Understanding Study Inclusion and Exclusion Criteria in Human Subjects Research Protocols

Purdue University Human Research Protection Program (HRPP)

1. Recruitment (flyers, ads, social media, etc.)
   List inclusion criteria. (These are designed around your study.)

2. Study inclusion criteria.
   Include those who are able to participate and those who represent the population where your study is relevant. List the criteria that makes someone eligible for your study.

3. Screen those who meet inclusion criteria for other features that change the risk level (mental, physical, emotional, etc.). These will be the exclusion criteria.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition.

4. Welcome into Informed Consent Process and option for study enrollment.