Additional detail on the consent and sample handling processes utilized by the Better Outcomes for Children (BOfC) project at Cincinnati Children's Hospital Medical Center (CCHMC)

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Further explanation of the consent process and training program for the hospital registrars:

The consent process used in BOfC is certainly not a traditional consenting process. The institution went to great lengths to gather information from representative samples of both the current and prior CCHMC patient populations as well as from the CCHMC's primary catchment population. These interactions were used to create a consent document that meets both regulatory requirements and is focused on the information that was identified as being most relevant to these populations. These groups then vetted the resulting document for readability. All of this was completed prior to, and in addition to, the required IRB review and approval.

All registrars working in clinics where consent for BOfC is being obtained participate in a specialized service that trains them for their limited role in this project. As matter of the specific regulatory determinations, the registrars are not engaged in the consenting process as a traditional member of the research team normally would. The registrar's role involves the following steps:

1. Provide the patient with a brief scripted introduction to the project, along with the consent document.
2. Ask the patient if they have questions. If the patient has questions, the registrar is only able to direct the patient to information already in the consent document. If the requested information does not exist in the consent document, the registrar must record the consent as "deferred" in the EHR with a request that a member of the research team follow-up with the family.
3. If the patient has no questions, the registrar presents the appropriate signature option, based on the patient's decision.
4. The patient signs the electronic signature pad.
5. The registrar prints a copy of the signed consent document and provides it to the patient.

Communicating with patients interested in more information about the project, does this present HIPAA issues?

The offer is for patients to initiate contact with the research team members via e-mail. Any information contained in the e-mail is considered to be a voluntary disclosure to CCHMC and thus not covered under HIPAA. With all that said, the purpose of this communication vehicle is not to actually exchange PHI but rather to simply coordinate an opportunity to personally respond to questions.

What happens when consent is deferred?

When consent is deferred, Epic prompts the registrar to ask for consent again after 7 days. This time is given to allow the family to consider the study, and seek additional information from study staff or other source.

The use of the consent deferred option is used in multiple settings, most importantly in cases when, due to the clinical circumstances of the patient/family, it is not appropriate to request consent for the BOfC project. The deferral is in effect for 7 days, after which the patient can be offered participation in BOfC.

Do patients have time to review the consent form, ask questions about the research, and consult with family, friends and others before signing?

Yes. All of the above are available to the patient/family if they choose. If they wish to discuss participation with others, or wish to have additional time to consider the project, etc., the deferred consent option is utilized. There is both printed and web content available regarding BOfC that the patient/family can refer to as needed in order to make their consent decision.

Is it an issue to solicit consent immediately before beginning an elective procedure or scheduled therapy?

It is our opinion that obtaining consent before an elective procedure or scheduled therapy would be an ideal time to approach the patient as these situations would present the least amount of pressure related to the clinical environment. Conversely, a less desirable setting would be in the ED or before a non-elective procedure as those clinical environments are likely to be more stressful for the patient/family.

Is the consent form also signed by the consent designee?

No, this is not a regulatory requirement. Even so, as consent is recorded in Epic, the person logged into the system at that time is identified.

How does the consent designee evaluate whether a participant understands the information in the consent form?

The registrar asks the patient/family if they have questions or would like additional information. If the answer to either question is yes, the registrar would attempt to direct the patient/family to verbiage in the consent document. If this is not successful, consent would be deferred and the registrar would refer the patient/family to additional materials and/or provide contact information for the research team.

What happens if a patient withdraws consent? Is the process explained to patients in the consent form? How are specimens and derivatives tracked?

If a patient withdraws consent, any existing samples held by the biobank are destroyed. In the case that the samples have been released from the biobank and research has already been performed, the samples may be retained to allow investigators to perform follow-up experiments as requested by a journal or granting agency. No new research may be performed on the sample. Once all

of the follow-up needs have been met, the samples are destroyed. This information was inadvertently left out of the original submission, and language addressing this was added in the revision. The consent form provides information on how participants can contact BOfC personnel to withdraw consent, which can occur at any time. Samples and derivatives are tracked in the institutional sample tracking system, BTM.

What quality measures are tracked with the residual samples? Time to Freeze? And what Standard Operating Procedures (SOPs) are used when handling samples?

Sample collections have many different quality metrics. For this collection, approximate TTS (time to stabilization) can be determined but is not controlled. These are tracked as part of routine clinical practice. An alternative is to control these variables but that is not the design used for this project. These samples will be appropriate for some research purposes but not for others. Samples are processed using clinical SOPs, which are also available.