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

<table>
<thead>
<tr>
<th></th>
<th>Grant Applications / Study Design</th>
<th>Conference Abstracts</th>
<th>Manuscript</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ideal date to contact*</td>
<td>4-6 months prior to RMG deadline*</td>
<td>6 weeks prior to deadline</td>
<td>3 months prior to deadline</td>
</tr>
<tr>
<td>Latest date to contact*</td>
<td>1 month prior to RMG deadline*</td>
<td>3 weeks prior to deadline</td>
<td>6 weeks prior to deadline</td>
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<tr>
<td>Latest date for final, cleaned data (or information for power analysis) sent to statistician*</td>
<td>3 weeks prior to RMG deadline*</td>
<td>2 weeks prior to deadline</td>
<td>4 weeks prior to deadline</td>
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*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.

**Additional Resources**
- Manuscript writing (Wright et al., 1999): https://pdfs.semanticscholar.org/e5e4/ae7c9259e81ae0ed813ce0579bb2de4c925a.pdf