«In the name of god»

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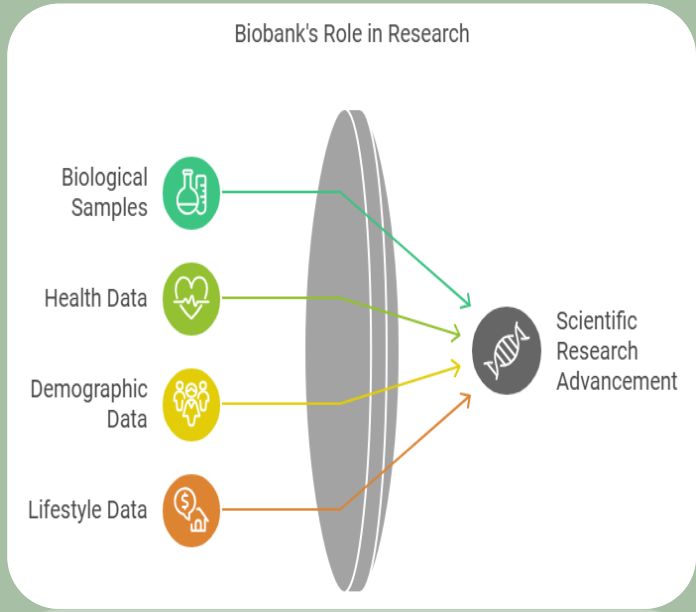
Establishing Biobanks: Designs, Classifications, and Fundamental Types

What is a Biobank?

A *biobank* is an integrated, governed system that collects, processes, and stores human biospecimens together with linked, consented data to enable reproducible research.



Biospecimens

- Whole blood, serum, plasma, buffy coat
- Tissue (fresh-frozen, FFPE)
- Urine, saliva, stool
- DNA/RNA
- CSF where applicable

Linked Data

- Demographics & encounters
- Diagnoses, procedures, medications
- Labs & imaging
- Outcomes & follow-up

Why Build a Biobank?

1. Facilitate Research

- Provide high-quality, well-annotated biospecimens for hundreds of projects
- Enable testing of hypotheses in real-world populations
- Allow rapid access to patients with defined phenotypes, speeding study design and execution

2. Identify Biomarkers

- Provide large numbers of patient and control samples for biomarker discovery and validation
- Support development of biomarkers for early cancer detection, prognosis, and treatment monitoring

3. Understand Disease Mechanisms

- Link biospecimens to rich clinical, lifestyle, and environmental data
- Clarify how factors such as diet, and physical activity interact with genetic background
- Support large-scale analyses that reveal new biological pathways and refined disease classifications

4. Develop Personalized Medicine

- Integrate genetic, phenotypic, and clinical information
- Define precise patient subgroups based on molecular and clinical profiles
- Enable tailored drug selection, individualized follow-up strategies, and risk prediction before disease onset

5. Support Epidemiological Studies

- Population-based biobanks represent defined communities (e.g., city, region, or country)
- Link biospecimens to longitudinal health records, environmental exposures, and lifestyle data
- Allow detailed study of disease incidence, time trends, and risk factors

6. Improve Healthcare Outcomes

- Contribute to new diagnostic tests, better patient stratification, and more precise therapies
- Inform screening and prevention programs and help reduce the burden of chronic diseases

7. Encourage Collaboration

Types of biobanks

Biobanks can be classified based on:

- Tissue type
- Purpose
- Ownership
- Participant demographics
- Size

Common classifications include:

- Population-based biobanks
- Disease-oriented biobanks
- Tissue Banks
- Umbilical Cord Blood Banks
- DNA/RNA Banks

Population-Based Biobanks:

- Collect biospecimens and data from a defined general population, not a single disease group.
- Link samples to demographics, lifestyle, environment, and health records, often longitudinally.
- Enable large-scale epidemiology, gene–environment studies.
- Aim to map prevalence, distribution, and determinants of disease and genetic variation.

