Criteria for IRRB Approval

(Note: The following is based on the “Common Rule” 45.CFR.46)

When Morningside’s IRRB reviews a research proposal, we are bound to follow the “Common Rule” in the Federal Code of Regulations, i.e. 45.CFR.46. Beginning in January of 2018, we will be following the “Final Common Rule,” which includes some revisions to the common rule. The criteria below, however, remain consistent. The list below is a summary.

In order for the IRRB to approve of a proposed research study involving human participants, the following criteria must be met:

1. Risks to participants are minimized.
2. Risks to participants are reasonable, in relation to any anticipated benefits from the research.
3. Selection of participants is equitable.
4. Informed consent will be sought from each participant (and/or legal representative).
5. Informed consent will be appropriately documented OR appropriately waived.
6. If needed, incoming data will be monitored to protect the safety of participants.
7. If needed, there are provisions to protect participants’ privacy and maintain confidentiality of the data.
8. If vulnerable populations are involved, additional safeguards are included, appropriate to that population.