VCU IRB Study Branching

Initial Setup Section

1. Study Identification *(branching to the following pages based on responses)*

- Humanitarian Use Device Details → Documents
- Emergency Use
  - Emergency Use Consent → Documents
- Grant Review Details → Documents
- Not Human Subject Research Justification → Documents

2. Federal Regulations

3. IRB Panel Setup

4. Review Setup

Background, Rationale & Goals Section — *IRB Criteria for Approval 45 CFR 46.111 #1, 3*

5. Background, Rationale & Goals

6. Study Population

Research Plan Section — *IRB Criteria for Approval 45 CFR 46.111 #1, 2, 3, 7, 8*

7. Study Procedures

8. Project Details *(branching to the following pages based on responses)*

- EFIC Certification
  - EFIC Study Details
  - Exception from Informed Consent
- Behavioral Intervention Details
- Deception Details
- Bio-Medical Drug / Biologic / Supplement / Other Compound Details
- Bio-Medical Device Details
- Bio-Medical Treatment Use of an Investigational Product
- Sample Collection Details
- Passive Internet Collection Details
- Active Internet Collection Details
- Secondary Data/Specimen Details

9. Costs to Participants

10. Compensation

Consent Plan Section — *IRB Criteria for Approval 45 CFR 46.111 #4, 5*

11a. Exempt Information Sheet Upload *(exempt studies only)*

11b. Consent Process *(branching to the following pages based on responses)*

- Waiver of Some or All Elements of Consent
- Waiver of Documentation of Consent
- Short Form Consent
- Waiver of Assent by Child or Decisionally Impaired Adult

Risks, Privacy, and Confidentiality Section *IRB Criteria for Approval 45 CFR 46.111 #1, 2, 6, 7*

12. Risks, Discomforts, Potential Harms and Benefits *(expedited & full board studies)*

13. Privacy

14. Data Confidentiality and Storage

15. Data Retention

16. Future Sharing Plan *(branching to the following pages based on responses)*

- Existing Registry/Repository Details
- New Registry/Repository Details
- Genomic Data Sharing Submission Details

17. Pertinent and Incidental Findings

Populations with Special Considerations *IRB Criteria for Approval 45 CFR 46.111 #8; Subparts B, C, D*

18. Populations with Special Considerations *(branching to the following pages based on responses)*

- Children
- Wards of the State
- Pregnant Women or Fetuses
- Prisoners
- Decisionally Impaired Adults
- Limited English Proficiency
- Neonates: Uncertain Viability
- Neonates: Nonviable

Institutional Requirements Section *IRB Criteria for Approval 45 CFR 46.111 #1, 2, 7, 8*

19. Study Funding

20. Types of Sites

21. Personnel

22. Conflict of Interest

23. Other VCU Requirements

- HIPAA *(branching to the following pages based on responses)*
  - De-Identified Data
  - Waiver of Authorization
  - Partial Waiver of Authorization

Documents Section

24. Documents

Protocol Complete

External IRB Study Branching

Initial Setup Section

1. Study Identification

2. Federal Regulations

3. IRB Panel Setup

Background, Rationale & Goals Section

4. External IRB Study Summary

Populations with Special Considerations Section

5. Populations with Special Considerations

Institutional Requirements Section

6. External IRB Funding Details

7. External IRB Sites

8. Personnel

9. Conflict of Interest

10. Other VCU Requirements

- HIPAA *(branching to the following pages based on responses)*
    - De-Identified Data
    - Waiver of Authorization
    - Partial Waiver of Authorization

Documents Section

11. External IRB Document Upload

Protocol Complete