NOTIFICATION LETTER TEMPLATE

Protocol: IRB-[identifier]

IRB Protocol Title: [title]

Date: [date]

Dear [Research Participant]:

You are receiving this communication because you are a participant in the research study listed above. The purpose of this letter is to notify you of a change to the information in the consent form that you read and signed.

Boston Children’s Hospital has recently implemented a new electronic medical record (EMR) system. The new electronic system includes information about individuals that participate in research. This change was made to facilitate clinical research operations such as scheduling, billing, ordering tests and communicating with participants. Your medical record now includes reference to participating in the research noted above. All other information contained in the original consent form remains unchanged. Your medical record is protected in accordance with the with hospital policies and laws. Information about your research participation may not be given to anyone unaffiliated with Boston Children's Hospital in a way you can be identified unless we obtain your permission, or it is permitted or required by law.

You can talk to a research team member about any questions. Please contact [\*\*\*\*].

If you have questions about your rights as a research participant, please email irb@childrens.harvard.edu.

Thank you.

[PI name]

[PI contact information]