Constitution and Bylaws

Dystonia Coalition Mission Statement

The mission of the Dystonia Coalition (DC) is to advance clinical and translational research in the dystonias to improve our understanding of its clinical manifestations and pathogenesis, and to find better treatments and a cure. The DC will focus on cooperative planning, implementation, conduct, and reporting of clinical and translational studies, including clinical trials. The DC also is interested in educating professionals and the public by providing scientific and medical information about dystonia. The DC is committed to the principles of open communication, scientific peer review, full disclosure of conflicts-of-interest, and democratic governance of its activities.

Dystonia Coalition Sponsorship

Sponsorship for DC programs comes from several sources. Sponsorship is not tied to a single grant or source of funding. Sponsorship comes in part from NIH funding, PAGs, industry sources, professional societies, and other sources. While sponsorship comes from many sources, the majority of funding is currently provided by NIH under grant award U54 NS116025, with a project period through June 30, 2024.

Dystonia Coalition Membership

The DC is a collaboration of medical researchers and patient advocacy groups (PAGs), one of the consortia of the Rare Diseases Clinical Research Network (RDCRN) supported by The National Institute of Neurological Disorders & Stroke (NINDS) and The Office of Rare Diseases Research (ORDR) in the National Center for Advancing Translational Sciences (NCATS) of the National Institutes of Health (NIH). More information can be found online on the DC web site.

Current DC members include investigators at sites that participate in DC projects and/or committees. These sites are divided into three categories. Project Centers are sites that take responsibility for organizing and conducting Main Clinical Research Projects outlined below. Project centers are not permanent but may change as projects are completed and new ones are started. Recruiting Centers are sites where research subjects may be recruited for Main Clinical Research Projects. Recruiting centers must have sufficient expertise and ability to recruit patients for studies, with quotas for membership determined by individual studies. Affiliate Centers are sites that want to keep informed of events and opportunities, but do not actively recruit subjects for Main Clinical Research Projects. Affiliate Centers may become Recruiting Centers, and vice versa. All centers may participate in research projects, submit proposals for new projects, or nominate candidates for career development awards. The DC has an open-door policy in which new investigators and institutions may be invited to join at any time. Investigators interested in membership should contact the DC Program Manager (dystoniacoalition@emory.edu).

Dystonia Coalition Officers & Committees

DC activities are organized through an Executive Committee, a Steering Committee, a Pilot Projects Program Committee, a Career Development Award Committee, and separate committees for specific projects as determined by the Executive Committee.

1. **The Executive Committee** serves as the main decision-making body for the DC. Executive Committee members will include a Chair who is PI of the DC, leaders of each of the Main Clinical Research Projects, a representative from the NINDS, a representative from ORDR/NCATS, and at least one representative from a DC Patient Advocacy Group (PAG). This committee oversees all DC activities, including appointing members of other committees described below.
2. **The Steering Committee** is a group of senior investigators and NIH representatives who serve an advisory role to the Executive Committee. The Steering Committee will review progress, make recommendations on future goals, and arbitrate any disagreements that are not satisfactorily addressed by the Executive Committee. Steering Committee members are appointed by the Executive Committee and include at least three clinical scientists with expertise in dystonia research, a representative from NINDS, and a representative from the ORDR/NCATS.
3. **The Pilot Projects Program Committee** serves as an advisory committee to the Executive Committee by soliciting, collecting, and reviewing pilot grant proposals submitted to the DC. This committee will consist of a standing Chair, at least one additional DC member (who will be selected on the basis of expertise needed for reviewing grants received), a representative from the NIH, and at least one medical or scientific advisor from the DC PAGs.
4. **The Career Development Award Committee** serves as an advisory committee to the Executive Committee by soliciting, collecting, and reviewing Career Development Award proposals submitted to the DC. This Committee will consist of a Chair, at least 3 individuals with expertise in dystonia research, and at least one representative from the NIH.
5. **The Dystonia Natural History Committee** will oversee the development and operations of the DC Natural History Study. This study collects, stores, and distributes clinical data and videos, from patients with dystonia and potentially related conditions. This committee will include three permanent members: The Project PI as Chair, the DC PI, and a representative from the NINDS. Other members will be added as additional expertise is needed.
6. **The Dystonia Patient-Centered Outcomes Committee** will oversee a study devoted to developing a tool for patient-related outcomes for the most common types of dystonia. This committee will include three permanent members: The Project PI as Chair, the DC PI, and a representative from the NINDS. Other members will be added as additional expertise is needed.
7. **The Objective Measures of Dystonia Committee** will oversee a study devoted to the development of objective measures for the most common dystonias. This committee will include three permanent members: The Project PI as Chair, the DC PI, and a representative from the NINDS. Other members will be added as additional expertise is needed.
8. **The Dystonia Biobank Resource Committee** will oversee the expansion of a previously created DNA repository to include blood and other potential biomaterials to enable exploration of new biomarkers. This committee will include three permanent members: The Project PI as Chair, the DC PI, and a representative from the NINDS. Other members will be added as additional expertise is needed.