Disease-Oriented Biobanks:

- Collect biospecimens from patients with a specific disease or syndrome
- Collect serial biospecimens at key time points across the disease course.
- Link samples to granular clinical data: disease type and stage, treatments received, response, adverse events, imaging, and long-term outcomes.
- Main goals are to elucidate disease mechanisms, discover and validate diagnostic/prognostic biomarkers, identify therapeutic targets, and enable disease-specific precision medicine.

Tissue Banks:

- Focus on the collection, processing, storage, and distribution of human tissues (e.g. tumor tissue, biopsies, surgically resected specimens, and sometimes transplantable tissues such as bone or cornea).
- Typically embedded within hospital pathology departments, using leftover surgical and biopsy material after completion of routine diagnosis.
- Each sample is linked to core pathological and clinical data, including diagnosis, grade and stage, site of sampling, and type of treatment.

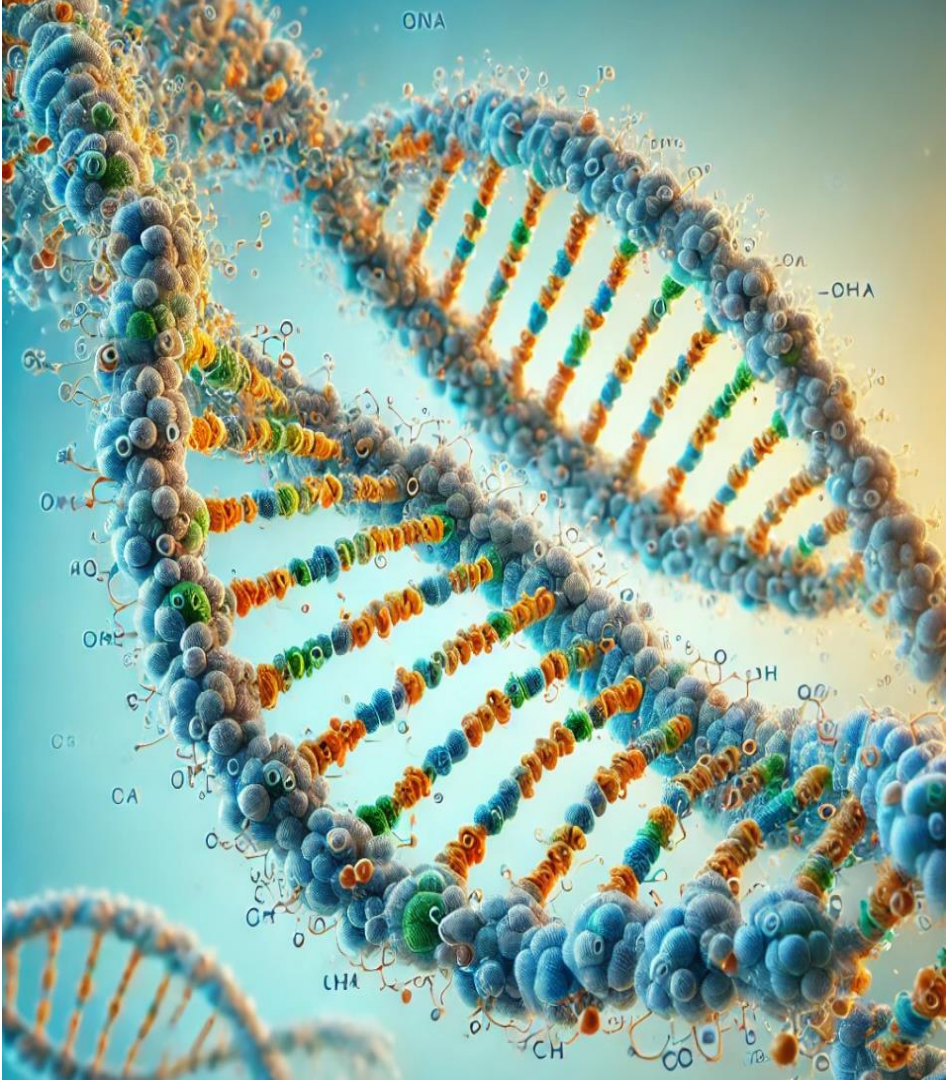
Umbilical Cord Blood Banks:

