each institution needs to provide an IRB approval letter)

Does the project have financial support from the DC?  Yes  No

Does the project have other financial support? Yes  No

Funding agency: Click here to enter text.

PI Name: Click here to enter text.

Grant Title: Click here to enter text.

Grant Number: Click here to enter text.

Funding Period: Click here to enter text.

Original Data Request Updated request (same data) Modified data request

Updated or Modified Date of Proposal: Click here to enter text.

Updated or Modified: Are there new or different people working on the study? Yes No

**Project Description (Briefly describe your project below, or attach additional pages if necessary)**

Click here to enter text.

**SPECIFIC DATA REQUESTED**

**Data available for Natural History Project:**

* **Diagnosis:** The subtype of dystonia can be specified by (a) diagnosis (reported by site investigator), (b) initial site of onset (patient reported site), (c) body region(s) affected (examination at study visit). Occasionally, site diagnosis differs from body regions affected on exam. Please select a, b, and/or c.

**a. Diagnosis given by recruiting site:**

Focal Dystonia

Cervical Dystonia

Blepharospasm

Oromandibular dystonia

Laryngeal dystonia

Lower limb dystonia

Upper limb dystonia

Segmental

Hemi-dystonia

Multi-focal

Generalized dystonia

Other dystonia syndrome

Non-dystonia syndrome

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **b. Initial site of dystonia onset** | **c. Body region/s affected on exam** | | | |
| Upper Face | Upper Face | Dystonia | Tremor | No Tremor |
| Lower Face | Lower Face | Dystonia | Tremor | No Tremor |
| Shoulder | Shoulder | Dystonia | Tremor | No Tremor |
| Upper Arm | Upper Arm | Dystonia | Tremor | No Tremor |
| Hand | Hand | Dystonia | Tremor | No Tremor |
| Upper Leg | Upper Leg | Dystonia | Tremor | No Tremor |
| Foot | Foot | Dystonia | Tremor | No Tremor |
| Tongue | Tongue | Dystonia | Tremor | No Tremor |
| Jaw | Jaw | Dystonia | Tremor | No Tremor |
| Neck | Neck | Dystonia | Tremor | No Tremor |
| Trunk | Trunk | Dystonia | Tremor | No Tremor |
| Pelvis | Pelvis | Dystonia | Tremor | No Tremor |
| Larynx | Larynx | Dystonia | Tremor | No Tremor |

**Please enter any other specific inclusion or exclusion criteria below, or attach additional pages**

* **From which visit type do you want data?**

Data available for initial and all follow-up visits. The majority of follow-up visits are completed within one to four years of most recent visit.

The first visit only

The most recent visit only

All visits (initial visit and all follow-up visits)

* **Data for subjects in Natural History Project:**

The Natural History data are collected for all subjects at their initial visit, and at specific time points afterwards. Data collected over the years has changed slightly, so not all data available for all cases.

Date of data collection

Participant details: age, gender, race, ethnicity, handedness

Medical History: age of onset, duration, characteristics of dystonia (sensory trick, etc.), other neurological conditions (self-reported depression/anxiety)

Genetic testing, if available (participant recall)

Medications & botulinum toxin history

Surgical treatment for dystonia

Family history

Family history of dystonia

Family history of other disorders

Family history of genetic testing (patient recall)

Other family history (medical history, raceof grandparents, familial consanguinity, and others.

Global Dystonia Rating Scale (GDRS)

Fahn Marsden Dystonia Scale (FM)

Short Form Health Survey-36 (SF-36)

Beck Depression Index-II (BDI-II) \*

Hospital Anxiety & Depression Scale (HADS) \*

Liebowitz Social Anxiety Scale (LSAS)\*

Patient Health Questionnaire-9 (PHQ-9)\*

\*not available for most participants before 2020

* **Neurological exam videos:**

View only (viewable on Dystonia Coalition website) OR

Original video on encrypted hard drive (Additional approval needed. Requester is responsible to send encrypted hard drive along with FedEx return label)

Original video transfer via an encrypted box

* **Biosamples:**

The Natural History Project has collected over 3000 DNA samples from initial visits.

Biobank Project will start to collect DNA, RNA, and plasma samples in 2020 for initial and follow-up visits.

