

# Component Analysis

Research Compliance Office  
Stanford University



<http://researchcompliance.stanford.edu>



# Component Analysis



Versus



# 21 CFR 50 Children's Findings

- §50.51 - No greater than minimal risk
- §50.52 - Greater than minimal risk but presenting the prospect of direct benefit to individual subjects
- §50.53 - Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about subjects' disorder or condition
- §50.54 - Not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children



# Component Analysis

Study Population: 12-17 year old children with skin rash

## ARM 1

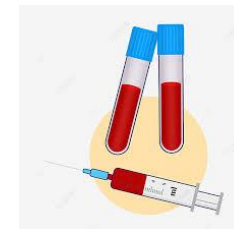
- INVESTIGATIONAL drug
- Punch biopsy w/ topical pain relief
- Two blood draws
  - 10ml ea
  - More than 1 week apart

INVESTIGATIONAL  
DRUG

Versus

## ARM 2

- FDA APPROVED drug
- Punch biopsy w/ topical pain relief
- Two blood draws
  - 10ml ea
  - More than 1 week apart

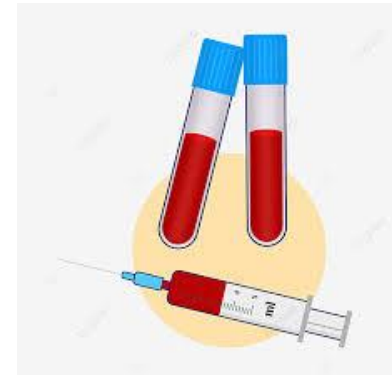


# Arm 1: Investigational Treatment Group

Greater than minimal risk but presenting the prospect of direct benefit to individual subjects (§50.52)

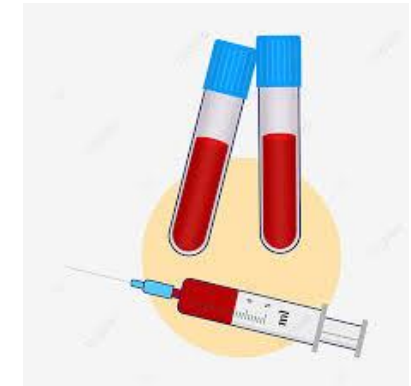


**INVESTIGATIONAL  
DRUG**



# Arm 2: FDA approved Treatment Group

Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about subjects' disorder or condition (§50.53)



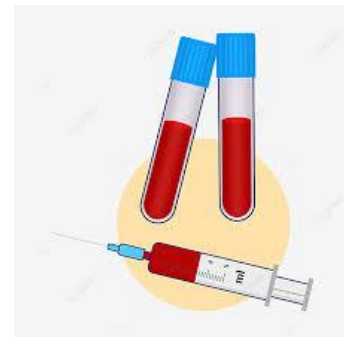
# Component Analysis



INVESTIGATIONAL  
DRUG



Versus



# Healthy Children as Participants



§50.51 - No greater than minimal risk





# Questions?



<http://researchcompliance.stanford.edu>

