



Participant Protection Policy FAQ

The Framingham Heart Study

1. What steps have been taken to maintain confidentiality of data and privacy (or anonymity) of research participants?

The Study has implemented multiple layered procedures to enforce confidentiality and privacy of the participants. The primary layer of enforcement consists of three steps. First, all obvious identifiers (name, address) are removed before the dataset is even distributed to internal investigators. Second, less obvious unique, or nearly unique, identifiers (e.g. missing limb) are also removed from the dataset. Third, all datasets being distributed outside the Study have the true Framingham IDs removed and replaced with randomly generated IDs.

Another layer of protection is the ‘firewall’ between genetic data and the participants. All DNA and genetic data is stored off-site at the Framingham Genetics Lab or with the Genetics Data Management Group on the BU Medical Campus. The consequence of this separation is that any worker with access to genetic data (data managers, statisticians, geneticists) has no access to participants. Conversely, Framingham workers who interact with participants (MDs, nurses, technicians) have no access to genetic data.

The final layer of protection is the special permissions required to receive Framingham data. All investigators must obtain permission to perform their research from their IRB and sign a data distribution agreement. Framingham is a small enough community that a combination of variables (e.g. height, weight, number of children, medical status) could be sufficient to uniquely identify a participant. For this reason, the BUMC IRB and NHLBI have decided that Framingham research is always research on human subjects. ‘Exempt’ status is not allowed. All projects must obtain full or expedited IRB review. The data distribution agreement imposes on all investigators the responsibility to enforce the Framingham informed consent document. This document must be agreed to by the investigator’s institution. It makes it clear that the external investigator and his institution are not indemnified against violations of confidentiality or privacy.

ACCESS RESTRICTIONS

These data will be used only for research purposes. They will not be used to determine the individual identity of any person or their relationship to another person. The investigator will acknowledge the FHS, the NHLBI and Boston University in any publications, including posters, platform presentations, articles, press releases, and manuscripts. This investigator agrees to write this acknowledgement according to the Data Distribution

Agreement as well as to follow all other terms of the Data Distribution Agreement. In particular, the recipient acknowledges that they have complied with will applicable state, local, and federal laws or regulations and institutional policies regarding human subjects and genetics research. Secondary distribution and shared use of this data by secondary parties is prohibited.



2. Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

The overall potential of this research for psychological, social, and/or physical harm is minimal.

The potential violations of privacy and confidentiality are minimized by the Study's strong barriers to identifying individual participants. All personal identifiers are removed from a dataset prior to distribution to any investigator, including Framingham investigators. The Study has instituted a 'firewall' between genetic data and the participants. All DNA and genetic data is stored off-site at the Framingham Genetics Lab or the Genetics Data Management Group on the BU Medical Campus. The consequence of this separation is that any worker with access to genetic data (data managers, statisticians, geneticists) has no access to participants. Conversely, Framingham workers who interact with participants (MDs, nurses, technicians) have no access to genetic data.

The potential for adverse effects on insurability, employability or social status is minimized by two things. First, the study has a Certificate of Confidentiality that protects the genetic data from insurance company requests for data. Second, providing data to the participant's doctor is entirely at the option of the participant. Our informed consent gives the participant total control over whether and when their doctor gets their data.

The potential for harm from disclosure of paternity is minimized by the Study's privacy and confidentiality measures mentioned above. In addition, the Genetics Data Management Group removes all putative non-paternities from the dataset prior to distribution. This should prevent even a legitimate investigator from detecting a non-paternity. Furthermore, in the unlikely event that a non-paternity escapes our internal checks, our data distribution agreement, which all investigators must sign, forbids any public disclosure and requires the investigator to report the non-paternity to the Study.

The potential for a harmful change to immigration status or educational opportunities is close to non-existent. All of the participants were either residents of Framingham in 1948 or are their descendants. Therefore the vast majority of participants are US citizens.