

## IRB Policy

June 2023

If none of the authors' institutions has an IRB, then authors must (1) state in the main text that one's institution does not have an IRB and so IRB review was not obtained; and (2) include an appendix section that should convince reviewers that the research would be deemed ethical under the U.S. federal IRB regulations. This Appendix should answer at least the following questions:

- Who were the human subject participants in the research? Were vulnerable populations recruited (e.g., children, prisoners, pregnant women, victims of violence, etc.)?
- How were the subjects recruited? If you provided compensation or there were other benefits from participation, was the opportunity to participate made available fairly?
- How were the subjects compensated, if at all?
- Did subjects participate voluntarily? E.g., did students feel obligated to participate by a professor in a course, or employees by their employer?
- What are the risks posed to human subjects from participating in the research? It is expected that most research poses minimal risk, meaning there is little chance of upset, distress, physical harm, or discomfort greater than would be encountered in daily life. This minimal risk category includes benign behavioral interventions ("brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing").
- What are the risks posed to human subjects from accidental disclosure of original data? Is the original data fully anonymous, or, is it possible to identify subjects from the original data? Beware that combinations of multiple demographic categories, IP addresses, IDs from websites such as MTurk, etc. can all be considered identifiable. If the original data is identifiable or potentially identifiable, what risks to subjects would accidental disclosure of the data pose, and what security steps have been taken to limit the risk of accidental disclosure? For example, do the original data contain sensitive personal information (e.g., identity card numbers) or data which could put subjects at risk of embarrassment or civil or criminal liability?
- Was informed consent obtained from research participants, and if so, how? Note that informed consent is not necessarily required for minimal risk studies if not obtaining consent

does not adversely affect the welfare or rights of subjects, if it is impractical to obtain consent, and if debriefing subjects would not be appropriate.

- Did the research take place in a country which requires government ethics review of human subjects research, and if so was such an approval obtained?
- Please note that this list is not exhaustive and authors should review US OHRP regulations and discuss any further issues relevant to their research: <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html>