NYU Division of Hand Surgery

Prospective Clinical Research Proposal

Instructions

For any prospective clinical research,please submit a proposal to be reviewed by the hand surgery faculty prior to writing an IRB protocol and undergoing IRB review.

Proposals should be sent to victoria.comunale@nyulangone.org by the **Friday before the research meeting, at noon.** Proposals submitted after this time will not be reviewed at the research meeting and will be delayed.

**Outcomes.** Common outcome measures are listed before.

* Range of motion (elbow, forearm/wrist, digits)
* Grip strength
* Key pinch
* Semmes-Weinstein Monofilament
* 2-Point Discrimination
* Patient-reported outcomes
	+ DASH or QuickDASH
	+ PROMIS UE
	+ Michigan Hand Outcomes Questionnaire (MHQ) or brief MHQ
	+ Patient-Rated Wrist Evaluation (PRWE)
	+ Thumb Disability Examination (TDX)
	+ Unité Rhumatologique des Affections de la Main (URAM) for Dupuytren’s
	+ Boston Carpal Tunnel Questionnaire (BCTQ)
* Imaging or procedures
	+ XR
	+ CT
	+ MRI
	+ EMG
	+ US

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| **PI**:  |  |
| --- | --- |
| **Research Question**: | Is the research question feasible, interesting, novel, ethical, and relevant? |
| **Study Design**: Describe the methodology (experimental vs observational, randomized vs non-randomized, etc.) How will this study be executed? |  |
| **Inclusion Criteria**: |  |
| **Exclusion Criteria**: |  |
| **Define control and treatment group(s).** If applicable, include dosage and frequency. If applicable, include dosage and frequency. | Are the control and treatment group(s) comparable? |
| **Relevant Literature Search Results.** What do we already know about this research question? What would this study add to the existing body of literature? |  |
| **Primary Outcome(s).** See page 1 for common outcome measures. For each outcome measure, justify. | Do these measures of outcomes answer the research question? Have they been validated? Is it feasible to do all of the study measurements in the office? |
| **Secondary Outcome(s).** For each outcome measure, justify. |  |