

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
- XREFExhibit 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

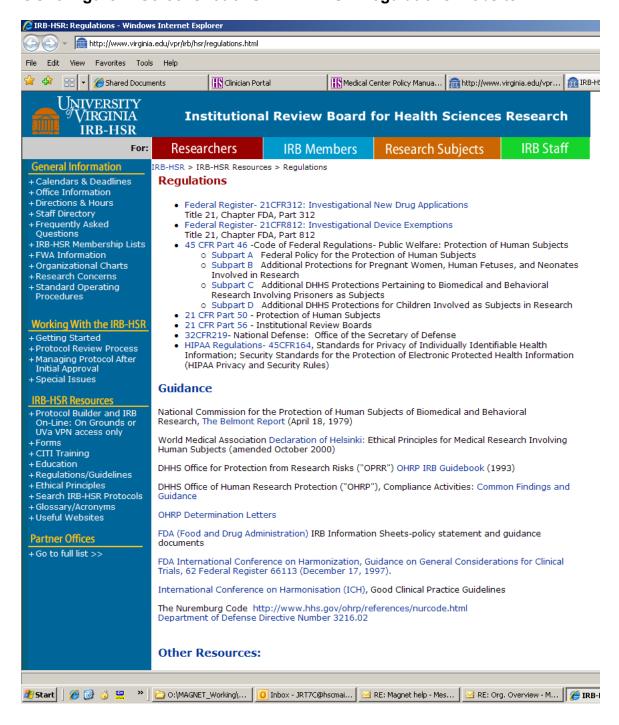
UVA Internal Review Board (IRB) Standard Operating Procedures:

- 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





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

