Statistician meeting prep-sheet

The purpose of this worksheet is to help scientists gather and think about certain aspects of their upcoming study, so that their first meeting with a statistician is as productive as possible. This worksheet is a general framework to be used prior to protocol development and designing an in vivo study.

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1. What are you hoping to get from this meeting (design/analysis advice or support)?

2. What is the goal of the study and what level of evidence is needed?
   a. What specific question are you asking? What do you hope to determine from the study?

   b. What are you applying your treatment to? For example, is a drug being incorporated into the food, manipulating animal genetics, or directly dosing each animal?

   c. What level of evidence do you need? - Are you comparing different groups and looking for statistically significant difference or statistical equivalence within a margin? Are you evaluating one or more groups and looking for a reliable estimation of parameters of interest. Characterize a new model (e.g., evaluate data variability, etc.)?

3. List & prioritize the most important measures you plan to document in your study.

Outcome measure	**Data, examples, or previous knowledge available?**	**MEASUREMENTS**		
		Type: categorical, binary, time to an event, limit of quantification/detection, etc.)	**Unit** :(cage, animal, tissue, cell, well)	**Number** of

4. Describe the design of the study.
   a. List all your general cohorts/groups and controls you plan to use in this study.

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b. Are both sexes being used? If not, why?

c. When and how will the treatments be applied? Will the treatment be given more than once?

d. Will the study be run all at once or in batches over time (e.g. limited support to process all the samples in a short period, number of surgeries you can do at once, cage space, or testing equipment)?

e. How many animals per cage? Will different treatment groups be included in one cage?

f. Will multiple people be responsible for documenting or recording data? How will animals or specific measurements be assigned between different people?

g. In what order will animals, groups, or cohorts be sampled or measured? Is a whole treatment group dosed first?

h. How and when will the data be collected? Will you include baseline data?

5. What's the plan for randomization and blinding (masking)? What is the unit (sample, animal, tissue, cage) being randomized?

6. What are the potential covariates and confounders that can affect the endpoints on this study?
   a. Any design factors that can help describe variability (e.g. assignment to cage, batch, time point)

   b. Any baseline characteristics that can be covariates (e.g. animal bodyweight, activity, age)?

7. Any other things that you think are relevant for your statistician to know about (e.g. blood collection limitations; known variation or effects of the treatment, are you using a new animal strain from previous studies)?