

In order to receive a limited dataset from a completed NHLBI study, you have to submit a signed letter from your IRB, stipulating

1. Does the Study's informed consent permit use of these data for research purposes by investigators who were not part of the original study?
2. If the answer to (1) is no, is the protection of privacy so great, and the risk to the participants so low, as to merit waiver of informed consent?
3. Have all reasonable personal identifying items been removed from the data set, or modified appropriately?
4. Will the recipient investigators provide appropriate safeguards for protection of participant privacy?
5. Has the recipient investigator signed the data distribution agreement with the NHLBI pledging to protect confidentiality, not to contact individuals in any way, and to use the data in the manner specified in the agreement?

Ignoring the idiocy that 5 is a requirement for you to get the dataset in the first place, how would an IRB know the answers to 1-3 if the people who created the dataset don't? And finally, how could 4 ever be determined, and how do you locate someone in the US based on things like their blood pressure or body mass index? Is it conceivable that anyone has ever been protected by this procedure????