IRB REVIEW CRITERIA

I. Beneficence

- **A. Risk/Benefit Analysis**
  1. **Consider magnitude of harm and probability of harm**
  2. **Identify risks and should not rely solely on investigators to identify risks**
     - **a. No one can be objective about their own work**
     - **b. People underestimate the risks involved in things they are very familiar with**
     - **c. People over estimate the benefit of things that are important to them**
  3. **Risks to subjects are minimized**
     - **a. What are alternatives**
     - **b. What are precautions**
     - **c. What are contingencies**
  4. **Risks are reasonable in relation to anticipated benefits**
     - **a. Evaluation is subjective judgment**
     - **b. Must decide if anticipated benefits justifies asking subjects to undertake the risks**
     - **c. Should take into account different subject populations and individual differences among subjects**
  5. **Selection of subjects is equitable**
  6. **Informed consent is appropriately sought from each subject and is documented**
  7. **Data collection is monitored to ensure subject safety**
  8. **Privacy and confidentiality of subjects is protected**
  9. **Additional safeguards are included for vulnerable populations**
- **B. Experimental Design**
  1. **Is the science good enough to justify the risks**
  2. **If minimal risk study, the standards for science need not be as high**
- **C. Qualifications of PI**

II. Justice

- **A. Subject Selection**
  1. **Selection should be justified by the science**
  2. **Avoid exploitation (i.e., students)**

3. **Minimize coercion and undue influence**
4. **Should not *overprotect* vulnerable populations**
5. **If study funded by NIH, must justify exclusion of women, minorities or children**

B. B. Inclusion/Exclusion

1. **Clearly indicated and justified**

C. Recruitment

1. **Recruitment is part of consent process**
2. **Information in recruitment should be consistent with protocol**
3. **Recruitment should not be coercive or unduly enticing**
4. **Recruitment should clearly indicated it is for research and not make unfounded claims**
5. **Must review recruitment procedures including advertising**
6. **Full disclosure of nature of research and subject's participation**
7. **Adequate comprehension by subjects**
8. **Subject is making voluntary choice to participate**

III. Respect for Persons

A. Informed Consent

1. **Educational process between investigator and prospective subject**
2. **Full disclosure of nature of research and subject's participation**
3. **Adequate comprehension on part of subject**
4. **Subject's voluntary choice to participate**
5. **Basic Elements**
   - **a. Purpose/Duration of Research**
   - **b. Procedures**
   - **c. Experiments**
   - **d. Risks**
   - **e. Benefits**
   - **f. Alternatives**
   - **g. Confidentiality**
   - **h. Compensation for injury**
   - **i. Whom to contact**
   - **j. Right to refuse or withdraw**
6. **Additional Elements**
   - **a. Unforeseeable risks**
   - **b. Termination of participation**

c. Additional costs to subjects

d. Consequence of withdrawal

e. Informing of new findings

f. Number of subjects

7. **Procedures**
    - **a. Subject has legal and mental capacity to give consent**
    - **b. Sufficient opportunity to consider**
    - **c. Possibility of coercion or undue influence is minimized**
    - **d. Language understandable to subject**
    - **e. No "exculpatory" language**
8. **Documentation**
    - **a. Be brief but complete basic information**
    - **b. be readable and understandable to most people**
        - **1) Max 8th grade reading level**
        - **2) Ordinary language**
        - **3) Active tense**
        - **4) Shorter sentences**
        - **5) Logical sequences**
    - **c. Be in format that helps people comprehend and remember**
    - **d. Serve as script for face-to-face with subjects**
9. **Waiver of Consent**
    - **a. Research involves no more than minimal risk**
    - **b. Will not adversely affect rights and welfare**
    - **c. Research could not practicably be carried out without waiver**
    - **d. When appropriate, subjects provided with additional pertinent information after they have participated**
    - **e. Procedures do not require written consent when performed outside of a research setting**
    - **f. principle risks are those associated with a breach of confidentiality and consent is only record linking subject with research**

B. Surrogate Consent (Assent)

1. **Consent same as above**
2. **Assent for those capable of giving but not legally and/or mentally allowed**

C. Privacy and Confidentiality

1. **Privacy – having control over extent, timing and circumstances of sharing oneself with others**
2. **Confidentiality – methods used to ensure information obtained is not improperly divulged**
3. **Names are not the only identifiers**

4. **Subjects participation as well as their data may need to be kept confidential**
5. **More elaborate procedures may be necessary for studies on sensitive matters (sexual behavior, criminal activities, etc.)**
6. **Any written record linking subject to study can create a threat to confidentiality, including consent forms**

D. Vulnerable Populations

1. **Children, pregnant women and fetuses, prisoners**
2. **Provide additional information regarding cognitively impaired or others who who are likely vulnerable to coercion or undue influence**
3. **Decisonally or cognitively impaired**
4. **Non-English speaking**
5. **Desperately ill**
6. **Economically and/or Educationally disadvantaged**
7. **Students**
8. **Employees**
9. **Need to ask detailed questions on characteristics of potential populations**
10. **Need to evaluate potential vulnerabilities**
11. **Need to ask what extra protections are in place**
12. **Need to assess adequacy of extra protections**
13. **Need sufficient expertise on vulnerable populations**