

**Master Thesis**

**A Unified Framework for Efficient and Effective Establishment of  
Prospective Collection in a Centralized Academic Biobank Setting**

Submitted by

**Khawla Al Zarooni**

For the academic degree of Master of Science Biobanking

**MSc CE Biobanking**

At the

**Medical University of Graz**

Under the Supervision of

**Professor Berthold Huppertz**

Submitted

Graz, 08 January 2025

## Declaration of Academic Integrity

I, Dr Khawla AL Zarooni, hereby confirm that the presented in this Master's Thesis titled *A Unified Framework for Efficient and Effective Establishment of Prospective Collection in a Centralized Academic Biobank Setting* is the result of my own independent scholarly work. I also confirm that in all cases, where material from the work of others (in books, articles, essays, dissertations, and on the internet) is acknowledged, quotations and paraphrases are clearly indicated. No material other than that cited in the reference list has been used. I have read and understood the Medical University's regulations and procedures concerning plagiarism.

Graz, 09 January 2025  
Dr. Khawla Alzarooni

# Acknowledgment

I would like to thank my family and friend for their unwavering support and encouragement. I am extremely thankful to my supervisor, Professor Berthold Huppertz, for his invaluable insights and guidance. I also extend my appreciation to Professor Karine Sargsyan for inspiring me to enrol in the course and for her continued support and expertise. A special thanks goes to Gabriele Hartl, whose assistance has been instrumental in streamlining and enhancing our experience throughout the course.

I am incredibly thankful for the faculty, course providers, administrators of the Masters of Biobanking program at the Medical University of Graz, and my fellow students. It has been wonderful to exchange knowledge, learn from each other and to get to know all of them.

Additionally, I wish to extend my appreciation to my colleagues at the Dubai Health Biobank, Mohammed Bin Rashid University of Medicine and Health Sciences, and the broader team at Dubai Health. Within the Dubai Health community, we work collectively to deliver health for humanity, with the patient-first value guiding our care, discovery, learning, and giving missions.

## Abstrakt

Biobanken sind heterogen und komplex und umfassen unterschiedliche Typen und Klassifizierungen. Sammlungen von Bioproben und zugehörige Daten sind für die biomedizinische Forschung von entscheidender Bedeutung. Eine zentralisierte Biobank-Infrastruktur in einem integrierten akademischen Gesundheitssystem wird verschiedene Forscher bedienen und Biobanking-Dienste für verschiedene Projekte bereitstellen. Die Einrichtung von Biobanken nach hohen Standards, sorgfältige Planung und Ressourcenzuweisung gewährleistet die Einbindung der Interessengruppen, betriebliche Effizienz, fördert die Vorausplanung und gewährleistet Nachhaltigkeit durch die Integration aller Bereiche des Nachhaltigkeitsmodells für Biobanken. Ziel dieses Projekts war die Entwicklung eines umfassenden und praktischen Toolkits zur Erfassung von Projektmanagement-, Geschäftsplanungs- und Dokumentenstandardisierungstools für betriebliche Effizienz.

Methoden: Die Studie folgte einem strukturierten, dreiphasigen Ansatz: konzeptioneller Rahmen, Design und Entwicklung sowie Einführung und Verfeinerung, um ein Toolkit für Projektmanagement, Geschäftsplanung und Dokumentenstandardisierung für die Probensammlung in Biobanken zu erstellen und zu implementieren. Darüber hinaus wurden Fallstudien ausgewertet, um ein tieferes Verständnis zu ermöglichen und Best Practices und häufige Nachteile für Projektmanagement und Geschäftsplanung von Biobanken zu identifizieren.

Ergebnisse: Der konzeptionelle Rahmen des Toolkits wurde entwickelt, um Standards und Best Practices zu umfassen, die die Biobanking-Standards ISBER und ISO 20387:2018 abdecken, sowie die Ausrichtung auf Organisationspläne, einschließlich Biobankrichtlinien, SOPs und Geschäftsplänen als Instrument zur Umsetzung der strategischen Ziele der zukünftigen Probensammlung und Toolkit-Komponenten, die Geschäftsplanungs- und Projektmanagement-Tools unter dem Dach internationaler Standards und Best Practices integrieren. Eine thematische Literaturrecherche konzentrierte sich auf die konzeptionellen Rahmenkomponenten, um die Rahmen und Themen zu validieren, die sich auf die Auswahl der Toolkit-Tools und -Komponenten auswirken. Die digitale SharePoint-Plattform wurde als Host für das Toolkit ausgewählt, um die Benutzerfreundlichkeit und Zugänglichkeit zu verbessern.

Schlussfolgerung: Der Rahmen und das Design des Toolkits basierten auf der Überprüfung von Best Practices, Fallstudien, Online-Biobankprofilen und Geschäftsmodellüberprüfungen. Der

in dieser Forschung entwickelte konzeptionelle Rahmen dient als grundlegender Schritt zur Implementierung einer innovativen, technologieorientierten Lösung zur Optimierung der Einarbeitung und Verwaltung von Biobankprojekten.

## Abstract

Biobanking is heterogeneous and complex with different types and classifications. Biospecimen collections and associated data are key for biomedical research. A centralized biobank infrastructure in an integrated academic health system setting will cater for different researchers and provide biobanking services for different projects. Establishing biobanks at high standards, careful planning and resource allocation ensures engagement of stakeholders, operational efficiency, promote forward planning and ensure sustainability by integrating all areas of biobank sustainability model. The aim of this project was to develop a comprehensive and practical toolkit to capture project management, business planning, and documents standardization tools for operational efficiency.

### Methods:

The study followed a structured, three-phase approach: conceptual framework, design and development, and rollout and refinement, to create and implement a toolkit for project management, business planning, and standardization of documents for biobank sample collection. In addition, case studies were assessed to allow deeper understanding and to identify best practices and common drawbacks for biobanks project management and business planning.

### Results:

The toolkit's conceptual framework was developed to encompass standards and best practices covering ISBER and ISO 20387:2018 biobanking standards, alignment with organizational plans including biobank policies, SOPs and business plan as a tool to implement the prospective sample collection's strategic objectives, and toolkit components that will incorporate business planning and project management tools under the umbrella of international standards and best practices. A thematic literature search focused on the conceptual framework components to validate the frames and themes that impact the selection of the toolkit tools and components. The SharePoint digital platform was chosen to host the toolkit, enhancing usability and accessibility.

### Conclusion:

The framework and design of the toolkit was based on review of best practices, case studies, online biobank profiles and business model reviews. The conceptual framework developed in this research serves as a foundational step toward implementing an innovative, technology-driven solution to streamline biobank project onboarding and management.

# Table of Contents

Declaration of Academic Integrity.....	2
Acknowledgment.....	3
Abstrakt.....	4
Abstract.....	6
<b>List of Abbreviations.....</b>	<b>9</b>
<b>1. Introduction.....</b>	<b>11</b>
1.1 Statement of the problem.....	11
1.2 Study aims and objectives.....	12
1.3 Literature review.....	13
1.3.1 Biobank Definition, Classification, and Business Model.....	13
1.3.2 Biobanking past, present and future.....	15
1.3.3 Establishing a Prospective Collection.....	17
1.3.4 Managing Complexity in Biobanking - Biobank Impact.....	17
1.3.5 Biobanking infrastructure and business planning.....	18
1.3.6 Project Management in biobanking.....	20
1.3.7 Biobanking and advancement of biomedical research.....	22
1.3.8 Biobanking operations and sample collection.....	23
1.3.9 Toolkits in Biobanking and Research.....	24
<b>2. Methods.....</b>	<b>27</b>
2.1 A Three-phase Approach.....	27
2.1.1 Phase 1: Conceptual Framework.....	27
2.1.2 Phase 2: Design and Development.....	28
2.1.3 Phase 3: Rollout and Refinement (Future directions).....	28
2.2 Case Studies.....	29
2.2.1 The Rare Paediatric Eye Cancer (R-PEC) Biobank.....	29

2.2.2	German Biobank Node: Start-up Biobanks Starter Kit.....	30
2.2.3	The FinnGen project.....	31
3.	Results.....	32
3.1	Institutional Guidelines and Best Practices Alignment.....	32
3.2	Tool Identification .....	34
3.2.1	Literature Search.....	34
3.2.2	Case Studies Review .....	35
3.3	Toolkit Model and Format .....	37
3.4	Toolkit Content.....	43
4.	Discussion.....	46
5.	References.....	51
	Annex 1: Biobank Definitions .....	61
	Annex 2: Biobank Project Protocol: Business Plan Template.....	63
	Annex 3: The Project Onboarding Toolkit PowerPoint Slides.....	65

## List of Abbreviations

<b>BBMRI-</b>	Biobanking and Biomolecular Resources Research Infrastructure –
<b>ERIC</b>	European Research Infrastructure Consortium
<b>BIMS</b>	Biobank Information Management System
<b>CCPM</b>	Colorado Centre for Personalized Medicine
<b>CHTN</b>	Cooperative Human Tissue Network
<b>CTRNet</b>	Canadian Tumor Repository Network
<b>DHBB</b>	Dubai Health Biobank
<b>EHRs</b>	Electronic Health Records
<b>ELSI</b>	Ethical, Legal, Societal Issues
<b>FAIR</b>	Findable, Accessible, Interoperable, Reusable
<b>GA4GH</b>	Global Alliance for Genomics and Health
<b>GBA</b>	German Biobank Alliance
<b>IARC</b>	International Agency for Research on Cancer
<b>IRB</b>	Institutional Review Board
<b>ISBER</b>	International Society for Biological and Environmental Repositories
<b>ISO</b>	International Organization for Standardization
<b>IT</b>	Information Technology
<b>MIABIS</b>	Minimum Information About Biobank Data Sharing
<b>MS</b>	Microsoft
<b>NCI</b>	National Cancer Institute
<b>OECD</b>	Organization for Economic Cooperation and Development
<b>PRiSM</b>	Project Integrating Sustainability Methods Sustainability
<b>QMS</b>	Quality Management System
<b>R-PECs</b>	Rare Pediatric Eye Cancers
<b>SOP</b>	Standard Operation Procedure
<b>SSOT</b>	Single Source of Truth
<b>STD</b>	Sexually Transmitted Diseases
<b>SWOT</b>	Strengths, Weaknesses, Opportunities, and Threats

## List of Figures

<i>Figure 1 Biospecimen Lifecycle</i> .....	12
<i>Figure 2 Repository Lifespan</i> .....	19
<i>Figure 3 Toolkit Development Methodology</i> .....	27
<i>Figure 4 The Toolkit's Conceptual Framework</i> .....	32
<i>Figure 5 Toolkit Proposed Framework Scope and Purpose</i> .....	37
<i>Figure 6 - Toolkit Design Strategy</i> .....	38
<i>Figure 7 - Overview of the Biobank Project Onboarding Site</i> .....	39
<i>Figure 8 - Toolkit Framework and Outline</i> .....	41
<i>Figure 9 - Biobank Project Onboarding Process, Toolkit and SharePoint Setup</i> .....	45

## List of Tables

<u>Table 1 - Biobank Definitions</u> .....	61
<u>Table 2 - Biobank Business Plan Template</u> .....	63

# 1. Introduction

Biobanks are platforms that act as accelerators of precision and personalized medicine through providing high-quality biological material and data generated from the standardization of the collection, handling, storage, and distribution of biospecimen and data (Bettio et al., 2023). The Organization for Economic Cooperation and Development (OECD) defined biobanks as structured resources that can be used for the purpose of genetic research, including human biological materials and/or information generated from genetic analysis and associated information (Hewitt and Watson, 2013).

Biobanking in health care is key towards the advancement and enhancement of medical research. The establishment of biobanks has globally increased since it is currently considered an essential piece of infrastructure and exceptional tool for advancing personalized medicine, providing new possibilities to learn more about the function of the living systems in physiological and pathological conditions (Caenazzo and Tozzo, 2020).

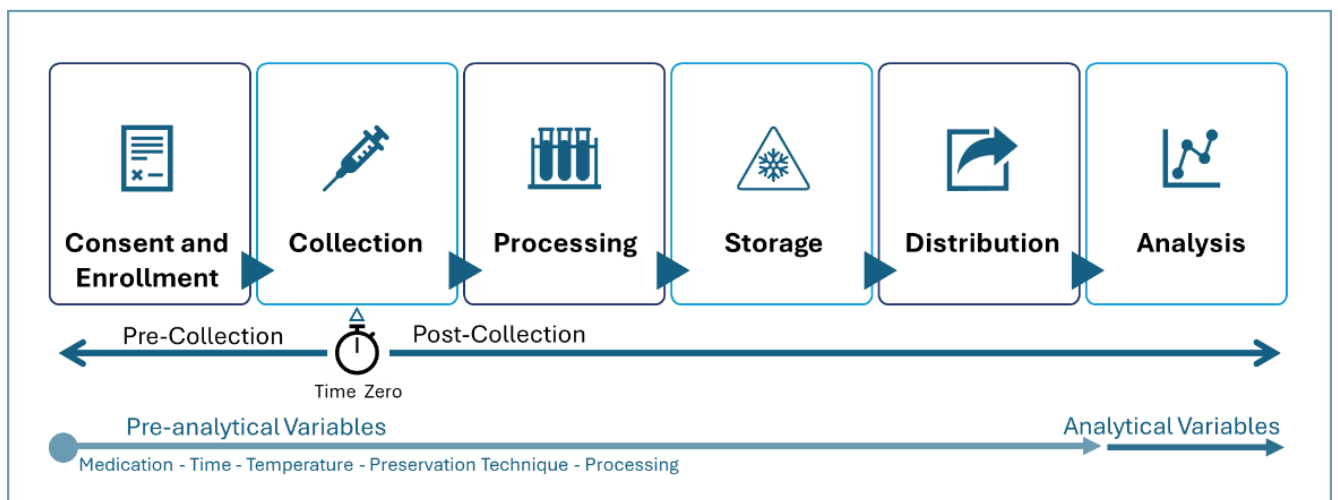
Biomedical research, presently and in the future, depends on collections of human biospecimens including tissues and blood containing genetic material. Biomedical researchers across different ranges of scientific disciplines can study this genetic material. Large quantities of human biospecimens can be obtained, processed, and stored in a biorepository or biobank. This amount of biospecimens together with its corresponding clinical data can accelerate and advance research in all biomedical and health related fields requiring high-quality biospecimen. This information can then be linked to all other disciplines, such as proteomics, metabolomics, or glycomics. The scientific community has recognised that the collection of these biospecimens can significantly promote the precision and personalized medical approach since the genotypic data, combined with clinical and physical information of individuals (the phenotypic data) can be congregated. Unfortunately, the current system for collecting and maintaining biospecimens is decentralized and run in an ad hoc basis, which adversely affect the collection process resulting in poor quality biospecimens with limited utility (Riegman et al., 2008).

## 1.1 Statement of the problem

Establishing a biobank requires the right environment and preparation to overcome any operational difficulties with the concept and workflow. Even though biobanks can significantly

advance personalized care and precision medicine through its potential of improving the process of molecular investigations and bioinformatics analysis of high quality biospecimens, the current operation system is mostly not optimal. The genetic data produced, the link to other omics data and its integration with personal, health, lifestyle, socioeconomic, and demographic information could have huge impact on several medical and research disciplines.

The ideal operation system imposes standardization and optimization of sample collection. The standardization and harmonisation of the collection, handling, storage, and distribution of biospecimens and data is critical and should follow the scientifically agreed on criteria and standards. Figure 1 outlines the lifecycle of a biospecimen and the multiple pre- and post-analytical variables that can affect the molecular integrity of the sample.



*Figure 1 Biospecimen Lifecycle*

**Figure 1:** The lifecycle of a biospecimen and the multiple pre- and post-analytical variables that can affect the molecular integrity of the sample. Adopted From/Source: Vaught, J., et al. (2011). An NCI perspective on creating sustainable biospecimen resources. *Journal of the National Cancer Institute - Monographs*, 42. <https://doi.org/10.1093/jncimonographs/lgr006>

## 1.2 Study aims and objectives

The aim of this thesis was to develop a comprehensive and practical toolkit to capture project management, business planning, and document standardization tools for operational efficiency to achieve targets and impact the quality and sustainability in a prospective and project-driven biobank environment.

The biobank project management and business planning toolkit objectives are:

- To identify ways to streamline project management, business planning and standardisation in biobanking for institutional research/biobank projects
- To establish a biobanking project onboarding framework for timely and efficient services
- To develop a biobanking toolkit checklist that is accessible, practical and efficient
- To efficiently support the management of multidisciplinary teams
- To increase knowledge and awareness about the biobank sustainability framework

## 1.3 Literature review

### 1.3.1 Biobank Definition, Classification, and Business Model

The idea of biobanking is not new. Biospecimens have been collected and stored in many countries since long. However, genetic engineering and the sequencing of the human genome have revolutionised the use of biospecimens for research purposes, promoted the development of new methods to study diseases and encouraged a new era of biomedical research (Domaradzki and Walkowiak, 2024).

Biobanks' first appearance in literature could be traced to the word "biobanque" used in 1992 to describe a collection of annotated biospecimens collected for sexually transmitted diseases (STD) (Bledsoe et al., 2019). In another account, the term "biobank" first appeared in the scientific literature to depict population-based biobanks in 1996, the term then evolved to include a broader range of biobanking operations and facilities and can be found to have multiple definitions in different sources (Hewitt and Watson, 2013).

In 2009 biobanking was listed as one of "10 ideas changing the world right now" in a special issue of the Times Magazine to illustrate the importance and value of biobanking (Henderson et al., 2024; Park, 2019; Simeon-Dubach and Watson, 2014). In 2022, "*biobanks were forecast to be valued globally at 71.4B USD and predicted to rise to \$157.75B by 2032 with a compound annual growth rate of 8.3%*" ("Biobanking Market Size to Hit Around USD 169.62 Bn by 2033," 2024; Henderson et al., 2024)

There is no consensus about the definition and classification of the diverse types of biological collections. Several terms have been used interchangeably in the past (Simeon-Dubach and Watson, 2014). As a core feature, all biobank definitions align on biospecimens and associated

data as the building blocks of biobanking (Annaratone et al., 2021; Fonseca et al., 2022). In the International Organization for Standardization (ISO), the definition alludes to the legal position of biobanks and then further delineates the operational activities of biospecimen and data collection, handling, processing, storing, distribution and analysis in a systemic framework (Annaratone et al., 2021; ISO, 2018). The definition can be further summarized as a systematically organized collection of human biological samples and associated information for research or healthcare purposes (Henderson et al., 2024). A key distinguishing feature of biobank collections from research collections is the established governance mechanisms and the access policies that allow sharing of biological resources and data (Fonseca et al., 2022). Biobanking and biobanks are diverse and heterogeneous entities. A deeper look at the biobank classification and business model allows for a more practical and efficient design of operational workflows, document standardisations and toolkits to implement and maximise the derived benefits. The thesis focuses on academic biobanks in the context of an integrated academic health system.

The heterogeneity of biobanking can be extended to the classification system adopted, as there is no universal classification system (Annaratone et al., 2021). Biobank classification could relate to the benefits and impact of the biobank or based on the type of collections accrued and shared. The Canadian Tumor Repository Network (CTRNet) categorizes biobanks based on functional elements that encompass who the donors or participants are, the collection methods and design, including the sourcing method and timeline, whether the collection is retrospective or prospective, the size and the scope of the collection or repository, the biospecimen type and storage conditions, and finally, the type and number of end-user type that utilize the biobank (Annaratone et al., 2021; Watson and Barnes, 2011).

According to the International Society for Biological and Environmental Repositories (ISBER)'s Best Practices for Biorepositories (5<sup>th</sup> Edition), several components determine biobank classification including the collection purpose, type of stored biospecimen and associated data, collection format as single collection, or centralized biobanking service that caters for multiple researchers and end-users, financial resources and funding, such as public, academic government, commercial or private funding. Furthermore, the organizational structure and sample and data retention time determine the biobank typology (Akyüz et al., 2021; Snapes et al., 2023).

Since different types of biobanks have been proposed, the activities performed in support of the project-specific needs will influence to ultimate operational model, including actual physical or virtual collections, processing, conservation, and distribution activities (Valdivieso-

Gómez et al., 2021). Thus, the classification based on function may seem to be more appropriate to categorize the diverse types, purposes and operational designs of collections (Simeon-Dubach and Watson, 2014).

Despite the diverse classification systems, biobanks operate according to strict adherence to SOPs (Standard Operation Procedures) in alignment with national and international guidelines and best practices such as the ISBER, CTRNet, in addition to IARC (International Agency for Research on Cancer), NCI (National Cancer Institute) and BBMRI-ERIC (Biobanking and Biomolecular Resources Research Infrastructure - European Research Infrastructure Consortium). This level of standardization allows for high levels of harmonization and coordination among repositories and ultimately impacts biospecimen quality and quantity, in addition to opportunities for collaboration among different biobanks to source significant numbers of samples to capture the full disease spectrum (Speirs et al., 2021). For example, MIABIS (Minimum Information About Biobank Data Sharing) by BBMRI-ERIC allows for standardization in biobank registries to enhance visibility, findability and interoperability of repositories and the reusability of collections. Adoption of such modalities will be significant not only at the international network level, but also in the national and institutional level since biobanks will operate according to equivalent standards, quality framework, and sample and data integrity (Speirs et al., 2021).

### 1.3.2 Biobanking past, present and future

Biobanking has evolved significantly since its inception in the early 20th century from university-based repositories to support specific research studies with limited storage technologies and standardization. The technological advances in cryopreservation techniques, the automation in the preservation and processing procedures, and the information technology advance to handle and link complex datasets have revolutionized biobanking, enabling long-term storage of diverse biological materials such as tissues, blood, and DNA. However, these early efforts lacked centralized coordination, consistent ethical guidelines, and robust data management systems, limiting their scalability and scientific utility, as biobanks need to progress from heterogeneous and decentralized models towards centralization to implement harmonization throughout the lifecycle stages of biospecimen, incorporating qualification methods and procedure harmonization (Coppola et al., 2019).

