J Tissue Sci Eng 2015, 6:2
http://dx.doi.org/10.4172/2157-7552.S1.019

OMICS International
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International Conference and Exhibition on
Tissue Preservation & Bio-banking
July 20-22, 2015 Barcelona, Spain

Using an e-consent system for biobank patient consent; why, what, and how

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The rapid increase in the use of biobanks for research specimen storage has led to increased discussion of the format, role and extent of patient consent. Patient informed consent for the collection and maintenance and use of specimens in biobanks is a given in today's drug research and development world. Major issues around patients informed consent for use of bio-banked specimens includes one or more of the follow topics: Use of an Opt-in or Opt out system, use of Broad or a Dynamic consent process for research on stored specimen, maintenance of patient confidentiality when specimens are used in future research, and patient ability to withdraw permission. This presentation will provide an overview of the strengths and weakness of the use of an e-consent system to consent patients, maintain consent records, and act as an Honest Broker when specimens are requested for later research. A review of how such an e-consent system can meet both EU and FDA regulatory requirements, and integrate with a sample management system will be provided. A live demo will provide attendees with an overview of an e-consent system, audit trail, metrics and patient-facing education and consent platform including the use of handwritten digitally rendered signatures.

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