Dystonia Coalition Main Clinical Research Projects

The DC plans several projects and other activities. DC sites may participate in any or all of the projects and programs as approved by the associated DC committees. All sites recruiting patients for the main clinical studies must be members of the DC. All domestic sites participating in main clinical studies that involve multiple centers must agree to use of a single IRB. International sites may use their local IRBs. Additional information regarding each project may be found in the associated study manuals or on the DC website. Prior to collecting data, investigators at each site will be trained to ensure uniformity of the highest quality data collection. All clinical data will be collected centrally at the DC data center core, currently located at Washington University in St. Louis (WashU). All data also may be collected at other sites designated by ORDR/NCATS, including the Rare Diseases Clinical Research Network Data

Management and Coordinating Center (DMCC). The DMCC provides for long-term storage and potential future distribution of data. Participants and their samples will be identified by different, but linked, unique identifying codes at different locations.

1. **Dystonia Natural History Project.** Joel Perlmutter at WashU is Chair of this project. The main purpose of this project is to continue and to expand a resource of longitudinally-collected data for dystonia subjects. The main goal is to characterize the evolution of different types of dystonia over time. Another goal is to develop a resource that can be used for additional studies that may arise in the future. Any DC Recruiting Site may recruit subjects for this study.
2. **Dystonia Patient-Centered Outcomes Project.** Sarah Pirio Richardson at the University of New Mexico is Chair of this project. The main purpose of this study is to develop patient-reported outcome measures for the most common types of dystonia. A major goal will be to quantify between-subject and within-subject variation in responses to botulinum neurotoxin over time. This project is not open to all DC sites; only specific centers will participate.
3. **Objective Measures of Dystonia Project.** David Peterson at the University of California and the Salk Institute in San Diego is Chair of this project. The main purpose of this project is to develop objective measures for the most common dystonias. A major goal is to develop tools to diagnose and/or quantify symptoms from video-based materials. This project is not open to all DC sites; only specific centers will participate.
4. **Dystonia Biobank Resource Project.** Carlos Cruchaga at Washington University in St. Louis (WashU) is Chair of this project. The main purpose of this project is to extend the current DNA repository and develop a centralized repository for blood and other biomaterials. The major goal is to develop a resource rather than conduct a specific study. Additional goals may be to conduct or support pilot projects that aim to delineate biomarkers for diagnosis or monitoring severity. Biomaterials for this project may be processed and stored at multiple locations. Because biosamples are a limited resource, the Biobank Resource Committee may establish working groups for specific studies to avoid redundant or wasteful studies. This project is open to all DC sites that can follow the associated protocols for biomaterial collection and processing.

Additional Dystonia Coalition Programs

1. **Pilot Projects Program**. Approximately 1-2 times yearly, the DC may solicit applications for pilot projects. The goal of this program is to provide funding or other resources to promote development of promising clinical research projects. The frequency and extent of this program depends on resources available from the NIH and from private patient advocacy groups. Applications will be reviewed by the Pilot Projects Program Committee. Any qualified applicant may apply. Membership in the DC or affiliation with an American institution is not required. However, all recipients of data, materials, or funding must agree to the guidelines described in the DC Bylaws and Constitution.
2. **Career Development Award Program**. Approximately 1-2 times yearly, depending on resources available, the DC may solicit applications for its Career Development Award. The goal of this program is to promote career development for investigators interested in dystonia research and to foster interactions between investigators at all levels. Applications will be reviewed by the Career Development Award Committee. Any qualified applicant may apply. Membership in the DC or affiliation with an American institution is not required. However, all recipients of data, materials, or funding must agree to the guidelines described in the DC Bylaws and Constitution.

Data & Resource Sharing by the Dystonia Coalition

The DC encourages timely and efficient use of data and materials through sharing. All Recruiting Sites have unrestricted access and rights to their own data. Access to data and materials collected from other sites is available via three different processes.

1. Data or materials may be requested from the DC through the Data and Materials Request Form. 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. 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 Coriell or the DMCC. 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 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. At publication, all results must be returned to the central site at WashU and the DMCC and made publicly available without restriction to access. Any studies involving genomic data must comply with NIH policies on sharing of genomic data.
2. 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 to Coriell by non-DC members too. These data and materials do not fall within the purview of the DC and are not subject to the DC embargo.
3. Original data and materials stored by the DMCC are governed by the policies and procedures of the RDCRN. In general, all materials are subject to an embargo period during the period of active collection, analysis, and reporting 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.

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, 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 or projects receiving data or materials directly from the DC. These policies do not apply to data or materials obtained from Coriell or DMCC.

Authorship of different publications 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.

Because the DC organizes projects that use data and resources from many different investigators, the Executive Committee is responsible for the approval of all publications related to data or materials received directly from the DC as described further below. It will be responsible for implementation and revision of the publication policies, verification 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 preparation for publications, the lead author must submit a proposal to the Executive Committee for approval. 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. Such approval is additionally intended to ensure that all publications involving data and materials provided by the DC appropriately acknowledge those contributions to the publication.
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. The Executive Committee has the right to determine timelines and may designate other members instead.
4. Nothing herein shall be construed to prevent its investigators from publishing data created or generated solely at his or her own site. Investigators are encouraged to publish or otherwise use any data or samples collected or generated at their own sites without restriction.

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 all three conditions. 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 offered authorship.
2. Each author should have participated sufficiently in the work to take public responsibility for relevant portions of the content.
3. For the DC, “significant acquisition of data, or analysis and interpretation of data” may include recruitment, diagnosis, video examination, and rating dystonia for a significant number of subjects included in a publication by a recruiting investigator of the DC. In general, the DC has suggested the guideline that recruitment and evaluation of at least 20 subjects for a study was a significant contribution for authorship eligibility.
4. Actively recruiting sites (Project Sites and Recruiting Sites) may be eligible for authorship, but past or passive involvement (Affiliate Sites) does not constitute automatic eligibility for 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.
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 the sources of support for the DC. All publications receiving data or materials must also site these sources of support. They include grants from the NIH including NS065701, TR001456, and NS116025. The following statement is recommended: *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 the National Institute of Neurological Disorders and Stroke and NIH Office of Rare Diseases Research in the National Center for Advancing Translational Sciences at the NIH through grants NS065701, TR001456, and NS116025.*
2. 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 DC grant support as described above.
3. In some cases, supplementary funds, such as those provided by Patient Advocacy Groups, the Dystonia Study Group, or Industry sponsors, must also be acknowledged, where applicable.
4. Support from the DMCC, including non-financial support through provision or analysis of data, must be acknowledged, where applicable.
5. Research coordinators, medical monitors, and/or members of the data and safety monitoring boards may 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 it 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. It applies 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 representatives, as well as the DMCC.
3. Failure to comply with the publication policy outlined above may result in 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 Copyright & Patent Policy

The DC does not intend to hold 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 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.

Specific Terms & Conditions for Resources Provided through the Dystonia Coalition

Recipient acknowledges and agrees that all activities conducted under this Constitution and Bylaws are supported by the National Institutes of Health and are subject to 45 CFR Part 75, as well as the applicable NIH Grants Policy (http://grants.nih.gov/grants/policy/nihgps/HTML5/introduction.htm). Recipient agrees that it shall comply with the NIH Grants Policy statement, including but not limited to, the Requirements, Objectives, or Appropriation Mandates as identified for Consortium Participants in Section 4.1, Public Policy Requirements and Objectives, Exhibit 4.

Any resources provided through the DC must be used in accordance with the NIH Request for Applications RFA-TR-18-020 (https://grants.nih.gov/grants/guide/rfa-files/RFA-TR-18-020.html) , as well as the terms of agreement in the Notice of Grant Award for U54 NS116025. The Recipient will allow auditors from Emory University (the primary NIH grant recipient), the DMCC, or the federal government access to records pertinent to related projects during normal business hours.