Biobanking has evolved and progressed through three stages, referred to as Biobanking 1.0, that focused on the quantity of biospecimens and data, to biobanking 2.0 that focused on the quality of biospecimens and data, with an internal focus on operational efficiency, and finally, biobanking 3.0 that focuses on external stakeholders' engagement to propagate the understanding of the value and impact of biobanking. Adopting biobanking 3.0 is a way to ensure biobank sustainability (Lin et al., 2020; Simeon-Dubach and Watson, 2014).

In 2010, a project was launched to consolidate sample collections into a unified platform with a shared database to capture a minimum dataset for the samples received at IARC (International Agency for Research on Cancer). This centralised model of a common platform, protocols, and a catalogue of available resources encourages the adherence to best guidelines and standards. The three key benefits that resulted are maintaining storage facilities under the best possible conditions, capturing the minimum dataset and pre-analytical variables linked to biospecimens to facilitate the harmonisation and interoperability between sample collections and associated databases. Lastly, integrating the diverse sample collections into a global catalogue to optimize the utility and visibility of biobank resources, fostering collaborations (Mendy et al., 2019). Centralization is also a step towards consolidating communication to enable biobanks to shift from an inventory model towards a wider scope of services and offering capabilities in supporting investigators/researchers in designing and planning of prospective collections and better managing of resources (Hartman et al., 2019).

Nowadays, biobanking is instrumental in advancing biomedical research and personalized medicine, driven by innovations in genomics, big data analytics, and artificial intelligence, with an emphasis on standardization, quality assurance, and data interoperability. The reliability and reproducibility of research findings are improved. Moreover, compliance with ethical considerations, including informed consent and data privacy regulations, are now central to biobanking operations and have paved the way for a future of biobanking embracing digital transformation and sustainability. With innovations to enhance efficiency and collaboration, such as virtual biobanks, AI-driven sample management, and blockchain for secure data sharing. Additionally, the inclusion of more diverse populations in biobank repositories to address health disparities and ensure the benefits of biobank-driven research are equitably distributed (Battineni et al., 2022).

### 1.3.3 Establishing a Prospective Collection

In a prospective collection model, biospecimens and data are collected based on requests from researchers in contrast to the 'Classic Biobank' biospecimen-centric model where collection is based on prediction of future requests and potential applicability in research. The centralized business model allows unifying stakeholders and ensures sustainability despite the complexity and challenges that might arise. This collaborative framework ascertains the needs and incentives of stakeholders, policies and procedures aligned with the strategic values of transparency and trust, having clear lines of accountability and cost management, and finally, a focus on output driven enterprise that recognizes the value of sharing data derived from biospecimen sharing, hence a wider vision on the return on investment in a non-monetary form (Vaught et al., 2011).

The Cooperative Human Tissue Network (CHTN) was established in 1987 and has operated under the prospective model since then. A review article published in 2018 presented the key principles that ensure the success of this operational model. The principles included flexibility in the operations of different sites, clear channels of communication, working closely with investigators to co-develop the operating protocols, robust request management processes, rigorous adherence to a quality management system, and supporting IT infrastructures and informatics. The model made it possible to increase biospecimen utilization and maintain public trust and strong stewardships over collections. Hence, the prospective offers numerous advantages, making it an ethical and effective approach to biospecimen collection and handling, being investigator-centric prompts high utilization rates, the model is flexible to support diverse research needs, adaptable to rapidly changing regulatory and technological advancements, allows for cost-effective management of resources, and ultimately advances biomedical research with efficiency and sustainability (Grizzle et al., 2018).

### 1.3.4 Managing Complexity in Biobanking - Biobank Impact

According to the National Institute of Mental Health, research needs to meet the '4 Ps' of personalized medicine; Predictive, Preventive, Personalized and Participatory criteria. This was exemplified by the creation of the Signature Biobank, a longitudinal collection of multiple cross-sectional indicators of interest including biological, psychological, sociodemographic, diagnostic indicators of over 1000 patients diagnosed with various psychiatric disorders. This

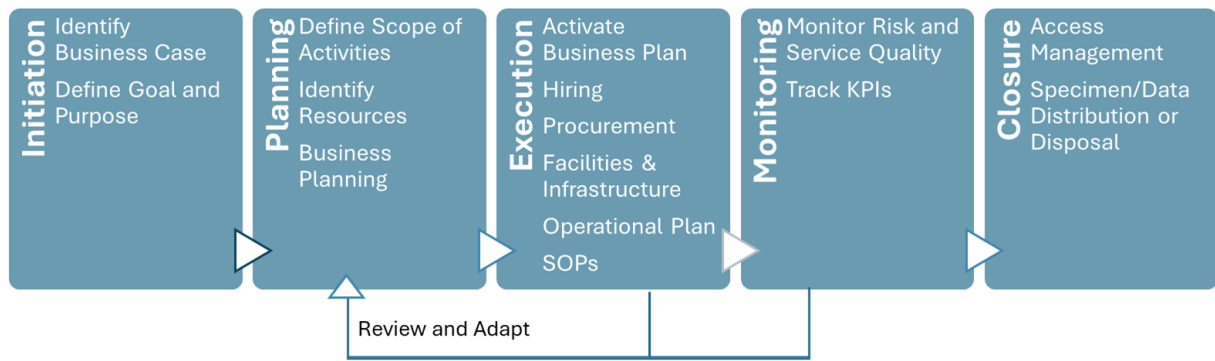
model allowed for innovative research to contribute towards effective discoveries in the fields of neuroscience and psychiatry.

Key strengths in the success of the longitudinal biobank included stakeholders' engagement, knowledge exchange among the key stakeholder, the patients, practitioners and scientists. Implementing of a cost recovery model and open science practices with research using the Signature Biobank produced meaningful implications in diverse areas of psychiatric research. This example illustrates not only the complexity of establishing biobanks but also the impact of biobanking on research and personalized medicine, as well as the necessity for meticulous planning and operational efficiency needed to achieve the biobanks targets (Geoffrion et al., 2022; Kerr et al., 2024).

### 1.3.5 Biobanking infrastructure and business planning

Factors to consider when establishing biobanks include infrastructure, equipment, financial support and highly specialised and suitably qualified personnel. *“Highly trained personnel with clear and precisely defined duties are the key to the proper functioning of a biobank.”* (Chróścicka et al., 2022).

Parry-Jones et al. (2017) promote the concept that the establishment of a biobank should be considered a project with five distinct phases starting with initiation, followed by planning, execution, monitoring and controlling, and finally, closing. The phases are an integral part of biobank operations and process management ([Figure 2](#)). Such perspective allows the incorporation of risk management processes in the planning stage to reduce the initial high-risk level associated with setting-up a biobank to a more acceptable and predefined risk level (Parry-Jones et al., 2017).



*Figure 2 Repository Lifespan*

**Figure 2:** Repository Lifespan: Phases of a repository (Adapted from ISBER Best Practices, 5<sup>th</sup> Edition)

Annaratone et al. (2021) described the basic principles of setting up a biobank around exploring the 5W's (why, what, who, where and when). Hence, a business plan is a detailed document that describes the biobanks goals and what strategies are in place to achieve them. The core questions to ask are 1) Where are we now? 2) Where do we want to go? and 3) How are we going to get there? (Van Der Stijl et al., 2019) The essence of a business plan is to define and classify the business model, to align with international standards and best practices, to design infrastructures that meet quality standards throughout the different stages of the biospecimen lifecycle and to create channels of communication and networking (Annaratone et al., 2021). Biobanks incorporate business approaches in their planning to attain financial sustainability, achieve institutional value, and credibility among clinicians, researchers and the community (Henderson et al., 2015). Biobanks are long-term investments that require a sound business plan for financial sustainability. However, few biobanks have a robust business plan (Alves et al., 2022).

The ISBER Best practice 5<sup>th</sup> edition states that business planning is key for the success of biobanks/repositories, the plan provides a framework for setting core goals, addressing and meeting stakeholders' needs, designing biospecimen collection methods, defining the repository services and financial strategies for cost recovery, maintaining operations and ensuring sustainability.

### 1.3.6 Project Management in biobanking

Biobanking operations are multidisciplinary, encompassing scientific, ethical, and logistical compliance with ethical, legal and regulatory requirements and quality considerations that require a structured project management approach to achieve specific goals within time, resource, and cost constraints. A closed-loop model that integrates planning, controlling, assuring and improving that follows a structured five-phase project lifecycle that is interchangeable with the term repository lifecycle, that includes initiation, planning, execution, monitoring and closing with specific tasks and tools for each phase that are critical for handling the establishment of biobank collections, manage request of access to biospecimen and data while maintaining quality and integrity of biobank resources. “Good projects need good plans” Using information technology is key in supporting the project phases, starting from planning, execution, monitoring, and control; this allows careful planning of and achieves the project objectives by remaining competitive with a robust budget planning (Berisha-Shaqiri and Neziraj, 2024).

The project phases in biobanking start with the initiation phase that focuses on defining objectives aligned with the mission, conducting feasibility assessments to evaluate the scientific, ethical, and financial viability, and stakeholder engagement to address the diverse needs of researchers and funding bodies to donors and regulators. Moving on to the planning phase, the emphasis is on tools to define deliverables and work packages, using project scheduling tools like Gantt charts to organize tasks and timelines, risk management and quality planning ensure project robustness, and resource allocation to assign specialized personnel, equipment, and budgets to meet objectives. Whereas, execution involves implementing the project plan, team management, communication, and task coordination. Monitoring and controlling ensure the project remain on track, using Key Performance Indicators (KPIs) and progress reports to track performance and address risks. Quality control measures verify that samples and data meet required standards, while change management processes allow for controlled adaptations to scope or timelines. Finally, the closing phase involves reviewing deliverables, documenting lessons learned, and achieving formal closure through stakeholder sign-off and resource release. By applying these structured project management approaches, biobanking projects can achieve their scientific objectives effectively while maintaining high ethical and quality standards (Gramatiuk and Hartl, 2022; Hartl and Sargsyan, 2023).

Project management intersects with process and knowledge management to create strategic and operational frameworks that enhance the biobank's success and enable scientific discovery and innovation. Effective project management ensures systematic handling of research collaborations and biospecimen requests. Process management streamlines operations for efficiency and compliance. Knowledge management fosters a culture of continuous learning and adaptability. Process modelling tools like flowcharts enhance clarity and efficiency by outlining task sequences and responsibilities. This systematic approach harmonizes operational efficiency, ensuring biobank activities meet customer and organizational expectations effectively. By incorporating knowledge management into daily operations, biobanks aim to become learning organizations that adapt to evolving scientific and regulatory landscapes. Knowledge management facilitates transforming tacit knowledge—embedded in individual expertise—into explicit, actionable formats that foster collaboration and innovation, ensuring sustained organizational growth and the ability to meet future challenges (Gramatiuk and Hartl, 2022; Hartl and Sargsyan, 2023).

Song et al. (2024) identified key project management challenges in translating the development of new biological products in the R&D setting, including level of support, structure and output driven vision in the project definition and evaluation, implementing a systematic approach to project planning and the scientific values in managing the time, scope, quality and cost related with proper resource allocation, real time project management in the execution phase and capturing all the necessary project information and documentation in the closure phase (Song et al., 2024). Thus, understanding project management models and incorporating sustainability measures with project handling protocols such as the PRiSM approach. PRiSM refers to the Project Integrating Sustainability Methods Sustainability in project management and is a collection of principles that overarch the entirety of the project lifecycle including stakeholder engagement, environmental awareness, efficient resource management, continuous monitoring and reporting on sustainability performance. The P5 Standard is a sustainability models of that begins with the correct definition of the project in the initiation stage, and encompasses a framework that examines the Product, Process, People, Planet and Prosperity impact as methods to drive innovation and cooperation among diverse stakeholders not only in the setting of disease management but also research and collection management (Juchniewicz et al., 2021).

### 1.3.7 Biobanking and advancement of biomedical research

Biobanks play a critical role in advancing biomedical research by ensuring the availability of quality biospecimens, and associated data in quantities that are of research value. Biobanks are multidisciplinary environments that balance both societal and research expectations. Sustainability is challenged by technical, logistical, ethical, legal, and privacy-related issues and a growing demand for quality, fair adaptability, transparency, and accountability (Van Der Stijl et al., 2021).

Biobanking in health care is key towards the development and significance of medical research. This can be attributed to the growth of the biobanking field and its impact on accelerating biomedical research, drug development, and medical practice. Furthermore, the technological advances in omics sciences and big data have positioned biobanks as vital resources in precision medicine. The harmonization of procedures, adherence to ethical guidelines, functioning as integrated systems involving key stakeholders has allowed the impactful growth of biobanks and the change in the type of biospecimen and data stored and the development of capabilities to integrate bioimages with clinical data, supporting fields like radiomics and radiogenomics. These new complex systems require infrastructure integration to interconnect systems, adaptive policy frameworks, collaboration through networks, standardization and harmonizing of procedures crucial for quality assurance and data comparability, and ultimately long-term sustainability measures that encompass financial management, ethical compliance, expansion of biobanking capabilities, staying abreast with new technologies and continuous evaluation and development to meet demands and offer standardized service that meet with the needs of researchers and key stakeholders (Coppola et al., 2019).

The diversity of biobanking models is crucial for advancing personalized medicine through integrating large-scale genomic and clinical data and linking genetic information with electronic health records (EHRs). This integrated model empowers researchers and clinicians to develop more precise and effective treatments for various diseases. To elaborate, the Colorado Centre for Personalized Medicine (CCPM) Biobank combines both research and clinical applications by integrating genomic data with EHRs from over 200,000 participants, allowing researchers and clinicians to explore health patterns and develop targeted medical interventions. This model supports translational research, enabling discoveries that directly benefit patient care by returning clinically actionable genetic findings to participants and their healthcare providers. With the implementation of broad consent process and engagement with diverse populations, the CCPM biobank significantly accelerated the integration of genomics

into routine healthcare, enhancing research opportunities and personalized treatment approaches (Wiley et al., 2024).

Furthermore, digital biobanks facilitate the sharing of curated and standardized imaging data, clinical, pathological and molecular data, to enable the development of personalized data-driven diagnostic approaches and computational predictive models to foster innovative and personalized approach to disease management (Brancato et al., 2024).

### 1.3.8 Biobanking operations and sample collection

Establishing biobank collections presents challenges at several levels that defining the scope and mission, determining cohort profile and sample types, designing recruitment and sourcing strategies, managing the collection timeline, and aligning with the patient's standard of care journey. It is also necessary to determine the extent of data collection while ensuring the integrity of samples at all stages. Other considerations include logistics, sample processing and handling, defining governance structures and oversight responsibilities, clarifying provenance and ownership, establishing procedures for accessing samples and data and additionally, making decisions regarding upstream and downstream analysis, managing results, ensuring data security, identifying funding sources, and ensuring regulatory compliance.

Therefore, successfully establishing and maintaining a biorepository requires detailed planning, structured execution, adequate technical capabilities, optimal financial resources, stakeholder support, and flexible, resilient management to adapt to changing environments and needs (Naides, 2024).

To ensure the harmonization and quality of samples collected for multicenter prospective research studies, it is key to design specifications to avoid pre-analytical bias and ultimately contribute to the validity of the downstream analytical results. This requires a framework of biobanking processes and quality measures based on best practices with continuous monitoring of timestamps, traceability data throughout the sample and data lifecycle. Designing prospective multicenter projects requires accounting for multiple variables, including sample type and number, location and number of sites, location of analytical laboratories, pre-analytical variables, and sample derivatives.

To drive professionalism in biobanking it is key to incorporate quality considerations during the planning stage of the establishment of prospective collections to preserve the integrity of biomarkers and the validity of analytical results. This quality effort depends significantly on controlling pre-analytical variables. Hence, providing researchers with tools to clearly define

the project's scope and consider all required resources to systemically manage the design and execution, enhance procedural strategy and allows for centralized management of samples throughout their lifecycle while ensuring traceability and alignment with biobanking standards and best practices.

Additionally, a quality-driven framework involves standardizing sample collection and the preservation of derivatives through centralized preparation of consumables for sample collection, processing, and preservation; establishing evidence-based SOPs for sample processing and quality control; monitoring storage and transportation; ensuring traceability of biological samples through an electronic database that tracks all processes; and identifying materials and samples with unique standardized codes generated by the electronic database.

Quality Management System (QMS) models involve protocols, records, documents management, and risk management tools. QMS can be defined as a process-oriented approach adhering to the plan-do-check-act cycle, focusing on the quality of products or services and user satisfaction and the methods used to achieve them. Another example is ISO 20387:2018, which outlines general requirements for biobanking in biotechnology, including the quality considerations (Valdivieso-Gómez et al., 2021).

### 1.3.9 Toolkits in Biobanking and Research

Organizations develop "toolkits" to document interventions and facilitate the improvement of processes and the implementation of projects and initiatives, guide the implementation of best practices, aid in planning and setting up pilot projects into large-scale rollouts and monitor the maintenance of interventions over time. Toolkit models are variable and are composed of diverse tools and of different formats (Hempel et al., 2019). A "toolkit" is an action-oriented compilation of related information, resources, or tools that together can guide users to develop a plan or organize efforts to conform to evidence-based recommendations or meet evidence-based specific practice standards. A "tool" is an instrument like surveys, guidelines, or checklists that aid users to accomplish a specific task that contributes to meeting evidence-based recommendations or practice standards (Academy Health and Kleimann Communication Group, 2013; Ganz et al., 2018).

There is no consensus on the methodology of toolkit development and no standard guidelines to support design, application and assurance of the impact and value of such toolkits. A scoping review conducted in 2014 showed that toolkits do not specify the strategy and evidence base

to support their development methodology and effectiveness as a knowledge translation strategy (Barac et al., 2014; Hempel et al., 2019).

The Global Alliance for Genomics and Health (GA4GH) was launched in 2013 to promote effective genomic and health-related data exchange to accelerate genomic research and health impact, and in 2020 Gap analysis revealed the need to focus on technical standards, interoperability and alignment with external practices, active implementation of the standards, and a closer engagement with healthcare and clinical requirements. Thus, a matrix was proposed to define the needs, create a standard and policy framework and implement products to solve real-world problems. Key activities included championing driver projects, strategic partnerships to drive sustainability, organizational membership and buy-in from participant organizations, and the inclusion of individual contributors. A starter kit was developed to achieve the strategic refresh plan. The kit was characterized by accessibility, adaptability, and a modular and federated design. Apart from the starter kit, specific products were developed, including a consent toolkit to help researchers and clinicians draft informed consent forms, enhance participant enrolment, and support researchers to achieve consistency via six document templates that address different case scenarios that can be encountered to allow for accurate data sharing (“GA4GH Connect\_ 2022 Strategic Refresh.pdf - Google Drive,” n.d.; “GA4GH refreshes its strategic plan – GA4GH,” n.d.).

In the context of biobanking, a toolkit could be defined as a collection of adaptable documents to inform and facilitate the establishment of prospective biobank collection to standardize the collections, execute projects in timely and cost-effective manner, and increase the number of projects under review and facilitate the required funding and approvals (Maraganore et al., 2020; Thoele et al., 2020).

The use of tools in biobanking extend to meeting the rising need for accurate and reproducible disease trait phenotyping especially with the increased in the number of biobanks and genome-wide association studies (Nelissen et al., 2014).

Safe handling of data requires data infrastructure and databases, as well as integrated methods of sample tracking, data integrity, data security, and data management. Data transfer mediums are informed consent and Material/Date Transfer Agreements. The paper discussed the concept of a “newcomer starter pack” and training on sample management to ensure staff safety and well-being of staff members (Roux et al., 2021).

The collection of data and associated data in a systemic biobanking framework enables the development and application of scientific research and fosters collaborations at different levels. Some challenges identified in a systemic review of biobanks in Latin America were the lack of

consensus on biobank terminology, definition, quality-related regulations and laws, and informed consent design situation (Rivera-Alcántara et al., 2024).

Developing a biobank data dictionary is a collaborative process that requires engaging stakeholders to identify relevant core data elements that address research and healthcare priorities. Aligning with the FAIR principles (Findable, Accessible, Interoperable, Reusable) for data management and prioritizing sustainability, biobanks can increase their capacity to support translational research, foster collaborations, and contribute to the broader scientific ecosystem (Eklund et al., 2024; Kodra et al., 2018; Viktor et al., 2023).

Moreover, informed consent is an essential regulatory and ethical requirement to enable donors and patients to have autonomy in participating in biobank cohorts despite the lack of international consent or universal templates. Biobanks commonly rely on a broad consent model (Henderson et al., 2019b).

