

U.S. Air Force Academy

Integrity - Service - Excellence



Keys to Success with an IRB

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7-Step Process

- 1. Prepare yourself with knowledge**
- 2. Begin writing your protocol**
- 3. Begin your informed consent**
- 4. Have your protocol reviewed**
- 5. Submit your protocol to the IRB**
- 6. Conduct your research**
- 7. Plan for the future**



Prepare yourself with knowledge

- Meet with an IRB member or administrator at your institution



- Every IRB has different policies and procedures
 - Don't decide your research is exempt
- Read everything first
[USAFA IRB Website](#)
 - Create a schedule
[USAFA IRB Meeting Schedule](#)



Step 2



Prepare yourself with knowledge

Begin writing your protocol



Begin writing your protocol Procedures

- Use current template [USAFA Protocol Preparation](#)
- Include all hypotheses
- Include all procedures – **BE SPECIFIC**
 - Informed consent
 - Time requirements
 - Deception and debriefing
 - Provide all scripts



Begin writing your protocol

Subject Recruitment & Selection

- Need for human subjects & power analysis
 - Anticipate attrition
- Availability for duty
- Diminished autonomy - Coercion
 - Instructor or coach
 - Military position
- Fairness or equity of participation
- Recruitment material
 - Flyer, email, script
 - Laymen's terms



ALL GOOD AMERICANS
GIVE THEIR FAIR SHARE





Begin writing your protocol Risk Assessment

- **Subject Identification**
 - **SSAN and ID numbers**
 - **Constellation of demographic information**
- **Private data to be obtained**
- **Safeguards of privacy/data**
 - **Controversial responses**
 - **Student projects**
- **Risk vs Benefits**
 - **Deception and debriefing**
 - **Summary**
 - **Indirect vs direct benefits**





Common Researcher Errors in Protocol Preparation

- Not using the current protocol template
- Not stating why need human subjects or power analysis
- Not stating hypotheses
- Not stating how daily duties will be affected
- Incomplete list of private data to be acquired
- Not ensuring the security or privacy of data
- Not providing recruitment materials or methods/materials lead to perception of undue influence
- Recruitment material beyond 12th grade reading ability
- Incomplete documentation of risk and/or procedures
- Not stating how risks outweigh benefits
- Not providing a debriefing when appropriate



Begin your informed consent document

- Use current template [USAFA Protocol Preparation](#)
- Include all sections and required words – DON'T DELETE SECTIONS or NECESSARY WORDS
 - Subject pool
 - Video taping and Bill of Rights
- Be consistent with the protocol
 - Number of subjects
 - Time requirements
- Use laymen's terms
 - Avoid acronyms and jargon
- Remove military ranks



Common Researcher Errors in ICD Preparation

- Not using the current ICD template
- Not addressing all sections in the template
- Deleting required wording in the template
- Using acronyms without definition and jargon
- Not removing military ranks
- Not ensuring the security or privacy of data
- Not including total number of subjects & participation time
- Not including participation time as a risk or inconvenience
- Description of procedures too complicated



Have your package reviewed

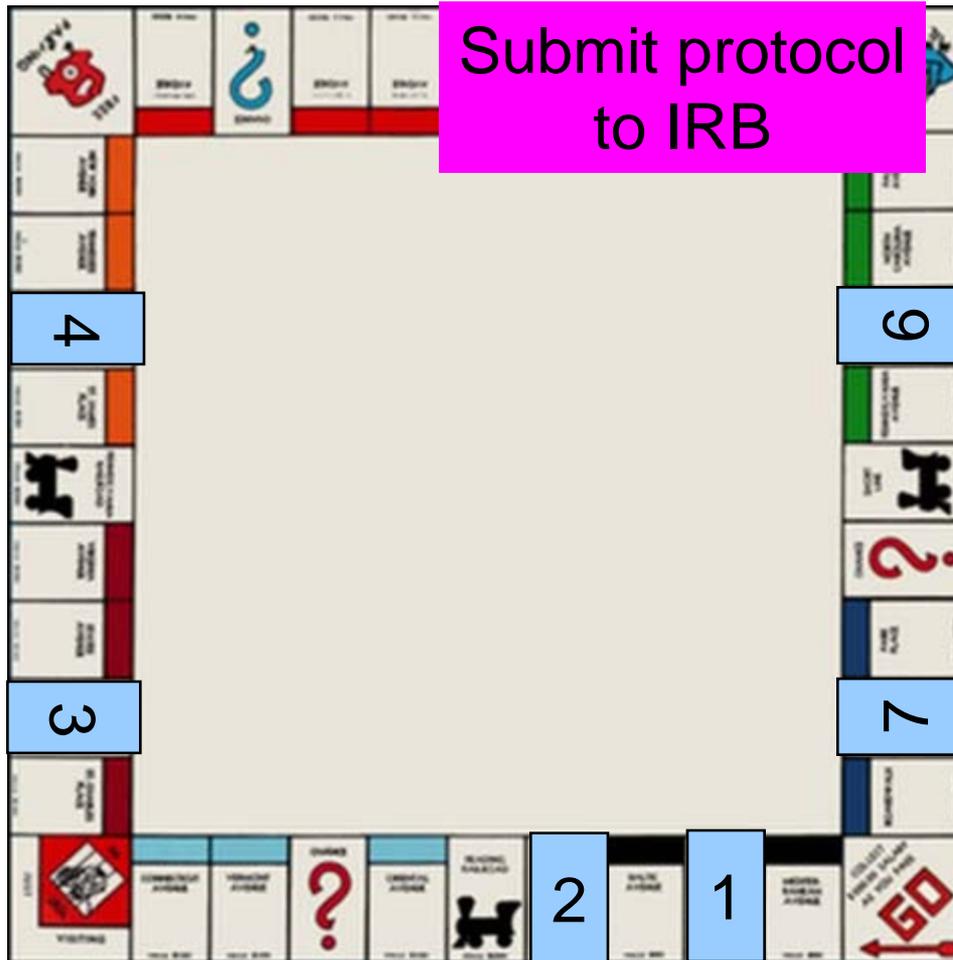
- **Colleague**
 - **Design**
 - **Errors**
- **IRB member**
 - **Best methods**
 - **Appropriate detail**
- **Commander**
 - **Institutional appropriateness**