1. Recipient agrees to use the funds provided to advance the DC-funded project only, as described in the DC Projects Manual or the approved Pilot Project Award or Career Development Award, abiding by standard NIH guidelines regarding appropriate use of grant funds (https://grants.nih.gov/policy/nihgps/index.htm) including those for clinical trials if applicable (www.clinicaltrials.gov).
2. Recipient will comply with all federal financial requirements and shall retain all relevant financial records for a period of three years following its termination from the project. Recipient certifies that is in compliance with cost principles and Cost Accounting Standards in accordance with 2 CFR § 200 Subpart E-Cost Principles, or 48 CFR Part 31.2 (for for-profit entities only), as appropriate.
3. If Recipient receives more than $750,000 per year in federal funds, it agrees to comply with the audit requirements in 2 CFR §200 Subpart F-Audit Requirements. In order that Emory University, as primary NIH grant recipient, can comply with its obligations under 2 CFR §200 Subpart F-Audit Requirements, Recipient shall provide Emory University with a copy of its annual single audit report, which shall include any exceptions noted on the audit. If the audit report includes any findings related to funds received from Emory University, Recipient must inform Emory University within ninety (90) days following issuance of the audit report. Failure to adhere to this requirement could result in immediate termination of these Bylaws and/or repayment of all amounts previously paid hereunder. If Recipient does not receive more than $750,000 per year in federal funds and is not subject to the audit requirements in 2 CFR §200.500, Recipient shall provide Emory University with a copy of any annual audited financial statements if they have findings related to any Dystonia Coalition Project or Program.
4. Recipients of Pilot Project and Career Development Awards will submit an interim progress report 6 months after the start of the award and a final report no later than 30 days after the end of the award period. Reports should be submitted to the DC Program Manager (dystoniacoalition@emory.edu).
5. Recipients of Pilot Project and Career Development Awards will notify DC Program Manager in writing immediately if the Recipient changes institutions or discontinues work on the funded research. If the Recipient fails to perform the work in good faith according to the proposal provided and the terms and conditions of the award, Recipient agrees to return unused funds upon request.

6. The Recipient hereby assure the DC that all sources of overlapping funding for the proposed project have been or will be disclosed immediately. After beginning the project, any funding received by the Recipient that will be used to support any research that is being supported by the DC must be disclosed as soon as the new funding has been approved. Under any circumstances where there is or has been duplication of support, the DC reserves the right to alter or suspend further support of all parts of the project and request repayment of duplicated funds.
7. The Recipient and all other members of the DC agree to hold each other harmless from liability of any nature or kind including costs or expenses from, or on account of, any suits or claims of any kind resulting from injuries or damages sustained by any person or persons or property by virtue of the Coalition member's own performance within this project except when such suits or damages arise out of gross negligence or willful misconduct of another party to this project.

Protection of Human Subjects in Research Sponsored by the Dystonia Coalition

For any involvement of human subjects, the Recipient warrants and agrees to comply with the Common Federal Policy for the Protection of Human Subjects, as codified by the Department of Health and Human Services at 45 CFR Part 46. Recipient further agrees that any human subjects research shall be conducted in accordance with its Federalwide Assurance and that such Federalwide Assurance shall be kept active throughout the period of performance of this agreement. For multisite studies, all domestic centers will be required to use a single IRB of record. For multisite studies, foreign centers may use their local IRB for approval. International sites will provide certification to the DC at Emory University at least annually that an ethical review committee has reviewed and approved any procedures that involve human subjects. Foreign sites will also need additional approval from the NIH and State Department. Recipient shall bear full responsibility for the proper and safe performance of all work and services involving its use of human subjects under this agreement.

The Recipient acknowledges that during the term of this Agreement and the Study, it may receive protected health information (PHI) as defined in the Health Insurance Portability and Accountability Act of 1996. The Recipient agrees to restrict use or access to any PHI provided by through DC, shall maintain the confidentiality of any and all PHI, and shall not disclose (whether directly or indirectly) or use (whether directly or indirectly) said PHI for any purpose other than performance of this Agreement and those purposes permitted by the Informed Consent or subject authorization. Recipient further agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for in this Agreement and in the Informed Consent or Subject Authorization. Recipient shall restrict dissemination of PHI to persons involved in the Study, to persons that have a need-to-know such information, to regulatory authorities and when use and disclosure is required by law. Recipient ensures that each employee, agent, subcontractor, customer, or vendor to whom PHI is disclosed is aware of and agrees to comply with Recipient's obligations with respect to PHI disclosed as part of this study.

