Orthopaedic Biostatistics Consulting Information

To Initiate a New Project with Biostatistics

- Email ortho_biostats@stanford.edu or go directly to following link to complete the **project initiation form**: https://is.gd/ortho_biostats_request

Timeline for Consultation

	Grant Applications / Study Design	Conference Abstracts	Manuscript
Ideal date to contact*	4-6 months prior to RMG deadline[+]	6 weeks prior to deadline	3 months prior to deadline
Latest date to contact*	1 month prior to RMG deadline[+]	3 weeks prior to deadline	6 weeks prior to deadline
Latest date for final, cleaned data (or information for power analysis) sent to statistician*	3 weeks prior to RMG deadline[+]	2 weeks prior to deadline	4 weeks prior to deadline

*These are estimates for typical projects. For projects requiring more complex/involved analyses or multiple iterations of analyses, turn-around time may be longer

[+]Power & sample size calculations must be completed BEFORE a budget is submitted to RMG (which should be done at least 1 month before the grant is due)

Why Consult with a Biostatistician?

- Meeting during the design phase of your project is **strongly recommended** to:
  - Refine research question(s)
  - Optimize the study design and outcomes for the question(s) being asked
  - Identify validated outcome instruments, or plan instrument development and validation
  - Ensure the planned data collection is amenable to analysis
  - Identify the number of patients/samples needed
- In addition to performing statistical analyses, the biostatistician will aid in:
  - Interpretation
  - Tabular and visual presentation of results for abstracts/manuscripts/presentations
  - Drafting statistical methods sections and power/sample size statements
  - Refining results sections to ensure proper formatting of descriptive statistics, p-values, etc.
- Funding agencies and peer reviewers are increasingly scrutinizing statistical methods, and many now require or strongly prefer to see a statistician collaborator or co-investigator included on submissions

What to Bring When Meeting With Biostatistics

- Analyses:
  - Research question(s)
  - Data set(s) *[see data formatting below]*
  - Relevant literature
- Power / Sample Size Calculations:
  - Research question(s)
  - Primary Outcome(s)
  - Typically, mean & standard deviation or the proportion observed for your primary outcome(s) previously in similar cohort(s)/sample(s) from the literature
  - Minimum clinically important difference (if available) or minimum desired difference to detect between groups
  - Feasible sample size to enroll within a reasonable time frame

IRB & Sending Data Files

- Your statistician will need to be added to the project IRB
- Data should be de-identified if possible

- If sending data containing PHI via email, use the SECURE: label in the subject line
- Data can also be shared using Stanford Medicine Box
- What constitutes PHI: https://en.wikipedia.org/wiki/Protected_health_information

Data Formatting

- Data sets should be in Excel or .csv format
- Data should typically be in one large table with each row containing a patient/sample, and each column containing a variable/outcome
- Avoid special characters in variable names, make names concise but intuitive
- Formatting should be standardized,
  - Example: “no”, “NO”, and “No” are treated as 3 different responses by statistical software, so ensure that capitalization and spelling are consistent
- In a separate tab, include a data dictionary that contains information on the variables such as units, definitions, and/or calculations used
- Copy and paste as values any data derived from excel formulas after they are calculated to avoid errors creeping in if data is edited/moved; formulas should be listed in the data dictionary
- A good article on dataset formatting (Broman and Woo 2018): https://www.tandfonline.com/doi/full/10.1080/00031305.2017.1375989

Additional Resources

- ISAKOS Practical Guide to Research: Design, Execution, & Publication: https://www.arthroscopyjournal.org/article/S0749-8063(11)00123-X/abstract
- Manuscript writing (Wright *et al.,* 1999): https://pdfs.semanticscholar.org/e5e4/ae7c9259e81ae0ed813ce0579bb2de4c925a.pdf
- ICMJE Authorship Guidelines: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html