Consent / Introduction

Hi [*insert subject name*], my name is [*insert researcher name*] and I'm with Dr Park's research team. Is this still a good time for you? Are you in a place where you can be free from distractions and feel free to give candid responses?

[*Indicate if anyone else is on the call (eg, for training purposes); make sure that this is OK.]*

Thank you for agreeing to hear about this study. The aim of the study is to help us understand more about the implementation of the CoC Operative standards in breast surgery and the synoptic operative report (SOR; abbreviated this way only for text; please call them synoptic operative report during the interview). SORs are template checklist format op report that documents certain technical aspects of the surgery. For the new COC accreditation standard, the breast SOR elements highlight technical aspects of the sentinel lymph node biopsy and axillary lymph node dissection. When we refer to "SOR implementation" throughout the interview, we mean the surgeon using an electronic templated checklist to document the technical aspects predefined by the CoC with regards to sentinel lymph node biopsy and axillary lymph node dissection (either in place of a narrative operative report or in conjunction with).

Using SOR sometimes involves several people in a cancer program. During this interview, I will ask about your perspective on using SOR.

Your responses will help us understand how best to implement SOR in practice.

Our discussion should last between 30 and 60 minutes.

There is a small risk of breach of confidentiality, but we will do our best to keep all of your responses confidential and only be reported in aggregate. Because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

Your de-identified information may be used or shared with other researchers without your additional consent. Participation is voluntary. If you decide not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled. You can, of course, decline to answer questions, as well as to stop participating at any time, without any penalty or loss of benefits to which you are otherwise entitled. You may choose to stop the interview at any time, and there is no penalty to your or your organization for not completing the interview.

IRB #: 2021B0281
IRB approval date: 11/5/2021
Once you complete the interview, we will email (or mail if preferred) you a $100 Amazon.com gift card to thank you for your time. You can expect this to be sent within 1 week of completion.

Before we begin, we would like to record our discussion. The interview will be transcribed, however, your name or any personal identifiers will not be associated with any of the notes. The audio recordings will be deleted once the project is complete. If you have any additional questions concerning this research or your participation in it, please feel free to contact me, Dr Park the principal investigator, or our university research office at any time.

[*Provide contact information, or ask if they preferred it emailed*]

PI: KoUn.Park@osumc.edu
Research Office: 1-800-678-6251
Consenter: email / phone #

Do you have any questions before we begin? [*Ask other person (if applicable) on call to begin recording*.]