Dystonia Coalition Conflict of Interest Guidelines

Members of the DC should maintain the highest personal and professional standards in conducting clinical research and trials. Real and perceived conflict-of-interest must be avoided.

The Recipient certifies that it has implemented and is in compliance with a financial conflict of interest policy that complies with 42 C.F.R. Part 50/ 45 CFR Part 64 (2011), as may be amended from time to time. Prior to engaging in any work under this Agreement, Recipient Institution shall notify Emory University, as primary NIH grant recipient, of any financial conflicts of interest of Recipient Institution Investigators that relate to the work hereunder prior to expenses being incurred. Recipient Institution Investigators are those members of the research team who meet the NIH definition of Investigator and who are not employees of Emory University. For Financial Conflicts of Interest that are identified after the work has

begun, Recipient Institution shall notify Emory University within 30 days. For any Financial Conflicts of Interest that are identified, Recipient shall provide Emory University the information required for reporting the Financial Conflict of Interest to the agency as enumerated in 42 CFR 50.605/45 CFR 94.5 and shall provide updated information to Emory University annually. Additionally, if Recipient, as part of a retrospective review, makes a determination of the presence of bias, Recipient shall provide Emory University a copy of its mitigation report within one hundred twenty (120) days from its finding of noncompliance. All notices under this clause shall be sent to COI-OFFICE@listserv.cc.emory.edu.

Emory University shall provide Recipient a copy of notifications sent to NIH that involves Recipient under this Agreement. Emory University will provide information to the public in a written format as outlined in its policy (see http://policies.emory.edu/7.7) and will provide a copy to Recipient. In addition to compliance with 42 CFR Part 50, the following principles apply:

1. DC members have an obligation to act in the public interest and should be willing to educate the scientific and lay communities. DC members agree that such practices are permitted provided there is no disclosure of confidential information or any potential for jeopardizing the successful outcome of any clinical study or trial that may be in progress.
2. DC members shall not benefit financially as a result of their participation in and knowledge of DC studies. In particular, DC members agree not to own or trade in the equity of other companies or entities likely to benefit from the outcomes of DC studies. "Involved entities" are defined as entities that may benefit from the performance or outcome of a DC-sponsored study, including an entity whose drugs or products are being investigated by the DC. Further, DC members or their immediate family members shall not benefit financially from the information obtained as a result of their participation or knowledge of DC studies.
3. Project Committees for each study agree to identify Involved Entities associated with each study and inform participating DC investigators. Project Committees may not be aware of all conflicts of interest. DC members are expected to exert vigilance regarding conflicts of interest and inform the Project Committee on learning that a conflict of interest exists. The Project Committee shall submit a written recommendation to the Executive Committee for review and final decision.
4. These Conflict of Interest Guidelines will apply from the time of recruitment of subjects into a study until peer-reviewed publication of the results of the study, or after an interval of 2 years after the study database is closed. This will be binding for all members including those who might leave the study, for any reason, prior to its completion.
5. In these Conflict of Interest Guidelines, a DC member is defined as an investigator, study coordinator, data processor, statistician, consultant, or any other person involved with or privy to information regarding DC studies.
6. Members of the DC should insist on full and meaningful disclosure of financial support for educational events to which they are invited to participate.
7. Members of the DC should fully disclose their research support and any significant financial interest with manufacturer(s) of commercial products related to the topic of their presentation for education events in which they participate.

Investigators Statement of Agreement

This agreement will replace any prior agreement for the Dystonia Coalition. The signatories below acknowledge having carefully read this document, any associated study documents, and budgets as applicable. We will conduct these studies in accordance with associated study protocols, and in accordance with current local regulatory requirements. Any changes in procedure will only be made if necessary to eliminate immediate hazards and/or to protect the safety, rights or welfare of subjects.

The Executive Committee or appropriate Project Committee will provide copies of the relevant protocols and all other information relating to DC projects and programs, as applicable, to all DC Investigators and other study personnel participating in these studies under their direction. The appropriate Committee member(s) will discuss this information with them to assure that they are adequately informed regarding the conduct of the study.