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Step 5



Submit protocol to IRB

Prepare yourself with knowledge

Begin writing your protocol

Begin your Informed consent

Have your package reviewed



Submit protocol to the IRB

- **Attend the meeting when it is reviewed**
 - **Onsite clarification**
 - **Better understanding of process / discussion**
- **Comply with IRB requests/requirements**
 - **That's the law!**





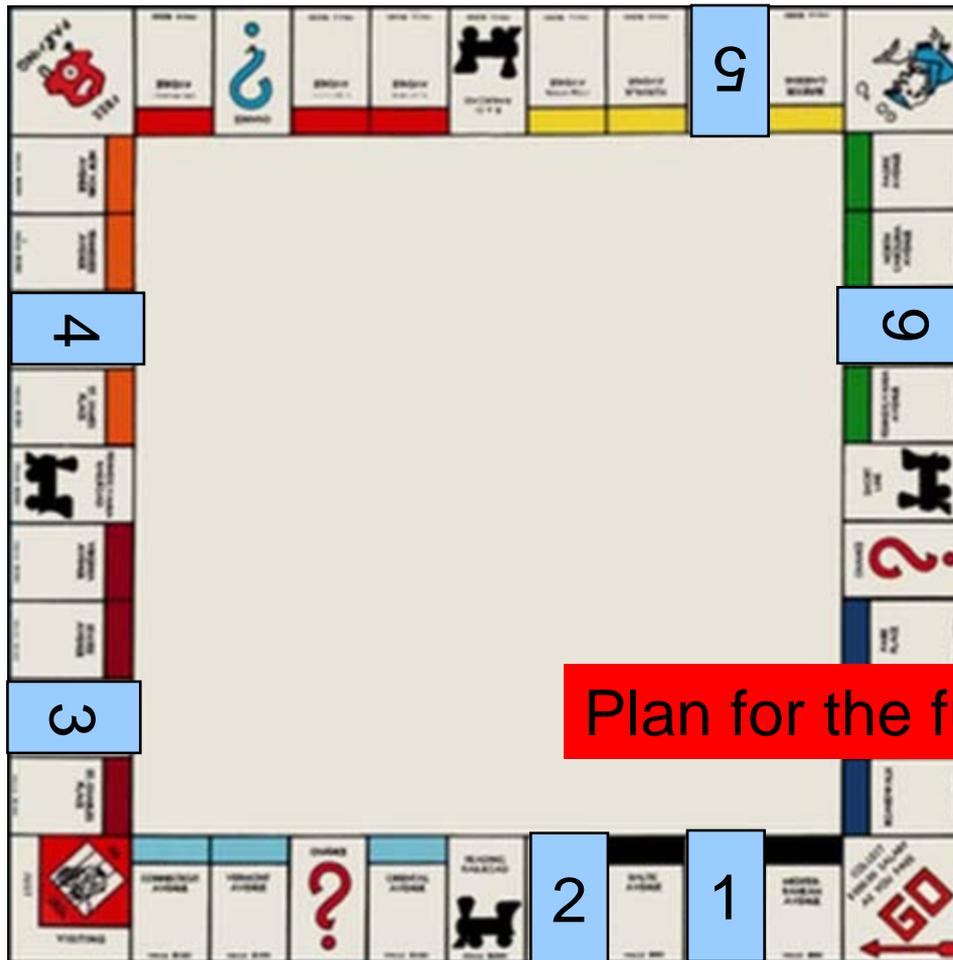
Conduct the Research

- **DON'T CHANGE ANYTHING WITHOUT IRB APPROVAL**
- **DON'T CHANGE ANYTHING WITHOUT IRB APPROVAL**
 - Recruitment
 - Methods
 - Number of subjects
- **EXECUTE INFORMED CONSENT APPROPRIATELY**
 - Signed
 - Witnessed
- **SECURE ICDs**