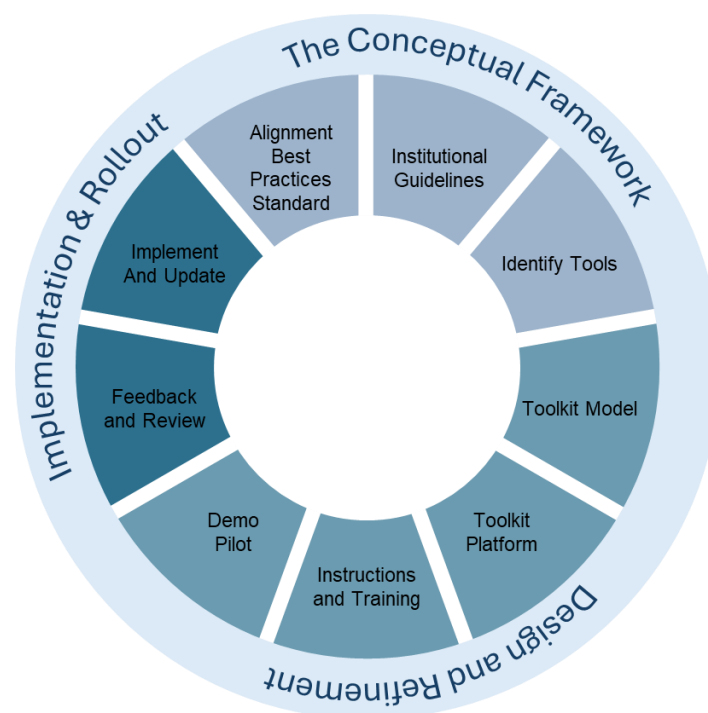
The production of a national harmonized template of informed consent form and patient information was co-developed by the Irish National Biobanking Working Group in collaboration with patient partners as a tool to ensure legislation compliance and promote the knowledge and awareness of biobanking in Ireland (O'Sullivan et al., 2021).

In a systemic review of academic literature on consent models, 207 consent models across the fields, with biobanking research and genetics and genomics research scoring the most mentions of the models in publications, highlighting the heterogeneity in biobanking consent models. The review defined the key consideration in developing consent models and tools to allow flexibility and customization with different applications. It revealed that consent toolkits can improve and simplify participant experience and aid in communication with donors, foster trust and transparency, facilitate data sharing, enhance patient autonomy and promote participation. Additional considerations must ensure the futureproofing of the consent toolkit, and continuous review and evaluation are necessary to maintain its effectiveness and impact. (Loosman and Nickel, 2022).

## 2. Methods

### 2.1 A Three-phase Approach

The study followed a structured, three-phase approach: Conceptual Framework, Design and Development, and Rollout and Refinement, to create and implement a toolkit for project management, business planning, and standardization of documents for biobank sample collection (Figure 3).



*Figure 3 Toolkit Development Methodology*

#### 2.1.1 Phase 1: Conceptual Framework

- **Institutional Guidelines and Best Practices Alignment:** International and institutional guidelines, such as ISBER Best Practices, Fifth Edition: A New Process for Relevance in an Evolving Landscape, published by International Society for Biological and Environmental Repositories (Snapes et al., 2023) were reviewed to establish a reliable basis for the toolkit. To ensure the toolkit aligned with standardized protocols the ISO 20387:2018, was also analysed (ISO 20387:2018, 2020)

- **Tool Identification:** This involved a comprehensive literature review to identify existing tools and processes to recognise gaps and unmet needs. Detailed information on the criteria of the search strategies can be found in the results section.

### 2.1.2 Phase 2: Design and Development

- **Toolkit Model:** Core components of the toolkit, checklists, forms and thematic tools, were defined based on the needs assessment. The model incorporated tools and templates that address the toolkit framework domains, including business planning, project management standardised processes, workflows, and institutional documents to meet the researcher's (end-users) needs. Initial meetings with the internal prospective collection study lead, including clinical and academic principal investigators contemplating the establishment of prospective repositories, the discussions involved members from multidisciplinary members, including the biobank team, research assistants, and study project managers. In addition to representatives from research administration, other core facility leads, concerned team members from the medical laboratory and pathology department, medical records and information security and data governance representatives. The meetings were productive in understanding the requirements and expectations to plan the process better once the central biobank moves to the operational phase in March 2025. The proposed collections focused on clinical areas, including Woman's Health, Type 2 Diabetes, Genomic Studies and Kidney Transplant cohorts. The meetings and discussions resulted in the overall framework for the prospective collection establishment requirements adhering to the conceptual framework of biobanking best practices and policies.
- **Toolkit Format:** The toolkit was developed in two formats, a primary exchangeable file in Excel and Power Point Format published in MS teams and accessible to investigators at the initiation phase of the project, please refer to Annex 3 for more details. The secondary format is a digital Single Source of Truth platform in the form of a customisable Microsoft SharePoint Biobank Project Onboarding Site.

### 2.1.3 Phase 3: Rollout and Refinement (Future directions)

- **Focus Group:** A structured method to collect detailed qualitative data about the toolkit design, model and format and gain an in-depth understanding about the alignment of

the toolkit with the end-users. Focus groups will allow for interaction among focus groups participants to generate recommendations to refine and review the toolkit.

- **Training Materials:** Role-specific training modules will be developed to ensure proper implementation and adherence to protocols.
- **Pilot Testing:** The toolkit will be piloted in a biobank setting to test its functionality, comprehensiveness, and impact on efficiency and standardisation.

## 2.2 Case Studies

This section explores case studies comparable with biobank projects to identify best practices and common drawbacks. The focus was on approaches used specifically for project management and business planning. The selection of the case studies was based on the following criteria:

1. Thematic alignment with specific toolkit related themes including project management, business planning, standardizations, and sustainability.
2. Relevance of the case to propose solutions to overcome challenges in relevant approaches to inform the design and development of the toolkit.
3. Adaptability to provide comprehensive insights to approaches that can be adopted to biobanking context, especially in a prospective collection centralized biobanking model.

### 2.2.1 The Rare Paediatric Eye Cancer (R-PEC) Biobank

The Rare Paediatric Eye Cancer (R-PEC) Biobank, hosted at The Hospital for Sick Children (SickKids) (Toronto, Canada), was created to address the challenges of studying rare paediatric eye cancers. Its success relies on a comprehensive business plan and a structured project management approach. The business planning methodology focused on developing the strategic framework, highlighted with the mission and vision to support global research and improve patient outcomes by collecting high-quality biospecimens and data, adopting patient-centered governance model with internal and external oversight to ensure transparency and inclusivity. Embedding financial sustainability by calculating projections and implementing cost-recovery strategies secured long-term viability and the development of a comprehensive implementation plan that included a phased execution methodology, with marketing, and risk mitigation strategies. Moreover, the biobank establishment process adopted efficient and systemic project management strategy aligned with the biospecimen lifecycle phases, with activities to incorporate the recruitment and consent of donors, collection of biospecimen and data, utilizing secure centralized storage, and regulated resource sharing. A significant focus of

the project plan was to incorporate strategies to engage and manage multiple committees involved in operations, patient advocacy, and resource access, with external advisors ensuring ethical and scientific requirements, with patient engagement and integration into governance and decision-making activities played a major role in enhancing trust and the research quality. The robustness of the protocol of establishing the biobank was supported by continuous improvement with regular reviews to refine processes and adapt to stakeholder needs.

The establishment of the Rare Paediatric Eye Cancer (R-PEC) Biobank portrays a systematic and structured approach to achieve a sustainable model for rare disease research, enabling impactful global collaborations while prioritizing patient trust and engagement (Argento, 2024; Dimaras, 2023; Flegg et al., 2024).

### 2.2.2 German Biobank Node: Start-up Biobanks Starter Kit

The German Biobank Alliance (GBA) integrates and connects 36 biobanks in Germany. The GBA supports emerging biobanks through its “Starter Kit” developed in the German language accessible online for registered users. The purpose of the kit is to help and guide “young” biobanks in the phase of planning or early stages of establishment with tools from subject matter experts involved in the kit development. The ‘Starter Kit’ was developed to ensure the quality of samples and promote interdisciplinary research and to overcome the complexity of biobanking. The complexity stems from the challenges in collecting biospecimens and data, and the uniqueness and non-replicability of the biospecimens. The ‘Starter Kit’ ensures meeting the high-quality parameters and the ability to integrate multiple entities and collaborate with multidisciplinary teams and specialities including clinicians, pathologists, IT specialists, and biobank managers and personnel.

The scope of the ‘Starter Kit’ is to address functional structures in biobanks, biobank basics, and requirements for setting up a repository in a structured, and modular framework composed of information, guidelines, checklists, documents, and links to other resources. In addition, there is a series of webinars relevant to key biobanking aspects covering:

- Organisation and governance
- Finance
- Human resources
- ELSI
- Laboratory
- Repository
- IT
- Quality management
- Study and project management
- Further education and training
- Communications and public relations

Thus the ‘Starter Kit’ is a tool to attain long-term sustainability by incorporating financial models, offering guidance and best practices to adhere to strict scientific, technical, ethical and legal standards to maximise biobanks’ scientific and societal value (“German Biobank Node: Starter kit for start-up biobanks,” 2023; “German Biobank Node: Starter kit for start-up biobanks,” 2023).

### 2.2.3 The FinnGen project

The FinnGen project is a large-scale public-private partnership combining genomic and longitudinal health registry data based on samples and data collected by a nationwide network of Finnish biobanks with a total of 500,000 biobank participants. The key features of the project are the collaborative partnerships and the collective benefit to promote and impact healthcare delivery at a national and global level. To support the analysis, interpretation, and discovery of this data, the FinnGen Analyst Handbook was developed as a centralized resource for researchers, clinicians, and analysts. The FinnGen project successfully streamlined the management of the Analyst Handbook and resources, enabling its multidisciplinary team to maximize the potential of genome and digital health data. This case exemplifies how leveraging on SharePoint can be used to enhance the organization, accessibility, and security of complex biobank projects (Kurki et al., 2023; Niemi, 2022).

## 3. Results

The toolkit's conceptual framework was developed to encompass:

- 1) Standards and best practices covering ISBER best practices and ISO 20387:2018 biobanking standards
- 2) Alignment with organisational plans including biobank policies, SOPs and business plan as a tool to implement the prospective collection's strategic objective as related to the biobank's organisational plans and strategies
- 3) Toolkit components that will collectively incorporate business planning tools, project management tools, and standardised organisational tools that reflect the organisational plan, under the umbrella of international standards and best practices (Figure 4).



*Figure 4 The Toolkit's Conceptual Framework*

### 3.1 Institutional Guidelines and Best Practices Alignment

Business planning is key for the success of biobanks/repositories. The toolkit's framework plan provides a framework for setting cores goals, address and meet stakeholders' needs, design biospecimen collection methods, define the repository services, financial strategies for cost recovery, maintain operations and ensure sustainability.

A review of ISBER Best Practices Fifth Edition was conducted to identify the key considerations in establishing biobanks as it relates to the prospective biobank collection model in a centralized academic biobanking infrastructure setting. The ISBER standard review focused on the concept of repository lifespan versus biospecimen lifecycle. Repository phases or lifespan describe all activities from conception to closure aligned with five stages of initiation, planning, execution, monitoring, and closure regardless on the type or classification of the biobank while a biospecimen lifecycle covers all the activities associated with the collection, storage, distribution, and disposal of biospecimens and their associated data. Central biobanks involved in multiple and multidisciplinary collections or cohorts rely on ‘Project associated collections’, thus are project driven in nature and should be able to periodically review the phase they are operating at, plan activities, adopt governance, business plans and operations to meet the needs of each project at different project maturity stages.

The ISO 20387:2018 standards and best practices underpin the quality in biobanking at all levels in and all the key areas of biobanking, ensuring that biospecimens and data are fit for purpose and that research findings are reproducible. The ISO 20387:2018 focuses on the technical and quality requirements to drive competency, impartiality and consistency in biobank operations. It provides harmonized guidelines to standardize the collection, management, storage, retrieval and distribution of biospecimens and data, with overarching competency adhering to Ethical, Legal, and Societal Issues (ELSI). The standards and guidelines are reflected in the biobank governance, facilities and infrastructure, quality management systems and approaches, communication and marketing strategies, financial management and risk management systems in a harmonized scientifically and technically sound approach. Furthermore, the “ISO/TR 22758:2020 Implementation Guide for ISO 20387” references ISBER Best Practices, indicating a deliberate effort to harmonize the standard with established best practices in biobanking. The use of assessment tools and implementation guides that reference both ISO 20387 and ISBER Best Practice further supports this alignment for the use in the current project (Allocca et al., 2020; ISO, 2020, 2018; Snapes et al., 2023).

## 3.2 Tool Identification

### 3.2.1 Literature Search

A thematic literature search focused on the conceptual framework components to validate the frames and themes that impact the selection of the toolkit tools and components, the design and format to determine the use and implementation practical considerations.

The objectives of the literature search were to:

- Identify the benefits and constraints of toolkit utilisation in biobank settings
- Define the operational efficiency parameters for sustainable biobanking
- Compare literature on business planning, project management, and standardisation's role in operational efficiency, quality, and sustainability.

To maximise the value of the search, no limits were placed on the study design, the language was English, the search results range was 2012 to 2024. The identification process aimed to include studies that met the search criteria and were relevant to the subject area.

- A. Toolkits
- B. Business Planning
- C. Project Management

The thematic search identified a diverse set of publications. The key themes that emerged included:

- To identify relevant toolkits that could inform the design of a thesis toolkit for biobanking, the keywords "biobank" and "toolkit" were searched across all fields in academic databases to maximise the breadth of results. The search yielded 33 results. The toolkits focusing on genomics, software development, and machine learning were excluded to narrow the scope to those more relevant to biobank operations and management. Following this filtration, six toolkits were selected based on their alignment with the goals of structured data collection, quality improvement, and ethical compliance in biobanking.

Even though the identified toolkits do not directly match the proposed thesis derived toolkit concept, the selected results provided valuable insights into frameworks and methodologies for toolkit development. Particularly, the reported prevalence of toolkits in biobanking and their emphasis on structured data collection, quality assurance, and compliance with international standards was instrumental in shaping conceptual

frameworks that align with organisational guidelines and international biobanking standards.

- The keyword search on "Biobank\* and Business Plan" identified 11 studies, all included in the review. These studies collectively emphasise the critical role of business planning in biobanking operational success and long-term sustainability of biobanks. The research highlights that biobanks with well-developed business plans demonstrate more professional structures, better resource utilisation, and enhanced stakeholder engagement, supporting both internal and external projects. Key factors discussed include financial sustainability, cost-recovery models, stakeholder alignment, and innovative approaches to maximize biospecimen utilisation. The studies underscore that comprehensive business strategies are essential for addressing challenges such as limited funding, low utilisation rates, and economic instability, thereby ensuring biobanking infrastructures' continued value and functionality.
- The keyword search on "Biobank and Project Management" identified 11 studies, all emphasising project management's critical role in ensuring operational efficiency, sustainability, and long-term success. The studies highlighted that structured project management frameworks are essential for maintaining high-quality biospecimens, refining resource allocation, and coordinating stakeholder engagement and that effective project management integrates ethical, technical, and operational standards to support biospecimen collection, data management, and compliance with quality guidelines.

### 3.2.2 Case Studies Review

The case studies illustrated approaches and solutions employed in biobank development and management to overcome challenges and achieve sustainability. The findings from the three case studies are summarized below:

The R-PEC Biobank addressed the critical need for studying rare paediatric eye cancers through a structured business plan and integrated project management. Key deliverables of this approach included establishing a robust governance structure, incorporating patient-centred decision-making and operational transparency, ensuring financial sustainability through detailed projections and cost-recovery models, and enhancing international collaboration to achieve accrual targets for rare conditions. The proposed model also included periodic review

and adaptation of operational models to meet stakeholder needs. This case demonstrated how strategic planning and stakeholder engagement can create a sustainable centralized biobank.

The German Biobank Alliance Starter Kit provided a structured, modular framework for guiding biobank establishment. Key elements included comprehensive resources such as guidelines, checklists, and training modules addressing key aspects of biobanking related to governance, ethical, legal, and social implications as well as quality management. The case highlights the role of incorporating inbuilt training tools to ensure interdisciplinary collaboration within a standardized starter kit is a resource to facilitate the onboarding process for developing and integrating emerging biobanks.

The FinnGen Project portrayed a large-scale biobank integration using a centralized platform that ensures access to the FinnGen Analyst Handbook as an efficient tool for data management and role-specific customization. SharePoint enhances resource accessibility, security, and collaboration. The project showcased how digital tools can streamline biobank operations and facilitate multidisciplinary teamwork.

In summary, the case review highlighted the importance of systemic frameworks to address the challenges and complexity of biobank establishment and sustainability. Each case demonstrates the significant role of structured approaches, interdisciplinary collaboration, and flexible tools in achieving long-term success. These insights contribute to developing a comprehensive toolkit for biobanking in integrated academic health settings.

The current proposed biobank project management toolkit combines business planning, project management, and operational guidelines into a cohesive framework. Key features include:

- Adaptable and customizable tools collected in a toolkit manual to facilitate the initiation and planning of prospective collections.
- Integrating biobank phases, from initiation to downstream research, ensures a lifecycle approach.
- Centralized SharePoint access for templates, SOPs, and project documentation.
- A focus on communication, dynamic updates, and secure access to protect data and enhance collaboration.

The toolkit standardizes and optimizes prospective biobank collection's onboarding processes while maintaining compliance and stakeholder engagement.

### 3.3 Toolkit Model and Format

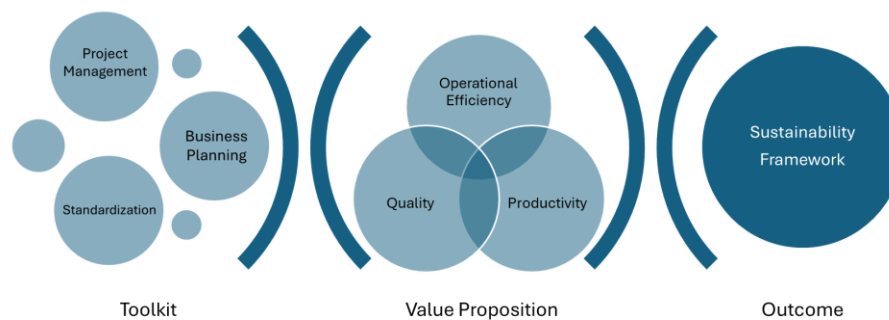
Toolkit Components included

- Business plan
- Project management
- Other operational and standards tools

The proposed toolkit framework and value proposition emphasizes the toolkit’s structural elements, core values and outcome. The key elements include:

1. Project Management tool to ensure a structured planning and implementation, a systemic approach to communication and oversight.
2. Business planning tools used to guide the strategic and operational governance and ensure compliance with standards and guidelines at an organizational level and a broader international scope.
3. Standardization to drive uniformity and consistency in the process management using biobank tools derived from the central biobank policies, SOPs, forms and checklists.

The key elements allow the intersections with the core objective to enhance operational efficiency while balancing quality standard compliance, enhancing productivity, and optimising outputs (Figure 5).

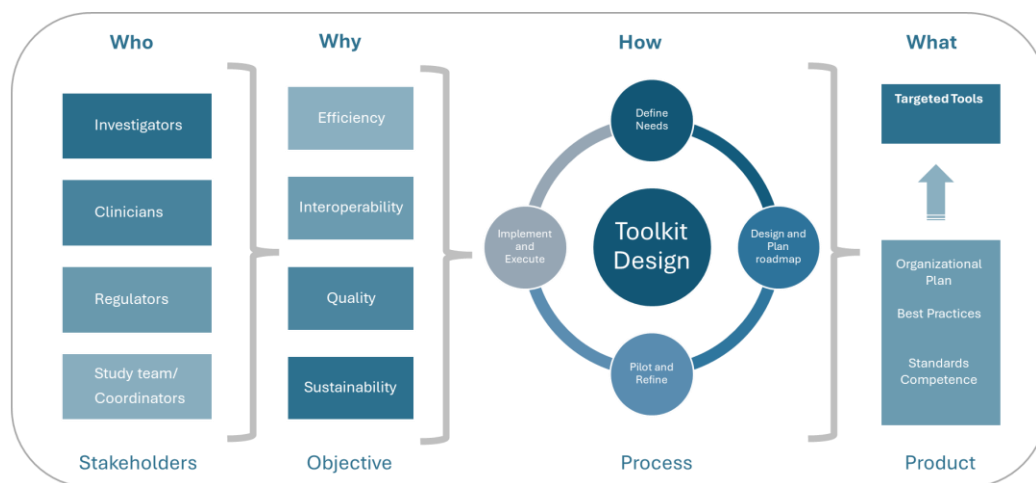


*Figure 5 Toolkit Proposed Framework Scope and Purpose*

To develop the toolkit, the following design strategy was adopted (Figure 6):

1. Who? Identifying the key stakeholders for the toolkit

2. Why? Determining the objectives of the toolkit
3. How? Designing the methodology, using a Plan-Do-Check-Act Cycle to assess the needs, design the roadmap, test the toolkit, refine it and then move to implementation.
4. What? Determining the toolkit's conceptual framework to align with organizational plans, best practices standards and competencies to vet the targeted tools to be relevant, current, evidence-based, easy to understand, easy to use, adaptable, and supporting the organization.



*Figure 6 - Toolkit Design Strategy*

Microsoft SharePoint was the designated digital platform to host the toolkit and upload the document and resources library to support researchers in complying with institutional and international requirements in establishing prospective collections in a structured and systemic framework. SharePoint provides a fully customisable site architecture to enable collaboration, project management, and real-time access to information. Successful SharePoint implementations were explored, including the Memorial Sloan Kettering Biofluids Division, which streamlines IRB processes, and the UK Biobank, using SharePoint to facilitate data requests. Additionally SharePoint's is also applicable in academic biobank settings, for example the University of Groningen's Cohort and Biobank Coordination Hub is comprehensive SharePoint resource platform for biobank-related services and updates.

The key methodological objectives of the proposed toolkit and platform project were to create a structured site architecture that integrates business planning, project management, and document standardisation while enhancing accessibility and data integrity. Therefore, it was essential to incorporate the development of the basic SharePoint site, customised with features such as document libraries, user access management, and collaboration tools. Initial feedback and insights gathered from this phase will guide future platform iterations.