DNA

RNA

Plasma

**Data available for Cervical Dystonia Rating Scale Project (209 subjects)**

This project recruited 209 subjects with CD for assessment of clinical rating scales. All subjects also participated in the NH project, so data listed above are available for these cases too. Additional data collected specifically for this project include:

Toronto Western Spasmodic Torticollis Rating Scale – 2 (TWSTRS-2) Pain

Toronto Western Spasmodic Torticollis Rating Scale – 2 (TWSTRS-2) Disability

Toronto Western Spasmodic Torticollis Rating Scale – 2 (TWSTRS-2) Psychiatric

Toronto Western Spasmodic Torticollis Rating Scale – 2 (TWSTRS-2) Motor Severity

Cervical Dystonia Impact Profile (CDIP-58) Quality of Life

Structured Clinical Interview for DSM-IV-TR Axis I Disorders (SCID)

**Neurological exam videos:**

View only (viewable on Dystonia Coalition website) OR

Original video on encrypted hard drive (Additional approval needed. Requester is responsible to send encrypted hard drive along with FedEx return label)

Original video transfer via an encrypted box

**Data available for Laryngeal Dystonia Assessment Project (184 subjects with LD and matched voice controls)**

Subjects in this project also participated in Natural History, so data listed for Natural History are available for most of these subjects too. This project included control subjects with other voice disorders (muscle tension dysphonia, vocal tremor, vocal paralysis, etc…). Additional data collected specifically for this project include:

Site diagnosis from live exam

External rater diagnoses from recorded materials

Speech-language pathologist (SLP) evaluation

Ratings of 20 standard sentences, vowels, gliding, singing, humming, shouting, whispering

Video recordings of the same items

Spasmodic Dysphonia Attribute Inventory (SDAI; Ludlow et al, 2018)

ENT evaluation with nasolaryngoscopy

Standard tasks (vocalizations, whistle, sniff, shout), anatomical and functional symmetry, functional symmetry, tremor, spasms)

Video recording of same items

Neurologist evaluation

Assessment of voice, dystonia or tremor in other body regions, other deficits

Neurological exam on video

Patient Questionnaire (Patient report of speaking effort/difficulty, ability to laugh, cry, shout, etc…)

**Data available for Blepharospasm Rating Scale Project (211 subjects with BSP, 130 disease controls, 53 normal controls)**

Subjects in this project also participate in Natural History. Data listed for Natural History will be available for these subjects too. This project also had some normal controls (no dystonia) and controls with other facial disorders (hemifacial spasm, facial tics, etc…). Data collected specifically for this project include:

Jankovic Rating Scale (JRS)

Blepharospasm Severity Rating Scale (BSRS, from Defazio 2015)

Blepharospasm Diagnosis Rating Scale (BDRS, from Defazio 2013)

Blepharospasm Scale- Mini (BSP-mini)

Craniocervical Dystonia Questionnaire-24 (CDQ-24)

Oromandibular Dystonia Questionnaire-25 (OMDQ-25)

Obsessive Compulsive Inventory-R (OCI-R)

Blepharospasm Psych Screening Questions (BSQ-P)

Blepharospasm Motor Screening Questions (BSQ-M)

Eye Symptoms in Blepharospasm (dry eye, photophobia, itchiness, etc…)

Blepharospasm Disability Index (BSDI)

**Neurological exam videos:**

View only (viewable on Dystonia Coalition website) OR

Original video on encrypted hard drive (Additional approval needed. Requester is responsible to send encrypted hard drive along with FedEx return label)

Original video transfer via an encrypted box

Neurological exam videos are ***viewable*** on the Dystonia Coalition Video Repository website. If your study requires original videos sent to you on an encrypted drive for data analysis, please specify why in box below.

Please specify….

**DYSTONIA COALITION DATA & MATERIALS ACCESS AGREEMENT**

**Data & Resource Sharing by the Dystonia Coalition**

Data shared by the Dystonia Coalition are provided in a de-identified manner, with a code number only. Video recordings of the face are classified as Protected Health Information (PHI) according to Health Insurance Portability and Accountability Act (HIPAA), and therefore are considered identifiable data. These recordings are shared only with extra provisions for the recipient that they not be copied or stored, and no attempts made to link images with other identifiable data. All data collected by the Dystonia Coalition is compliant with the EU General Data Protection Regulation (EU GDPR); specifically, those obtaining data or specimens collected from European Citizens will be required to destroy any specific data or specimens at the request of a specific participant if possible. Dystonia Coalition policy requires all investigators requesting data or samples to sign this data access agreement that explicitly addresses sharing and how contributing investigators are most appropriately acknowledged. The Dystonia Coalition (DC) encourages timely and efficient use of data and materials through sharing. Access to data and materials is available via three different routes.

