Ethical Review and Data Governance Documentation

This document outlines the ethical, consent, and security procedures for the research project: "Personalized Medicine Approach for Hypertension Management: A Multi-Omics Study in a High-Risk Cohort."

1. Ethical Overview

Field	Detail
Ethical Approval Status	Pending Submission (Anticipated Submission Date: 2025-11-01)
Ethical Approval Ref Number	TBD-2026-03 (Reserved for submission)
Ethics Board	Institutional Review Board (IRB) - Main Campus
Approval Date	2026-02-01 (Anticipated)

Ethical Compliance Statement

The study will be conducted in strict accordance with the principles set forth in the Declaration of Helsinki (2013). The protocol ensures minimal risk to participants. The primary risk involves routine blood draws; all procedures will be conducted by trained clinical staff. The potential benefits—advancing personalized medicine and improving hypertension treatment—significantly outweigh the minimal risks involved.

2. Consent Procedures

Key Features of the Consent Process

1. **Comprehensive Information:** Participants will receive a consent document written at an 8th-grade reading level.
2. **Two-Stage Consent:**
    - **Stage 1 (Clinical):** Consent for participation, clinical data collection, and initial blood draws.
    - **Stage 2 (Omics/Future Use):** Detailed consent for genetic sequencing, metabolomic analysis, and the potential for future, unspecified research use of de-identified biological samples and data (Opt-in).

3. **Time for Reflection:** Participants will be given a mandatory minimum of 48 hours to read the consent form, discuss it with family, and ask questions of the Principal Investigator (PI) or a designated research nurse before signing.
4. **Voluntariness and Withdrawal:** Participation is entirely voluntary. Participants may withdraw at any time without prejudice to their ongoing medical care.

3. Data Security and Privacy Measures

Protecting the privacy and confidentiality of clinical and genetic data is paramount.

Measure	Description
Data Security	All data storage is compliant with HIPAA standards. Data resides on an encrypted, firewall-protected institutional server managed by the central IT department.
Pseudonymization	All identifying information (names, dates of birth, addresses) is separated from research data upon collection. A unique study ID is assigned, and a key-linked file (only accessible to the PI and the Data Security Officer) is stored separately.
Access Control	Role-based access control (RBAC) is implemented. Clinical staff can access clinical data; Bioinformatics staff can only access anonymized omics data; the PI has access to the full linkage file.
Genomic Data Release	Only de-identified, summary-level genomic data will be made publicly available via controlled-access repositories (e.g., dbGaP). Raw sequence data is never released publicly.

4. Related Publications and Documentation (Mock Data)

Ethical Documentation (Simulated Structure)

The following documents have been submitted to the IRB:

1. **Investigator Protocol:** The full detailed research plan.
2. **Informed Consent Form (ICF):** (Version 3.0, Dated 2025-10-15)
3. **Recruitment Materials:** Flyers and scripts.
4. **PI/Staff Training Records:** Proof of CITI training certification.

Related Publications (Mock Literature)

1. Chen, L. et al. (2024). Metabolomic Signatures Associated with ACE Inhibitor Efficacy in African American Hypertensive Patients. *JAMA Cardiology*, 9(4), 450-461.
2. Patel, A. V., & Sharma, B. K. (2023). Polygenic Risk Scores and Therapeutic Response in Essential Hypertension: A Systematic Review. *Circulation: Genomic and Precision Medicine*, 16(2), 150-165.