



**OO18 – The organization’s policies, procedures, charters or bylaws (including institutional Review Board) that protect the rights of participants in research.**

**Abbreviations used in categories of policies below:**

- UVA: University of Virginia; academic entities as well as Health System
- MCP: Medical Center Policy
- HRP: Medical Center Human Resources Policy
- PCS: Patient Care Services Policy; overseen by Chief Nursing Officer

**UVA Health System Policies – These apply to all patients and staff, including those involved in research studies:**

- [XREF Exhibit OO12.bk](#): MCP 0026: Patient Rights and Responsibilities
- [XREF Exhibit OO12.bi](#): MCP 0105: Ethics and Patient-Care Consultation
- [XREF Exhibit OO12.j](#): MCP 0084: Health-Information Request for Non-Patient Care Usage
- [XREF Exhibit OO14.a](#): MCP 0217: Corporate Compliance Auditing and Monitoring Program
- [XREF Exhibit OO14.b](#): MCP 0235: Compliance Code of Conduct
- [XREF Exhibit OO12.bm](#): MCP 0024: Informed Decision-Making
- [XREF Exhibit OO12.bo](#): MCP 0191: Refusal of Treatment
- [XREF Exhibit OO12.a](#): MCP 0021: Confidentiality of Patient Information
- [XREF Exhibit SE6.a](#): MCP 0269: Provision and Documentation of Patient and Family Education
- [XREF Exhibit OO12.bn](#): MCP 0293: Disclosure of Outcomes
- [Exhibit OO18.a](#): MCP 0076: Management of Medical Devices Used in Patient Care
- [XREF Exhibit OO12.bj](#): MCP 0233: Conflict of Interest
- [XREF Exhibit OO15.i](#): MCP 0259: Medication Management

**UVA Internal Review Board (IRB) Standard Operating Procedures:**

- [XREF Exhibit OO19.a](#): [UVA IRB Standard Operating Procedures](#) includes a very in-depth description of UVA’s Human Subject Protection Program and its principles and roles.
- [XREF Exhibit OO19.b](#): [UVA IRB-HSR Members’ Guide](#) includes detailed expectations for members’ human subject protection considerations during their review of protocols.



- OO18 Figures 1 and 2 below are screenshots showing examples of the many guidance resources that the UVA IRB-HSR provides on its website for UVA staff engaged in research.

**OO18 Figure 1. Screenshot of UVA IRB-HSR Regulations Website**

**IRB-HSR: Regulations - Windows Internet Explorer**

http://www.virginia.edu/vpr/irb/hsr/regulations.html

File Edit View Favorites Tools Help

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**UNIVERSITY OF VIRGINIA**  
**IRB-HSR**

**Institutional Review Board for Health Sciences Research**

For: **Researchers** IRB Members Research Subjects IRB Staff

IRB-HSR > IRB-HSR Resources > Regulations

**Regulations**

- [Federal Register- 21CFR312: Investigational New Drug Applications](#)  
Title 21, Chapter FDA, Part 312
- [Federal Register- 21CFR812: Investigational Device Exemptions](#)  
Title 21, Chapter FDA, Part 812
- [45 CFR Part 46 -Code of Federal Regulations- Public Welfare: Protection of Human Subjects](#)
  - o [Subpart A Federal Policy for the Protection of Human Subjects](#)
  - o [Subpart B Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research](#)
  - o [Subpart C Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects](#)
  - o [Subpart D Additional DHHS Protections for Children Involved as Subjects in Research](#)
- [21 CFR Part 50 - Protection of Human Subjects](#)
- [21 CFR Part 56 - Institutional Review Boards](#)
- [32CFR219- National Defense: Office of the Secretary of Defense](#)
- [HIPAA Regulations- 45CFR164, Standards for Privacy of Individually Identifiable Health Information; Security Standards for the Protection of Electronic Protected Health Information \(HIPAA Privacy and Security Rules\)](#)

**Guidance**

[National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report \(April 18, 1979\)](#)