The proposed site integrates features such as a document repository for SOPs, toolkits, and training materials. To facilitate seamless coordination and real time progress track the project management tools, including a project tracker, issue tracker, budget tracker, and Gantt chart, are incorporated into the project management page. To foster engagement and knowledge sharing the resource page and navigation pane will include links to training resources and a bulletin board will also provide researchers with access to educational resources and updates on key milestones, with additional features of automated workflows, such as alerts or reminders, ensure effective stakeholder communication (Figure 7).

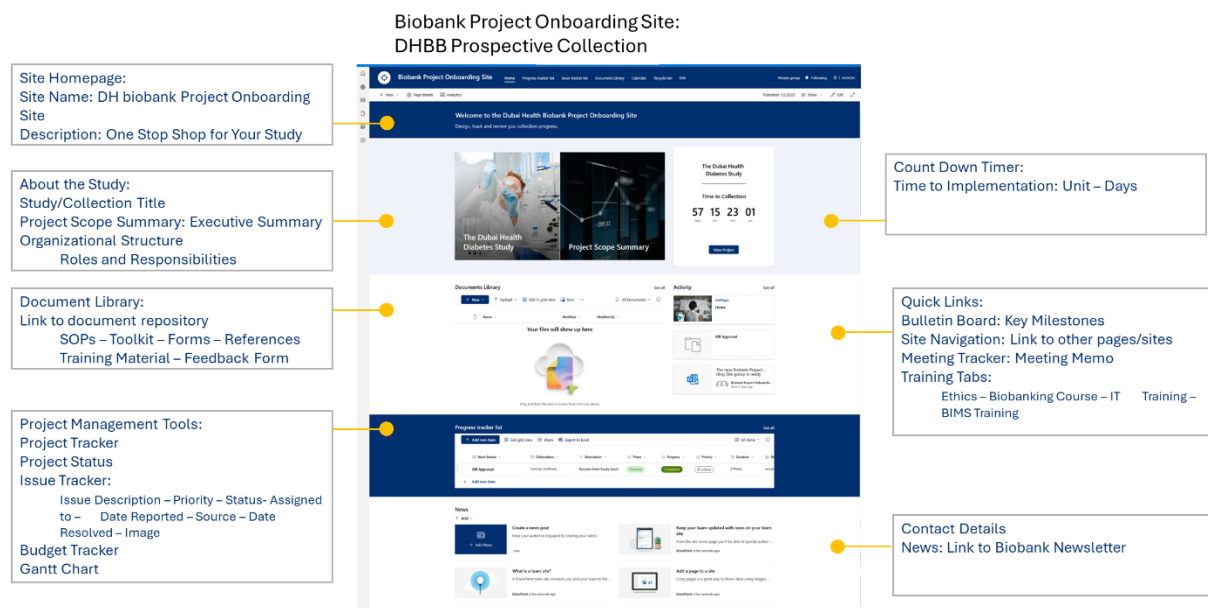


Figure 7 - Overview of the Biobank Project Onboarding Site

**Figure 7:** Overview of the Biobank Project Onboarding Site: This figure demonstrates the user-friendly layout and key functionalities of the SharePoint platform, including project tracking, resource navigation, and centralised document access. The platform's design aligns with institutional goals to enhance operational efficiency and ensure compliance with biobanking standards.

Developing a toolkit involves bringing together information from diverse sources as well as ideas from stakeholders and end-users to cater for a diverse range of collections and studies. In the current project, setting the informal feedback from researchers on potential studies and collections was a key driver to exploring the different strategies involved in managing the establishment of prospective collections and to adapt to requirements of large-scale and efficient operations to provide valuable bioresources for research aligned with biobanking protocols designed to standardize specimen collection, processing, management, and quality control.

Thus, the framework and design of the toolkits were based on a review of best practices, case studies, online biobank profiles and business model reviews to provide real-world examples and derive insights to enhance the toolkit's relevance and usability ([Figure 8](#)).

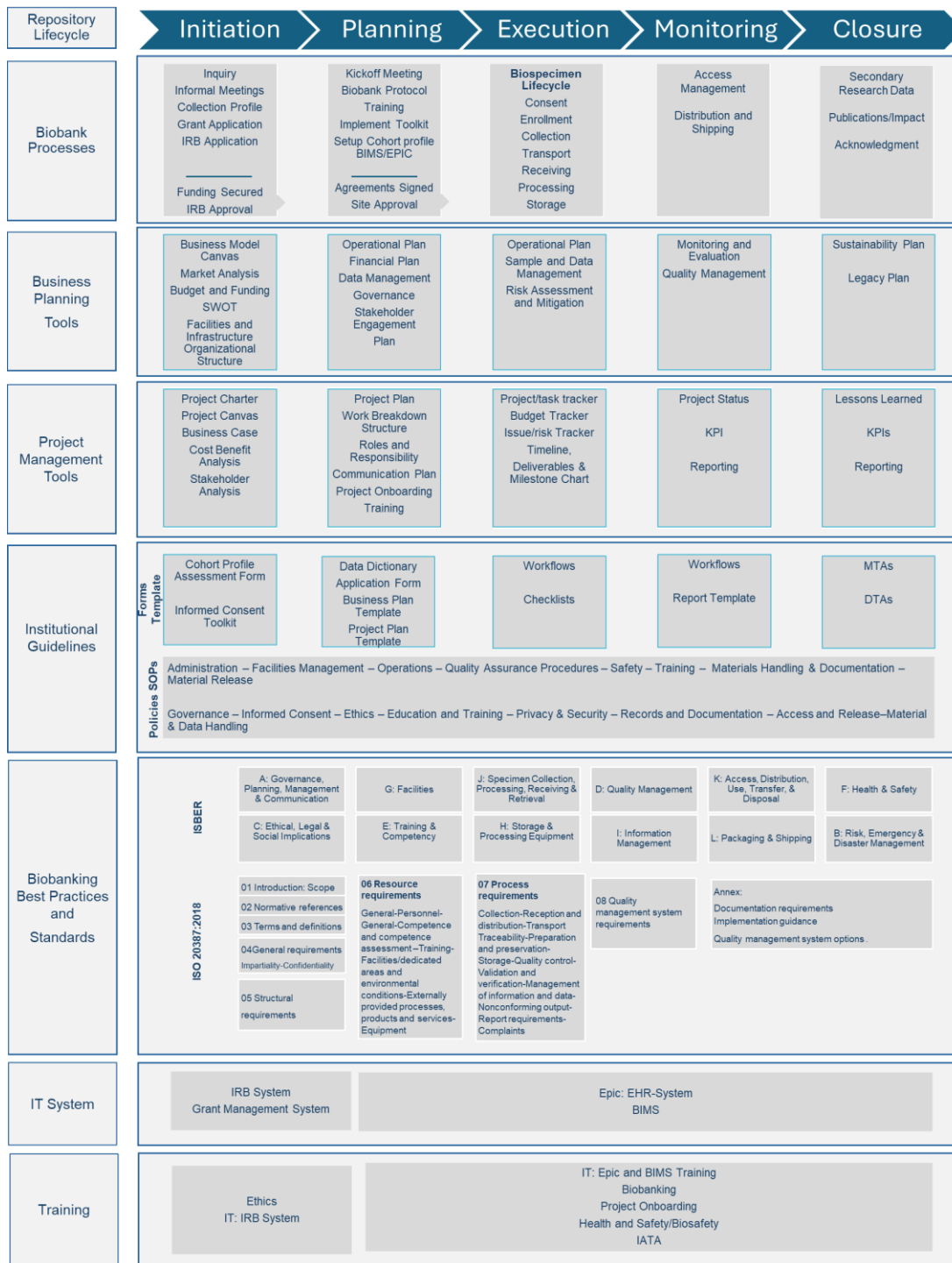


Figure 8 - Toolkit Framework and Outline

The framework and outline for the biobank project onboarding toolkit, structured across the lifecycle of repository management: Initiation, Planning, Execution, Monitoring, and Closure. It integrates core elements such as biobank processes, business planning, project management tools, institutional guidelines, best practices, IT systems, and training. The design plan is intended to determine the main components of the toolkit across the repository lifecycle and

incorporates the detailed biospecimen lifecycle processes that encompass consent, enrolment, collection, transport, and storage as part of the post-design and implementation phase.

Figure 8 explains the integration of the toolkit components across the biobank's operational, regulatory and process workflows; the key highlights are:

### **1. Biobank Processes**

- Define activities like inquiry, grant applications, and IRB approval during initiation.
- Monitoring access management and closure through secondary data and acknowledgment practices.

### **2. Business Planning Tools**

- Incorporate frameworks like Project Canvas, SWOT analysis, and financial planning during early phases.
- Risk assessment, sustainability plans, and legacy documentation are emphasized during later stages.
- Outlines the key structural components of developing a business plan

### **3. Project Management Tools**

- Utilise project charters, work breakdown structures, trackers, and lessons learned documentation to streamline workflows and plan and execute the project.
- Offer a collection of templates and systematic methodologies to manage scope, risk, and evaluation metrics.

### **4. Institutional Guidelines**

- Source of cohort profile assessment forms, SOPs, policies, and tools for data collection, informed consent, and compliance.
- Include institutional workflows and templates for efficient operations.

### **5. Biobanking Best Practices and Standards**

- Anchored on ISO 20387/2018 standards covering governance, facilities, biospecimen processing, quality, and health safety.

- Focus on resource and process management, risk assessment, and quality control measures.

## **6. IT Systems**

- Highlight the role of specialized IT tools for IRB systems, grant management, electronic health records (EHR), and Biobank Information Management Systems (BIMS).
- Emphasizes IT training for operational support and efficiency.

## **7. Training**

- Structured training across ethics, project onboarding, biosafety, and IT systems to ensure competency in biobanking practices.

This framework emphasizes that integrating of systematic planning of project and business management, compliance with international and operational standards are key to support biobank project onboarding, ensuring quality, sustainability, efficiency and effective biospecimen management.

### **3.4 Toolkit Content**

The toolkit was developed to support researchers in their journey to establish a prospective biobank collection hosted in the centralised biobank, The PowerPoint-based toolkit is an extensive library of ready-to-use practical tools for project management and business planning in a framework aligned with the ISBER and ISO 20387 best practices and standards. The design is in a flexible format composed of frameworks, tools, checklists, and templates to be utilised during different project stages to navigate the complexity of biobanking projects, make informed decisions, and drive the collections' strategic objectives forward. At the initiation phase, the toolkit is helpful to engage with researchers and the study team to aid with the discussions and provide practical support to outline issues important for the process and to have an efficient and productive complete picture of the next steps. The slide deck comprises 43 slides and starts with an introduction and an overview of the toolkit's content, value and objectives, followed by the tools for each project phase. The toolkit contains a list of tools, including project canvas, project plan template, Gantt Chart, Budget trackers, issue and risk tracker table, timeline, status reports template and other tools (see Annex 3).

The slide deck targets the investigators and the research teams, including principal investigators, co-investigators, project managers, research managers, research coordinators, research assistants, the biobank team and people who influence the off-site operations. The toolkit is a reference guide to codevelop the planning, documentation and workflows. A key feature of it is that each tool can be used separately to tackle or focus on a specific task or deliverable. The other utility of the kit is to build workshops and educational and training resources based on end-users' feedback and work in collaboration with the project management office and learning and development team at the institutional level. Furthermore, the toolkit is the basis for the design methodology of the single source of truth MicroSoft SharePoint project onboarding site (Figure 9). The platform facilitates team communication and collaboration among multidisciplinary teams, seamless sharing of updates and progress, scalability at different stages of the repository maturation. In addition, to incorporating project management tools for task management, and the ability to meet the specific needs of the project and each prospective collection by creating dedicated libraries, metadata, and tagging for easy retrieval, as well as building automated workflows for document approvals and milestone tracking.

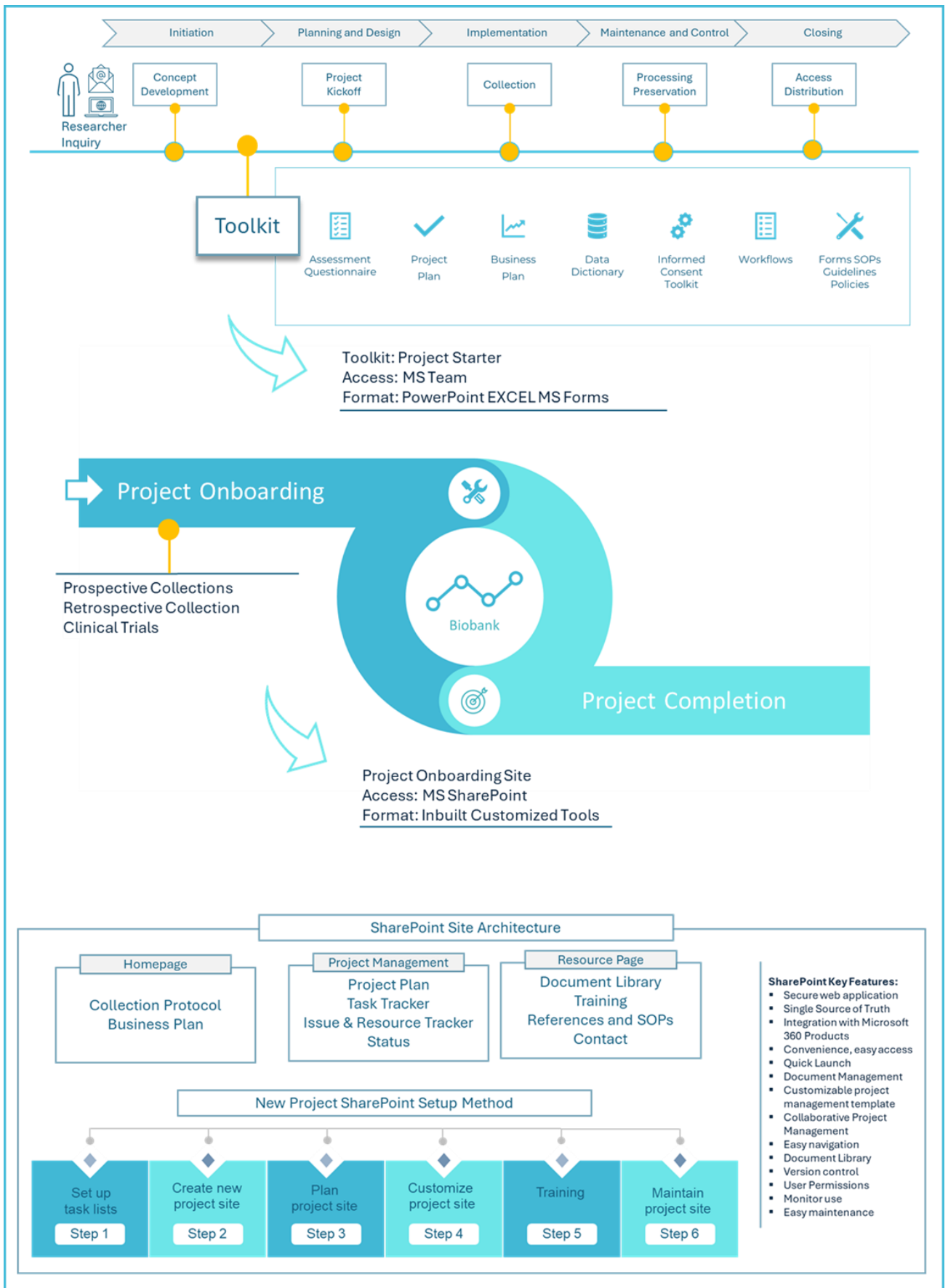


Figure 9 - Biobank Project Onboarding Process, Toolkit and SharePoint Setup

## 4. Discussion

Biobanks are considered crucial tools for the purpose of advancing medical research through their role in providing high-quality biological specimens and associated data. However, biobanking is a heterogeneous and project-driven environment, with complex operational requirements, including compliance to regulatory and ethical guidelines, local and international standards, administrative challenges and the coordination between multidisciplinary teams. This often presents significant difficulties that require structured and systemic approach beyond the traditional methods that depend on using disparate tools for documentation, communication, and project tracking and can lead to inefficiencies, duplication of effort, and ineffective communication. These challenges adversely impact biobank productivity, delay project completion timeframes, and risk compliance with biobanking best practices (Rudan et al., 2011; Somiari and Somiari, 2015).

To address these challenges, this project aimed to develop a comprehensive and practical toolkit to capture project management, business planning, and document standardization tools for operational efficiency to achieve targets and impact the quality and sustainability in a prospective and project-driven biobank environment for Dubai Health Biobank.

Biobanks play a critical role in advancing biomedical research by ensuring the availability of quality biospecimens in quantities that are of research value. This complex and dynamic nature of biobanking poses challenges to sustainable biobanking. Biobanks are multidisciplinary environments that balance both societal and research expectations. Sustainability is challenged by technical, logistical, ethical, legal, and privacy-related issues and a growing demand for quality, FAIR adaptability, transparency, and accountability (Van Der Stijl et al., 2019).

The development of a toolkit to facilitate operating project management, business planning, and documents standardization tools of the biobank is particularly relevant in modern biobank operations, where scalability, data integrity, and adaptability are critical. The conceptual framework developed in this research serves as a foundational step toward implementing an innovative, technology-driven solution to streamline biobank project onboarding and management. The findings will inform subsequent platform development phases and contribute to the broader discourse on leveraging technology to enhance biobank sustainability and research impact.

Key to the success of biobanks is the strict adherence to quality and security standards with overarching governance, ethical, legal and societal laws and regulations to promote the sustainability of the biobank resources and reap the long-term utilization of biobanking outputs. In the Dutch model to create an environment for sustainable biobanking in the Netherlands, nine themes are identified and stratified against eight stakeholder groups that play a central role in putting the derived recommendations into practice. The themes are collaboration at a national level, funding collections, biobanks and utilization, incentivising use and reuse, harmonized and standardised procedures and applications, quality and reproducibility of data and samples, linkages, findability of biospecimen and data, reputation and image, and public-private partnerships. The key stakeholders identified include biobanks, private/commercial companies, funders, network organizations, patient organizations, policymakers and regulators, researchers, and research institutions (Van Der Stijl et al., 2019). Ensuring adherence to such frameworks and sustainability-driven strategies in the initiation and planning phase of establishing biobank collection will address the challenges, drivers and constraints to sustainability with the use of business planning tools, project management, and standardization toolkit will address risks at the social, operational, and financial areas of sustainability.

Parry-Jones et al. (2017) promote the concept that establishing a biobank should be treated as a project with five distinct phases, starting with initiation, followed by planning, execution, monitoring and controlling, and finally, closing. The phases are integrated with the biobank operations and process management. Such perspective allows the incorporation of risk management processes in the planning stage to reduce the initial high-risk level to a predefined acceptable level (Parry-Jones et al., 2017). This lifecycle approach aligns with the ISBER and reflects project management standards per the Project Management Body of Knowledge (PMBOK) (Araza, 2017). A publication in 2015 described that Quality and Project Management (PM) principles are ignored in non-regulated scientific research despite their wide application in industrial and business sectors as means of enhancing efficiency, achieving results and reducing costs; this gap in the application of PM inspired a network of Italian National Research Council institutes to implement a project management lead to enhanced time management, project standardization, and generate impactful research. The adopted tool combined quality management, project management and teamwork methods to disseminate a model of Total Quality Management (Bongiovanni et al., 2015). The impact of the adopted model lead to fast and efficient management of projects through the utilization of a toolkit comprising of tools for brainstorming, constraints and preferences analysis, decision matrix,

debriefing, meeting minutes, project charter, Gantt chart, project charter, Plan–do–check–act (PDCA) cycles, failure mode and effect analysis (FMEA), and a risk analysis tool, in addition to other tools to support project design, and statistical analysis (Bongiovanni et al., 2015).

Part of a series on sustainable biobanking published in 2019 (Van Der Stijl et al., 2019) , aimed to maximise the use of biobanking resources for health research by offering recommendations, good practices, and practical business tools to promote biobank sustainability encompassing the capacity for biobank infrastructures to remain operative, effective and competitive over its lifetime. The interlinked relation between financial, social and operational considerations is the overarching framework of sustainability to balance the heterogeneity and diversity in biobanking and the shared value model to accelerate research and impact care delivery and results. The report included a review of 22 Biobank Case Studies and identified five dimensions of good practices including: 1) A business model dimension to cover a cost recovery, core facility, project-based, service-based, donation-based, contract research, strategic partnerships and collection-on-demand model. It was deemed that the collection-on-demand model is most viable, although it cannot apply to all types of studies or collections. 2) Stakeholder identification, analysis and engagement are key to addressing their needs and availing their buy in to communicate the biobanking value; this dimension is also strongly linked with the marketing and communications strategies needed to promote the biobank’s visibility by capturing its unique selling points, value and impact. Stakeholder engagement can ultimately foster partnerships and commercial collaborations. 3) Funding and financial planning must start in the repository lifecycle planning phases, consolidate a cost calculation system to better design the services offered and the cost recovery strategies in alignment with the end user profile, in addition in supporting prospective researchers in the grant application and budgeting for either establishing a repository or as end user to access biospecimen and data for secondary research and downstream analysis. The cost dimension is closely related to funding and financial planning; a transparent system should be in place to capture all cost elements and develop annual financial reports. For sustainability in this dimension the report recommends costs effective strategies such as leveraging on existing sample collection pathways in the clinical side, consolidating and centralising biospecimen collection efforts to achieve economy of scale, an on-demand model of collection, in addition inventory management, just-in time procurement and logistical and operational efficiency. 5) Business tools: The report delineates the key business tools to support sustainability strategies, which include having a business plan to articulate the scope and future vision and objectives, thus setting a strategic roadmap to determine the operational strategies and risk planning to overcome challenges, a solid business

plan is also dependent on internal and external stakeholder engagement. An important feature of the business plan is its dynamic nature, where it is reviewed and updated on a six-monthly or annual basis, and the timing is key, starting early in the project initiation and planning phase. Other tools in the business plan include using a SWOT analysis – or Strengths, Weaknesses, Opportunities, and Threats analysis for strategy development, in addition to a marketing plan, risk management and business improvement processes. The proposed toolkit is aligned with the proposed sustainability consideration and is enhanced by incorporating project management tools and aligning with institutional standards and best practices. The current project assessed the feasibility of using Microsoft SharePoint as a "Single Source of Truth" platform for biobank project management. SharePoint's robust document management, real-time collaboration, and customizable workflow capabilities offer a unique opportunity to create a centralized hub for project planning, execution, and tracking (C D Waghmare, 2023; Charles David Waghmare, 2023)

The toolkit benefit examples include: 1) data collection tools that capture data more stringently from field or collaborator collection events; 2) workflow curation tools to ensure each process occurs in the same way every time, regardless of how much time has passed since the last event needing that workflow; 3) data quality audit practices; 4) data visualization tools to manage capital assets such as freezers; and 5) a tool to conduct physical position audits in a rapid manner. Combined, these tools and associated approaches have significantly reduced data entry errors, accelerated time-intensive data quality activities, and provided at-a-glance insights into the function and status of the biorepository. The general approach, as well as discrete benefits and reasons for the creation of five specific tools, will be discussed. Custom data tools such as these are currently saving the NIST Biorepository over 1,000 hours of staff time annually and highlight the necessity of a technical data manager in modern biorepositories. This presentation targets repository managers, data managers, and those interested in improving data quality practices and streamlining biorepository operations (Gramatiuk et al., 2022; Henderson et al., 2019; Van Der Stijl et al., 2019).

