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Medication Adherence Given Individual SystemCHANGE™ in Advancing Nephropathy (MAGICIAN) Pilot Study

### **Statistical Design and Power.**

**A.1. Statistical Design.** This two-arm randomized single masked experimental design pilot study compares SystemCHANGE™ with attention control patient education using repeated measures in adults with CKD and poor adherence to prescribed RAAS inhibitor medication. Randomization will be stratified by *moderate* (.70 - .84) and *low* (<.70) *medication adherence*.

**A.2. Sample Size Justification and Power Analysis.** Sample size is based on considerations for designing pilot studies<sup>44</sup> and based on this study's aims. Hertzog<sup>44</sup> suggests 30 participants per group is sufficient for estimating preliminary efficacy.<sup>44</sup> Based on these practical considerations and anticipated attrition based on our prior studies, we will enroll 66 individuals, to retain 60 with CKD stage 1-4 and poor adherence. The resulting 30 participants per group will be sufficient for estimating preliminary efficacy.<sup>44</sup> Statistical analyses will be conducted to determine acceptability, outcome expectancy and credibility (Aim 1) and to calculate preliminary effect size estimates (Aim 2) that may be used in combination with other evidence to justify a future randomized trial; however, efficacy estimates themselves will not solely be used to determine the sample size for the larger study (Leon AC, Davis LL, Kraemer HC. The Role and Interpretation of Pilot Studies in Clinical Research. *J Psychiatr Res* 2011 May; 45(5): 626-629; doi:10.1016/j.jpsychires.2010.10.008).

**A.3. Analytic Plan.** We will conduct rudimentary analyses to ensure that data have been properly collected and to identify outliers or errors. Data manipulation and analysis will be conducted in SAS Version 9.4 (SAS Institute Inc., Cary, N.C.) and all syntax documented to ensure reproducibility. We will calculate the proportion eligible that enroll and complete the intervention. Aim 1: We will tabulate responses to acceptability, outcome expectancy and credibility items. Aim 2: Effect sizes will be estimated by fitting ANCOVA models with treatment group as the explanatory variable and outcomes: 1) adherence and 2) personal systems behavior. Effects sizes will be estimated with  $\omega^2$ . Analyses will be intent-to-treat. Supplementary analyses will investigate how the adjustment for levels of the covariate (e.g. male and female for sex) impacts effect size estimates by adding interaction terms to models and estimating effect sizes separately for the different levels. **Missing Data:** We will compare baseline variables between subjects who drop out of the study to those who do not using two-sample *t* tests, chi-square tests or non-parametric equivalents as appropriate. If we find that missing data appear to be not missing at random, this information will be used in designing the larger trial. Due to the relatively small sample size, we will not attempt to model the missing data mechanism in this pilot study. **Sex as a biological variable:** As noted above, we will estimate effect sizes by sex for all outcomes. Additionally, for Aim 1, qualitative interviews will be recorded, transcribed verbatim, and entered into the NVivo 12 (QSR Int.) qualitative software. We will use standard content analysis procedures<sup>47</sup> to code data into meaningful categories regarding acceptability. The resulting qualitative data will be combined with quantitative data in side-by-side summary tables to derive integrative summary statements to draw conclusions about participant acceptability.