POPULATION SCIENCES

Concept Review Form

INSTRUCTIONS: UM/SCCC investigators in the planning stages of an investigator-initiated non-treatment intervention trial or non-intervention study must present their initial study plan during a site disease group (SDG) meeting. The PI will discuss study alignment with the SDG, design and rationale, and available resources to the PI (e.g., budget, staffing). Meetings may also address ideas to enhance study rigor and/or identify potential collaborators. The presenting PI must complete this form and submit it to sbs.prmc.startup@miami.edu, who will work with the PI to select the SDG meeting date for a discussion. After this meeting, the study will be routed to the Population Sciences Research Group (PSRG) for oversight (i.e., pre-review, feasibility review, final SDG sign-off, and PRMC submission).

Please enter the study information in brief detail below.

1. Principal Investigator	
PI Name **Primary Academic Department** **Email**	
2. Concept Information	
Working Title	
Target population(s): Only include major proposed major eligibility criteria.	
Proposed Sample Size Can be an estimate. Formal sample size calculation is not needed here but please provide a brief justification.	
Study Design (e.g., single-arm pilot, RCT, qualitative, prospective longitudinal data collection, phase I-IV non-treatment trial).	
Method Briefly describe study flow including proposed recruitment strategy, assessment and/or intervention timepoints, data sources, and interventions.	
Aims and Rationale Specific aims and any hypotheses.	
Multi-site Indicate which site will be primary any plans to enroll at other sites (JMH, other institutions)	
3. Support	
Funding Source(s) Status of any funding sources (planned, under review, pending, or awarded) or plan for unfunded study.	
Recruitment Pool Source of recruitment and requested SDG support for meeting recruitment goals (e.g., estimated number of potentially eligible participants, clinician support).	
Regulatory Support Plan for preparing, submitting, and maintaining IRB correspondence (applications, amendments, continuing reviews, events, deviations, etc.).	
Study Operations Staffing plan for conduct of study operations (screening, recruitment, enrollment, data collection, data entry, intervention delivery, project management).	
Ancillary services	

Indicate any ancillary services that may require other committee sign off (e.g., radiation safety).	
6. Questions	
List any questions or concerns about study design, resources, budget, etc. to meet your study goals, that you would like to discuss at the SDG meeting.	

10. Population Sciences (PS) Research Leader Endorsement of Concept	
Instructions to the CC/PS Research Leader in the SDG – Providing your signature acknowledges the above concept has been reviewed and has received your support to pursue further development within the PS group. (**NOTE:** Formal Population Sciences review and endorsement of a full protocol is still required prior to PRMC submission)	
CC Research Leader Approval Signature and Date	

Any notes/comments about the concept or its development should be placed below.

FOR INTERNAL USE

SDG:
SDG CC/POP SCI LEAD:
INITIAL SDG MEETING DATE:
APPROVAL
DEFERRED

FINAL FULL STUDY SDG SIGN-OFF DATE: