

## **MWCCS Values and Code of Conduct**

The MACS/WIHS Combined Cohort Study (MWCCS) is committed to rigorous research that is based on principles of scientific integrity conducted in an environment of mutual respect. The MWCCS culture embraces the diversity of backgrounds and areas of expertise needed to address the scientific aims of the study. All individuals who are, or seek to be, actively engaged with the cohort are required to abide by the following Code of Conduct.

### **Research Code of Conduct**

All research within the MWCCS requires approval by the institutional review boards of the engaged investigators. Research conducted in the MWCCS is expected to align with the principles outlined in the Belmont Report<sup>1</sup> that include:

- i. Respect for persons - recognize the autonomy of participants and be mindful of and protect individuals with limited autonomy;
- ii. Beneficence – treat all participants in an ethical manner and seek to promote the well-being of participants; and
- iii. Justice – ensure fairness in the distribution of risks associated with research.

Critical to the principles outlined in the Belmont report is privacy. Maintenance of privacy for MWCCS participants is essential.

### **Scientific Integrity**

The MWCCS has a concept sheet approval process that involves Executive Committee (EC) review of proposals, abstracts and manuscripts that use data and samples collected by the MWCCS. The overall goal of the review process is to ensure that the data are interpreted and represented accurately. The terms for scientific engagement are detailed at <https://statepi.jhsph.edu/mwccs/work-with-us>.

Investigators who engage with the MWCCS under approved concept sheets must abide by the terms of use outlined in the signed concept sheet agreement; research conducted must remain within the scope of approved concept sheet. Any potential conflicts of interest must be reported to a MWCCS PI or the Code of Conduct Advisory Group (see below) to ensure transparency and allow for management of any perceived conflicts in alignment with the study protocol and our commitment to our participants and funders.

Investigators must abide by the MWCCS publication policies and obtain approval of abstracts and manuscripts from all coauthors and the MWCCS EC as outlined in detail at <https://statepi.jhsph.edu/mwccs/publication-policies/>. Approval of all coauthors must be obtained before submission of the abstract or manuscript to the EC for approval, and approval of the EC must be obtained before submission of the abstract for presentation or the manuscript for publication. While the MWCCS EC promotes the use of MWCCS data through this process, in accordance with the terms of agreement for receipt of NIH funding for the MWCCS, a public use data set is also available upon request.

Any misuse or misrepresentation of data or samples, and breaches of the publication policy will be investigated. Incidents of scientific misconduct that include fabrication, falsification, or plagiarism will be referred to the investigator's institution and the NIH for further review.

### **Professional Conduct**

We uphold the principles of equality, diversity, and inclusion as core tenets of the MWCCS in recognition of the diversity of participants, investigators, staff, and subject areas that contribute to the success of the cohort. We expect all individuals to maintain civility in their interaction with others, with the objective of maintaining a professional, respectful, fair, and welcoming environment for all individuals. Acts of discrimination or harassment are not tolerated by the MWCCS. Discrimination or harassment on the basis of race, gender/sex, age, marital status, national origin, religion, disability, or sexual orientation is not condoned by the MWCCS. Behaviors that create a hostile or offensive environment are also not tolerated. The MWCCS is fully committed to ensuring that interactions within the cohort are aligned with these principles of professionalism in all forms of communication, written and spoken.

Harassment is defined as an unwanted behavior directed at another person that is severe or pervasive such that a reasonable person would find the result to be creation of a hostile, intimidating, humiliating, offensive, and/or abusive environment. Any reports of harassment will be referred to the MWCCS Code of Conduct Advisory Group. Examples of harassment are available at <https://policymanual.nih.gov/1311>.

Other inappropriate behaviors such as bullying, intimidating, belittling, threatening, or offensive or disparaging words or actions targeting an individual(s) or that negatively affect the work environment, will not be tolerated. Examples of inappropriate behaviors that may result in action from the MWCCS leadership can be found at <https://policymanual.nih.gov/1311>.

