Constitution, Bylaws, Terms & Conditions

Dystonia Coalition Mission Statement

The mission of the Dystonia Coalition (DC) is to advance the pace of clinical and translational research in the dystonias to find better treatments and a cure. The DC will focus on cooperative planning, implementation and conduct, analysis, and reporting clinical trials and other research studies aimed at improving the understanding and treatment of dystonia and related disorders. 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 organization and activities.

Dystonia Coalition Membership

The DC is a collaboration of medical researchers and patient advocacy groups supported by the Office of Rare Diseases Research (ORDR) and The National Institute of Neurological Disorders & Stroke (NINDS) of the National Institutes of Health (NIH). More information can be found at www.rarediseasesnetwork.epi.usf.edu/dystonia. Current DC members include individuals who are involved in DC projects and committees described below. The DC has an open-door policy in which new investigators and institutions are invited to join at any time. Each of these centers may participate in ongoing research projects, submit proposals for new projects, or nominate candidates for career development awards. Investigators interested in membership should contact the DC Program Coordinator (see appendix for contact information).

Dystonia Coalition Officers & Committees

The DC will be governed by an Executive Committee, a Steering Committee, a Pilot Projects Program Committee, a Career Development Award Committee, separate Committees for three Main Clinical Projects, and others 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 three main projects, a liaison from the ORDR, a science officer from the NINDS, and at least one representative from the Coalition of Patient Advocacy Groups.
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 settled by the Executive Committee. Steering Committee members are appointed by the Executive Committee and include at least three academic clinical scientists with expertise in dystonia research, a representative from the ORDR and a representative from NINDS.
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 for funding. The Pilot Projects Program Committee will consist of a standing Chair and Co-Chair, both of whom are not eligible to submit proposals for funding. The Committee also will include at least two additional rotating DC members 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 Coalition of Patient Advocacy Group.

4. **The Career Development Awards Committee** serves as an advisory committee to the Executive Committee by soliciting, collecting, and reviewing career development award proposals submitted to the DC for funding. The Career Development Awards Committee will consist of at least 3 clinical scientists with expertise in dystonia research, and at least one representative from the NIH.
5. **The Project 1 Committee** will oversee the development and operations of the DC's prospective Natural History Study and Biorepository for clinical data and DNA samples dedicated to primary focal and segmental dystonia. This committee currently consists of three permanent members: the Project 1 PI as Chair, the Dystonia Coalition PI, and a science officer from the NINDS. It will also include at least two rotating members from the DC who are anticipated to have a special interest in the use of resources being developed.
6. **The Project 2 Committee** will oversee the revision and testing of comprehensive rating tools for patients with cervical dystonia. This committee currently consists of the Project 2 PI as Chair, the Dystonia Coalition PI, the lead statistician, the lead psychiatrist, and at least one investigator from a participating site.
7. **The Project 3 Committee** will oversee the development and testing of a new scale for diagnosing and assessing patients with spasmodic dysphonia. This committee will consist of the Project 3 PI as Chair, and at least one representative from each of 4 participating centers.

Dystonia Coalition Projects

The DC plans several projects and other activities outlined below. Additional information regarding the projects may be found in the respective study manuals or on the DC website.

1. **Project 1: Natural History & Biorepository.** Joel Perlmutter at Washington University in St. Louis is leader for this project. The primary purpose of Project 1 is to develop a resource of data and biomaterials that will be of interest to investigators for future studies. The initial focus will be on adult-onset primary focal dystonia: cervical dystonia, blepharospasm, craniofacial dystonia, laryngeal dystonia (spasmodic dysphonia), and limb dystonia. It also will include segmental and multifocal dystonias. The ultimate goal will be to collect clinical data and material for at least 1,000 cases for each of the five primary focal dystonias. We will not include generalized or secondary dystonias, though these may be added in the future. All investigators who contribute data or samples for Project 1 must be members of the DC. Prior to collecting data or materials, investigators at each site will be trained to ensure uniformity of the highest quality clinical data and specimen collection. All clinical data, including videotapes showing facial images, will be logged at a central site at Washington University in St. Louis (WashU) with identifying information accessible only to the submitting site and WashU. A portion of the clinical data and a blood sample will be sent to the NINDS Human Genetics Resource Center at Coriell (NINDS Biorepository). The NINDS Biorepository will return 20 µg of DNA to the central site at WashU as a backup. An additional 3 µg of DNA may be returned by the NINDS Biorepository to the site where it was originally collected. The NINDS Biorepository serves as an independent storage and distribution center for samples and biomaterials. All clinical data also will be stored at another site designated by the ORDR as the Data Management and Coordinating Center (DMCC), currently at the University of South Florida in Tampa. The DMCC provides for long-term storage and future distribution of data. Participants and their samples will be identified by different, but linked, unique indentifying codes at different locations.