1. The right to access any original unpublished data or materials collected and stored by the DC will be supervised by the Executive Committee. These rights will include access to original data or materials for further research studies, grant proposals, manuscripts, any public presentations, internet communications, and any commercial products. It is anticipated that data from the many measures being collected for each DC project may be analyzed and presented separately, or in combination. In addition to the planned primary analyses, other secondary analyses may be conducted in the future.

The purpose of the Executive Committee review is not to block access to data or materials, but instead to serve as a broker to bring together different individuals with similar interests. Before accessing any original data or materials, all investigative teams will be required to submit a proposal to the Executive Committee that fully describes the planned analyses, an assessment of feasibility, and a timeline. Once approved, the investigators will be given access to data or materials, which may involve the NINDS Human Genetics Resource at Coriell, which stores most of the DNA collected in the Natural History and Biorepository Project, or the Rare Diseases Clinical Research Network (RDCRN) Data Management and Coordination Center (DMCC) designated by NIH/NCATS, which serves as a back-up data center for all Main Projects, as needed. If two or more investigative teams submit proposals with similar aims, they will be informed and encouraged to collaborate. If the investigative teams do not wish to work together, the Executive Committee may honor both requests. Any disputes arising from actions of the Executive Committee will be addressed by the Steering Committee.

Original data and materials provided by the DC will be used strictly for research studies approved by the Executive Committee. Data or materials may not be used for other purposes or shared with other investigators without advance approval of the Executive Committee. Immediately upon publication, all results must be made available to the DC without restriction to access. Any studies involving genomic data must comply with NIH policies on sharing of genomic data.

1. Data and materials sent by DC members to the NINDS Human Genetics Resource at Coriell are subject to a one year embargo period from the time of collection. During this embargo period, access to materials is subject to approval by the DC Executive Committee. After this period, data and materials may be distributed by Coriell without approval from the DC. Since the NINDS biorepository is a public resource, data and materials may be submitted by non-DC members. These data and materials are not subject to the DC embargo, but may be subject to any embargo or other restrictions imposed by the non-DC member.
2. Original data and materials stored by the DMCC are subject to an embargo period during the period of active collection, analysis, and reporting of results by DC members. During this period, access to all materials is subject to approval by the DC as outlined above. Following publication of specific results or termination of DC grant support, data and materials stored by the DMCC may be distributed without approval from the DC, according to the policies and procedures of the RDCRN.

**Dystonia Coalition Policies for Authorship, Acknowledgements, and Reporting**

Publication of research data by members of the DC is encouraged. The term “publication” is applicable to all forms of communication related to the release of information generated by the DC, including but not limited to manuscripts, abstracts, statements submitted to scientific and medical journals, presentations at conferences, news media, internet sites, and other public information sources. The policies below apply to any projects receiving financial resources from the DC and projects receiving data or materials directly from the DC. These policies do not apply to data or materials obtained from Coriell or the DMCC.

Authorship of different products is expected to vary according to differing contributions. Authorship will be determined according to contributions to the study being reported. It is expected that not all members of the DC will be co-authors for every study, particularly those studies that are organized and executed by one or a few sites, such as Pilot Projects or Career Development Awards. However, all studies receiving financial support or resources from the DC must acknowledge the DC and appropriate sources of DC grant support as specified below.

The Executive Committee will be responsible for the final approval of all publications related to data or materials received directly from the DC. It will be responsible for implementation and revision of the publication policies, verification of the correct designation of authorship and acknowledgements, verification of compliance with NIH policies regarding publications and data sharing, and ensuring appropriate communications regarding publications with the NIH and DMCC.

