



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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William L. Harper



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Information Security Management Handbook, Sixth Edition Harold F. Tipton, Micki Krause, 2007-05-14 Considered the gold standard reference on information security the Information Security Management Handbook provides an authoritative compilation of the fundamental knowledge skills techniques and tools required of today's IT security professional Now in its sixth edition this 3200 page 4 volume stand alone reference is organized under the CISSP Common Body of Knowledge domains and has been updated yearly Each annual update the latest is Volume 6 reflects the changes to the CBK in response to new laws and evolving technology

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understanding essential management and leadership concepts tailored for healthcare organizations and clinical laboratories Each chapter begins with a real world case in point guiding you through critical topics such as healthcare finance quality assurance and regulatory issues laboratory safety personnel management and team dynamics ensuring that current and future laboratory leaders are well equipped to navigate the complexities of their roles Management and leadership concepts are presented through the lens of healthcare organizations and medical laboratories Management practices explored include principles in operations management healthcare finance and managing budgets regulation and compliance human resource management and method validation Leadership topics include managing and leading a diverse workforce self and external awareness leading teams and developing others Learning objectives highlight management and leadership competencies Problem based approach in each chapter introduces the topic with a case in point followed by a list of discussion points for you to consider as you navigate the chapter content Self assessment tools follow up learning activities and tips for managers and supervisors provide additional content and opportunities for further engagement Personal reflection and application exercises at the end of each chapter reinforce comprehension and retention of key concepts

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

Developing and Managing Engineering Procedures Phillip A. Cloud,2001-01-16 This book provides hands on techniques for writing engineering procedures to achieve ISO 9000 compliance It is designed for individuals responsible for writing these procedures in any industry Readers will find actual examples of clearly written compliant engineering procedures ready to adapt to your own

industry and your own particular needs and use immediately It answers virtually all your procedure writing questions Procedure writers will gain a general understanding of engineering documentation principles and how to apply them to their own situations Simple diagrams and other graphics illustrate key ideas giving a bird s eye view of what is coming next The intent of the book is to familiarize the reader with the essential elements and concepts of engineering procedure development and management and show how to apply these concepts to their own specific applications The author emphasizes engineering principles and tools that are common to all engineering disciplines with examples for their use Step by step procedures shown for each document format enable readers to apply each format to their own engineering documentation programs quickly and easily The book provides a fingertip reference that covers the entire engineering procedure process using the latest technology for engineering documentation systems Management Policy and Procedure Manual Trans World Airlines,1946 Illinois EPA Policy & Procedure Manual Illinois. Environmental Protection Agency,1978 **Handbook of Institutional Pharmacy Practice** Thomas R. Brown,2006 This comprehensive text provides fundamental information on a broad spectrum of essential topics in health system pharmacy practice From an overview of health delivery systems and hospital pharmacy through various practice settings such as home care long term care hospice and palliative care ambulatory care and managed care this text focuses on various elements important to health system pharmacies The Handbook of Institutional Pharmacy Practice is the first step in developing a career in pharmacy and provides opportunities for study in career enhancement New chapters included in the fourth edition Integrity of the Drug Supply Overview of the History of Hospital Pharmacy in the United States Interprofessional Teams Collaborative Practice Models Development Implementation and Monitoring Therapeutic Plans and Evidence Based Medicine **Law Office Policy & Procedures Manual** Robert C. Wert,Howard I. Hatoff,2000 A manual for the law office this volume can serve as a reference for staff or as a training tool for new employees and associates It covers departments and committees organization and administration support personnel file systems office security and more The disk contains all the text **Policy and Procedure** Michigan. Department of Natural Resources,1977 Medical Laboratory Management and Supervision Lionel A. Varnadoe,1996 A textbook for college students intending to enter leadership positions in medical laboratories a study guide for laboratory workers preparing for a management certification examination or a self study tutorial for those familiar with the technical and medical aspects of the laboratory who would like to know more about its management Includes sample exam questions for each section Annotation copyright by Book News Inc Portland OR Pharmacy Policy and Procedures American Society of Consultant Pharmacists,1977 Pharmacy Practice for Technicians Zachary I. Hanan,1994 *California. Court of Appeal (2nd Appellate District). Records and Briefs* California (State)., *Reference Policy and Administrative Documents* American Library Association. Reference and Adult Services Division,1985 Summarizes reference department administrative and policy documents collected as part of a survey conducted under the auspices of the division s

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