- Dedicated to the collection, processing, and storage of umbilical cord and placental blood immediately after birth as a rich source of hematopoietic stem cells.
- May operate as public banks:

(serving unrelated patients nationally/internationally)

or private banks:

(stored for potential autologous or family use)



DNA/RNA Banks:

- Focus on storing DNA and RNA samples.

- They are essential for genetic research, including studies on hereditary diseases.

Benefits of Creating a Biobank

For researchers:

- **Access to High-Quality Samples and Data**
- **Time and Cost Efficiency**
- **Collaboration Opportunities**
- **Enhanced Grant and Publication Potential**

For Patients:

- **Accelerated Discovery of Treatments**
- **Improved Diagnostics**
- **Personalized Medicine**
- **Improved Public Health Outcomes**

Design of a Biobank

1. Define the Biobank's Purpose and Objectives

2. Stakeholder Engagement

- Collaborators
- Patients
- Funders

3. Ethical and Legal Framework

- Ethical Compliance
- Informed Consent

4. Governance Structure

5. Infrastructure and Resource Planning

- Facility Design
- Equipment and Supplies
- Personnel

6. Sample and Data Types

- Biological Samples
- Clinical and Lifestyle Data

7. Participant Recruitment and Engagement

- **Recruitment Strategy**
- **Inclusion/Exclusion Criteria**
- **Retention**

8. Standard Operating Procedures (SOPs)

Standard Operating Procedures (SOPs) are detailed, written instructions that outline the processes and protocols followed in a biobank to ensure consistency, quality, and compliance with ethical and regulatory standards. They are critical for maintaining the integrity of the biobank and its resources.

9. Data Management Systems

- Data Security
- Interoperability

10. Quality Assurance and Control

- Sample Integrity
- Staff Training

11. Collaboration and Access Policies

12. Monitoring and Evaluation

Standard Operating Procedure

Importance of SOPs:

- Consistency
- Compliance
- Efficiency

1. Participant Recruitment

- Inclusion/exclusion criteria

2. Informed Consent Process

- Standardized informed consent procedures

3. Sample collection

- Collection Date & Time
- Sample Type & Container
- Sample Volume
- Patient Condition at Draw
- Collection Site
- Collector ID
- Time to Laboratory

4. Sample processing

- Processing Date & Time
- Operator ID
- Centrifuge Settings
- Interval: Collection to Processing
- Interval: Processing to Freezing
- Processing Temperature / Conditions
- Fixative Type & Fixation Time (Tissue)
- Aliquot IDs & Volumes

5. Transport Guidelines

- Dispatch/Receiving Date & Time
- Responsible Person
- Transport Temperature
- Maximum Transport Duration
- Cold Chain Integrity Check
- Packaging Type & Leak-Proof Containers
- Transport Route / From–To Location
- Chain of Custody Documentation

6. Sample labeling

- Unique Sample ID
- Pseudonymized Participant Code
- Barcode Generation
- Label Content Standards
- Label Placement on Vials
- Label Material & Durability
- Linkage to Database
- Date & Time of Labelling
- Double-Check / Verification Step

7. Sample storage and preservation

- Defined Storage Temperatures
- Freezer Type and Capacity Specification
- Rack / Box Location Tracking in database
- Continuous Temperature Monitoring and Alarms
- Backup Freezers and Emergency Transfer Procedures

8. Data management

- Structured Clinical and Demographic Data Capture
- Standardized Data Formats and Coding
- Pseudonymization and De-identification of Participants
- Secure Data Storage, Encryption and Backups
- Role-based Access Control and Audit Trails
- Data Sharing Policies and Data Use Agreements
- Regular Data Validation and Cleaning Procedures