1. Prior to commencing the preparation of publications, the corresponding author must submit a proposal to the Executive Committee. This proposal shall outline the format for publication, a description of items to be included and method of analysis, contact information for the corresponding author, and the list and order of all authors with their respective responsibilities.
2. To ensure adherence to the plan originally proposed when data or materials were provided, a final draft of the publication will need to be approved by the Executive Committee prior to submission by the authors.
3. The Executive Committee itself may propose publication projects to members of the DC when it determines that the results of a study project are ready for publication or there is a need to relay the information to the scientific and medical community or general public. Such recommendations must be acted upon in a timely manner or the Executive Committee may designate other members instead.

In general, authorship should conform to guidelines provided by the Council of Science Editors, following the lead of several other collaborative research networks. Briefly, authorship will be based on 1) substantial contributions to conception and design, significant acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. All other contributing members of the DC may be listed in an appendix or supplement. Authorship should be assigned according to common standards applied equally to all contributing members. Authorship order will be determined by the lead author.

1. All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
2. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
3. For the DC, “significant acquisition of data, or analysis and interpretation of data” include recruitment, diagnosis, video examination with video, and rating dystonia for a significant number of subjects included in a publication by a recruiting investigator of the DC.
4. Acquisition of funding or general supervision of a research group alone does not constitute authorship.
5. Prior to commencing the preparation of a publication, the list and order of all authors with their responsibilities will need to be clearly stated in the publication proposal.
6. For major publications arising from the Main Clinical Projects, authors shall include: Lead Project Investigator (or designee), Project Committee members, others who have made outstanding contributions to the study (such as biostatisticians, contributors of data from a significant proportion of patients, or members of the NIH or DMCC as applicable), followed by “for The Dystonia Coalition” with a footnote denoting additional contributing members. The footnote may be supported in the acknowledgments or a supplement with contributing members in the following order: site investigators and clinical evaluators (in order of number of recruited or completed patients), medical monitor(s) or members of a data and safety monitoring board, and any participating members of the DMCC.
7. Authorship on publications derived from smaller studies, including ancillary studies relating to the Main Clinical Projects, Pilot Projects and Career Development Awards, may be decided by those who proposed and conducted the project, but are subject to the Executive Committee’s approval as outlined above.
8. Authorship on invited reviews and chapters will be determined by the invitee. However, when such authors require the use of DC data that are not already in press in a peer review journal, they will need to obtain approval from the Executive Committee, and the DMCC if data are supplied by them.
9. Publications that describe the DC and its functions, such as objectives or overall outcomes, require approval of the Executive Committee to ensure accuracy.

The Executive Committee is responsible for ensuring that all publications appropriately acknowledge support from sponsors, including financial, material support, or logistical support. Source of financial and administrative support will vary across publications, making oversight by the Executive Committee essential for complete and accurate disclosure of all sponsors.

1. All publications supported in whole or part by funds provided through the DC must acknowledge support through DC grants NS065701 TR001456 and/or NS116025 from the ORDR/NCATS and the NINDS at the NIH. The following statement has been recommended by the NIH: *The Dystonia Coalition is part of the NIH Rare Diseases Clinical Research Network. Funding and /or programmatic support for this project has been provided by NS065701, TR001456, and NS116025 from the NIH Office of Rare Diseases Research in the National Center for Advancing Translational Sciences and the National Institute of Neurological Disorders and Stroke.*
2. All publications using resources generated in whole or part by the DC also must acknowledge support from DC grant NS065701, TR001456, and NS116025 as described above. Resources include but are not limited to data and biomaterials.
3. Authors of invited reviews, chapters, internet-based communications, or other advertisements not using data or resources generated by the DC, but supported by the DC for their work on that area of research, also should acknowledge support through DC grant NS065701, TR001456, and NS116025 as above.
4. In some cases, sources of supplementary funds, such as those provided by Patient Advocacy Groups, the Dystonia Study Group, or Industry sponsors, must also be acknowledged, where applicable.
5. Support from the DMCC, including non-financial support through provision or analysis of data, must be acknowledged, where applicable.
6. Medical monitors and/or members of the data and safety monitoring boards must be acknowledged, where applicable.

The Executive Committee is responsible for ensuring that appropriate NIH regulations are followed, including adherence to NIH Public Access Policy. NIH requires that the results and accomplishments of the activities that its funds be made available to the public at large, as described in detail at: <http://grants.nih.gov/grants/sharing.htm>.

