Supporting Individuals through
Research, Education, and Mentorship

1.) McRae, A. D., Taljaard, M., & Weijer, C. (2016). Cluster-randomized trials: A closer look. Clinical trials.

In a recently published commentary, three examples drawn from the ClinicalTrials.gov registry were used to illustrate challenges associated with the cluster-randomized trial design. The commentary argued that the Ottawa Statement fails to provide comprehensive ethical guidance. In this article, the authors illustrate the application of the Ottawa Statement to the three trials. They challenge the conclusions reached in the commentary by demonstrating that an ethical analysis requires complete information. The authors correct some misperceptions about the cluster-randomized trial design by collecting additional information. They contacted the authors of trials. The authors used the Ottawa Statement to conduct an ethical analysis of each trial and to address a number of substantive concerns raised regarding the identification of study participants, informed consent and harm benefit analysis. In the two cases in which they were able to obtain detailed study information, the authors were able to complete the ethical analysis prescribed by the Ottawa Statement. They argued the Ottawa Statement does provide a useful framework for the ethical design, review and conduct of cluster-randomized trials.

2.) Fan, C., Zhang, D., Wei, L., & Koch, G. (2016). Methods for Missing Data Handling in Randomized Clinical Trials with Non-normal Endpoints with Application to a Phase III Clinical Trial. Statistics in Biopharmaceutical Research, 1-38.

This paper develops asymptotic properties of the mean rank imputation method and attempts to demonstrate its validity to test the primary endpoint under certain mild distributional and missing mechanism assumptions.

3.) Rosenberger, W. F., & Lachin, J. M. (2016). Randomization in clinical trials: theory and practice. John Wiley & Sons.

An overview of the theoretical and practice issues pertaining to randomization procedures.

4.) Chan A.-W., Hróbjartsson A., Jørgensen K. J., Gøtzsche P. C., Altman D. G. Discrepancies in sample size calculations and data analyses reported in randomised trials: comparison of publications with protocols. BMJ 2008; 337: a2299.

The intent of this study was to evaluate how often sample size calculations and methods of statistical analysis are pre- specified or changed in randomised trials.

5.) Taljaard, M., Teerenstra, S., Ivers, N. M., & Fergusson, D. A. (2016). Substantial risks associated with few clusters in cluster randomized and stepped wedge designs. Clinical trials.

The increased attention to quality improvement, comparative effectiveness research, and pragmatic trials embedded has led to the increase use of the cluster randomization design. Issues such as increased probability of chance imbalances and type I and type II error, limited perceived or actual generalizability, and fewer options for statistical analysis is discussed in this paper.