

Study Title:

Principal Investigator:

Include the following information in the written statement about the research, when applicable:

- This is a research study
- Purpose of the research
- Sponsor of the research
- How you obtained their name and contact information
- Why you are asking them to participate, and how many people will participate
- **New:** If you are collecting specimens, which is only allowed with consent, you must include the following statement if you ever wish to share specimens or use for commercial/development purposes:
 - *We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.*
- Discussion of extent of confidentiality and data security and risk of a breach of confidentiality
- **New:** Identify whether de-identified data/specimens may be used in other future research, include the following statement:
 - Your de-identified information may be used or shared with other researchers without your additional informed consent.
- OR
 - Your de-identified information will not be used or shared with other researchers.
- Clarification of whether information collected will be used or not used in clinical care, who will see their responses/data.
- Any risks associated with participation

- Discussion of sensitive information being collected, and how this will be handled, when applicable
- Information about them that will be gathered from other sources (e.g., medical records)
- Participation is voluntary and can stop at any time
- Deciding not to participate won't affect medical care they receive at Mass General Brigham now or in the future, or any benefits they receive now or have a right to receive
- For studies with clinicians/trainees: Deciding not to participate won't affect professional standing or evaluations in the program or department
- PI contact information for questions
- IRB contact information: “If you’d like to speak to someone not involved in this research about your rights as a research subject, or any concerns or complaints you may have about the research, contact the Mass General Brigham IRB at (857) 282-1900.”
- Add this statement when collecting or using Protected Health Information (PHI):

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.