**The toolkit conceptual framework:** Developing a toolkit involves bringing together information from diverse sources as well as ideas from stakeholders and end-users to cater for collections and studies. In the current thesis setting the informal feedback from researcher on potential studies and collections was a key driver to explore the different strategies involved in managing the establishment of prospective collections and to adapt to requirements of large-scale and efficient operations to provide valuable bioresources for research aligned with biobanking

protocols designed to standardize specimen collection, processing, management, and quality control. Thus, the conceptual framework of the proposed toolkit was based on a review of best practices, case studies, online biobank profiles and business model review to provide-real world examples and derive insights to enhance the toolkit's relevance and usability.

## **Conclusion and outlook**

The thesis emphasis was on the development and design phase. The next stage and progression will involve focus group feedback, piloting the toolkit, evaluating, improving and updating the content and format after receiving feedback from end-users, and ultimately measuring its usefulness and impact by evaluating key KPI's and user metrics in considerable timeframe after utilization in ongoing projects with inbuilt reporting guidelines in the project site and furthermore, keeping abreast with the evolution of tool and technologies in biobanking and specifically comparing with similar toolkits in similar settings. A key area of recommendation is consolidating the review to produce research studies and scientific publication on the development and devaluation of the tools used in establishing biobank cohorts and to bridge the gap in literature on the development an impact of using single source of truth, MS SharePoint to incorporate business planning, project management and standardization components of biobank sustainability in alignment with sustainability models.

## 5. References

AcademyHealth and Kleimann Communication Group, I., 2013. Section 6: Toolkit Guidance Contents. AHRQ Knowledge Transfer and Applications Support., AcademyHealth and Kleimann Communication Group, Inc.

Akyüz, K., Chassang, G., Goisau, M., Kozera, Ł., Mezinska, S., Tzortzatou, O., Mayrhofer, M.T., 2021. Biobanking and risk assessment: a comprehensive typology of risks for an adaptive risk governance. *Life Sci Soc Policy*. <https://doi.org/10.1186/s40504-021-00117-7>

Allocca, C.M., Snapes, E., Albert, M., Bledsoe, M.J., Castelhana, M.G., De Wilde, M., Furuta, K., Kozlakidis, Z., Martin, D., Martins, A., McCall, S.J., Schacter, B., 2020. Biobanking in the COVID-19 Era and Beyond: Part 2. A Set of Tool Implementation Case Studies. *Biopreserv Biobank* 18. <https://doi.org/10.1089/bio.2020.0083>

Alves, A., Gibbon, A., Carvalho, S., Rodriguez-Justo, M., Miranda, E., 2022. Biobank and Pathology Facility: A Successful Combination. *Journal of Biomolecular Techniques* 33. <https://doi.org/10.7171/3fc1f5fe.a423c94f>

Annaratone, L., De Palma, G., Bonizzi, G., Sapino, A., Botti, G., Berrino, E., Mannelli, C., Arcella, P., Di Martino, S., Steffan, A., Daidone, M.G., Canzonieri, V., Parodi, B., Paradiso, A.V., Barberis, M., Marchiò, C., 2021. Basic principles of biobanking: from biological samples to precision medicine for patients. *Virchows Archiv*. <https://doi.org/10.1007/s00428-021-03151-0>

Araza, L.L., 2017. PMBOK: A Guide to the Project Management Body of Knowledge.

Argento, F., 2024. Patient Engagement in Biobanking – RB Canada Research [WWW Document]. URL <https://www.rbcnadaresearch.com/patient-engagement-in-biobanking/> (accessed 1.5.25).

Barac, R., Stein, S., Bruce, B., Barwick, M., 2014. Scoping review of toolkits as a knowledge translation strategy in health. *BMC Med Inform Decis Mak*. <https://doi.org/10.1186/s12911-014-0121-7>

Berisha-Shaqiri, A., Neziraj, E., 2024. The relationship between information technology, project planning, decision-making and competitive advantage. *International Journal of Business Excellence* 32. <https://doi.org/10.1504/IJBEX.2024.136888>

Bettio, V., Mazzucco, E., Aleni, C., Cracas, S., Rinaldi, C., Antona, A., Varalda, M., Venetucci, J., Ferrante, D., Rimedio, A., Capello, D., 2023. UPO Biobank: The Challenge of Integrating Biobanking into the Academic Environment to Support Translational Research. *J Pers Med* 13. <https://doi.org/10.3390/jpm13060911>

Biobanking Market Size to Hit Around USD 169.62 Bn by 2033 [WWW Document], 2024. . Web Page. URL <https://www.precedenceresearch.com/biobanking-market> (accessed 1.4.25).

Bledsoe, M.J., Watson, P.H., Hewitt, R.E., Catchpoole, D.R., Grizzle, W.E., 2019. Biobank: What's in a Name? *Biopreserv Biobank*. <https://doi.org/10.1089/bio.2019.29053.mjb>

Bongiovanni, A., Colotti, G., Liguori, G.L., Di Carlo, M., Digilio, F.A., Lacerra, G., Mascia, A., Cirafici, A.M., Barra, A., Lanati, A., Kisslinger, A., 2015. Applying Quality and Project Management methodologies in biomedical research laboratories: a public research network's case study. *Accreditation and Quality Assurance* 20. <https://doi.org/10.1007/s00769-015-1132-5>

Brancato, V., Esposito, G., Coppola, L., Cavaliere, C., Mirabelli, P., Scapicchio, C., Borgheresi, R., Neri, E., Salvatore, M., Aiello, M., 2024. Standardizing digital biobanks: integrating imaging, genomic, and clinical data for precision medicine. *J Transl Med*. <https://doi.org/10.1186/s12967-024-04891-8>

Caenazzo, L., Tozzo, P., 2020. The future of biobanking: What is next? *High Throughput*. <https://doi.org/10.3390/biotech9040023>

Chróścicka, A., Paluch, A., Kalaszczyńska, I., Szabłowska-Gadomska, I., 2022. Biobank Personnel — The Key to its Success. *ATLA Alternatives to Laboratory Animals*. <https://doi.org/10.1177/02611929221113976>

Coppola, L., Cianflone, A., Grimaldi, A.M., Incoronato, M., Bevilacqua, P., Messina, F., Baselice, S., Soricelli, A., Mirabelli, P., Salvatore, M., 2019. Biobanking in health care: Evolution and future directions. *J Transl Med*. <https://doi.org/10.1186/s12967-019-1922-3>

Dimaras, H., 2023. Development of a Biobank for Rare Pediatric Eye Cancers. Grant Award: W81XWH-22-1-0535. Annual Report. The Hospital For Sick Children. <https://apps.dtic.mil/sti/trecms/pdf/AD1210813.pdf>.

Domaradzki, J., Walkowiak, D., 2024. When Biobanks Meet Religion: Association Between Religiosity and Attitudes of Polish Medical Students Toward Biobanking of Human Biological Material for Research Purposes. *J Relig Health* 63. <https://doi.org/10.1007/s10943-023-01932-2>

Eklund, N., Pätsi, S.M., Lehtiniemi, H., Rohkimainen, S., Kivelä, J., Öhman, H., Sauramo, M., Sutinen, K., Keskinarkaus, A., Terho, P., Seppänen, T., Nyberg, P., Männikkö, M., Silander, K., 2024. Connecting cohorts of Finnish biobanks creates a research resource for the study of healthy ageing. *Scand J Public Health*. <https://doi.org/10.1177/14034948241228482>

Flegg, K., Noronha, R., Restevski, I., Mallipatna, A.C., O'Donoghue, S., Tarling, T., Watson, P., Dimaras, H., 2024. Governance and public trust: a case study of the rare-pediatric eye cancer biobank. *Canadian Journal of Ophthalmology*.

Fonseca, A.C., Afonso, Â., Félix Martin, M., Faria, C.C., 2022. How Can Biobanks Help You in Your Research Projects? *Stroke* 53. <https://doi.org/10.1161/STROKEAHA.121.036917>

GA4GH Connect\_ 2022 Strategic Refresh.pdf - Google Drive [WWW Document], n.d. URL <https://drive.google.com/file/d/14QbeOXbaJLdlz7QHKgtTnvgDla89c57D/view> (accessed 1.5.25).

GA4GH refreshes its strategic plan – GA4GH [WWW Document], n.d. URL [https://www.ga4gh.org/news\\_item/ga4gh-refreshes-its-strategic-plan/](https://www.ga4gh.org/news_item/ga4gh-refreshes-its-strategic-plan/) (accessed 1.5.25).

Ganz, D.A., Barnard, J.M., Smith, N.Z.Y., Miake-Lye, I.M., Delevan, D.M., Simon, A., Rose, D.E., Stockdale, S.E., Chang, E.T., Noël, P.H., Finley, E.P., Lee, M.L., Zulman, D.M., Cordasco, K.M., Rubenstein, L. V., 2018. Development of a web-based toolkit to support improvement of care coordination in primary care. *Transl Behav Med* 8. <https://doi.org/10.1093/tbm/ibx072>

Geoffrion, S., Nolet, K., Giguère, C.É., Lecomte, T., Potvin, S., Lupien, S., Marin, M.F., 2022. Psychosocial Profiles of Patients Admitted to Psychiatric Emergency Services: Results from the Signature Biobank Project. *Canadian Journal of Psychiatry* 67. <https://doi.org/10.1177/07067437211018793>

German Biobank Node: Starter kit for start-up biobanks [WWW Document], 2023. . Web Page. URL [https://www.bbmri.de/service/press/?L=1&tx\\_news\\_pi1%5Bnews%5D=684&tx\\_news\\_pi1%5Bcontroller%5D=News&tx\\_news\\_pi1%5Baction%5D=detail&cHash=6a9c6e7ce072eed11368399a676ad187](https://www.bbmri.de/service/press/?L=1&tx_news_pi1%5Bnews%5D=684&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Baction%5D=detail&cHash=6a9c6e7ce072eed11368399a676ad187) (accessed 12.30.24).

Gramatiuk, S., Hartl, G., 2022. Sustainability Plan and Project Management of a Biobanking Network. *Biobanks in Lowand Middle-Income Countries: Relevance, Setup and Management* 95–98. [https://doi.org/10.1007/978-3-030-87637-1\\_14](https://doi.org/10.1007/978-3-030-87637-1_14)

Gramatiuk, S., Macheiner, T., Sarkisian, T., Muradyan, A., Hartl, G., 2022. Business Planning for Biobanks, in: *Biobanks in Lowand Middle-Income Countries: Relevance, Setup and Management*. [https://doi.org/10.1007/978-3-030-87637-1\\_5](https://doi.org/10.1007/978-3-030-87637-1_5)

Grizzle, W.E., Sexton, K.C., McGarvey, D., Menchhofen, Z. V., LiVolsi, V., 2018. Lessons Learned During Three Decades of Operations of Two Prospective Bioresources. *Biopreserv Biobank*. <https://doi.org/10.1089/bio.2018.0073>

Hartl, G., Sargsyan, K., 2023. Project and Process Management [Lecture], 9\_2\_Management and Communication. . Lecture Notes. .

Hartman, V., Matzke, L., Watson, P.H., 2019. Biospecimen complexity and the evolution of biobanks. *Biopreserv Biobank* 17. <https://doi.org/10.1089/bio.2018.0120>

Hempel, S., Miake-Lye, I., Brega, A.G., Buckhold, F., Hassell, S., Nowalk, M.P., Rubenstein, L., Schreiber, K., Spector, W.D., Kilbourne, A.M., Ganz, D.A., 2019. Quality Improvement Toolkits: Recommendations for Development. *American Journal of Medical Quality* 34. <https://doi.org/10.1177/1062860618822102>

Henderson, M.K., Goldring, K., Simeon-Dubach, D., 2019. Advancing Professionalization of Biobank Business Operations: A Worldwide Survey. *Biopreserv Biobank* 17. <https://doi.org/10.1089/bio.2018.0079>

Henderson, M.K., Kjellqvist, S., Yanak, B.L., 2024. Biobank Resilience Through Disasters: Role of Funding, Business Planning, Best Practices, and Standards. *Biopreserv Biobank* 22, 95–97. <https://doi.org/10.1089/bio.2024.29136.editorial>

Hewitt, R., Watson, P., 2013. Defining biobank. *Biopreserv Biobank* 11. <https://doi.org/10.1089/bio.2013.0042>

ISO, 2018. *Biotechnology — Biobanking — General requirements for biobanking*. ISO 20387:2018.

ISO 20387:2018, 2020. *Biotechnology — Biobanking — Implementation guide for ISO 20387*. ISO/TR 22758:2020.

Juchniewicz, M., Rzempala, J., Skweres-Kuchta, M., 2021. Initiating and Defining a Sustainable Project on the Example of Rare Disease Therapy. *EUROPEAN RESEARCH STUDIES JOURNAL* XXIV. <https://doi.org/10.35808/ersj/2377>

Kerr, P., Le Page, C., Giguère, C.É., Marin, M.F., Trudel-Fitzgerald, C., Romain, A.J., Taschereau-Dumouchel, V., Ouellet-Morin, I., Lecomte, T., Potvin, S., Geoffrion, S., Sasseville, M., Caihol, L., Lipp, O., Pelletier, J.F., Dumais, A., Lesage, A., Labelle, R., Lavoie, M., Godbout, R., Vincent, P., Boissonneault, J., Findlay, H., Lupien, S.J., Guay, S., Juster, R.P., Consortium, S., 2024. The Signature Biobank:

A longitudinal biopsychosocial repository of psychiatric emergency patients. *Psychiatry Res.* <https://doi.org/10.1016/j.psychres.2024.115718>

Kodra, Y., Weinbach, J., Posada-De-La-Paz, M., Coi, A., Lemonnier, S.L., van Enckevort, D., Roos, M., Jacobsen, A., Cornet, R., Ahmed, S.F., Bros-Facer, V., Popa, V., van Meel, M., Renault, D., von Gizycki, R., Santoro, M., Landais, P., Torreri, P., Carta, C., Mascalzoni, D., Gainotti, S., Lopez, E., Ambrosini, A., Müller, H., Reis, R., Bianchi, F., Rubinstein, Y.R., Lochmüller, H., Taruscio, D., 2018. Recommendations for improving the quality of rare disease registries. *Int J Environ Res Public Health.* <https://doi.org/10.3390/ijerph15081644>

Kurki, M.I., Karjalainen, J., Palta, P., Sipilä, T.P., Kristiansson, K., Donner, K.M., Reeve, M.P., Laivuori, H., Aavikko, M., Kaunisto, M.A., Loukola, A., Lahtela, E., Mattsson, H., Laiho, P., Della Briotta Parolo, P., Lehisto, A.A., Kanai, M., Mars, N., Rämö, J., Kiiskinen, T., Heyne, H.O., Veerapen, K., Rüeger, S., Lemmelä, S., Zhou, W., Ruotsalainen, S., Pärn, K., Hiekkalinna, T., Koskelainen, S., Paajanen, T., Llorens, V., Gracia-Tabuenca, J., Siirtola, H., Reis, K., Elnahas, A.G., Sun, B., Foley, C.N., Aalto-Setälä, K., Alasoo, K., Arvas, M., Auro, K., Biswas, S., Bizaki-Vallaskangas, A., Carpen, O., Chen, C.Y., Dada, O.A., Ding, Z., Ehm, M.G., Eklund, K., Färkkilä, M., Finucane, H., Ganna, A., Ghazal, A., Graham, R.R., Green, E.M., Hakanen, A., Hautalahti, M., Hedman, Å.K., Hiltunen, M., Hinttala, R., Hovatta, I., Hu, X., Huertas-Vazquez, A., Huilaja, L., Hunkapiller, J., Jacob, H., Jensen, J.N., Joensuu, H., John, S., Julkunen, V., Jung, M., Junttila, J., Kaarniranta, K., Kähönen, M., Kajanne, R., Kallio, L., Kälviäinen, R., Kaprio, J., Kerimov, N., Kettunen, J., Kilpeläinen, E., Kilpi, T., Klinger, K., Kosma, V.M., Kuopio, T., Kurra, V., Laisk, T., Laukkanen, J., Lawless, N., Liu, A., Longerich, S., Mägi, R., Mäkelä, J., Mäkitie, A., Malarstig, A., Mannermaa, A., Maranville, J., Matakidou, A., Meretoja, T., Mozaffari, S. V., Niemi, M.E.K., Niemi, M., Niiranen, T., O'Donnell, C.J., Obeidat, M., Okafo, G., Ollila, H.M., Palomäki, A., Palotie, T., Partanen, J., Paul, D.S., Pelkonen, M., Pendergrass, R.K., Petrovski, S., Pitkäranta, A., Platt, A., Pulford, D., Punkka, E., Pussinen, P., Raghavan, N., Rahimov, F., Rajpal, D., Renaud, N.A., Riley-Gillis, B., Rodosthenous, R., Saarentaus, E., Salminen, A., Salminen, E., Salomaa, V., Schleutker, J., Serpi, R., Shen, H. yi, Siegel, R., Silander,

K., Siltanen, S., Soini, S., Soininen, H., Sul, J.H., Tachmazidou, I., Tasanen, K., Tienari, P., Toppila-Salmi, S., Tukiainen, T., Tuomi, T., Turunen, J.A., Ulirsch, J.C., Vaura, F., Virolainen, P., Waring, J., Waterworth, D., Yang, R., Nelis, M., Reigo, A., Metspalu, A., Milani, L., Esko, T., Fox, C., Havulinna, A.S., Perola, M., Ripatti, S., Jalanko, A., Laitinen, T., Mäkelä, T.P., Plenge, R., McCarthy, M., Runz, H., Daly, M.J., Palotie, A., 2023. FinnGen provides genetic insights from a well-phenotyped isolated population. *Nature* 613. <https://doi.org/10.1038/s41586-022-05473-8>

Lin, J.C., Hsiao, W.W.W., Fan, C. Te, 2020. Transformation of the Taiwan Biobank 3.0: Vertical and horizontal integration. *J Transl Med.* <https://doi.org/10.1186/s12967-020-02451-4>

Maraganore, D.M., Freedom, T., Simon, K.C., Lovitz, L.E., Musleh, C., Munson, R., Nasir, N., Patel, S., Paul, J., Viola-Saltzman, M., Meyers, S., Chesis, R., Hillman, L., Tideman, S., Pham, A., Vazquez, R.M., Frigerio, R., 2020. Quality improvement and practice-based research in sleep medicine using structured clinical documentation in the electronic medical record. *Sleep Sci Pract* 4. <https://doi.org/10.1186/s41606-019-0038-2>

Mendy, M., Caboux, E., Wild, C.P., 2019. Centralization of the IARC Biobank: Combining multiple sample collections into a common platform. *Biopreserv Biobank* 17. <https://doi.org/10.1089/bio.2018.0036>

Naides, S.J., 2024. Establishing a Pregnancy Lyme Disease Biobank, in: *Methods in Molecular Biology.* [https://doi.org/10.1007/978-1-0716-3561-2\\_17](https://doi.org/10.1007/978-1-0716-3561-2_17)

Niemi, M., 2022. Guidelines for clinicians and scientists to make most out of FinnGen genome and digital health care data - The FinnGen Analyst Handbook. Tampere University , Trepo.

O'Sullivan, L., Carroll, T.P., Clarke, N., Cooper, S., Cullen, A., Gorman, L., McCann, B., Mee, B., Miller, N., Murphy, V., Murray, M., O'Leary, J., O'Toole, S., Snapes, E., Bracken, S., 2021. Harmonising the human biobanking consent process: an Irish

experience. HRB Open Res 4, 96.

<https://doi.org/10.12688/HRBOPENRES.13384.2>

Park, A., 2019. 10 ideas changing the world right now. Times.

Parry-Jones, A., Hansen, J., Simeon-Dubach, D., Bjugn, R., 2017. Crisis Management for Biobanks. Biopreserv Biobank.

<https://doi.org/10.1089/bio.2016.0048>

Riegman, P.H.J., Morente, M.M., Betsou, F., de Blasio, P., Geary, P., 2008. Biobanking for better healthcare. Mol Oncol 2, 213–222.

