EMORY UNIVERSITY

DEPARTMENT OF ORTHOPEDICS

BIOS BIOSTATISTICAL CONSULTATION REQUEST FORM

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| Name: | | | Robert Runner | | | | | | | | Date: | | | 10/7/10 | |
| Position: | | | | Faculty  Resident/Fellow  ATC **Medical Student** | | | | | | | | | | | |
|  | | | | Other (please specify): | | |  | | | | | | | | |
| Principal Investigator (must be faculty): | | | | | | | |  | | | | |
| Office Address: | | | | |  | | | | | | | | | |
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| Email: | rrunner@emory.edu | | | | | | | | | | | |

**Are you:**

**Planning a study (e.g. writing a protocol, preparing a grant, etc.)**

Analyzing data from an existing study:

Preparing an abstract, manuscript, presentation, or report

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| Other (please specify): |  |

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| IRB number (required for existing data on human subjects research): |  |

**What specific type of methodological assistance do you require?**

Statistical analysis

**Sample size/power analysis**

Experimental design

**Questionnaire/data form development**

Data entry/data management

Statistical results write-up/explanation

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| --- | --- |
| **Other** (please specify): | Randomization method |

Briefly describe your research question:

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| 1. We will be randomizing patients to one of two arms of the study. Is the easiest way to take the last number of the MRN and split odds vs evens? Is there a better way?  2. What is the best way to estimate the withdrawal/refusal rate?  3. For our study we will compare high vs low tourniquet pressures and their effects on muscle injury. Comparing lower pressures and muscle damage has not been studied in mice/dogs. Metabolic changes and total tourniquet time have been studied. Since we do not have a study to extrapolate our expected difference between the groups, what is the best way of determining power, sample size etc?  4. We want to make sure we have an appropriate case report form so the data can be easily analyzed. |

Please email completed form and protocol to [**shawndra.woodard@emoryhealthcare.org**](file:///\\euh\ehc\Users\vpd6wsd\home\Research%20Studies\Statistics\shawndra.woodard@emoryhealthcare.org)

For your questions,

1. Your method mentioned here may be an easy way, but may not be the best, except the MRN number is totally randomized for odds and evens.

Depend on how many groups you like to split into, the common method is to generate the random number between 0 and 1 for each observation, then divided the sample into groups based on the generated number value. Suppose we want to split into 5 groups, if the generated number, x, is in 0 ~ 0.2, then it can be assigned to group A, if x is in 0.2 ~ 0.4, then group B, etc. For two group cases, if you want to the two groups have equal size, then if x < 0.5, then group A, otherwise group B. But if you like the groups have unequal size, such as group A has 40% of sample, another group B has 60% samples, then if x <0.4, it belong to group A, otherwise it belong to group B. The method I described here is quite easily realized.

1. I have no conception about the withdrawal/refusal rate you mentioned here, you may give me some descriptions for them so that I can help you on this.
2. If you would like to compute the sample sizes, the parameters required for the computation include the mean difference between the two treatment groups, and the standard deviation for each groups. Suppose we want the power to be 0.9 or else, the sample can be computed base on these parameters. The power conception is used for hypothesis testing; it could be calculated based on the tests, such as two samples t-test.

If you have specific questions, such as do randomization for your data, please contact me for further help.