



1 PURPOSE

- 1.1 This document describes the policies and procedures for developing, implementing, and revising policies and procedures for the UW Institutional Review Board (IRB) and the Human Subjects Division (HSD).

2 POLICIES

- 2.1 HSD has and maintains written policies and procedures for the major functions of the UW IRBs and HSD. As required by federal regulations, this includes procedures which the IRB will follow for:
 - 2.1.1 Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and institution;
 - 2.1.2 Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and
 - 2.1.3 Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects.
- 2.2 HSD and IRB policies and procedures must be consistent with:
 - 2.2.1 Applicable federal and state regulations;
 - 2.2.2 The terms of the UW's Federalwide Assurance (FWA);
 - 2.2.3 UW Executive Order No. 24.
- 2.3 The HSD Director has delegated authority from the Vice Provost of Research to develop, implement, and revise policies and procedures for the IRB and HSD (Reference 7.3).
 - 2.3.1 The HSD Director is expected to consult with other UW offices, groups, and individuals in developing policies and procedures, and in interpreting regulations and regulatory guidance.
- 2.4 As established by the Vice Provost for Research (Reference 7.3), policies must have the written concurrence of the Institutional Official listed on the UW's FWA.
- 2.5 Procedures should provide sufficient step-by-step description with key operational details so that an independent observer can understand how HSD and the IRB operate and conduct their major functions.

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Table of Contents Example Of Policy And Procedure Document

1. Understanding the eBook Example Of Policy And Procedure Document
 - The Rise of Digital Reading Example Of Policy And Procedure Document
 - Advantages of eBooks Over Traditional Books
2. Identifying Example Of Policy And Procedure Document
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Example Of Policy And Procedure Document
 - User-Friendly Interface
4. Exploring eBook Recommendations from Example Of Policy And Procedure Document
 - Personalized Recommendations
 - Example Of Policy And Procedure Document User Reviews and Ratings
 - Example Of Policy And Procedure Document and Bestseller Lists

5. Accessing Example Of Policy And Procedure Document Free and Paid eBooks
 - Example Of Policy And Procedure Document Public Domain eBooks
 - Example Of Policy And Procedure Document eBook Subscription Services
 - Example Of Policy And Procedure Document Budget-Friendly Options
6. Navigating Example Of Policy And Procedure Document eBook Formats
 - ePub, PDF, MOBI, and More
 - Example Of Policy And Procedure Document Compatibility with Devices
 - Example Of Policy And Procedure Document Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Example Of Policy And Procedure Document
 - Highlighting and Note-Taking Example Of Policy And Procedure Document
 - Interactive Elements Example Of Policy And Procedure Document
8. Staying Engaged with Example Of Policy And Procedure Document
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Example Of Policy And Procedure Document
9. Balancing eBooks and Physical Books Example Of Policy And Procedure Document
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Example Of Policy And Procedure Document
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Example Of Policy And Procedure Document
 - Setting Reading Goals Example Of Policy And Procedure Document
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Example Of Policy And Procedure Document
 - Fact-Checking eBook Content of Example Of Policy And Procedure Document
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning

- Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
- Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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