<https://doi.org/10.1016/J.MOLONC.2008.07.004>

Rudan, I., Marušić, A., Campbell, H., 2011. Developing biobanks in developing countries. J Glob Health 1, 2.

Simeon-Dubach, D., Watson, P., 2014. Biobanking 3.0: Evidence based and customer focused biobanking. Clin Biochem 47.

<https://doi.org/10.1016/j.clinbiochem.2013.12.018>

Snapes E (Editor-in-chief). Hurtado-Ortiz R, et al (contributors). B.F. et al (reviewers)., 2023. ISBER Best Practices: Recommendations for Repositories Fifth Edition., 5th ed. ISBER.

Somiari, S.B., Somiari, R.I., 2015. The Future of Biobanking: A Conceptual Look at How Biobanks Can Respond to the Growing Human Biospecimen Needs of Researchers. Adv Exp Med Biol 864, 11–27. [https://doi.org/10.1007/978-3-319-20579-3\\_2](https://doi.org/10.1007/978-3-319-20579-3_2)

Song X, Gao M, Li X, Wang Y, Hu Y, 2024. Analysis of Major Project Management Problems in the Research and Development of New Biological Products in China.

Speirs, V., Foden, H., Hair, J., Tate, R., Pitman, H., Oien, K., Hall, A., Thomas, G., 2021. The Cellular and Molecular Pathology Biobanking Sample Quality Improvement Tool: A Guide for Improving the Quality of Tissue Collections for

Biomedical Research and Clinical Trials in Cancer. *Biopreserv Biobank* 19.  
<https://doi.org/10.1089/bio.2020.0009>

Thoele, K., Ferren, M., Moffat, L., Keen, A., Newhouse, R., 2020. Development and use of a toolkit to facilitate implementation of an evidence-based intervention: a descriptive case study. *Implement Sci Commun* 1.  
<https://doi.org/10.1186/s43058-020-00081-x>

Valdivieso-Gómez, V., Garrancho-Pérez, J., Aroca-Siendones, I., Aguilar-Quesada, R., 2021. Harmonized and Quality Sample Handling in Biobank-Supported Multicenter Prospective Studies, in: *Human Blood Group Systems and Haemoglobinopathies*. <https://doi.org/10.5772/intechopen.90947>

Van Der Stijl, R., Manders, P., Eijdem, E.W.H.M., 2021. Recommendations for a Dutch Sustainable Biobanking Environment. *Biopreserv Biobank* 19.  
<https://doi.org/10.1089/bio.2021.0011>

Van Der Stijl, R., Schmidt, M., Schaaij-Visser, T., NI, B., Lygature, /, Eijdem, E.W.H.M., 2019. *BBMRI.nl | sustainable biobanking*. Publisher Biobanking and Biomolecular Resources Research Infrastructure The Netherlands (BBMRI.nl).

Vaught, J., Rogers, J., Myers, K., Lim, M.D., Lockhart, N., Moore, H., Sawyer, S., Furman, J.L., Compton, C., 2011. An NCI perspective on creating sustainable biospecimen resources. *J Natl Cancer Inst Monogr*.  
<https://doi.org/10.1093/jncimonographs/lgr006>

Viktor, M., Sági Judit, C., Judit, M.M., 2023. Sharing sensitive research data in the practice of personalised medicine. *Orv Hetil*.  
<https://doi.org/10.1556/650.2023.32759>

Waghmare, Charles David, 2023. *Beginning SharePoint Communication Sites*, *Beginning SharePoint Communication Sites*. <https://doi.org/10.1007/978-1-4842-8960-0>

Waghmare, C D, 2023. Using SharePoint Communication Sites for Project Management, in: *Beginning SharePoint Communication Sites*. pp. 157–175.  
[https://doi.org/10.1007/978-1-4842-8960-0\\_6](https://doi.org/10.1007/978-1-4842-8960-0_6)

Watson, P.H., Barnes, R.O., 2011. A proposed schema for classifying human research biobanks. *Biopreserv Biobank* 9. <https://doi.org/10.1089/bio.2011.0020>

Wiley, L.K., Shortt, J.A., Roberts, E.R., Lowery, J., Kudron, E., Lin, M., Mayer, D., Wilson, M., Brunetti, T.M., Chavan, S., Phang, T.L., Pozdeyev, N., Lesny, J., Wicks, S.J., Moore, E.T., Morgenstern, J.L., Roff, A.N., Shalowitz, E.L., Stewart, A., Williams, C., Edelman, M.N., Hull, M., Patton, J.T., Axell, L., Ku, L., Lee, Y.M., Jirikowic, J., Tanaka, A., Todd, E., White, S., Peterson, B., Hearst, E., Zane, R., Greene, C.S., Mathias, R., Coors, M., Taylor, M., Ghosh, D., Kahn, M.G., Brooks, I.M., Aquilante, C.L., Kao, D., Rafaels, N., Crooks, K.R., Hess, S., Barnes, K.C., Gignoux, C.R., 2024. Building a vertically integrated genomic learning health system: The biobank at the Colorado Center for Personalized Medicine. *Am J Hum Genet* 111. <https://doi.org/10.1016/j.ajhg.2023.12.001>

# Annex

## Annex 1: Biobank Definitions

Table 1 - Biobank Definitions

Source and Term	Definition
<b>1.Declaration of Taipei</b>	
<b>Biobank:</b>	A biobank is a collection of biological material and associated data
<b>2.NCI Best Practices working definition</b>	
<b>Bio-repository:</b>	An organization, place, room, or container (a physical entity) where biospecimen are stored. In the context of the NCI Best Practices, only biorepositories containing human specimens intended for research purposes (research biorepositories) are addressed. The physical structure, policies, biospecimens, and data contained within it are defined collectively as a biospecimen resource, defined below
<b>3.IARC</b>	
<b>Biobank</b> <b>Bio-repository</b>	<p>Infrastructure for the collection, archiving, and storage of biospecimens and their associated data, and the procedures and related <b>services</b> connected to the biospecimens and associated data. The services include informing individuals who are approached to participate in a study, obtaining their consent, collecting and processing specimens for secure long-term storage, accessing and retrieving specimens appropriate for analysis, processing for preparation of biomaterials (e.g. DNA, RNA, proteins), quality control, and packaging and shipping of specimens. Many types of biobanks are relevant to cancer research.</p> <p>They include, among others, tumor and tissue biobanks for specimens and data obtained in the course of normal clinical procedures; specialized collections of specimens and data developed in the context of clinical trials, mechanistic studies, or diagnostic or prognostic studies; and collections of specimens and data developed in epidemiological studies and biomarker studies. Biobank samples include tissues, blood, cell lines, DNA, and proteins derived from individuals with a history of hereditary or familial cancer. Biobanks are also known as biorepositories.</p>
<b>Biobanking</b>	The process of storing material or specimens and associated data for future use.
<b>4.OECD</b>	
	One of the first definitions, i.e. “a collection of biological material and the associated data and information stored in an <b>organized system</b> , for a population or a large subset of a population”, was introduced by the Organization for Economic Cooperation and Development (OECD) [ <a href="#">5</a> , <a href="#">7</a> ]. This description was later updated to depict biobanks as “ <b>structured resources</b> that can be used for the purpose of genetic research and which include (a) human biological materials and/or information generated from the analysis of the same and (b) extensive associated information
<b>5.ISO 20387:2018</b>	
<b>Biobank</b>	<p>(3.6) Biobank A legal entity or part of a legal entity that performs biobanking</p> <p>(3.2) Biobanking process of acquisitioning and storing, together with some or all the activities related to collection, preparation, preservation, testing, analyzing, and distributing defined biological material as well as related information and data.</p>
<b>6.ISBER 5<sup>th</sup> Edition</b>	

<b>BIOBANK – See REPOSITORY</b>	In its simplest form, a place where collected parts or the whole of organisms and/or environmental specimens are stored for <b>safekeeping</b> . In the context of this document, the term applies more extensively to any entity focused on management and operations of specimens and associated data primarily intended for research purposes. Alternative terms may include biobank, biorepository, biological resource center, collection (e.g. microbial collection center, data collection center), cryogenic biobank, digital repository, gene bank, biodiversity biobank seed bank, virtual biobank, veterinary biobank, culture collection, gene bank, environmental specimen bank, tissue bank, cell bank among many others.
<b>BIOBANKING</b>	Performing functions associated with a repository.

#### References for Biobank Definition:

1. WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks – WMA – The World Medical Association. (2016, October). WMA General Assembly, Taipei, Taiwan. <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>
2. NCI Best Practices for Biospecimen Resources. (2016). Biorepositories and Biospecimen Research Branch National Cancer Institute National Institutes of Health. (2016). NCI Best Practices for Biospecimen Resources. Page 53. <https://biospecimens.cancer.gov/bestpractices/2016-NCIBestPractices.pdf>.
3. Mendy, M., Caboux, E., Lawlor T., R., Wright, J., & Wild, C. P. (2017). Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research (Issue 44) Page 2, 4. <http://publications.iarc.fr>
4. ISO. (2020). Biotechnology — Biobanking — Implementation guide for ISO 20387. In ISO/TR 22758:2020 (Vol. 1). International Organization for Standardization . <https://www.iso.org/standard/73829.html>
5. Annaratone L, De Palma G, Bonizzi G, Sapino A, Botti G, Berrino E, Mannelli C, Arcella P, Di Martino S, Steffan A, Daidone MG, Canzonieri V, Parodi B, Paradiso AV, Barberis M, Marchiò C; Alleanza Contro il Cancro (ACC) Pathology and Biobanking Working Group. Basic principles of biobanking: from biological samples to precision medicine for patients. *Virchows Arch.* 2021 Aug;479(2):233-246. doi: 10.1007/s00428-021-03151-0. Epub 2021 Jul 13. PMID: 34255145; PMCID: PMC8275637.
6. Snapes E (Editor-in-chief). Hurtado-Ortiz R, et al (contributors). B. F. et al (reviewers). (2023). *ISBER Best Practices: Recommendations for Repositories Fifth Edition*. (5th ed.). Page 190, ISBER.

## Annex 2: Biobank Project Protocol: Business Plan Template

Table 2 - Biobank Business Plan Template

Section	Content Description
<b>1. Biobank Overview</b>	Collection/Study Name: Institute and Hosting Biobank: Principal Investigator(s): Funding Source(s): Protocol Version/Date:
<b>2. Executive Summary</b>	Mission, Vision, and Objectives Key Benefits and Scientific Rationale Governance Overview
<b>3. Scientific and Strategic Context</b>	Background & Rationale: Research Scope: Clinical, public health, epidemiological context Summary of Supporting Literature Broader Research Collaboration: External/International collaborations Unique Selling Points
<b>4. Governance and Accountability</b>	Governance Structure: Organizational chart, committees (Management, Scientific Oversight, and Access) Roles and Responsibilities External Governance: Compliance Standards (e.g., ISO 20387, CTRNet), Ethics Board Approval, QA Programs Internal Governance: Policies, Operational Policies, SOPs, Conflict of Interest Management
<b>5. Operational Overview</b>	Enrolment and Withdrawal: Participant Enrolment, Inclusion and exclusion criteria, recruitment, retention, withdrawal/termination processes Participant Management: Recruitment, retention, and withdrawal processes Biospecimen/Data Collection: Types, workflows, and eligibility criteria Biospecimen Processing: Handling protocols and services Biospecimen Storage: Infrastructure, tracking systems, privacy, and data security Legacy Collection Management
<b>5. Data Management</b>	Tools, software/database, long-term storage, and security Study Record and Retention
<b>6. Access, Release and Utilization</b>	Eligibility for Access: Internal/external, academic/industry

	<p>Access Request and Application Management</p> <p>User Fees: Calculation and cost structure</p> <p>Material/Data Sharing Agreements: Policies and Intellectual Property Rights</p>
<b>7. Ethical, Legal, and Social Considerations</b>	<p>Confidentiality and Data Protection</p> <p>Research Finding: Handling of Incidental Findings, Procedures for Clinical Use</p> <p>Confidentiality</p>
<b>8. Quality Assurance and Standards</b>	<p>Certification and Accreditation Programs (ISO, CTRNet)</p> <p>Monitoring and Auditing Procedures</p> <p>Training Plan and Follow-Up</p>
<b>9. Risk Management</b>	<p>Protocol Deviation</p> <p>Risk Mitigation Plans: Identified risks and prevention strategies</p>
<b>10. Sustainability Plan and Funding</b>	<p>Funding Sources: Current and future strategies</p> <p>Exit Strategies and Legacy Planning</p> <p>Financial Management: User Fees</p>
<b>11. Publication and Data Sharing Policy</b>	<p>Open Access or Restricted Access Policies</p> <p>Authorship and Publication Guidelines</p> <p>Data Sharing</p> <p>Intellectual Property</p>
<b>12. Other Tools</b>	<p>SWOT Analysis</p>
<b>13. Appendices</b>	<p>SOPs, Informed Consent templates, governance documents</p>
<b>14. References</b>	<p>Literature, Regulations, and Supporting Documentation</p>

Adopted From:

1. Van der Stijl, R., Schmidt, M., Schaaïj-Visser, T., NI, B., Lygature, /, & Eijdem, E. W. H. M. (2019). *BBMRI.nl | sustainable biobanking* Publisher *Biobanking and Biomolecular Resources Research Infrastructure The Netherlands (BBMRI.nl)*. <https://bbmri.nl/services/knowledge/sustainable-biobanking>
2. Sick Kids Biobank. (2020, August 25). *sick kids biobank protocol template* -. <https://www.sickkids.ca/siteassets/research/reb/protocol-development-templates/sickkids-biobank-protocol-template-2020-2021.docx>
3. UBC. (2024). *OBER biobank protocol template* -. Office Of Biobank Educational Research, University of British Columbia. [https://researchethics.ubc.ca/sites/default/files/documents/Biobank\\_protocol\\_template\\_OBER\\_BRC2019-CREB%20edits.docx](https://researchethics.ubc.ca/sites/default/files/documents/Biobank_protocol_template_OBER_BRC2019-CREB%20edits.docx)

## Annex 3: The Project Onboarding Toolkit PowerPoint Slides



### **Project Management and Business Planning Toolkit**

#### Overview and Approach

#### **Contents**

---

- Introduction
- Initiation Phase
- Planning Phase
- Execution, Monitoring and Control Phases
- Closing Phase
- References

---

## **Introduction**

---

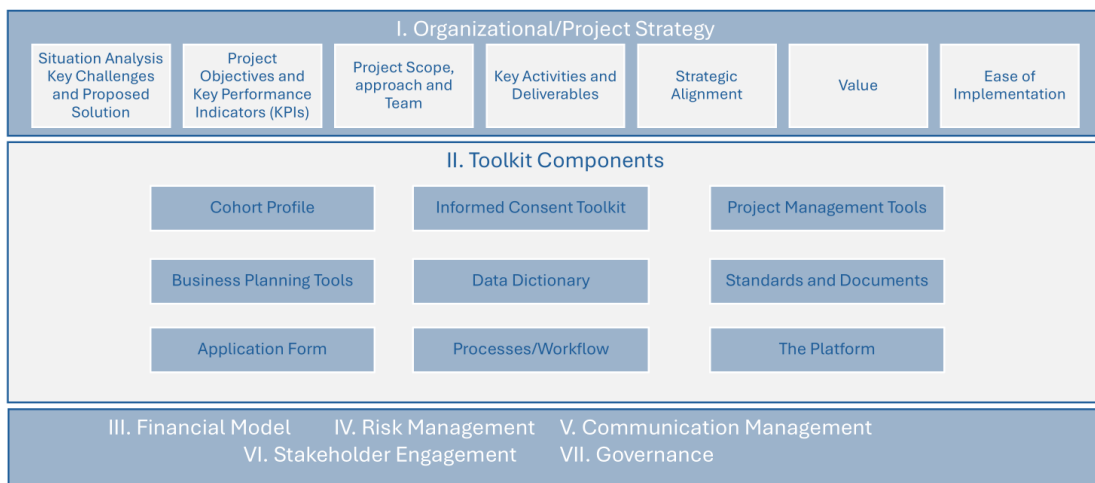
# Introduction

## Introduction

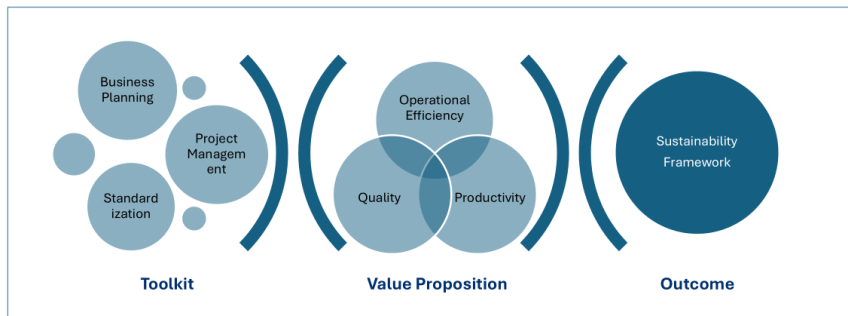


- To address the complexity of establishing biobanks it is fundamental to apply a systemic approach to tackle the challenges and streamline the process of onboarding projects in alignment with institutional guidelines, standards and best practices of biobanking
- The toolkit is designed to adapt to biobank processes and procedures.
- The tools are meant to be used during collaborative and co-development sessions in the project initiation and planning phases of the project.
- The toolkit manual will guide investigators, study team members and key stakeholders through a selection of tools in according to the different project phases.
- The tools are customizable and adaptable to study specific requirements.

## The Project Management and Business Plan Toolkit Focuses On Custom Tools To Meet Project and Strategic Objectives

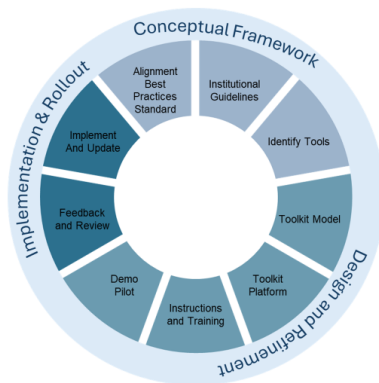


## Toolkit Value Proposition: Toolkit as a sustainability driver



**Solution: The Conceptual Framework** To Develop a comprehensive and practical toolkit to capture project management, business planning, and standardized documents for operational efficiency, achieve targets and impact the quality and sustainability of the collection.

### Toolkit Methodology



Fostering the Transition from concept development to tool Implementation Model

### Toolkit Components:

- Business Planning
- Project Planning
- Document Standardization: Forms, Checklist and templates

### Objectives:

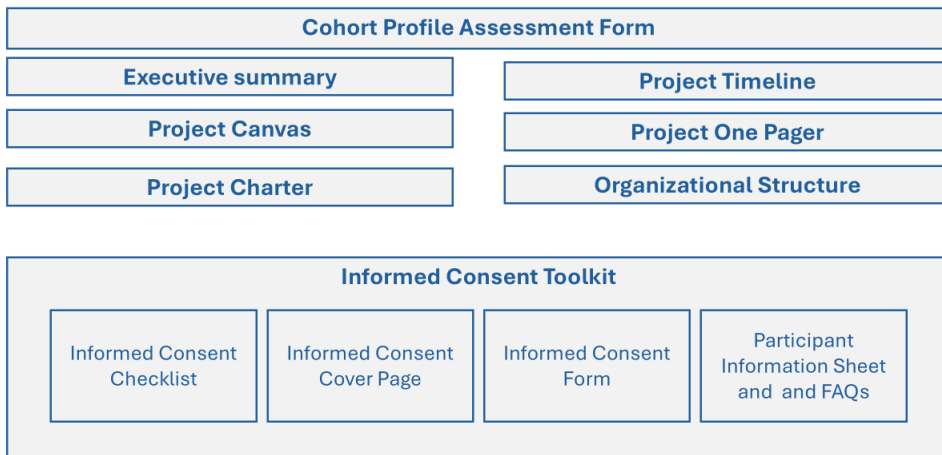
- Standardizations
- Increase knowledge
- Quality of operations, process management
- Strategic planning
- Financial implication
- Timely services and operations
- Quality and Integrity of collected Biospecimen and data
- Efficient management of multidisciplinary teams

## Toolkit Components: Checklist

Business Plan	Project Management	Standard Forms and Templates
<ul style="list-style-type: none"> <li><input type="checkbox"/> Purpose</li> <li><input type="checkbox"/> Scope</li> <li><input type="checkbox"/> Objectives</li> <li><input type="checkbox"/> Governance Structure</li> <li><input type="checkbox"/> Key elements and guiding principles</li> <li><input type="checkbox"/> Management and operations</li> <li><input type="checkbox"/> Financial Projections</li> <li><input type="checkbox"/> Accrual targets</li> <li><input type="checkbox"/> Marketing and Communication Plan</li> <li><input type="checkbox"/> Implementation Plan</li> <li><input type="checkbox"/> Risk management/mitigation</li> <li><input type="checkbox"/> SWOT</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Project Scope, objectives, deliverables</li> <li><input type="checkbox"/> Project Canvas</li> <li><input type="checkbox"/> Project Plan: Work Breakdown Structure (WBS)</li> <li><input type="checkbox"/> Project timeline</li> <li><input type="checkbox"/> Gantt Chart</li> <li><input type="checkbox"/> Budget and Resource allocation</li> <li><input type="checkbox"/> Governance and team structure</li> <li><input type="checkbox"/> Ethics and Regulatory Compliance</li> <li><input type="checkbox"/> Stakeholder Engagement</li> <li><input type="checkbox"/> Infrastructure and Logistics Plan</li> <li><input type="checkbox"/> Data Management Plan</li> <li><input type="checkbox"/> QA and QC</li> <li><input type="checkbox"/> Monitoring and Reporting</li> <li><input type="checkbox"/> Risk Management</li> <li><input type="checkbox"/> Training and Capacity building</li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> Cohort Profile Assessment Form</li> <li><input type="checkbox"/> Informed Consent Toolkit</li> <li><input type="checkbox"/> Data Dictionary</li> <li><input type="checkbox"/> Project Plan Template</li> <li><input type="checkbox"/> Business Plan Template</li> </ul>

