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.

Policy Document Template

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Table of Contents Policy Document Template

- 1. Understanding the eBook Policy Document Template
 - The Rise of Digital Reading Policy Document Template
 - Advantages of eBooks Over Traditional Books
- 2. Identifying Policy Document Template
 - Exploring Different Genres
 - o Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
- 3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Policy Document Template
 - User-Friendly Interface
- 4. Exploring eBook Recommendations from Policy Document Template
 - Personalized Recommendations
 - Policy Document Template User Reviews and Ratings
 - Policy Document Template and Bestseller Lists
- 5. Accessing Policy Document Template Free and Paid eBooks
 - Policy Document Template Public Domain eBooks
 - Policy Document Template eBook Subscription Services
 - Policy Document Template Budget-Friendly Options

- 6. Navigating Policy Document Template eBook Formats
 - o ePub, PDF, MOBI, and More
 - Policy Document Template Compatibility with Devices
 - Policy Document Template Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Policy Document Template
 - Highlighting and Note-Taking Policy Document Template
 - Interactive Elements Policy Document Template
- 8. Staying Engaged with Policy Document Template
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Policy Document Template
- 9. Balancing eBooks and Physical Books Policy Document Template
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Policy Document Template
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Policy Document Template
 - Setting Reading Goals Policy Document Template
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Policy Document Template
 - Fact-Checking eBook Content of Policy Document Template
 - 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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