[World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects \(amended October 2000\)](#)

[DHHS Office for Protection from Research Risks \("OPRR"\) OHRP IRB Guidebook \(1993\)](#)

[DHHS Office of Human Research Protection \("OHRP"\), Compliance Activities: Common Findings and Guidance](#)

[OHRP Determination Letters](#)

[FDA \(Food and Drug Administration\) IRB Information Sheets-policy statement and guidance documents](#)

[FDA International Conference on Harmonization, Guidance on General Considerations for Clinical Trials, 62 Federal Register 66113 \(December 17, 1997\).](#)

[International Conference on Harmonisation \(ICH\), Good Clinical Practice Guidelines](#)

[The Nuremberg Code http://www.hhs.gov/ohrp/references/nurcode.html](#)

[Department of Defense Directive Number 3216.02](#)

**Other Resources:**

**General Information**

- + [Calendars & Deadlines](#)
- + [Office Information](#)
- + [Directions & Hours](#)
- + [Staff Directory](#)
- + [Frequently Asked Questions](#)
- + [IRB-HSR Membership Lists](#)
- + [FWA Information](#)
- + [Organizational Charts](#)
- + [Research Concerns](#)
- + [Standard Operating Procedures](#)

**Working With the IRB-HSR**

- + [Getting Started](#)
- + [Protocol Review Process](#)
- + [Managing Protocol After Initial Approval](#)
- + [Special Issues](#)

**IRB-HSR Resources**

- + [Protocol Builder and IRB On-Line: On Grounds or UVA VPN access only](#)
- + [Forms](#)
- + [CITI Training](#)
- + [Education](#)
- + [Regulations/Guidelines](#)
- + [Ethical Principles](#)
- + [Search IRB-HSR Protocols](#)
- + [Glossary/Acronyms](#)
- + [Useful Websites](#)

**Partner Offices**

- + [Go to full list >>](#)

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OO18 Figure 2. Screenshot of UVA IRB-HSR Members' Resource Website

**IRB-HSR: For IRB Members - Windows Internet Explorer**

http://www.virginia.edu/vpr/irb/hsr/for\_members.html

File Edit View Favorites Tools Help

Shared Documents HS Clinician Portal HS Medical Center Policy ... http://www.virginia.e... IRB-HSR: Regulations IR

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For: **Researchers** IRB Members Research Subjects IRB Staff

IRB Home > For IRB Members

**For IRB Members**

**New to the IRB**

- IRB Members Guide
- Acronyms
- CITI Training
- Educational Offerings
- Ethical Guidelines
- Glossary
- IRB-HSR Administrative Staff
- Meeting Dates
- Federal Government Human Research Protection Org Chart
- UVa Human Research Protection Org Chart

**Commonly Used Forms**

- Scientific Reviewers Checklist
- Non-Scientist Reviewers Checklist
- Device Risk Determination SR vs. NSR Checklist
- Modification Reviewers checklist
- NCI CIRB Facilitated Reviewer's Checklist
- Serious Adverse Event/Unanticipated Problem Review Checklist
- Protocol Violation Checklist
- Vulnerable Populations Checklists
  - Children
  - Cognitively Impaired
  - Pregnant Women, Fetuses, Neonates
  - Prisoner
- Continuations Checklist

**Federal Regulations and Other Useful Resources**

- Federal Wide Assurance (FWA)
- Federal Regulations
- Resources for International Research
- Useful Websites and Links

**Other IRB References**

- HHS/OHRP - IRB Guidebook
- FDA - Guidance for IRBs
- PRIM&R Public Responsibility in Medicine and Research, otherwise known as PRIM&R, is a non-profit organization for those committed to promoting the highest ethical standards in the conduct of research. PRIM&R develops educational programs for those charged with the review and conduct of research.

Start | [Icons] | O:\MAGNET\_Working\... | Inbox - JRT7C@hscmai... | RE: Magnet help - Mes... | RE: Org. Overview - M... | IRB-HS