

Note to File:

CHMC Protocol / ePAS: 2011-2012

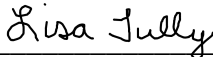
Study Title: “Using Patient Data to Transform Care and Improve Outcomes for Children, Adolescents, and Young Adults with Inflammatory Bowel Disease”

Date: 17/Nov/2016

Re: Mailing back consent forms when not present for consent

We anticipate the need to consent participants when they are not physically present and able to go through the traditional consent process. While we will follow the procedures for this situation as outlined in SOP 41-1.6 Obtaining Consent When the Participant is not Physically Present, we would like to make one additional alteration to the procedures. Currently, after the participant/LAR signs and dates the consent form, he/she is to electronically transfer a copy of the signed and dated document to the research team via fax or email. We will include the option to mail the signed and dated consent back to the research team. The person who consented the participant/LAR will sign and date the consent upon receipt, therefore the participant and witness' dates of signature will be different.

Some participants do not have access to the necessary technology to fax or email the consent back and we do not want to exclude a participant for this reason. The rest of the documentation of the consent process would remain the same. An additional benefit to this altered process would be the potential for bolstering recruitment.



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