9. Quality Assurance and Quality Control (QA/QC)

- Quality Management Framework
- Regular Calibration of Freezers, Centrifuges and Sensors
- Continuous Temperature Monitoring and Alarm Review
- Periodic Assessment of Sample Integrity (DNA/RNA/Protein)
- Staff Training Linked to Quality Requirements
- Ensuring Long-term Fitness of Samples for High-level Research

10. Equipment Maintenance

- Scheduled Preventive Maintenance
- Calibration and Performance Checks
- Maintenance Logs and Service Records

11. Training and Competency

- Staff training
- Regular Refresher Courses and Updates

12. Access policies

- Transparent Sample and Data Access Workflow
- Material Transfer and Data Use Agreements
- Fair and Responsible Use of Biobank Resources

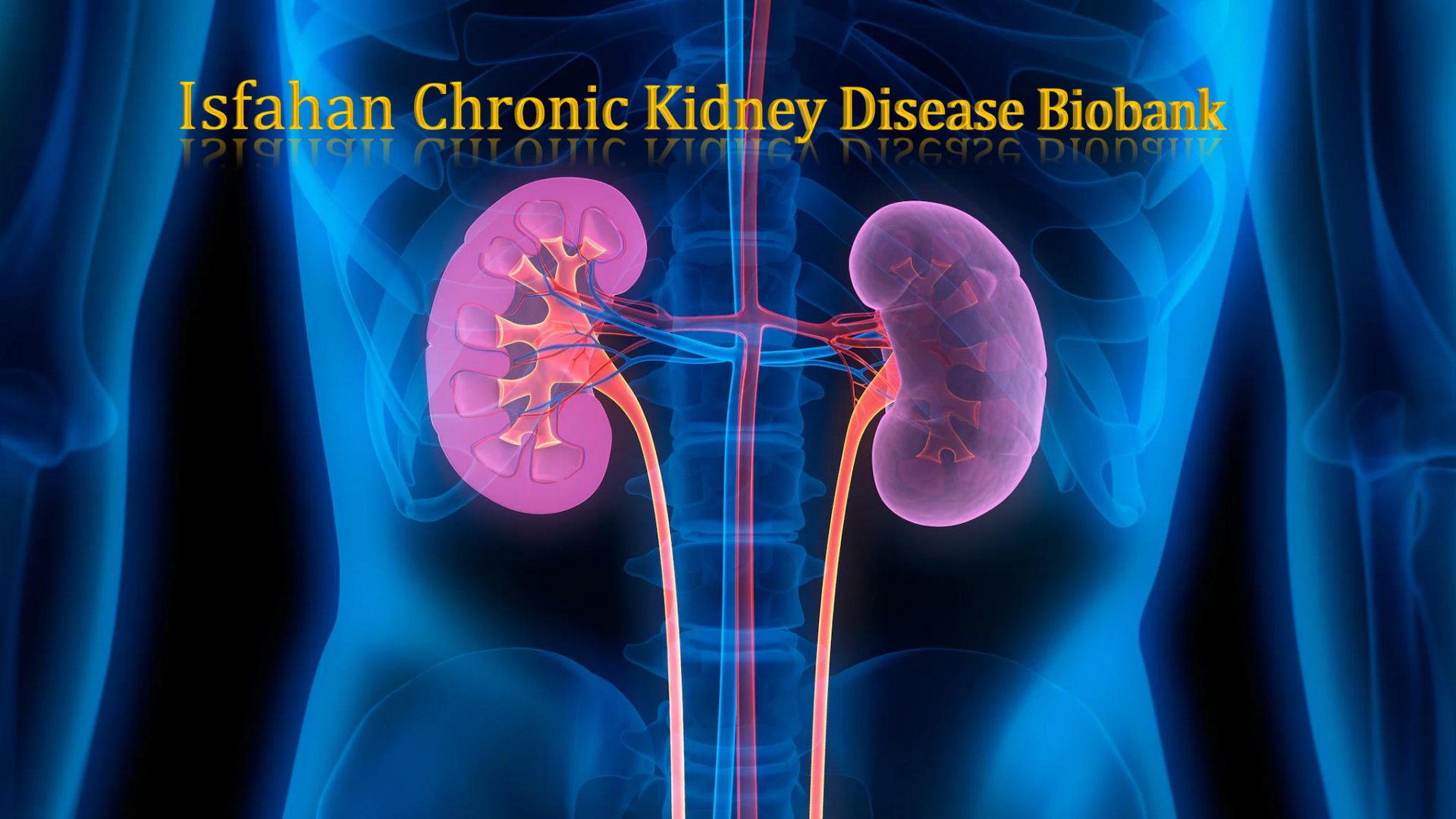
13. Emergency and contingency plans

- Disaster recovery
- Sample transfer

14. Monitoring and evaluation

- Scheduled SOP Review Cycles
- Incorporating Staff Feedback and QA/QC Findings
- Alignment with Updated Standards and Regulations
- Continuous Improvement of Biobank Practices

Isfahan Chronic Kidney Disease Biobank

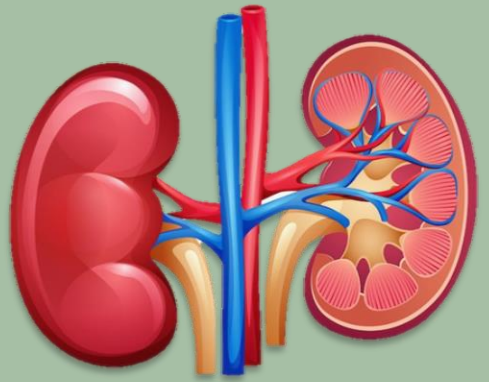


Rationale for a CKD Biobank

- Rising burden of CKD and unmet research needs