Step 7



Prepare yourself with knowledge

Begin writing your protocol

Begin your Informed consent

Have your package reviewed

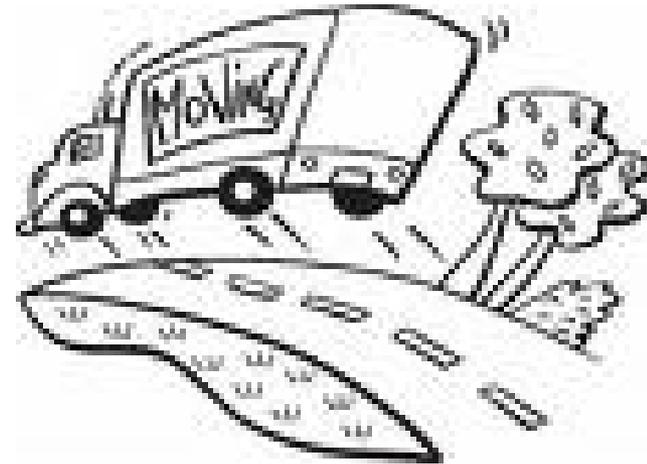
Plan for the future
Submit protocol to IRB

Conduct research



Plan for the future

- **Submit required reports on time**
- **Use current templates**
 - **Continuing**
 - **Final**
- **Transfer research before leaving!**





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How to Succeed with an IRB

1. Prepare yourself with knowledge
 - a. Meet with an IRB member or administrator at your institution
 - i. Learn local policies and procedures
 - ii. Learn local pitfalls
 - b. Read everything first
 - i. Review website, handbook, FAQ, whatever is available
 - ii. Review templates
 - c. Create a schedule
 - i. Identify meeting date and back out time requirements
2. Begin writing your protocol
 - a. Use current template
 - b. Procedures
 - i. Be specific
 - ii. Include all time requirements and hypotheses
 - iii. Include all scripts, debriefing forms
 - c. Subject Recruitment and Selection
 - i. Need for human subjects and power analysis
 - ii. Availability for duty
 - iii. Diminished autonomy
 - iv. Equity
 - v. Recruitment material
 - d. Risk assessment
 - i. Subject identification
 - ii. Private data and security
 - iii. Risk vs benefit assessment
3. Begin your informed consent document
 - a. Current template
 - b. Complete all sections
 - c. Be consistent with protocol
 - d. Laymen's terms (12th grade reading level)
 - e. Remove military ranks
4. Have your package reviewed
 - a. Colleague
 - b. IRB member
 - c. Commander
5. Submit protocol to IRB
 - a. Attend meeting when reviewed
 - b. Comply with IRB request/requirements
6. Conduct research
 - a. **DON'T CHANGE ANYTHING WITHOUT IRB APPROVAL**
 - i. Recruitment
 - ii. Methods
 - iii. Number of subjects
 - b. **SECURE ICDs**
7. Plan for the future
 - a. Submit required reports on time
 - b. Transfer research to colleague well prior to moving

IRB REVIEW CHECKLIST

3 May 2005

Protocol:

Review Date:

- 1) Risks to subjects are minimized by using sound research design

- 2) Risks to subjects are reasonable in relation to anticipated benefits to subjects or indirect benefits and the importance of the knowledge to be gained

- 3) Selection of subjects is equitable

- 4) Research provides adequate provisions for safety and privacy of subjects

- 5) Safeguards are in place to protect the rights and welfare of "vulnerable" research populations, especially cadets

- 6) Informed consent is sought and documented? Yes No
Eight elements of informed consent: present?
 - Description of study (purpose, duration, procedures, compensation/costs)

 - Description of risks (reasonably foreseeable risks, discomforts)

 - Description of benefits (direct benefits to subject; indirect benefits)

 - Disclosure of alternatives (same benefits/treatments available elsewhere?)

 - Extent of privacy(how will data be protected)

 - Standard statement re compensation or treatment for injury? Yes No

 - Contact for questions (Research, subject rights, research injury)

 - Standard voluntary participation statement? Yes No