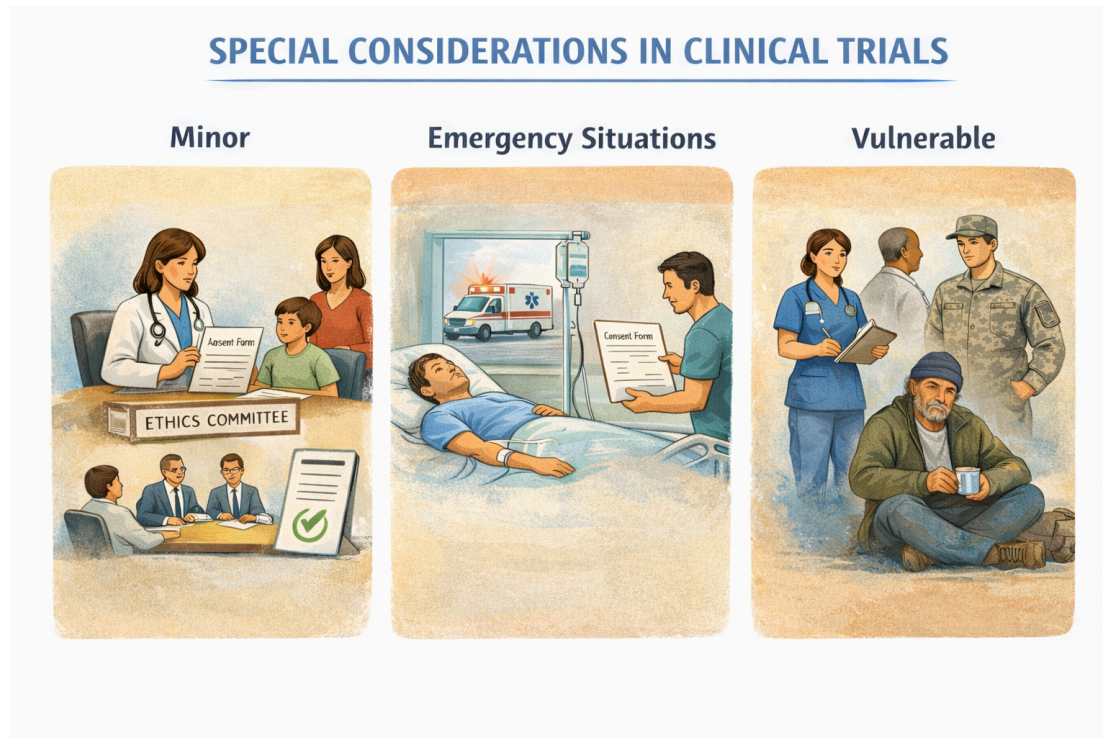


## Special Considerations



**Minor:** If a minor is participating in a trial, age-appropriate information should be shared and discussed with them and their assent to join the study should be obtained. If the minor reaches the legal age of consent during the trial, a new consent process should be followed as required by regulations. The assent form including any changes should be submitted to Ethics Committee for review and approval

**Emergency Situations:** If a participant cannot give consent in an emergency, consent should be obtained from their legally acceptable representative, if available. If neither the participant nor a representative can give consent, the participant enrolment should follow approved measures in the protocol and should have documented IRB/IEC approval to protect their rights, safety and well-being and to meet regulatory requirements. The participant or their representative should be informed as soon as possible and consent should then be obtained

**Vulnerable:** People who might feel pressured to join a clinical trial because they expect benefits or fear negative consequences from those in authority if they refuse, are considered vulnerable. This includes individuals in hierarchical groups like

medical, pharmacy, dental and nursing students; junior hospital or laboratory staff; pharmaceutical employees; military personnel and people in detention. Other vulnerable groups include those in nursing homes, people who are unemployed or poor, patients in emergencies, ethnic minorities, homeless individuals, nomads, refugees, minors and those who are unable to give informed consent.

Thus, vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent hence appropriate consideration should be given to trials that intend to recruit vulnerable participants