Pre-procedure Consent Process vs. Post-procedure Consent Process for Biorepository Sample Acquisition: A Prospective Survey at the Time of Pre-Admission
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**Background:** In the last 10 years, there has been an influx of biorepositories collecting human biological specimens for use in various types of research. One crucial component often overlooked is the consent process. It is proposed that the consent process would best serve the participant and the biorepositories when consent is obtained prior to the procedure(s). There are perceived limitations and downfalls to the post-procedure consenting process as it takes place when a patient is more vulnerable. Currently, federal regulations do not specifically mention this topic, nor do they offer guidance.

**Methods:** This qualitative/quantitative pilot research began on April 1, 2013, and evaluated participants’ perspectives regarding the importance of informed consent timing. The study aim was to determine which consenting process was favorable to patients, to ensure that patients were informed, and to establish a trend among different gender and age groups. Fifty patients were enrolled and were given a survey. Question types were limited in variability to provide ease of data analysis. The surveyed population consisted of adult male and female patients undergoing procedures to remove diagnosed or potentially pre-cancerous or cancerous human biological specimens. Eligible subjects were those who qualified to participate in the Academic Health Center Biorepository (AHCBR) during the advanced admission program (AAP).

**Results:** All 50 participants completed the survey (100% response). Ninety-two percent of the patients surveyed were female and 8% were male. Ninety-two percent responded as being very informed during the consenting process, 6% felt somewhat informed, and 2% felt not very informed. One hundred percent felt they had sufficient decision time. Ninety-six percent reported that they preferred to be consented during their AAP appointment. Two percent reported post-operatively or either for the consent timing. Ninety-eight percent of the patients consented were first time donors to a biorepository. One hundred percent of the patients consented agreed to participate with the AHCBR.

**Conclusions:** Overall, the participants felt very informed during the consenting process. The participants also felt that the AAP appointment time was the best time to be presented with the opportunity to participate in the AHCBR program.

**Limitations:** Although the response rate was good, males were underrepresented due to the population consisting mostly of gynecological patients. This also presented some limitations to the age group that was surveyed. It is anticipated that other institutions and potential biorepository donors will benefit from employing a pre-procedural consent process as a standard practice.