Vulnerable participants or populations

Vulnerable participants or populations are individuals or groups of individuals who are unable to give informed consent to take part in a clinical trial, such as children or people affected by mental health conditions, or who may come under pressure from others to take part. It also includes people whose willingness to volunteer in a clinical trial may be unduly influenced by their expectations of taking part.

If a trial is to include people from vulnerable populations, special attention should be paid to protecting their well-being, both by the investigators and the ethics committee that reviews the trial protocol.