|  |  |  |  |
| --- | --- | --- | --- |
| ***DRAFT POLICY:*** | | | |
| **Responsible Official/Party:** |  | | **Effective Date:** |
| **Approved by:** |  | | **Last Revision:** |
| [Who Should Know this Policy](#_Who_Should_Know)  [Policy Statement](#_Policy_Statement)  [Scope and Purpose](#Scope_Purpose)  [Definitions List](#DefinitionsList)  [Assumptions](#Assumptions) | | [Procedures and Guidelines](#Procedures_Guidelines)  [Appendix A: Definitions](#AppendixA)  [Appendix B: Frequently Asked Questions](#AppendixB)  [Appendix C: Help and Support](#AppendixC)  [Appendix D: Related Policies & Regulations](#AppendixD) | |

*Large and complex multicenter HCSRN projects (e.g., coordinating centers, consortia with multiple ancillary or sub-studies) may wish to develop project specific policies as part of their infrastructure and governance. Such guidance documents provide structure, clarification of responsibilities, and pre-defined practices for these projects. Use of this template is optional, but encouraged to promote consistency across consortia.*

### Who Should Know this Policy *(Select appropriate categories below)*

**HCSRN members Non-HCSRN collaborators**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Investigators/Faculty | Analysts, project programmers |  | Investigators/Faculty | Analysts, project programmers |
| IT Personnel | Data managers |  | IT Personnel | Data managers |
| Grants and Contracts/Research Administration | Project Managers/Coordinators |  | Grants and Contracts/Research Administration | Project Managers/Coordinators |
| Business Operations | Research Specialists/Assistants |  | Business Operations | Research Specialists/Assistants |
| Other: IRB Staff |  |  | Other: IRB Staff |  |

### Policy Statement

### Scope and Purpose

**Definitions List**

The following definitions essential to understanding this policy are including in Appendix A:

[Term A](#TermA)

[Term B](#TermB)

Etc.

### Assumptions

### 

### Procedures and Guidelines

**Appendix A: Definitions**

|  |  |
| --- | --- |
| **Term A** |  |
| **Term B** |  |
| **Etc.** |  |

### Appendix B: Frequently Asked Questions

### Q.

*A.*

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### Appendix C: Help and Support

|  |  |  |
| --- | --- | --- |
| **For questions about:** | **Contact:** |  |
|  |  |  |
|  |  |  |

**Appendix D: Related Policies & Regulations**

HCSRN Policies and Guidelines



HCSRN Member Site Specific Policies



Federal Regulations & Publications