**Biorepositories and Risk Assessment: Incorporating a Novel Tool of Combining Risk Strategies. A Proactive Approach.**

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**Statement of Problem**

Providing high-quality research material is challenging due to the intrinsic nature of activities involved throughout the biospecimen’s lifecycle. Investigators need confidence that biospecimens meet standards for fitness for purpose. Components of a biospecimen’s lifecycle include but are not limited to activities involved in collecting, accessioning, storing, processing, shipping, destroying, and tracking. Each activity possesses a level of risk to the biospecimen. Current “-omic”- type research utilizes complex platforms and requires high-quality biospecimens to produce reliable data. Challenges include preserving biospecimens stored for “future, unspecified research” where requirements may not be defined as *apriori*. Biorepositories have an opportunity to proactively identify and respond to risks by incorporating risk assessments as part of their quality management system.

**Proposed Solution**

Adopting a dynamic risk management method identifies and mitigates potential adverse events before they impact biospecimens and related processes. The proactive design used by the Veterans Affairs Albuquerque Central Biorepository utilizes a team of subject matter experts to determine the scope and classify risk based on biospecimen type. The risk level is assigned using likelihood and severity matrices. Detectability is also considered. Each risk is identified and ranked to its detectability and risk, then categorized by likelihood and severity. A control plan is established based on known factors. Severity and likelihood are reassessed considering the mitigation strategy; then, a determination is made. Significant findings are recorded, and each risk assessment undergoes continuous cycles of improvement through formal review at regularly defined intervals to assess overall effectiveness.

**Conclusions**

Quality processes and controls in biorepositories play a critical role in research by providing investigators with biospecimens fit for their intended purpose. Confidence in the associated data from high-quality biospecimens provides greater assurance in answering research questions.

Robust quality control steps are needed at every stage of the biospecimen’s lifecycle to support the goal of maintaining fitness for purpose. Continuous improvements made through identifying and managing risks can help biorepositories successfully manage biospecimens for valuable research.