The Recipient agrees to keep records on all subject information (case report forms, informed consent statements and all other information collected during the study) in accordance with the current GCP, ICH, local, national and European regulations, and as described in the study manual.

Finally, the Recipient Institution and Investigators agree:

1. To abide by the spirit of the guidelines for accessing and using data or materials outlined above.
2. To abide by the decisions of the Project Committees, Executive Committee, and/or Steering Committee.
3. To abide by the operational guidelines for the Main Clinical Projects as outlined above and described in more detail in the Project Manuals.
4. To not distribute or communicate any privileged information without consent of the Executive Committee. Privileged information may include findings from unpublished studies or presentations by any and all members of the DC.
5. To abide by the guidelines for authorship and publication described above.

Recipient Institution ("Recipient")

Name of Recipient Institution's Principal Investigator

Signature of Principal Investigator Date

Name and Title of Recipient Institution's Authorized Representative

Signature of Recipient Institution's authorized representative Date

Emory University
Primary Grant Institution

Holly Sommers, Director, Office of Sponsored Programs
Name and Title of Primary Grant Institution's Authorized Representative

Signature of Primary Grant Institution's Authorized Representative

Appendix 1: Memberships

The Dystonia Coalition
- PI: H. A. Jinnah, MD, PhD
- Co-PI: Joel Perlmutter, MD
- NINDS Representative: Codrin Lungu, MD
- ORDR/NCATS Representative: Tiina Urv

Executive Committee
- Chair & Director of the DC: H. A. Jinnah, MD, PhD
- Chair of the Dystonia Natural History Project: Joel Perlmutter, MD
- Chair of the Dystonia Patient-Centered Outcomes Project: Sarah Pirio Richardson, MD
- Chair of the Objective Measures of Dystonia Project: David Peterson, PhD
- Chair of the Dystonia Biobank Resource Project: Carlos Cruchaga, PhD
- Chair of the Pilot Projects Program: H. A. Jinnah, MD/PhD
- Chair of Career Development Program: Cynthia Comella, MD
- Patient Advocacy Group Representative(s): Kim Kuman & Janet Hieshetter
- NINDS Representative: Codrin Lungu, MD
- ORDR/NCATS Liaison: Tiina Urv

Steering Committee
- Anthony Lang, MD
- Marie Vidailhet, MD
- Alberto Albanese, MD
- Gerald Berke, MD
- Marina Tijssen, MD
- Mark Hallett, MD
- NINDS Science Officer: Codrin Lungu, MD
- ORDR/NCATS Liaison: Tiina Urv

Pilot Projects Committee
- Chair: H. A. Jinnah, MD, PhD
- Rotating Member(s): Joel Perlmutter, MD
- NINDS Representative: Codrin Lungu, MD
- ORDR/NCATS Liaison: Tiina Urv
- Patient Advocacy Group Representative(s): Mark Hallett, MD; Michael Okun MD; Jan Teller, PhD;

Career Development Awards Committee
- Chair: Cynthia Comella, MD
- Co-Chair and Patient Advocacy Group Representative: Jan Teller, MD
- Members: Alberto Albanese MD, Gerald Berke MD, Anthony Lang MD, Marina Tijssen MD, Marie Vidailhet MD
- NINDS Representative: Codrin Lungu, MD
- ORDR/NCATS Representative: Tiina Urv

Natural History Project Committee
- Chair: Joel Perlmutter, MD
- DC PI: H. A. Jinnah, MD, PhD
- NINDS Science Officer: Codrin Lungu, MD

Patient-Centered Outcomes Project Committee
- Chair: Sarah Pirio Richardson, MD
- DC PI: H. A. Jinnah, MD, PhD
- NINDS Science Officer: Codrin Lungu, MD

Objective Measures Project Committee
- Chair: David Peterson, PhD
- DC PI: H. A. Jinnah, MD, PhD
- NINDS Science Officer: Codrin Lungu, MD

Biobank Resource Project Committee
- Project PI: Carlos Cruchaga, PhD
- DC PI: H. A. Jinnah, MD, PhD
- NINDS Science Officer: Codrin Lungu, MD

DC Program Manager: Gamze Kilic-Berkmen, PhD (404-727-3381; dystoniacoalition@emory.edu)