# Mechanistic Behavioral Research Consortium Memorandum of Understanding

(Version 2 – Sept 25, 2024)

This document outlines the terms for the oversight, governance, and activities of the Mechanistic Behavioral Research Consortium (MBRC).

## 1. Background

The Mechanistic Behavioral Research Consortium (MBRC) is an international collaboration of researchers working to enhance the ease and scope of replicable mechanistic investigations of health behavior change. The MBRC is explicitly designed to promote the Science Of Behavior Change (SOBC) experimental medicine approach to develop mechanism-focused interventions across a range of study designs and to enhance the productivity of member researchers by facilitating cutting-edge investigations without the need for independent funding. Collaborative studies are designed to minimize burden to any one collaborating site and to rely on the number of sites to achieve sufficient sample size. The diversity of members' settings and clinical and research interests helps ensure that collaborators are available for a wide range of clinical conditions and core processes under study. Emphasizing a team approach to science, the consortium is inclusive and invites members across disciplines and settings. Members will be expected to comply with and abide by the terms of this memorandum of understanding (MOU) throughout their membership in the MBRC.

#### 2. Organization

In its pilot phase, the MBRC has a research arm only. As specific work groups coalesce within the MBRC, training and clinical dissemination arms may be added. For any active arm, MBRC resources and collaborations are managed by committees and overseen by a board of directors. Details for the organizational structure and committee responsibilities are described below.

## 2.1 Board of Directors

The board of directors oversees the direction of the MBRC and provides oversight to

committees. The board of directors is made up of 3-5 individuals. Board members have relevant expertise and a commitment to promoting research on healthy behavior change. The board of directors will meet on a quarterly schedule and on an ad-hoc basis as needed. Quorum will be set to 60%.

Responsibilities include the following:

- Work to further the mission of the MBRC
- Engage in transparent operation and open and timely communications
- Provide oversight and steering of consortium-wide goals and activities
- Provide guidance on formation of working groups
- Providing support and resolution as necessary
- Modify organizational structure of the consortium as needed

### 2.2. Research Arm

## 2.2.1. Research Steering Committee (RSC)

The RSC is tasked with providing scientific leadership and oversight. RSC membership includes 5 individuals who have mechanistic research expertise. The RSC meets on a quarterly schedule and on an ad-hoc basis as needed. Quorum is set at 60%. Responsibilities include the following:

- Direct scientific priorities and strategy
- Develop and pilot-test new research projects
- Review and approve new Research Working Group (RWG) or project proposals
- Review and approve investigator-initiated research project proposals (e.g., aims, design, preliminary studies/feasibility analysis, statistical approach, publication plan)
- Coordinate publication projects (e.g., review/develop proposals, track manuscripts)
- Provide support (e.g., letters) to working groups to facilitate funding
- Liaise with clinical arm leadership to guide the development of training activities and projects

## 2.2.2. Rigor and Reproducibility Committee (RRC)

The RRC is tasked with providing guidance on intervention, study design, assessment, and data analysis protocols for proposed research projects. This committee comprises members with relevant expertise. The RRC meets on a quarterly schedule and on an ad-hoc basis as needed. Responsibilities include the following:

- Develop and share detailed "tools" that support measurement and treatment procedures, including clinician training/monitoring, fidelity, and more (e.g., rating manuals, standard operating procedures, SOBC resources)
- Provide guidance on the selection of data analytic strategies for proposed research projects
- Consult on methodology, measurement, and data analysis for research projects to ensure correspondence between study aims and research strategies
- Establish and update data sharing policies
- Establish and maintain infrastructure to facilitate meta-analyses

## 2.2.3. Research Working Groups (RWG)

RWGs design and implement research projects (one or multiple) and subsequently shepherd the resulting papers through the team writing and publication process. Any consortium member can submit a new RWG proposal to be reviewed/approved by the RSC. RWGs include a chair and members with relevant expertise. RWGs meet on an as-needed basis.

Responsibilities include the following:

- Develop and submit research project proposals (aims, hypotheses, analyses, preliminary findings and feasibility data, procedures, publication strategy) to RSC for review/approval (please see MBRC Study Submission Form).
- Obtain lead site IRB approval and establish reliance agreements
- Pre-register studies on open science platforms (e.g., the Open Science Framework [OSF])

and ClinicalTrials.gov (as needed), submit pre- and post-study information on the mechanism under study to the SOBC Measures Repository (e.g., adding new measures, adding study evidence), and coordinate data management via REDCap

• Share data with consortium for follow-up analyses
Attend to *CLIMBR* guidelines for the resulting publication from the proposed work

# 3. Member Communication and Research Responsibilities

- In providing their contact information, MBRC members agree to receive group emails concerning meeting coordination, research opportunities and methods, and tasks for ongoing or completed studies.
- Members agree to follow relevant ethical guidelines as defined by their field to strive for clear and respectful communications with MBRC colleagues and collaborators.
- Members agree to follow relevant research ethical guidelines and to abide by the regulations and reporting requirements for the relevant Institutional Review Boards/ Human Research Ethics Committees for any project in which they are involved. This includes following research practices to minimize harms and risks and distribute benefits fairly while respecting human dignity, privacy, and autonomy.

## 4. Publications and Authorship

## 4.1 Publication Planning

As part of the writing process, RWGs submit a publication plan to the RSC for review/approval. This plan includes a working title, overall aims of the publication(s), and list of authors. The RSC regularly reviews the number of manuscripts in circulation and acts as a pre-publication committee to approve manuscripts prior to submission. The RSC keeps the membership informed on planned and ongoing publication projects and seeks their feedback. Each member has the right to independently publish the data and results collected by them (local project data taking into account the author's rights), provided that the questions and analytic strategy are not redundant with (e.g., focus on similar relationships in the data) and do not compromise a

planned publication project. Independent publications must be submitted by each RWG to the RSC for tracking purposes and to ensure non-overlap of publications.

## 4.2 Authorship

All authors meet standards for authorship (see <u>ICMJE</u>). Working groups will propose authorship positions as part of the publication plan. The RSC mediates any concerns regarding authorship representation. Consortium authorship is recommended for all papers, considering the following options as stated by the <u>JAMA Network</u>:

- Individual Authors "for" the Mechanistic Behavioral
   Research Consortium (All Members of the Group Are Not Authors)
- Individual Authors "and" the Mechanistic Behavioral Research
   Consortium (All Members of the Group Are Authors)
- The Mechanistic Behavioral Research Consortium
   (All Members of the Research Group Are Authors)

## 5.0 Membership

#### 5.1 Contributing Member

Contributing members are Individuals or organizations who have agreed to the MOU and have contributed meaningfully to MBRC projects or are actively involved in the governance of the MBRC.

## 5.2 Affiliate Member

Affiliate members are individuals or organizations who have agreed to the MOU and have expressed interest in contributing to the MBRC mission and aims in the future (e.g., when data/capacity permits).

## 6.0 Annual Meeting

To facilitate the exchange of ideas, formulation of research questions and projects, and active engagement in authorship and funding activities, the consortium will seek to hold annual meetings in the Spring of each year. Attendance is strongly recommended for all consortium members.