45 CFR 46*: Steps to Follow in Determining if IRB Review is Required or What Type of Review is Needed

- Research? 
  (OHRP FAQ on Quality Improvement) 
  (Federal Definition)

- Human Subject? 
  (2008 OHRP Coded Data or Specimens) 
  (Federal Definition)

- Exemption? (Or Non‐Exempt) 
  (OHRP FAQ on Exemption)

- Engagement? (If Applicable, Collaborative Research) 
  (Non‐Exempt Human Research) 
  (OHRP 2008 Engagement of Institutions)

- Expedited?

- Convened?

*Notice: Additional Steps are Required to Determine if the Research Falls Under FDA

Ada Sue Selwitz, University of Kentucky