Human Subjects
*Office of Research*
UNIVERSITY OF GEORGIA

# Levels of IRB Review / Risk Assessment

Human Subjects
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# IRB Review Categories

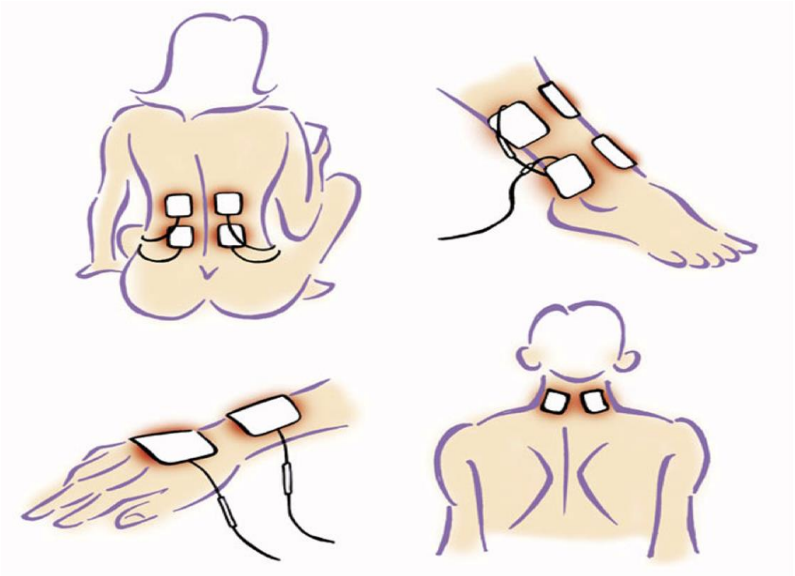
- Exempt
  - No more than minimal risk and fits within federally defined or institutional-specific categories
- Expedited
  - No more than minimal risk and fits within categories described in the federal regulations
- Full Committee
  - More than minimal risk or does not fit within the Expedited (or Exempt) categories. E.g., Projects where identification of the subjects place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing and risks related to invasion of privacy and breach of confidentiality cannot be reasonably reduced

# Expedited Review Categories

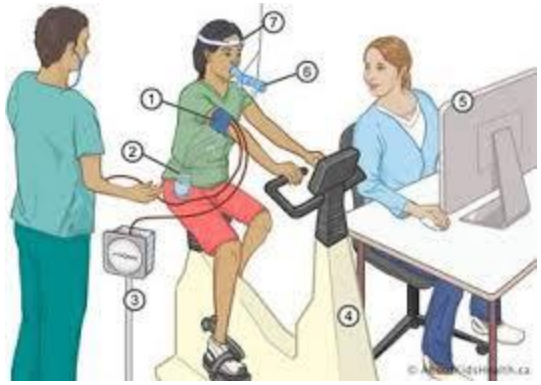
- *Clinical studies of approved drugs and medical devices used as labelled*
- *Noninvasive collection of blood samples within defined limits*
- *Prospective noninvasive collection of biological specimens for research purposes, e.g., saliva, urine, placenta tissue, amniotic fluid, external secretions*
- *Collection of data through noninvasive routine clinical procedures, e.g., EEG, ECG, weight measurement, ultrasound, MRI, BMI, moderate exercise*
- *Collection of data, documents, records or specimens already collected for non-research purposes*
- *Collection of voice, video, digital, or image recordings*
- *Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.*

**Minimal Risk – As of anticipated harm or discomfort, the possibility and severity is not greater than those encountered in daily life, or normal physical check-up or psychological examination. E.g., observational study**

**Low Risk – Risk greater than minimal risk; there is a possibility of reversible and mild adverse events. E.g., muscular pain after physical activity**



**Moderate Risk – Risk greater than low risk; there is a possibility of reversible and moderate adverse events, such as low glucose reaction, bronchial spasm, while sufficient monitoring and safety measures available to minimize the harmful outcome; there is no or few chance of severe harm.**



**High Risk – Risk greater than minimal; there is a possibility of severe and continuous adverse events that is related to the study; or there is much uncertainty for the nature or possibility of adverse events. E.g., new drug human study without human toxicity data, gene therapy, immune cell therapy.**