



Rigor, Reproducibility & Transparency: *Biological Variables*

Kim Littlefield, PhD
University of South Alabama
Asst. VP of Research Development & Learning

Questions? [205.934.7442](tel:205.934.7442) | ccts@uab.edu | www.uab.edu/ccts



Why are NIH requirements for biological variables?

- 4 main variables, but these are not all inclusive:
 - Age, weight, sex and propensity to disease states.
- All biological variables should be considered when it comes time to explaining outcomes.



What do I have to justify to reviewers?

- You want results to be as generalizable to the human condition as much as possible.
- It is justifiable to only use one sex, but you must explain why.
 - Example: Ovarian or prostate cancer.



And remember...

NIH requirements regarding biological variables applies to both human and animal studies.



Do I have to double my sample size?

- No.
- You can present your data as pool data but also as disaggregated.
- Gives a broader picture of all data and could be useful if there are trends.



Why do I have to justify which biological variables I use?

- The key is so that someone at another institution or a colleague can reproduce the data.
- Knowing which variable you used is vital to understanding how to reproduce the outcome.



Are biological variables scorable criteria?

- Yes.
- Consideration of the variable should be included in the research strategy discussion within the application.
- Reviewers will look for it.
- Defining biological variables makes the presentation of the data more transparent.