

**Institutional Review Board – Overview**

**Bronwyn Blackwood, IRB-SBS Director**

**Office phone: 243-2915 Email: [blb2u@virginia.edu](mailto:blb2u@virginia.edu)**

**Office website: <http://www.virginia.edu/vpr/irb/sbs.html>**

**IRB-SBS Office phone: 924-5999**

*March 14, 2011*

**What is this about?**

- Planning to involve people in your research?
- Research might confer benefit, pose risk, or have no effect (how do you know?)
- Conduct research responsibly (compliance) and with respect for people who enroll (ethics)

**What is the IRB?**

- Institutional Review Board
- Human subjects in research (not animals, not bench science, etc)
- Federal regulations set forth IRB responsibility at an academic institution
  - 45CFR46 (DHHS common rule) – protection of human subjects regulation sets rules in three areas: (1) IRB assurances; (2) conduct of IRB; (3) IC
  - 21CFR50, 56 and 32CFR219 (FDA – experimental drugs and devices)
  - 45CFR160 and 164 (HIPAA)

**How many IRBs do we have at UVa?**

- IRB-SBS (non medical research)
- IRB-HSR (research involving a biomedical intervention)

**Do I HAVE TO apply to the IRB?**

- Are you doing human subject research?
  - Human subject = living individual about whom an investigator (could be a student) conducting research obtains data through intervention or interaction with the individual OR identifiable private information
  - Research = systematic investigation designed to develop or contribute to generalizable knowledge (GK = results generalize past the sample cohort to the entire population that gave rise to the sample)
  - When to say yes: involves HS, is a systematic investigation, and you intend to disseminate findings in a public manner
  - When to say no: no HS or not a systematic investigation or no public dissemination
  - If unsure ask the IRB!!

### **What is the Belmont Report?**

- [www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)
- Regulatory compliance is the skeleton of the truly ethical conduct of research
- Sets forth three ethical principles
- 1. **Respect for Persons**
  - treat individuals as autonomous agents
  - do not use people as a means to an end
  - allow people to choose for themselves
  - give extra protection to those with limited autonomy
  - protect person's privacy and confidentiality of research data
- 2. **Beneficence**
  - Acts of kindness that go beyond duty
  - Do no harm, prevent evil, promote good
  - Sound research design
  - Monitor data to ensure participant safety
  - Benefits should outweigh risks
- 3. **Justice**
  - Treat people fairly
  - Fair sharing of burdens and benefits of research
  - Select participants equitably

### **What does the IRB want to see in a new application?**

- Thinking about possible ethical dilemmas that could arise
- Solid study design
- Favorable risk/benefit ratio
- Extra protections for vulnerable populations
- Respect enrolled subjects/respect for study site (minimize disturbances)
- Adequate recruitment procedures (advertisements must be approved by IRB before use, including scripts for verbal recruitment)
- Adequate informed consent process (honest, objective discussion, transparent, no undue influence, appropriate setting to have discussion)
  - The goal is not to "get consent" but to provide objective information and then let the person decide for themselves
- Protect privacy – if you don't need to know information – don't ask about it!!

### **If I have to apply to the IRB, how do I do it?**

- IRB-SBS: templates at [www.virginia.edu/vpr/irb/sbs\\_submit\\_newpro\\_how.html](http://www.virginia.edu/vpr/irb/sbs_submit_newpro_how.html)
- IRB-HSR: use protocol builder <http://www.irb.virginia.edu/>
  - Contact Margaret Ball (243-0639) if you need help with protocol builder

### **What happens to my research protocol after it has been submitted?**

- Pre-review by IRB staff member
  - Outcome—protocol changes are likely prior to an official review.

- Determination of **Administrative or Full-Board review**
  - Outcome—protocol changes are likely prior to final approval or exemption, OR the full board may table or reject a protocol.
- Final approval or exemption

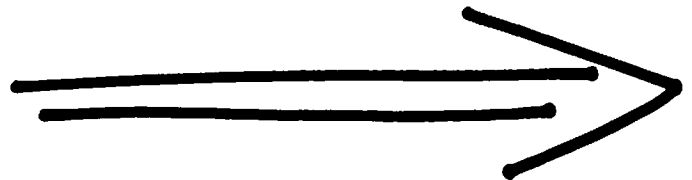
**What is the difference between exemption and approval?**

- **Exempt**—Four year approval (with yearly email)
  - Informed consent procedures may not be required. The IRB requires information be communicated to the participant about the nature of the study in most cases. Public observation of adults would be an exception.
- **Approved**—One year approval (expedited/full board)
  - Informed consent procedure and documentation required. In some cases, the board may choose to waive documentation of consent, but doesn't usually waive the consent requirement altogether.

**How do I keep the peace with the IRB?**

1. Make sure you get IRB approval if you need it. Ask the IRB and/or a faculty advisor for help if you are unsure
2. If you are conducting human subject research, you must obtain IRB approval *before* you begin to conduct the research
3. After the IRB approves your study, make sure *you follow your approved protocol (this is a contract between you, your department and UVa)*
4. If you want to change your approved protocol, *you must first get IRB approval for the change* before you implement the change in your research practices
5. Study documentation
  - Promotes integrity of your research data
  - Write down everything you do
  - Shows you followed your protocol
  - Backs up you and your study team – your decisions and actions
  - Help explain a discrepancy
  - Helps you remember what's happening between visits
  - Helps you remember the details when it's time to write a manuscript

*IRB Process*



# IRB-SBS Review Process

Website address:  
<http://www.virginia.edu/ypr/irb/sbs.html>

For questions contact:  
[irbsbshelp@virginia.edu](mailto:irbsbshelp@virginia.edu) or (434) 924-5999

Email address for protocol submissions:  
[irbsbs@virginia.edu](mailto:irbsbs@virginia.edu)

Staff Areas:  
 Maizie Jackson—Protocol Manager  
 Jeff Monroe—Education  
 Sandy Gardiner—Psychology  
 Bronwyn Blackwood—Other Program Director

IRB

\* Submit your new protocol to the IRB-SBS at [irbsbs@virginia.edu](mailto:irbsbs@virginia.edu) for pre-review \*



Data entry and pre-review by IRB-SBS staff

Are changes required prior to your official submission?

YES! Additional review required

NO!

\* Final administrative approval for submission \*

Official protocol submission

\* IRB-SBS staff or members will make a final decision as to whether or not your protocol qualifies for exempt, expedited or full board review based on the federal regulations

EXEMPT/EXPEDITED

FULL BOARD

Primary reviewer



Primary and secondary reviewers

Major revisions

YES! Additional review required

Are changes required to receive final exemption or approval?

Are changes required to receive final exemption or approval?

YES! Additional review required

Primary reviewer or staff member

NO!

NO!

Minor revisions

Primary reviewer or staff member

Final Exemption/Approval