CanPath.ca

CanPath
Canadian Partnership for Tomorrow's Health
Partenariat canadien pour la santé de demain

BIOSAMPLE FEASIBILITY REVIEW

All submitted biosample requests will undergo a feasibility review. The review evaluates both the request and the ability of the biorepository to fulfill such a request. The request will be assessed for 1) ensuring parsimonious use of the samples, 2) confirming that the analyte hasn't been measured previously in the same sample set, 3) evaluating the planned analysis for its potential to provide reliable, reproducible, and measureable results. Evaluation of the biorepository includes 1) assessing if the repository has sufficient material available to fulfill the request, 2) evaluating risk of sample depletion, 3) assessing its ability to meet the Applicant's timelines.

Parsimonious Biosample Use: Applicants will be required to provide and justify both the required and "dead" volume for each biosample type requested. CanPath encourages the use of low volume and multiplex assays whenever available and reliable. Asks of >500 µL for non-DNA samples and >2µg for DNA samples will require extraordinary scientific justification to be considered.

Analyte Previously Measured: Should the proposed analyte already be measured in the same sample set, CanPath will instead provide the corresponding analyte data upon project approval. CanPath requires Approved Users to return research results, after a period of exclusive access, to further enrich this valuable resource.

Evaluating Proposed Analysis: Applicants will need to provide evidence that the analyte(s) they are proposing to measure is(are) stable over time in the requested sample type. The CanPath Biorepository contains samples on participants at different times relative to their enrolment and the collection of their physical measures and questionnaires, so demonstrating that the analyte, as measured in a single specimen, can be an informative surrogate for the usual levels will help ensure judicious use of the limited sample. In addition any known pre-analytical factors that influence analyte levels will need to be acknowledged and referenced to justify additional sample selection criteria as well as demonstrate analyte stability. As well, the proposed analysis must be suitable for the requested biosample type (E.g., the melatonin metabolite 6-hydroxymelatonin sulfate is stable over time in urine, but not blood). Applicants will also be required to predict what analyte concentration range they would anticipate measuring in the requested sample type.

Evaluating Analysis Methodology: Applicants will be asked to provide both details on the assay itself plus the testing lab's assay experience, reproducibility and performance results. Required assay details will include sensitivity and specificity. The testing lab's experience can be highlighted by number of assays performed or number of years the lab has consistently used the assay. Coefficient variation, technical intra-class correlation coefficient, and batch effects are examples of the assay reproducibility and performance results.

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