Because the purpose of this project is to develop a resource and not to perform a specific study, guidelines are needed to ensure an appropriate balance between rewards to investigators who develop the resource and ready access to other investigators with expertise in pursuing relevant studies in a timely manner. The Project 1 Committee will establish working groups and designate a work group leader to develop plans for specific studies, including but not limited to genome-wide association studies, association studies of single nucleotide or other genetic polymorphisms, and phenotypic and genetic comparisons within or among different focal dystonias. Any participant in the DC may be a member of any working group and participants may be members of multiple working groups. Continued membership in a working group will require participation in at least 80% of all teleconferences or meetings of the working group.

2. **Project 2: Comprehensive Evaluation Tools for Cervical Dystonia**. Cynthia Comella at Rush University is leader for this project. The primary purpose of Project 2 is to refine and test rating scales for use in patients with cervical dystonia with the goal of monitoring progression and responses to treatments in clinical studies and treatment trials. These scales include measures for motor abnormality, pain, psychiatric difficulties, disability and quality of life. The Project 2 Committee will select specific centers to participate in this study; this is not an open protocol. All investigators who contribute to this project must be members of the DC. Prior to collecting data or materials, investigators at each site will be trained to ensure uniformity of the highest quality clinical data and specimen collection. All clinical data, including videos showing facial images, will be logged at a central site at WashU, with identifying information accessible only to the submitting site and WashU. All clinical data also will be stored at the DMCC as described above for Project 1. A subset of the clinical data and a blood sample will be forwarded to the NINDS Biorepository as described above for Project 1.

3. **Project 3: Diagnostic & Rating Tools for Spasmodic Dysphonia.** Christy Ludlow at James Madison University (JMU) is leader for this project. The goal of this study is to develop and test a novel diagnostic and clinical rating instrument that can be used to identify the disorder and measure its severity. This instrument is intended to help physicians more quickly and accurately diagnose spasmodic dysphonia and to help monitor responses to treatments in clinical studies and treatment trials. The Project 3 Committee will select specific centers to participate in this study; this is not an open protocol. All investigators who contribute to this project must be members of the DC. Prior to collecting data or materials, investigators at each site will be trained to ensure uniformity of the highest quality clinical data and specimen collection. All clinical data, including videos of facial images, will be logged at a central site at JMU in Harrisonburg VA with identifying information accessible only to the submitting site and JMU. All clinical data also will be stored at the DMCC as described above for Project 1. A subset of the clinical data and a blood sample will be forwarded to the NINDS Biorepository as described above for Project 1.

Data & Resource Sharing by the Dystonia Coalition

The DC encourages timely and efficient use of data and materials through sharing. The right to access any original unpublished data or materials collected and stored by the DC will be supervised by the Executive Committee, following evaluation by the related Project Committee, if one exists. 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 project described above may be analyzed and presented separately, or in combination. In addition to the planned primary analyses, other secondary analyses may arise in the future. Once published, data should be made publicly available without restrictions for access according to standard NIH policy.

The purpose of committee reviews 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 relevant Project Committee that fully describes the planned analyses, an assessment of feasibility and demonstration of adequate funds, and a timeline. Once approved, the investigators will be given access to data or materials for analysis, which may involve the NINDS Biorepository or the DMCC as needed. If two or more investigative teams submit proposals with similar aims, they will be encouraged to collaborate. If the investigative teams are unwilling or unable to work together, the relevant committee may honor both requests. Any disputes arising from actions of the project committees will be addressed first by the Executive Committee. Any further disagreements will be addressed by the Steering Committee.

Original data and materials collected and stored 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. Unused materials may be returned to the site where they were obtained. Immediately upon publication, all phenotypic and genotypic results (such as those from genome-wide association studies) must be returned to the central site at WashU and the DMCC and made publicly available without restriction to access.

Data and materials sent by DC members to the NINDS Biorepository are subject to a two-year embargo period from the time of collection. During this period, access to all materials is subject to approval by the DC as outlined above under Project 1. After this period, data and materials may be distributed by the NINDS Biorepository without approval from the DC to both DC members and non-members. 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.

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 or termination of DC grant support, data and materials stored by the DMCC may be distributed without approval from the DC. Following publication of studies, results also should be made publically available without restrictions to access.

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 all three Clinical Projects listed above, but also to other projects receiving resources from the DC, including Pilot Projects and Career Development Awards.

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

Two committees will have oversight over publications. The relevant Project Committee will be responsible for approving the preparation of publications generated by the relevant project. It also will be responsible for approval of all authors and their responsibilities, approval of the order of authorship,

the assurance that publications meet accepted scientific standards in regards to content and format, and submission of the publication plan to the Executive Committee.

The Executive Committee will be responsible for the final approval and supervision of all publications related to information generated by the DC and approved by the relevant Project Committee. It will be responsible for publications from ancillary studies, such as those receiving support as Pilot Projects or Career Development Awards, which lack a specific Project Committee. It will be responsible for implementation and revision of the publication policies, verification of the correct designation of authorship and acknowledgements, compliance with NIH policies regarding publications, and ensuring appropriate communications regarding publications with the NIH and DMCC, as applicable.

1. Prior to commencing the preparation of publications the corresponding author must submit a proposal to the chair of the relevant Project Committee (or Executive Committee in the case of ancillary studies, Pilot Projects, or Career Development Awards). This proposal shall outline the format for that publication, a description of items to be included and the method of analysis, contact information for the corresponding author, and the list and order of all other authors with their respective responsibilities. The Project Committee will be required to respond to proposals within 5 business days with either an approval, recommendations for modification or a denial.
2. The Project Committee then must inform the Executive Committee of decisions. The Executive Committee also must respond to decisions or proposals within 5 business days. After final approval of a proposal, the Executive Committee will inform WashU or the DMCC for the need to transfer any data and/or samples, where applicable. To ensure adherence to the proposed plan, a final draft of the publication will need to be approved by the Executive Committee prior to submission to an outside source by the authors.
3. The committees themselves may propose publication projects to members of the DC when it determines that the results of a study project, whether positive or negative, 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 committees may designate other members instead.

In general, authorship will conform to guidelines provided by the Council of Science Editors and will follow the lead of several other collaborative networks including other ORDR Consortia, and relevant study groups such as the Dystonia Study Group. 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 will be listed in an appendix or supplement. Authorship will be assigned according to common standards applied equally to all contributing members of the DC.

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. Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
4. 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 and approved by the relevant Project Committee.
5. Unless otherwise stated by the Project Committee, only those sites that contributed data or samples will be recognized in publications.

6. For major publications arising from the three projects outlined above, authors shall be listed in the following order: Lead Project Investigator (or designee), Project Committee members, others who have made outstanding contributions to the study (such as biostatisticians, contributors of a large proportion of patients, or members of the ORDR, NINDS, 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 three 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 respective Project Committee and Executive Committee, and the DMCC if data are supplied by them.
9. Publications that describe the DC and its functions, objectives, and outcomes (that are not focused on a specific study), require approval of the Executive Committee.

The Project Committee and Executive Committee are 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 Project and Executive Committees 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 grant NS067501 from the ORDR and the NINDS at the NIH. 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 NS067501 from the NIH Office of Rare Diseases Research and the National Institute of Neurological Disorders and Stroke. The views expressed in written materials or publications do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention by trade names, commercial practices, or organizations imply endorsement by the U.S. Government.*
2. All publications using resources generated in whole or part by the DC also must acknowledge support from DC grant NS067501 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 NS067501 as above.
4. In some cases, supplementary funds, such as those provided by Patient Advocacy Groups 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 Project and Executive Committees are 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 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 Copyright & Patent Policy

The Dystonia Coalition 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 Dystonia Coalition is NIH-funded, standard NIH copyright policies apply (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 Dystonia Coalition, such as diagnostic instruments or rating tools, may also be subject to copyrights. Such copyrights will reflect standard practice that recognizes joint ownership by all individuals involved in designing the products. 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 Dystonia Coalition. The Dystonia Coalition 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 Dystonia Coalition 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 Dystonia Coalition 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 Coordinator for inclusion in its annual progress report to the NIH.
4. Make efforts to commercialize the subject invention through patent or licensing.
5. Formally acknowledge the US Federal government's support in all patents that arise from the subject invention.
6. 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

Any resources provided through the DC must be used in accordance with the NIH Request for Applications RFA-OD-08-001, "Rare Diseases Clinical Research Network" (http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-08-001.html), as well as the terms of agreement in the Notice of Grant Award for U54 NS065701. The Recipient Institution 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 and Recipient's Institution agree 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 (http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm) including those for clinical trials if applicable (www.clinicaltrials.gov). 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.
2. Recipient 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 Coordinator (see appendix for contact information).
3. Recipient will notify DC Program Coordinator 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, the Recipient and the Recipient's Institution agree to return unused funds upon request.
4. The Recipient and Recipient's Institution 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.
5. The Recipient Institution 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 Institution and Investigators warrant compliance with the applicable federal laws, regulations and policies of the Department of Health and Human Services (DHHS). The Recipient and Recipient's Institution 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. For all DC projects, data sharing requires specific language in all informed consent forms and all IRB documents must be pre-approved by the DC Program Coordinator before a project can begin. Foreign sites will also need additional approval from the NIH. Recipient Institution 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 Institution and Investigators acknowledge 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 and recipient's institution agree to restrict use or access to any PHI provided by through DC, shall maintain the confidence 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 Institution and Investigators further agree 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 Institution and Investigators 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 Institution and Investigators ensure that each employee, agent, subcontractor, customer, or vendor to whom PHI is disclosed is aware of and agrees to comply with Recipient Institution'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 Institution and Investigators certify use of a written and enforceable conflict of interest policy that is consistent with the provisions of 42 CFR Part 50, Subpart F "Responsibility of Applicants for Promoting Objectivity in Research" and 42 CFR Part 94, "Responsible Prospective Contractors." These documents both are portions of the US Code of Federal Regulations published by the Public Health Service (PHS), Department of Health and Human Services. Their purpose is to promote objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded or performed under PHS contracts, grants, or cooperative agreements will be biased by an conflicting financial interest of an Investigator. Recipient Institution and Investigators further certify that to the best of their knowledge all financial disclosures required by its conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed, reduced or eliminated prior to the expenditures of any funds under this Agreement in accordance with the Recipient Institution's conflict of interest policy. For those individuals who have conflicts of interest requiring management, reduction or elimination, an explicit certification as to whether the conflict of interest has been managed, reduced, or eliminated must also be provided. Recipient Institution must also indicate whether the Investigator has agreed to comply with the management plan. Recipient Institution further agrees to notify Emory University within 30 days of identifying any conflict pertaining to this agreement that may arise during the course of the project.

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 & Institutional Statement of Agreement

By signing below we acknowledge that we have 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 the current Good Clinical Practice (GCP) regulations and International Conference on Harmonization (ICH) guidelines, and 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 Investigators will provide copies of the relevant protocols and all other information relating to these projects, furnished by the DC as applicable, to all physicians and other study personnel participating in these studies under their direction. The Investigators will discuss this information with them to assure that they are adequately informed regarding the conduct of the study.

The Recipient Institution and Investigators agree 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 Projects 1, 2 and 3 as outlined above and described in more detail in the Project Manual.
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.

Name of Principal Investigator

Signature of Principal Investigator Date

Name of Investigator's Institution

Name and Title of Recipient Institution's Authorized Representative

Signature of Recipient Institution's authorized representative Date

Emory University
Primary Grant Institution

Ken Packman, Associate 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 Science Officer: Wendy Galpern, MD/PhD
- ORDR Liaison: John Ferguson, MD

Executive Committee
- Chair: H. A. Jinnah, MD/PhD
- Project 1 Leader: Joel Perlmutter, MD
- Project 2 Leader: Cynthia Comella, MD
- Project 3 Leader: Christy Ludlow, PhD
- Director of Career Development Program: Mark Hallett, MD
- Patient Advocacy Group Representative(s): Kim Kuman & Janet Hieshetter
- NINDS Science Officer: Wendy Galpern, MD/PhD
- ORDR Liaison: John Ferguson, MD

Steering Committee
- Mahlon DeLong, MD/PhD
- Stanley Fahn, MD
- Anthony Lang, MD
- Marie Vidailhet, MD
- NINDS Science Officer: Wendy Galpern, MD/PhD
- ORDR Liaison: John Ferguson, MD

Pilot Projects Committee
- Chair: H. A. Jinnah, MD/PhD
- Co-Chair: Stewart Factor, DO
- Rotating Member(s): Joel Perlmutter, MD
- NINDS Science Officer: Wendy Galpern, MD/PhD
- ORDR Liaison: John Ferguson, MD
- Patient Advocacy Group Representative(s): Jan Teller, PhD; Michael Okun MD; Mark Hallett, MD; Christy Ludlow, PhD; Ramon Rodriguez, MD; David Standaert, MD/PhD

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- ORDR Liaison: John Ferguson, MD
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- Rotating Members: Mark LeDoux, MD/PhD; Laurie Ozelius, PhD; Christine Klein, MD
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- ORDR Liaison: John Ferguson, MD

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ORDR Liaison: John Ferguson, MD

Project 3 Committee
Project PI: Christy Ludlow, PhD
Project Co-PI: Mark Hallett, MD
Additional Members: Andy Blitzer, MD/DDS; Joel Blumin, MD; Michael Johns, MD; Randall Paniello MD
NINDS Science Officer: Wendy Galpern, MD/PhD
ORDR Liaison: John Ferguson, MD

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