1. The NIH Public Access Policy requires authors to submit final peer-reviewed journal manuscripts that arise from NIH resources to the digital archive PubMed Central upon acceptance for publication. Itapplies to any manuscript that is peer-reviewed and arises from any funding from an NIH grant or cooperative agreement or includes an NIH employee. It is the responsibility of the communicating author to make sure that the publication is submitted to PubMed Central. Instructions related to the submission process can be found at <http://publicaccess.nih.gov/>.
2. The communicating author is responsible for notifying the Executive Committee once a manuscript has been accepted for publication. The Executive Committee will in turn notify the NIH Project and Science Officers regarding the publication of manuscripts, as well as the DMCC.
3. Failure to comply with the publication policy outlined above may result in expulsion from or restrictions in ongoing studies, outright expulsion from the DC, loss of any rights to access data or materials under DC embargo, and/or formal withdrawal of the publication.

**Dystonia Coalition Policies for Copyrights & Patents**

The DC leadership does not intend to hold any claims over copyrights of its published studies. The publication of studies will be subject to standard practices that currently involve authors of the published works together with the associated publisher. Because the DC is NIH-funded, standard NIH copyright policies may apply to any products receiving funding from the DC (<http://grants.nih.gov/grants/policy/>). Specifically, the NIH must be given a royalty-free, nonexclusive, and irrevocable license for the Federal government to reproduce, publish, or otherwise use the material and to authorize others to do so for Federal purposes.

Other products of the DC, such as diagnostic instruments or rating tools, may also be subject to copyrights. Such copyrights will reflect standard practice that recognizes joint ownership by individuals involved in designing the products and the publisher. Any of the individuals involved in the concept or design of these tools will have the right to use the instruments and distribute them without charge to other academic investigators and clinicians. NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources are developed with NIH funds, and the associated research findings have been published, or after they have been provided to the NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

Patents also may arise from work supported in whole or part by resources from the DC. The DC leadership does not intend to hold any claims over patents arising from efforts it has supported. Patents will be governed by the individuals and institutions who develop them. Because the DC is supported by the NIH, standard NIH patent policies apply (<http://grants.nih.gov/grants/policy/>). As long as the individuals and institutions abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery. Individuals or institutions receiving funds through the DC who assert intellectual property rights to subject inventions must:

1. Report all inventions and patents directly to the NIH through iEdison.
2. Formally acknowledge the US Federal Government’s support in all patents that arise from the subject invention.
3. Report all inventions and patents to the DC Program Manager for inclusion in its annual progress report to the NIH.
4. Make efforts to commercialize the subject invention through patent or licensing.
5. Formally grant the US Federal government a non-exclusive, nontransferable, irrevocable, paid-up, worldwide license to the subject invention, consistent with NIH policies.

**Investigator’s Statement of Agreement**

I am requesting access to Dystonia Coalition data or samples for the research purposes described above. I agree to follow the policies described herein with regards to these data or samples.

By signing below, I acknowledge that I have carefully read this document and agree:

1. To abide by the guidelines for accessing and using data or materials outlined above.
2. To abide by the decisions of the Executive Committee and/or Steering Committee.
3. To not distribute or communicate any privileged information without consent of the Executive Committee.

By checking this box and entering your name below, you acknowledge agreement with the above terms.

Name of Requestor: Click here to enter text. Date of Request: Click here to enter text.

**OFFICE USE ONLY**

Date Request Received: Click here to enter text.

Request approved:  Yes  No - Date: Click here to enter text.

Type of transfer done:  Original Data Transfer:

Date: Click here to enter text.

Modified/updated Data Request Transfer:

Date: Click here to enter text.

Video Repository Access:

Date: Click here to enter text.

Videos Sent on Encrypted Hard Drive:

Date: Click here to enter text.

Videos transferred via the encrypted box

Date:

DNA Samples:

Number of samples: Click here to enter text.

Date: Click here to enter text.

FedEx# Click here to enter text.

RNA Samples:

Number of samples: Click here to enter text.

Date: Click here to enter text.

FedEx# Click here to enter text.

Plasma Samples:

Number of samples: Click here to enter text.

Date: Click here to enter text.

FedEx# Click here to enter text.