# Initiation Phase

## Preview: Project Initiation



## Project Initiation Phase: Cohort Profile Assessment Form Checklist

### 1. General Information:

Cohort ID:  
Title (Study Name):  
Principal Investigator:  
Contact Information:  
Funding Agency:

### 2. Description: Collection Summary

ICD 10/O Codes:  
Keywords:  
Collection/Cohort Size (as of December 2023):  
Informed Consent (IC) Type:  
Status:  
Inclusion Criteria:  
Age Distribution:  
Sex Distribution (Female:Male):  
Collection Timeline: Proposed Start Date/End Date – Duration  
Earliest Access:  
Quality Standards:  
Associated Publications/References:

### 4. Biospecimen Type, Primary Container Type, Volume, and Storage Conditions:

### 5. Additional Information: Exclusion Criteria:



Format:  
Microsoft Forms

## Project Initiation Phase: Informed Consent Toolkit Checklist (Part 1/2)

### Cover Page:

- Name of Collection
- Collection Custodian and contact details
- Where samples are/will be stored
- If relevant, the aims and scope of research that the Collection will support
- The type/s, amount, and frequency of collection of samples planned to be collected from participants
- The type/s and storage details of data that will be linked with participant samples
- The scenarios under which participants will be re-contacted after consent
- Examples of how researchers might use participants' samples and health information
- Who to contact if participants have concerns or complaints

### References:

NSW Health. (2020). *NSW Health Consent Toolkit V3 - NSW Health Statewide Biobank*.  
<https://biobank.health.nsw.gov.au/researchers/nsw-health-consent-toolkit/>

O'Sullivan, L., Carroll, T. P., Clarke, N., Cooper, S., Cullen, A., Gorman, L., McCann, B., Mee, B., Miller, N., Murphy, V., Murray, M., O'Leary, J., O'Toole, S., Snapes, E., & Bracken, S. (2021). Harmonising the human biobanking consent process: an Irish experience. *HRB Open Research*, 4, 96.  
<https://doi.org/10.12688/HRBOPENRES.13384.2>

### Patient Information Sheet:

1. Why are biobanks important?
2. What is the Dubai Health Biobank?
3. Why is research using human samples important?
4. Why have I been asked to take part?
5. What will happen if I take part?
6. What happens to the samples?
7. What is surplus tissue?
8. What happens to any leftover samples?
9. Could the samples be used in genetic research?
10. Will researchers have access to my medical records?
11. How does the biobank protect my privacy?
12. Will anyone know who I am?
13. What are the benefits to me?
14. Are there any risks to me?
15. Do I have to take part?
16. What if I change my mind?
17. Can I withdraw from the Biobank?
18. What happens to the results from research?
19. Will I be contacted about the results of research using my samples?
20. Has this biobank been approved by a research ethics committee?
21. How is the biobank funded?
22. Will I be paid for my involvement?
23. What are my rights?
24. What if I have a concern or wish to complain?
25. How do I find out more about the Biobank?

### Consent Form Checklist:

1. I understand the information provided about donating my samples.
2. My samples and data will be used for research studies.
3. Donating is my choice.
4. My decision won't affect my healthcare.
5. I can stop participating anytime.
6. I've had my questions answered.
7. My samples will be linked with my health information.
8. My identity will not be shared with researchers.
9. My samples will be safely stored in the Biobank.
10. My health information will also be securely stored.
11. My samples and data might be used for various future studies.
12. Research must be approved by an ethics committee.
13. My samples can be used in research worldwide.
14. Research might uncover serious health findings for me or my family.
15. I won't be informed about specific studies using my samples.
16. I won't be paid for my donation.
17. My samples could be stored indefinitely.
18. My privacy will be protected.
19. I consent to donate samples and health information for research.
20. I agree to have my samples stored at the Biobank.
21. I allow my data to be shared with researchers and governments for research.
22. I agree my samples and data can be used for approved future research.
23. I agree to be contacted:
  - At age 14 for consent renewal with my parent/guardian.
  - At age 18 for my own consent renewal.
  - If a serious health finding is discovered.

## Project Initiation Phase: Informed Consent Toolkit Checklist (Part 2/2)

### Frequently Asked Questions:

1. Why am I being asked to take part?
2. What is a biobank?
3. What is the NSW Health Statewide Biobank?
4. What are the benefits of participating?
5. Are there any risks?
6. How and when is my sample taken?
7. What happens to my sample after it is taken?
8. What can my samples be used for?
9. What is health and personal information?
10. What is data linkage?
11. Why is data linkage important for health and medical research?
12. What type of health data will be linked to my sample?
13. How long will my health and personal information be held for?
14. Who can access/use my sample and health data?
15. How will I know that the researchers accessing my samples and data are legitimate?
16. How long can a researcher hold my sample and health data?
17. Could I be identified from my health data?
18. Could my sample and health data be sent interstate or overseas?
19. Where is my data stored?
20. How is my privacy protected?
21. How old will I need to be to consent for myself?
22. Will I be told what research projects my sample is used for?
23. Do I get a say in what research projects my samples are used in?
24. What are serious findings?
25. How and when will I be told about serious findings?
26. Why am I being contacted about a serious finding?
27. Could taking part impact my ability to take out health or life insurance in the future?
28. What if I don't want to be told about a serious finding?
29. Will I be paid for my samples and health and personal information?
30. I've changed my mind. How do I withdraw my consent?
31. How do I change my personal or contact details?
32. Can I access the Participant Information Sheet, Consent Form, and FAQs in other languages?
33. Where can I find more information?

### Informed Consent Compliance Checklist:

- 1. Understand this is a research study (not routine healthcare).
- 2. Have read information materials.
- 3. Understand that participation is voluntary.
- 4. Have had an opportunity to ask questions.
- 5. Understand can withdraw at any time without affecting care.
- 6. Consent to donate to specified collection/biobank.
- 7. Specifics of sample/s (type, volume, frequency) collected are clear.
- 8. Consent to link the sample to health and personal information (data).
- 9. Consent to future unspecified research.
- 10. Understand that any current or future research will be approved by an ethics committee.
- 11. Understand that samples and data are released to researchers without identifying details.
- 12. Understand that samples and data could be shared nationally or internationally.
- 13. Understand we won't be able to tell you when your sample is used or the results of any research.
- 14. Understand they won't personally benefit (health or financial) from the donation.
- 15. Understand that samples will be held in perpetuity.
- 16. Understand that samples will be stored in the NSW Health Statewide Biobank.
- 17. Understand that they:
  - a. May be contacted to confirm consent.
  - b. Will be contacted to confirm consent by the Collection Custodian when you/your child turns 14 for permission to keep storing the sample (for consenting children only).
  - c. Will be contacted by the Collection Custodian when you/your child turns 18 for permission to keep storing samples and data (for consenting children only).

## Project Checklist Initiation Phase

Project Initiation			
No.	Description	Status	Comments/Actions
<b>D</b>	<b>Project Initiation</b>		
	Concept Introduction	Open	
	Develop Study Protocol	Open	
	Complete Biobank Cohort Profile Assessment Form	Open	
	Grant Application	Open	
	Secure grant award	Open	
<b>M01</b>	<b>Submit Study proposal</b>	Open	
<b>M02</b>	<b>Biobank Cohort Profile</b>	Open	
<b>M03</b>	<b>Securing funding</b>	Open	

### Tool List

- Cohort Profile Assessment Form
- Informed Consent Toolkit
- Executive summary
- Project Canvas
- Project Charter
- Project One Pager
- Project Timeline
- Organizational Structure

### Initiation Phase Checklist:

- Is the scope of the project clear?
- Is the project funding approved?
- Have all the stakeholders been identified?
- Has a sponsor been identified?
- Does the project contain 3rd Party or external resources?
- Have you confirmed in writing the project delivery expectations (time and scope) with all the stakeholders?
- Have all the project benefits been captured and are reasonable?
- Are you aware of the process of getting the project approved?
- Does the business case cover assumptions, dependencies and constraints?
- Do you need a risk assessment to be conducted?
- Will the project costs be capitalized?
- Do you have a high-level effort estimate for the project?
- Are you supposed to use a standard template for the initiation document?
- Has the project team been established or resources available to start the project?
- Does the project need an approved business case to start work?

## Executive summary

<b>Situation &amp; key challenge</b>			
<ul style="list-style-type: none"> <li>• Describe the situation of your company</li> <li>• Describe the key challenge that your company is facing</li> </ul>			
<b>Recommendation</b>			
Replace this text with your recommendation			
<b>Reason #1</b>	<b>Reason #2</b>	<b>Reason #3</b>	<b>Reason #4</b>
<p style="text-align: center;"><b>Insert the reason why you suggested your recommendation</b></p> <ul style="list-style-type: none"> <li>• Provide more information about the reason mentioned above</li> <li>• Provide more information about the reason mentioned above</li> </ul>	<p style="text-align: center;"><b>Insert the reason why you suggested your recommendation</b></p> <ul style="list-style-type: none"> <li>• Provide more information about the reason mentioned above</li> <li>• Provide more information about the reason mentioned above</li> </ul>	<p style="text-align: center;"><b>Insert the reason why you suggested your recommendation</b></p> <ul style="list-style-type: none"> <li>• Provide more information about the reason mentioned above</li> <li>• Provide more information about the reason mentioned above</li> </ul>	<p style="text-align: center;"><b>Insert the reason why you suggested your recommendation</b></p> <ul style="list-style-type: none"> <li>• Provide more information about the reason mentioned above</li> <li>• Provide more information about the reason mentioned above</li> </ul>

## Project Canvas

Business Model Canvas				
Study Title/Biobank Name : <input style="width: 150px;" type="text"/>		Prepared By: <input style="width: 150px;" type="text"/>		
Foundation (WHY?)	People (WHO?)		Creation (WHAT? HOW?)	
● Purpose	● Sponsorship	● Stakeholders	● Deliverables	● Plan
<ul style="list-style-type: none"> <li>▶ Why are we doing the project?</li> </ul>	<ul style="list-style-type: none"> <li>▶ Who is accountable for the project?</li> </ul>	<ul style="list-style-type: none"> <li>▶ What is the value we deliver to our customer?</li> <li>▶ What customer problems are we solving?</li> <li>▶ What is the customer need we are addressing?</li> <li>▶ What is our promise to our customer?</li> <li>▶ What are the products and services we create for our customer?</li> </ul>	<ul style="list-style-type: none"> <li>▶ What will the project produce, build, or deliver?</li> </ul>	<ul style="list-style-type: none"> <li>▶ How and When will the work/tasks be carried out?</li> <li>▶ How will roles and responsibilities be assigned?</li> </ul>
	● Resources			● Change
	<ul style="list-style-type: none"> <li>▶ What are the resources we need to deliver the project?</li> <li>▶ Who will manage the project? Which skills are needed to deliver the project?</li> </ul>			<ul style="list-style-type: none"> <li>▶ How would we engage stakeholders and Manage Risk?</li> <li>▶ How does our value proposition reach our stakeholders? How can stakeholders access the biobank resources?</li> </ul>
● Investment/Cost Structure			● Benefits	
<ul style="list-style-type: none"> <li>▶ How Much will the project cost? What are the costs of delivering the project?</li> </ul>			<ul style="list-style-type: none"> <li>▶ What Benefits and Impact will the project generate?</li> <li>▶ How will we measure project success?</li> </ul>	

## Project charter

Project name:

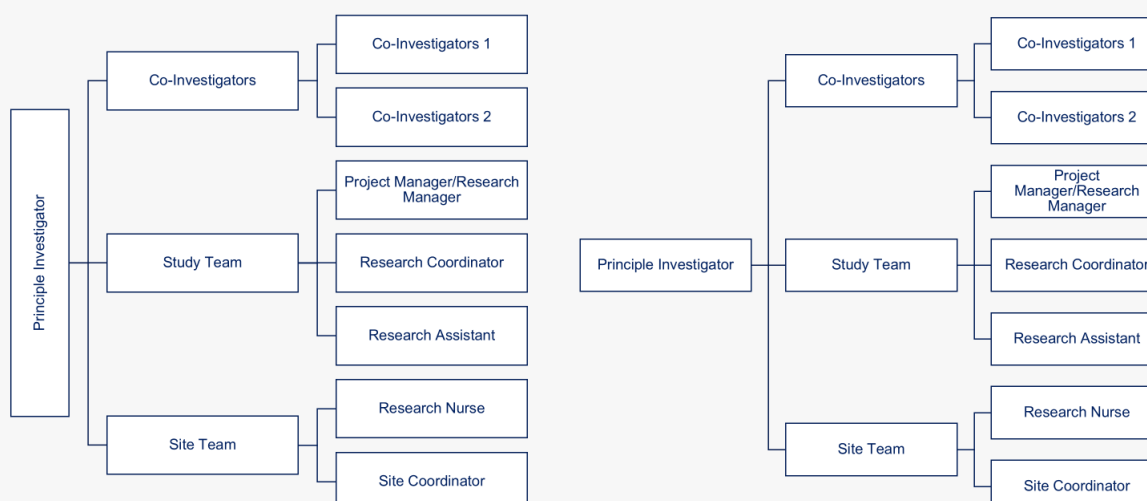
Sponsor:

<b>Problem statement</b>	Insert in this box what business issue will this project address
<b>Objective</b>	Insert in this box the objective of this project
<b>In-scope</b>	<ul style="list-style-type: none"> <li style="width: 50%;">• Insert what is in-scope</li> <li style="width: 50%;">• Insert what is in-scope</li> <li style="width: 50%;">• Insert what is in-scope</li> <li style="width: 50%;">• Insert what is in-scope</li> </ul>
<b>Out-of-scope</b>	<ul style="list-style-type: none"> <li style="width: 50%;">• Insert what is out-of-scope</li> <li style="width: 50%;">• Insert what is out-of-scope</li> <li style="width: 50%;">• Insert what is out-of-scope</li> <li style="width: 50%;">• Insert what is out-of-scope</li> </ul>
<b>Resources</b>	<ul style="list-style-type: none"> <li>• <b>Budget:</b> Insert your own text</li> <li>• <b>Project Manager:</b> Insert your own text</li> <li>• <b>Key Team Members:</b> Insert your own text</li> <li>• <b>Key Stakeholders:</b> Insert your own text</li> </ul>
<b>Key milestones</b>	<ul style="list-style-type: none"> <li>• Insert the name and target date of the milestone</li> <li>• Insert the name and target date of the milestone</li> <li>• Insert the name and target date of the milestone</li> </ul>

## Organizational Structure and size of the project/study team



## Organizational Structure and size of the project/study team



## Project one pager

Project name:

Sponsor/Principal Investigator:

As-Is situation / Problem description:

- ...
- ..
- ..

Goal(s):

- ...
- ...
- ...

Planned Deliverables:

- [Funding - Secure Grant]
- [Ethical Approval ]
- [Feasibility – Collection/Cohort Profile]
- ...

Project Team:

- Name 1 (department xxx)
- Name 2 (department xxx)

Involved parties / business units:

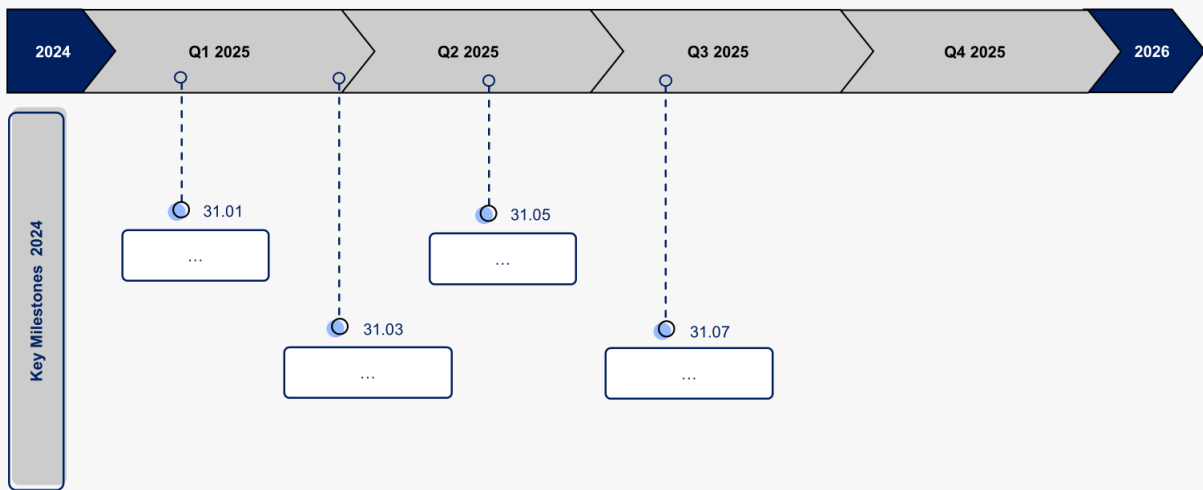
- [Legal]
- [IT]
- [Marketing]
- ...

Timeline

### Biobank Primary Research



## Project timeline – overview of key milestones



## Planning Phase

### Project Checklist Planning Phase

Project Planning			
No.	Description	Status	Comments/Actions
D	<b>Project Launch</b>	Open	
	Kick-off Meeting	Open	
	Develop Project Plan	Open	
	Review Toolkit: Informed Consent Toolkit, Data Dictionary, Business Plan Template, SOPs	Open	
	Develop Project Charter	Open	
	Develop Communication Plan	Open	
	Setup Teams Group/Share point folder	Open	
	Setup Group email	Open	
	Stakeholder analysis and engagement plan (Part of the Business Plan)	Open	
	Develop Project organizational structure	Open	
	Assign Resources/Roles and Responsibilities	Open	
M	<b>Review and Approve Toolkit</b>	Open	
M	<b>Setup Project Onboarding Site on SharePoint</b>	Open	
M	<b>Approve project plan</b>	Open	
D	<b>Obtain Research Ethics Board Approval</b>	Open	
	Prepare documents for IRB application	Open	
	Create IRB System Account	Open	
	Ethical Training Completion	Open	
	Submit IRB Application	Open	
	Obtain research ethics board approval	Open	
	Submit Biobank Application Form		
	Obtain Site approval for patient recruitment and sample collection		
	Execute material and data transfer agreements with Partner Sites [External Entities]		
M	<b>Complete Access and Document Upload IRB System</b>		
M	<b>Obtain IRB Approval</b>		
M	<b>Obtain Site Approval</b>		

#### Planning Phase Checklist:

- Have you organized a project kick off meeting?
- Does the project team need any training?
- Are you comfortable with the skill level of the project team?
- Do you need a project management plan?
- Do you have enough contingency or buffer in budget and schedule?
- Is there a vendor contract involved in the project?
- Have all the project components been estimated?
- Do you have a detailed project schedule drafted?
- Do you need a work breakdown structure?
- Have you created a baseline of the project plan?
- Is the project team comfortable with the project schedule?
- Do you have clearly defined the milestones for the project?
- How do you plan to track project progress?
- Have the team leave plans and public holidays been factored into the project plan?
- Do you have a resource plan for the duration of the project?
- Do you need to hire additional resources for the project? If yes, has the hiring process been kicked off?
- Have you factored in the resourcing costs in the plan?
- Are you aware of the SMEs required for the project?
- Is your project schedule detailed enough for the project team to understand their tasks?
- Is there a quality assurance plan for the project?

# Project Checklist Planning Phase

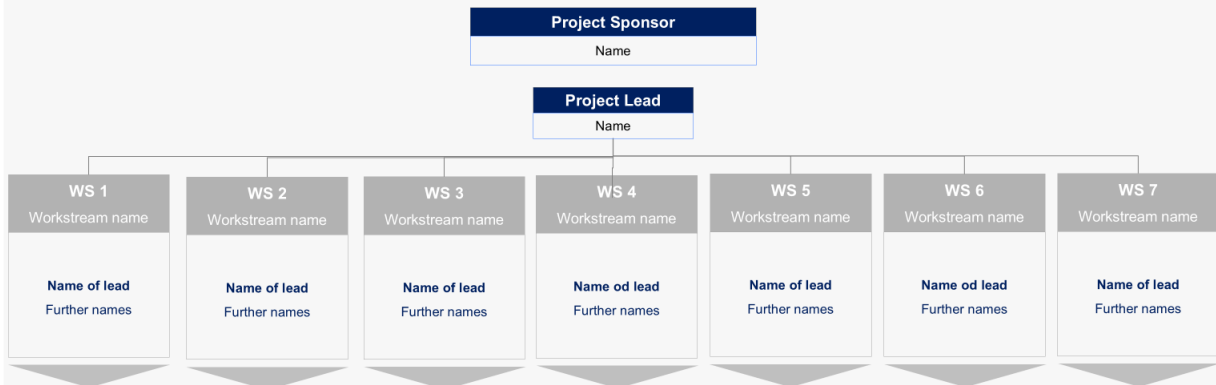
Project Planning			
No.	Description	Status	Comments Actions
D	<b>Setup Collection Protocol in BIMS, Epic, and IRB System</b>	Open	
	Setup Log in credentials in OpenSpecimen	Open	
	Setup collection protocol and workflows in OpenSpecimen	Open	
	Setup Login credentials in Epic research	Open	
	Setup collection protocol, consent, encounter, order and billing components	Open	
M	<b>Complete access and profile setup OpenSpecimen Requirements</b>	Open	
M	<b>Complete access and profile Epic</b>	Open	
D	<b>Develop and implement business plan</b>	Open	
	Submit Business case to Scientific Advisory Committee	Open	
	Develop business plan	Open	
	Implement business plan	Open	
	Prepare annual report	Open	
	Refine business plan	Open	
M	<b>Business plan created and revised to reflect initial 3 years of repository existence</b>	Open	
D	<b>Establish governance structure (Part of Business Plan)</b>	Open	
	Draft governance structure	Open	
	Establish data access committee	Open	
	Finalize governance structure	Open	
	Annual review of governance structure	Open	
M	<b>Publish (Intranet/webpage) and share Governance Policy and biobank model (including governance structure)</b>	Open	
D	<b>Recruitment and Hiring</b>	Open	
	Recruite - Project Manager	Open	
	<b>Facilities - Infrastructure - Equipment Requirement</b>	Open	
	Review update/upgrade/Procure as per study specs	Open	
D	<b>Develop and implement patient engagement in research plan</b>	Open	
	Develop patient engagement plan (Video, Brochure/Flyer, FAQ)	Open	
	Implement patient engagement plan	Open	
	Engage and mentor Patient Advocates	Open	
M	<b>Engage and Integrate patient Advocate(s)</b>	Open	
	Engage and mentor Patient Advocates	Open	
	<b>Engage and Integrate patient Advocate(s) as part of the biobank</b>	Open	

## Tool List

- Work Break Down Structure
- Structure and size of project workstreams
- Gantt Chart - Project timeline
- Risk Assessment
- PESTEL Analysis

26

## Structure and size of project workstreams



Milestones

Start by Oct 2025	...	...
Defining Service Agreements until end 2025	...	...

