



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

D Keegan



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How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements Stephanie L. Skipper, 2015-10-14 This book explains the requirements for compliance with FDA regulations and ISO standards 9001 13485 for documented information controls and presents a methodology for compliance The document control system DCS or documented information control system DICS is the foundation of a quality management system It is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle A well developed document control system benefits business by Improving knowledge retention and knowledge transfer within and across business units Improving access to knowledge based information Improving employee performance by providing standardized processes and communicating clear expectations Improving customer communication and satisfaction by providing documented information from which common understanding can be achieved Providing traceability of activities and documentation throughout the organization Improving organization of and access to documents and data Sample documents are included in the appendixes of this book to help clarify explanations and a full set of formatted procedures and document templates are available for download to get you off to an even faster start This book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system The Complete Company Policies Ian Long, 2024-03-29 This book is about a much neglected but essential element of the success of any business company policy This is a comprehensive guide to determining what policies your company needs and how to draft and approve the relevant documents and implement them throughout the organization From anti bribery laws to data privacy and health and safety your business is faced with a range of legal and regulatory obligations that must be identified and documented properly These obligations must be addressed for internal and external stakeholders The task of identifying and documenting effective policies is an essential step in establishing good corporate governance and ultimately a culture of compliance These policies in turn provide a solid foundation for the reputation and commercial success of the organization and form an essential bridge between the company s strategy and the various procedures needed to carry it out With many useful templates and practical examples this book will help you to ensure the accuracy and completeness of your policy documents It covers all areas of your business including financial reporting anti money laundering anti fraud conflicts of interest data privacy and security remote working social media whistleblowing and more This book will be useful to company directors company secretaries and senior managers and their advisers including consultants auditors and solicitors It will be particularly relevant to any business that needs to create or review their policies in light of current regulations and standards

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Model policy for inclusive ICTs in education for persons with disabilities Watkins, Amanda,2014-04-07

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Environments In Effective Cybersecurity William Stallings introduces the technology operational procedures and management practices needed for successful cybersecurity Stallings makes extensive use of standards and best practices documents that are often used to guide or mandate cybersecurity implementation Going beyond these he offers in depth tutorials on the how of implementation integrated into a unified framework and realistic plan of action Each chapter contains a clear technical overview as well as a detailed discussion of action items and appropriate policies Stallings offers many pedagogical features designed to help readers master the material clear learning objectives keyword lists review questions and QR codes linking to relevant standards documents and web resources Effective Cybersecurity aligns with the comprehensive Information Security Forum document The Standard of Good Practice for Information Security extending ISF s work with extensive insights from ISO NIST COBIT other official standards and guidelines and modern professional academic and industry literature Understand the cybersecurity discipline and the role of standards and best practices Define security governance assess risks and manage strategy and tactics Safeguard information and privacy and ensure GDPR compliance Harden systems across the system development life cycle SDLC Protect servers virtualized systems and storage Secure networks and electronic communications from email to VoIP Apply the most appropriate methods for user authentication Mitigate security risks in supply chains and cloud environments This knowledge is indispensable to every cybersecurity professional Stallings presents it systematically and coherently making it practical and actionable Essential

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