### **Reporting Possible Misconduct**

Individuals who experience or witness possible misconduct may report their concern to the MWCCS Code of Conduct Advisory Group at [ccs-conduct@googlegroups.com](mailto:ccs-conduct@googlegroups.com). We encourage reporting of possible misconduct as soon as possible after an incident, to allow for a full and rapid investigation. We encourage named reporting to allow us to conduct as full an investigation as possible. An individual may request anonymity when reporting an incident, but should be aware that this may impede the investigation or the ability to report the findings back to the reporting individual.

The MWCCS is committed to maintaining non-retaliation against individuals or witnesses who report an incident.

### **MWCCS Response to Misconduct Allegations**

**MWCCS Code of Conduct Advisory Group:** The Code of Conduct Advisory Group (CoCAG) will have primary responsibility for investigating each allegation of misconduct, determining its severity, and directing the MWCCS response. The CoCAG will be comprised of the Executive

Committee Co-Chairs, a DACC PI, two other MWCCS PIs, two NIH members, and the NCAB representative to the Steering Committee. One MWCCS PI will rotate off the committee each year, and the replacement will be appointed by the Executive Committee. If a CoCAG member has a conflict of interest or is involved with a case, the member will be recused.

**Response to Allegations:** Incidents will be handled discreetly and expeditiously with the goals of maintaining confidentiality and ensuring a fair process. When an allegation of misconduct is received, a three-member subgroup of the CoCAG will gather and review the facts of the case and interview the involved persons as needed.

### **Assessment of Severity of Alleged Misconduct and Response**

**No infraction:** These are incidents that, after review, are deemed not to rise to the level of misconduct. The three-member subgroup will make this determination, and, if the decision is unanimous, will dismiss the case. If the decision is not unanimous, the case will be referred to the full CoCAG.

**Minor infractions:** These are infractions that are not deemed severe or recurrent. In general, these types of infractions can be resolved with an apology to the affected person(s) for the offending behavior; resolution may also include a plan to reduce the probability of recurrences. In these minor cases, if the decision among the three-member subgroup is unanimous, a letter to file will be written which will include the facts of the case, the people involved, and the actions taken. The primary purpose of the letter to file is to document behaviors to identify patterns that may emerge and that may need further disciplinary action. If there is not consensus or if there is consideration for recommendations for remediative actions, the case will be referred to the full CoCAG.

**Major infractions:** These are serious infractions that may result in referral to the NIH and/or the accused individual's institution for further action. The three-member subgroup of the CoCAG will refer such cases to the CoCAG for full review and discussion.

- If after review the CoCAG determines that the infraction is insufficient to be classified as major, a letter to file will be written which will include the facts of the case, the people involved, and the actions taken.
- After review, the CoCAG may identify and recommend suitable remediative actions to address the problem. Once the CoCAG reaches consensus on the plan of action, a letter to file will be written which will include the facts of the case, the people involved, and the actions taken.
- Infractions that are egregious and are found to warrant escalation, the CoCAG will plan to report the case to the NIH and/or the individual's institution. A subset of the EC (sub-EC), comprises site PIs, three NIH representatives, and two NCAB representatives, will be made aware of infractions that rise to this level. If a member of the sub-EC requests to appeal this recommendation, a meeting of the sub-EC will be held to review the case. The appropriate action will be determined by consensus or, if there is no consensus, by vote.

The CoCAG will provide the MWCCS EC with a summary of cases reviewed annually. The objectives of this are to provide an annual review of the CoC policy; maintain transparency while maintaining confidentiality; and promote continued learning and growth of cohort members to minimize future incidents.

### **Reference**

1. The National Commission for the Protection of Human Subjects of, Biomedical and Behavioral Research. *The Belmont Report: Office of the Secretary Ethical Principles and Guidelines for the Protection of Human Subjects of Research.*; 1979. Accessed February 21, 2022. [https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c\\_FINAL.pdf](https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf)