

# IPMDS Tremor Study Group

## Bylaws and Contract for Study Group Members

### Mission Statement

Having completed its mandates in June 2017, the International Parkinson and Movement Disorder Society (IPMDS) Task Force on Tremor was transitioned into the Tremor Study Group (TSG). The mission of the TSG is to facilitate clinical and translational research in tremor disorders, particularly those disorders in which tremor is the only symptom or sign (e.g., essential tremor, task-specific and focal tremors, and primary orthostatic tremor).

### Membership

The TSG has an open-door policy in which members of the IPMDS are invited to join at any time. Members of the Task Force on Tremor are invited to continue membership in the TSG but are not obligated to do so. Persons interested in membership should contact one of the TSG chairs.

### Officers and Committees

Rodger Elble and Günther Deuschl were named as **co-chairs** when the TSG was initially established and will serve as co-chairs until the first TSG elections in May 2020. Elections for these positions will be held every three years in May. Nominations for co-chair can be made January 1 through March 31 of each election year.

The TSG will have an **Executive Committee** consisting of the co-chairs and the leaders of each active project. At-large TSG members can be co-opted by the executive committee.

Each research project will have a working project committee and designated project (committee) leader. The project (committee) leader will be the principal investigator (PI) of the project and will be a member of the Executive Committee.

### Projects

The TSG was formed in June 2017 with the following objectives and projects.

#### 1. Deep tremor phenotyping

A systematic, deep phenotyping of patients with monosymptomatic tremor disorders (e.g., essential tremor) is needed, according to recently published guidelines.<sup>1</sup> The TSG is therefore developing an ordinal assessment tool that will guide clinicians in deep tremor phenotyping, so as to distinguish essential tremor from essential tremor plus and other forms of tremor that are commonly mistaken as essential tremor. The assessment tool will capture subtle or questionable features of dystonia, myoclonus, parkinsonism and ataxia. A video protocol is being developed in conjunction with this tool. To validate this assessment and video protocol, each member of the TSG will produce a video assessment of three patients: essential tremor, essential tremor plus and a combined tremor syndrome that presented with the sole complaint of

tremor (monosymptomatic tremor disorder). The ultimate goal is to incorporate this assessment tool and video protocol into a web-based REDCap database that can be used in conjunction with clinical research studies.

## 2. Tremor scales development

### Orthostatic tremor severity scale

In our previous review of available tremor assessment scales, it was found that there is no validated scale for orthostatic tremor.<sup>2</sup> Treatment of this relatively rare condition is being approached pharmacologically and surgically, and a validated scale for orthostatic tremor is therefore being developed.

### Unified Tremor Rating Scale

A scale is needed that captures typical (action tremor) and atypical (i.e., rest tremor, prominent lower limb tremor) tremor in patients with essential tremor and essential tremor plus. We are developing a new scale that builds upon the strengths of the Fahn-Tolosa-Marín scale and the Essential Tremor Rating Assessment Scale (TETRAS).<sup>2</sup> This scale will become one of a battery of scales for the clinical assessment of tremor.

## 3. Instrumented measures of tremor

Certain aspects of tremor are believed to be useful in distinguishing essential tremor from other tremors (e.g., dystonic tremor and rhythmic cortical myoclonus). However, these tremor characteristics (e.g., irregularity in amplitude and rhythm, fluctuating axis of rotation, posturing of the head or limb) are very difficult to assess by clinical inspection. We believe there is a role for motion transducers, computerized video analysis, and other electrophysiologic methods in the characterization of tremor. We envision such methods being used in a deep phenotyping of tremor patients and in the quantification of tremor severity.<sup>3</sup>

## 4. Web-based tremor database

The TSG has the overall goal of promoting greater depth and standardization in the phenotyping of patients with tremor disorders, particularly monosymptomatic tremor disorders such as essential tremor. The scales developed by the TSG will be incorporated into a web-based tremor database that is compatible with the Dystonia Coalition database (common data elements). This database will be linked to an archive of patient videos and to repositories of DNA samples for research.

These projects will be modified or replaced when their objectives are completed. Any member of the TSG can propose a project by submitting a 1-2 page proposal to the Executive Committee.

## Data and Resource Sharing

Access to any original unpublished data or materials collected and stored by the TSG will be supervised by the TSG Executive Committee, following evaluation by the related Project Committee. These rights will include access to original data or materials for research studies, grant proposals, manuscripts, 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.

Before accessing any original data or materials, a proposal must be submitted to the relevant Project Committee that fully describes the planned analyses, feasibility assessment, funding, and project timeline. 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 TSG Executive Committee.

### **Policies for Authorship, Acknowledgements, and Reporting**

The policies below apply to 1) manuscripts, abstracts, statements submitted to scientific and medical journals, 2) presentations at conferences, and 3) presentations in news media, internet sites, and other public information sources that emerge from TSG projects.

All studies receiving support or resources from the TSG must acknowledge the TSG.

Not all members of the TSG will be co-authors for every study. 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. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. All other contributing members of the TSG will be listed in an acknowledgment, appendix or supplement.

In general, TSG publications will emerge from their relevant Project Committee. As a member of the Executive Committee, the Project Committee Leader will inform the Executive Committee of any planned publication. The Project Committee 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. The Executive Committee will be responsible for final approval of any publication that emerges from a TSG project. The Executive Committee shall ensure that all publications appropriately acknowledge support from sponsors, including financial, material support, or logistical support.

### **Copyright Policy**

The publication of studies will be subject to standard practices of the IPMDS that currently involve authors of the published works together with the associated publisher.

The proposed database and CDEs will be controlled by the Executive Committee of the TSG so as to facilitate their consistent use in clinical and translational research. It is hoped that this can be done without copyright protection.

### **Protection of Human Subjects in Research**

For any involvement of human subjects, each member of the TSG must receive approval from his/her local human subjects committee. Each TSG member shall bear full responsibility for the proper and safe

performance of all work and services involving the use of human subjects in any TSG project that the member is involved.

### Conflict of Interest Guidelines

Members of the TSG should maintain the highest personal and professional standards in TSG projects. Real and perceived conflict-of-interest must be avoided and should be reported to the Project Committee Leader, who will present this concern to the TSG Executive Committee for final action.

### Statement of Agreement

By signing below, I acknowledge that I have carefully read this document and will abide by the guidelines herein. I will conduct all TSG projects in accordance with associated 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.

I 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 protocol.

I agree to abide by the decisions of the Project Committees and Executive Committee as they pertain to TSG projects.

**Finally, I understand that my membership in TSG is not official until I have submitted videos of one patient each with ET, ET plus and a combined tremor syndrome, as defined in the 2017 IPMDS tremor classification paper.** These videos will be produced using the TSG video protocol and will be archived for validation studies of instruments for tremor classification.

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Name of TSG member

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Signature of TSG member

Date

### References:

1. Bhatia KP, Bain P, Bajaj N, et al. Consensus Statement on the classification of tremors. from the task force on tremor of the International Parkinson and Movement Disorder Society. *Mov Disord* 2018;33(1):75-87.
2. Elble R, Bain P, Forjaz MJ, et al. Task force report: scales for screening and evaluating tremor: critique and recommendations. *Mov Disord* 2013;28(13):1793-1800.
3. Haubenberger D, Abbruzzese G, Bain PG, et al. Transducer-based evaluation of tremor. *Mov Disord* 2016;31(9):1327-1336.