## Project timeline

Phase	2023											
	Q1			Q2			Q3			Q4		
	J	F	M	A	M	J	J	A	S	O	N	D
<b>Implementation Stream 1</b>	[Timeline bars for Implementation Stream 1]											
Core Process Design	[Timeline bar]											
Secure Funding	[Timeline bar]											
<b>Implementation Stream 2</b>	[Timeline bars for Implementation Stream 2]											
Ethical Approval	[Timeline bar]											
Signs Service Agreement	[Timeline bar]											
Develop Project Plan	[Timeline bar]											
Develop Business Plan	[Timeline bar]											
<b>Test Phase 1</b>	[Timeline bars for Test Phase 1]											
Governance	[Timeline bar]											
Proactive Procurement	[Timeline bar]											
Risk Assessment	[Timeline bar]											
Recruitment and Hiring	[Timeline bar]											
Communication Plan	[Timeline bar]											

█ Fixes timeframe; agreed with involved parties.

⋯ Buffer

28

# PESTEL Analysis

Identify threats and weaknesses used in SWOT analysis

PESTEL Analysis					
Organisation or Team:					
<b>P Political</b>			<b>E Environmental</b>		
1	What trading policies impact us?		1	How can we source, trade and test our products?	
2	What regulations must we follow?		2	Is everything we do ethically sound?	
3	What will happen if another party gains power?		3	What is our carbon footprint and is it worth reducing it?	
4	What future policies do we need to be aware of?				
<b>S Social</b>			<b>T Technological</b>		
1	Who is our target market?		1	What technology is critical for our day-to-day operations?	
2	How are consumer opinions changing regarding our product or service?		2	What new technology is available that could streamline our business?	
3	Is our core demographic growing or slowing down?		3	Do we depend on 3rd parties for any tech support or solutions?	
4	How do we interact on Social Media?		4	How are we using technology to stay ahead of the competition?	
			5	What can we learn from the data we collect?	
<b>E Economic</b>			<b>L Legal</b>		
1	What taxes impact our business?		1	How are we impacted by changes to legislation and regulation?	
2	Is the economy stable, unstable, or growing for your industry?		2	How do we keep ourselves compliant?	
			3	Are we up to date with data protection laws in all countries we operate in?	

# Risk Assessment

Risk Matrix Master Risk Matrix

Impact	Very Low	Low	Medium	High	Very High
Very High	Moderate	Severe	Severe	Critical	Critical
High	Sustainable	Moderate	Severe	Critical	Critical
Medium	Sustainable	Moderate	Moderate	Severe	Critical
Low	Sustainable	Sustainable	Moderate	Severe	Critical
Very Low	Sustainable	Sustainable	Sustainable	Moderate	Severe

Inherent Risk Matrix (before Controls)

Impact	Very Low	Low	Medium	High	Very High
Very High					
High	1			1	
Medium	1	1	1		
Low			1	1	
Very Low					

Residual Risk Matrix (after Controls)

Impact	Very Low	Low	Medium	High	Very High
Very High					
High					
Medium	1		2		
Low	1	2		1	
Very Low					

ID	Risk Description	Caused by & Consequences	Risk Owner (s) Name and Role	Inherent Risk (without controls)			Control (s)	Control Owner (s) Name and Role	Residual Risk (with controls)		
				Probability	Impact	Risk Rating			Residual Probability	Residual Impact	Residual Risk Rating
1	Risk 1	Caused by: Consequences:	Jemima Hamilton, VP Sales;	Medium	Very Low	Sustainable			Low	Very Low	Sustainable
				Low	High	Severe			Low	High	Severe
				Medium	Medium	Moderate			Medium	Medium	Moderate
				Low	Medium	Moderate			Low	Low	Sustainable
				High	High	Critical			Medium	Medium	Moderate
				High	Very Low	Sustainable			Medium	Very Low	Sustainable
				Medium	Low	Moderate			Low	Low	Sustainable

30

# Data Dictionary - Biospecimen Associated Data

## Pre-Analytical Variables – Minimum Required Data Checklist

<b>Patient Data</b>	ID-Patient-MRN ID-Patient-EID Patient-Gender	<b>Biospecimen Processing Data</b>	Processing-Start-Time Processing-Temp Prim-Centrifuge-Force Prim-Centrifuge-Temp Prim-Centrifuge-Duration Prim-Centrifuge-Brake Sec-Centrifuge-Force Sec-Centrifuge-Temp Sec-Centrifuge-Duration
<b>Case/Cohort Data</b>	ID-Case ID-IRB Consent-Type Consent-Answer Patient-Age-at-Collection Patient-age-unit Patient-prim-disease Patient-sec-disease	<b>Biospecimen Storage</b>	Sec-Centrifuge-Brake Post-Centrifuge-Temp Processing-Stop-Time Sample-id Sample-type Sample-volume Storage-container Freezing-time Freezing-delay
<b>Biospecimen Collection</b>	Collection-Institution/Site Collection-Time Collection-Year Specimen-Type Primary-Container-Type Patient-Fasting-Status Pre-transport-temp	<b>Biospecimen Distribution</b>	Retrieval-date Retrieval-reason Retrieval-reason-text Project-destination Delivery-temp
<b>Biospecimen Transport</b>	Transport-Temp		



Data Dictionary Format

31

# Application Form Service Agreement Checklist



Application Form Format

## 1. Applicant Details

Name of the collection

Contact person details:

Name, title, organization, position

Mailing address, email, phone number

Relationship to the project (e.g., Principal Investigator)

Lead Principal Investigator details (if different):

Name, title, organization, position

Mailing address, email, phone number

Relationship to the project (e.g., Principal Investigator)

Administering Institution

Custodian of the collection

## 2. Collection Details

Type of collection (e.g., Archival, Existing, Prospective)

Participant recruitment (current and target numbers)

Cohort type (e.g., disease-specific)

Research areas supported

Anticipated dates for biospecimen arrival

Duration of biospecimen activities

Research summary

Ethics approval details (IRB Approval status and documentation)

## 3. Biospecimen Access and Release

Management of access by DHBB – Access Criteria

Open access to biospecimens

Types of researchers with access

Formation of an access committee

Research permissions per consent

documents

## 4. Biospecimen Collection Plan

Collection Sites and location

Specific collection requirements

## 5. Biospecimen Processing

Processing protocols (e.g., aliquoting, fractionation, PBMC isolation)

Details for nucleic acid extraction, tissue processing, or other specialized processes

Customized protocols if deviating from DHBB SOPs

## 6. Biospecimen Transport

Transportation requirements (e.g., transit conditions, timing)

Transport and Logistics

Additional transport specifications

## 7. Biospecimen Storage

Storage requirements:

Type of cryovials and cryoboxes

Storage conditions (e.g., -70°C, liquid nitrogen) Storage

duration

Anticipated retrieval details

## 8. Data Management & Data Linkage

Additional data requirements (outside standard data elements)

Biospecimen data linkage

## 9. Appendix: List of Attachments

IRB Related/Shared Documents

CV of Principal Investigator

Ethics approval letter

IRB-approved documents detailing the collection

Collection, processing, and storage protocols

32

# Implementation Phase Monitoring and Control Phase

## Project Checklist - Implementation Phase

Project Execution			
No.	Description	Status	Comments/Actions
<b>D</b>	<b>Recruit patients</b>	Open	
	Introduce eligible patients to the biobank	Open	
	Obtain consent and release of medical information	Open	
<b>M</b>	<b>First Patient In / First Control</b>	Open	
	Last Patient in / Last Control	Open	
	100 participants recruited	Open	
<b>M</b>	<b>50% Participants recruited</b>	Open	
<b>M</b>	<b>Projected total enrolment targets achieve</b>	Open	
<b>D</b>	<b>Collect specimens and data</b>	Open	
	Collect Blood/Stool/ specimen (as part of standard of care)	Open	
	Send specimens to Site 1	Open	
	Process and store specimens	Open	
	Document data associated with specimen collection and processing	Open	
	Collect clinical data (as part of standard of care)	Open	
	Integrate clinical data to OpenSpecimen	Open	
	Collect tissue / Surgical	Open	
	Collect tissue / Biopsy	Open	
	Collect Peritoneal Fluid	Open	
	? Collect biomages (as part of standard of care)	Open	
	Send images report/link/digital image to DHBB	Open	
	Store and manage specimens and data	Open	
<b>M</b>	<b>First Sample In</b>	Open	
<b>M</b>	<b>Last Sample In</b>	Open	
<b>M</b>	<b>Completion of Sample Processing as per protocol</b>	Open	
<b>M</b>	<b>Completion of sample associated data completion.</b>	Open	

- Has the project scope been finalized by the stakeholders?
- Have the business requirements been finalized and signed off?
- Is there a peer / code review practice in place?
- Is the team aware of the project deliverables?
- Have all the hardware and infrastructure requirements been finalized and addressed?
- Does the project team need to be co-located?
- Is everyone in the team aware of roles and responsibilities for everyone including themselves?
- Is the team aware of the benefits and business value of the project?
- Is everyone in the team fully allocated to the project?
- Is the project team comfortable with the requirements and its details?
- Have you planned the resources required for the implementation?
- Is everyone in the project team aware of the project deadlines?
- Does the project team need to be co-located?
- Is everyone aware of the defect management process?
- Are you aware of the impact of systems shutdown for implementation?
- Do you need an implementation manager for the project?
- Is there a way of checking the systems are production deployment and before the business starts?
- Do you have commitment from business for testing resources?
- Do you have a plan to update the system documentation after the project is complete?
- Do you have a list of house keeping tasks for the project?
- Will the system need a User Manual?
- Do you have a list of critical tasks?
- Will there be a need on environment setup required?
- Does everyone in the project team have required hardware and software?

34

# Project Checklist - Monitoring and Control Phase

Project Execution			
No.	Description	Status	Comments/Actions
D	<b>Visibility: Disseminate biobank model</b>	Open	
	Develop content for biobank website/Webpage	Open	
	Publish content in Website/webpage	Open	
	Identify and link relevant End-Users to biobank catalogue	Open	
	Present at conferences	Open	
	Register biobank on relevant databases ISBER/Biobanking.org	Open	
	Publish and update key performance indicators (KPIs) and utilization metrics on website/reports	Open	
M	<b>Researchers and end-users are made aware of WHR biobank and the samples, data, and downstream derivatives available.</b>	Open	
D	<b>Generate biobank resources</b>	Open	
	Generate genome data	Open	
	Generate tumour organoids biobank resources	Open	
M	<b>Milestone #5: Generation of data and models</b>	Open	
D	<b>Review and approve data access requests</b>	Open	
	Setup early sample/data access date	Open	
	Set up WHR collection in DHBB Catalogue	Open	
	Receive data access requests from Platform/ DHBB Catalogue Users	Open	
	Review of data access requests by data access committee	Open	
	Respond data access requests	Open	
	Execute material and data transfer agreements with BB end-users	Open	
	Provide specimens and associated data to DHBB end-users	Open	
	Receive research findings from Platform end-users	Open	
	Add new research findings to the biobank	Open	
M	<b>Publish Catalogue</b>	Open	
	Utilized by internal Researcher (access)	Open	
	Biobank resources made available and utilized by DHBB end-users)	Open	
D	<b>Conduct mixed methods analysis to determine impact of patient engagement</b>	Open	
	Prepare research ethics board application	Open	
	Obtain research ethics board approval	Open	
	Administer Patient and Public Engagement Evaluation Tool	Open	
	Conduct semi-structured interviews	Open	
	Review adoption of patient engagement in research	Open	
	Analyse results	Open	
	Disseminate results	Open	
M	<b>Manuscript published on patient engagement analysis</b>	Open	

## Monitoring Phase Checklist:

- Is there a mechanism to change requests?
- Have you created a project change management plan?
- Do you have a communication plan?
- How often do you review your project budget?
- Do you have a detailed project schedule where the largest task is less than 5 days?
- Do you have a defect management process in place?
- What is the frequency of status reporting?
- Do you have a project status report for weekly and/or monthly reporting?
- Do you plan to conduct monthly project team meeting?
- Do you need to setup regular meetings with sponsors or project committee?
- Do you need all the resources on the project till the end?
- How will you track the resource utilization in the project?
- How to do plan to manage on going leave management for the team?
- Was a risk assessment conducted for the project?
- Is there a repetitive process to review the project risks?
- How will everyone be aware of the project risks and issues?
- Have you created a project risk and issue register?
- What is your stakeholder management plan?
- Will you be using a project management tool for tracking?
- How are you tracking the project dependencies?
- How are you tracking the project action items?
- Do you the required tools to capture timesheets?
- How do you plan manage project issues?
- Do you know who should be getting the project status report?

35

## Project status report

Project name: Insert your own text

Project manager: Insert your own text

**Overall status**

Time / Deadlines

- Millstone and Deliverables tracking
- Insert your own text - Insert your own text
- Insert your own text - Insert your own text

Cost / Budget

- Budget Plan
- Budget Tracking
- Insert your own text - Insert your own text
- Insert your own text - Insert your own text

Performance / Quality

- Non-Conformities
- Audit
- KPIs
- Insert your own text - Insert your own text

Key past milestones

- Insert Milestone
- Insert Milestone
- Insert Milestone

Key current milestones

- Insert Milestone
- Insert Milestone
- Insert Milestone

Key future milestones

- Insert Milestone
- Insert Milestone
- Insert Milestone

36

## Status report | KPIs: Details on performance layer

III Performance

Y2D Figures: ● ● ● FY23 Outlook: ● ● ●

Key News:

- ...

Performance Details

Status on KPIs actuals vs. budget 2023

Performance KPI	Year to Date			Full Year	Year to Go
	Actuals	Budget	Delta	Budget	Estimate
Volume	...				●
	...				●
	...				●
	... [#]				●
P&L	...				●
	... [k€]				●
Business	...				

37

## Budget Tracking

Budget Plan													
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
Starting Balance	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Income	-	-	-	-	-	-	-	-	-	170,000	-	-	-
Total Expenses	-	-	-	-	-	-	-	-	-	5,500	-	-	-
NET (Income - Expenses)	-	-	-	-	-	-	-	-	-	164,500	-	-	-
Projected End Balance	-	-	-	-	-	-	-	-	-	164,500	164,500	164,500	-
<b>INCOME</b>													
<b>Internal Funding</b>													
Department Budget	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Internal Income	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>External Funding/Other</b>													
Government Grants	-	-	-	-	-	-	-	-	-	-	-	-	-
Foundation Grants	-	-	-	-	-	-	-	-	-	-	-	-	-
Donations	-	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-	-
Total External Income	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total INCOME</b>													
<b>EXPENSES</b>													
[Category Name]													
[Itemized expense]										5,500			5,500
[Itemized expense]													
[Itemized expense]													
[Itemized expense]													
[Itemized expense]													
Subtotal										5,500			5,500
[Category Name]													
[Itemized expense]													
[Itemized expense]													
[Itemized expense]													
[Itemized expense]													
Subtotal													
[Category Name]													
[Itemized expense]													
[Itemized expense]													
[Itemized expense]													
[Itemized expense]													
Subtotal													
<b>Total EXPENSES</b>													
										5,500			5,500

39

## Biobank List of KPIs

- Participation Rate
  - Number of participants recruited
  - Number of enrolled participants
  - Number of Informed Consent
  - Number of Samples collected
  - Number of Collection Center
- Biobank
  - Liquid samples Stored and obtainable - total
  - Derivatives – Nucleic Acids, cells and other available on request
  - Newly stored liquid samples
  - Cryo samples stored
  - Newly stored cryo samples
  - Number of defined cohorts/collections/ disease spectrum
  - Tissue samples available on request:
    - FFPE Blocks total / newly stored
    - FFPE Slides total / Newly stored
  - IT framework - IT Sites covered by BIMS
- Sample/Data Utilization Rate:
  - Samples delivered to scientist to be used in medical projects
  - First-time Users requests
    - Samples
    - Dara
  - Research Project supported by DHBB services
  - Research project requests from Dubai Health
  - Project requests - external
  - Samples Requested:
    - FFPE Slides shared
    - FFPE blocks shared
    - Cryo samples provided
    - Liquid Samples provided
    - Diagnostic purpose FFPE Blocks / FFPE Slides
- Partnerships
- Publications
  - Publications Authored by DHBB
  - Publications as outcomes of research projects involving DHBB
- Acknowledgments

## Closure Phase

## Project Checklist Closure Phase

Project Close			
No.	Description	Status	Comments/Actions
D	Measure Impact	Open	
	KPIs and Metrics	Open	
	Sample Disposal	Open	
	Sample/Data Distribution	Open	
		Open	
		Open	

### Closing Phase Project Checklist:

- Was an implementation review conducted?
- Are all the project benefits still on track?
- Will there be a closure document?
- Have all the stakeholders authorized the project closure?
- Are there any pending or open issues because of the project?
- Do you have a list of lessons learnt?
- Have adequate arrangements been made for the handover of the new or updated systems/processes?
- Has the project budget been finalized?
- Are all the project resources released?
- Have all the post project activities been actioned?

## References

## References

The Toolkit was developed from frameworks, templates, and best practices from:

- Araza, L. L. (2017). *PMBOK: A Guide to the Project Management Body of Knowledge*. [https://www.academia.edu/44433705/PMBOK\\_A\\_Guide\\_to\\_the\\_Project\\_Management\\_Body\\_of\\_Knowledge](https://www.academia.edu/44433705/PMBOK_A_Guide_to_the_Project_Management_Body_of_Knowledge)
- Menon, S. (2024). Best Practices and Implementation Challenges in Effective Project Management. *International Business Research*, 17(2), 66. <https://doi.org/10.5539/IBR.V17N2P66>
- PMI. (2022, February). *Gantt Charts and Agile Planning*. <https://www.pmi.org/disciplined-agile/agile/agilegantt>
- Nieto-Rodriguez, A. (2021). *Antonio Nieto-Rodriguez. Harvard Business review project management handbook: how to launch, lead, and sponsor successful projects*. Harvard Business Review Press.
- Flegg, K., Noronha, R., Restevski, I., Mallipatna, A. C., O'Donoghue, S., Tarling, T., Watson, P., & Dimaras, H. (2024). Governance and public trust: a case study of the rare-pediatric eye cancer biobank. *Canadian Journal of Ophthalmology*.

### Informed Consent Toolkit:

- NSW Health. (2020). *NSW Health Consent Toolkit V3 - NSW Health Statewide Biobank*. <https://biobank.health.nsw.gov.au/researchers/nsw-health-consent-toolkit/>

### Data Dictionary:

- SBP. (2024). *SBP Core Datasets FOR HUMAN LIQUID SPECIMEN*. Retrieved January 4, 2025, from [https://swissbiobanking.ch/2022/wp-content/uploads/2022/09/SBP\\_CoreDataset\\_HumanLiquid.pdf](https://swissbiobanking.ch/2022/wp-content/uploads/2022/09/SBP_CoreDataset_HumanLiquid.pdf)
- SBP. (2024). *SBP Core Datasets FOR HUMAN TISSUE SPECIMEN*. [https://swissbiobanking.ch/2022/wp-content/uploads/2022/09/SBP\\_CoreDataset\\_HumanTissue.pdf](https://swissbiobanking.ch/2022/wp-content/uploads/2022/09/SBP_CoreDataset_HumanTissue.pdf)

### Cohort Profile:

- Medical University of Graz, B. (2023). Collection and Cohort Profile Form CL312 Seite 1 von 2. In *Form*. [https://biobank.medunigraz.at/frontend/user\\_upload/OEs/oeforschungsinfrastruktur/biobank/pdf/Kohorten/6001\\_10\\_Blood\\_Bank\\_Collection.pdf](https://biobank.medunigraz.at/frontend/user_upload/OEs/oeforschungsinfrastruktur/biobank/pdf/Kohorten/6001_10_Blood_Bank_Collection.pdf)

### Biobank Application Form:

- NSW Biobank. (2024, August 11). *Application Forms - NSW Health Statewide Biobank*. <https://biobank.health.nsw.gov.au/researchers/application-forms/>