

## W14-02

### METHODOLOGICAL APPROACHES AND EVIDENCE FOR EFFECTIVENESS IN CLINICAL TRIALS

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Recent publications by the Institute of Medicine have unearthed several fundamental flaws in clinical trial methodology that, if corrected by the next generation of clinical investigators, can transform the field of mental health intervention research. Using a clinician-friendly approach, Dr. Davis will succinctly review the essential elements of optimal design and implementation of a randomized controlled clinical study. These elements include the need for a hypothesis that has clinical relevance based on sound theoretical reasoning, reasonable and generalizable inclusion and exclusion criteria, feasibility of an enrollment goal and study timeline, and appropriate choice of a comparator intervention and primary outcome. Techniques to reduce the study's costs, risks, and participant burden will be described. Examples from psychopharmacologic, psychotherapy, and vocational rehabilitation trials for the treatment of posttraumatic stress disorder will be discussed. Following the didactic session by the two presenters, the participants will be encouraged to bring forth their own questions regarding clinical trial design for a 45-minute interactive discussion with the presenters. The objectives of the workshop are to improve the participants' understanding of the goals of clinical trial design and methods to achieve those goals in order to improve their own research techniques, grantsmanship, and abilities to more accurately judge the results of studies presented in the literature.