- Limitations of current diagnostic and prognostic markers

Core Aim of the CKD Biobank

- Establish a standardized, long-term repository of bio-samples and clinical data
- Enable high-quality, future-proof CKD research



Why New Biomarkers Are Needed

- Conventional markers change late in disease course
- Need for early, specific, and predictive indicators

Biobank Structure and Contents

- Harmonized collection of blood and urine samples
- Linked longitudinal registry of clinical, laboratory, and treatment data

Scientific Opportunities Enabled

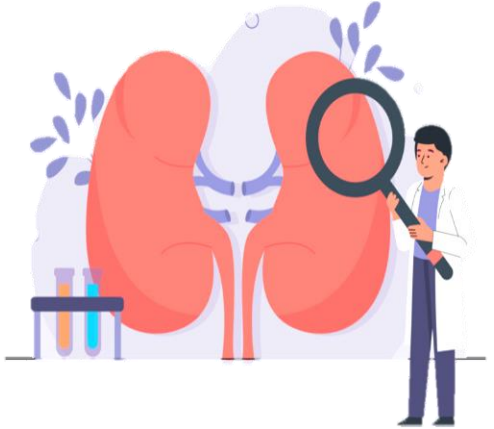
- Clarify molecular pathways and CKD heterogeneity
- Identify novel omics-based biomarkers (genomics, proteomics, metabolomics, transcriptomics)

Toward Precision Medicine in CKD

- Risk stratification and phenotyping
- Individualized prediction of progression and treatment response

Expected Clinical and Research Impact

- Accelerate large prospective and multicenter studies
- Improve early detection and targeted management
- Reduce progression and enhance patient outcomes



Total number of patients = 198	
Patient classification by nephropathy type	
Diabetic nephropathy	128
Hypertensive nephropathy	24
FSGS	20
MGN	8
SLE	6
PKD	2
IgA nephropathy	5
Wegner	3


Thank you
for your attention