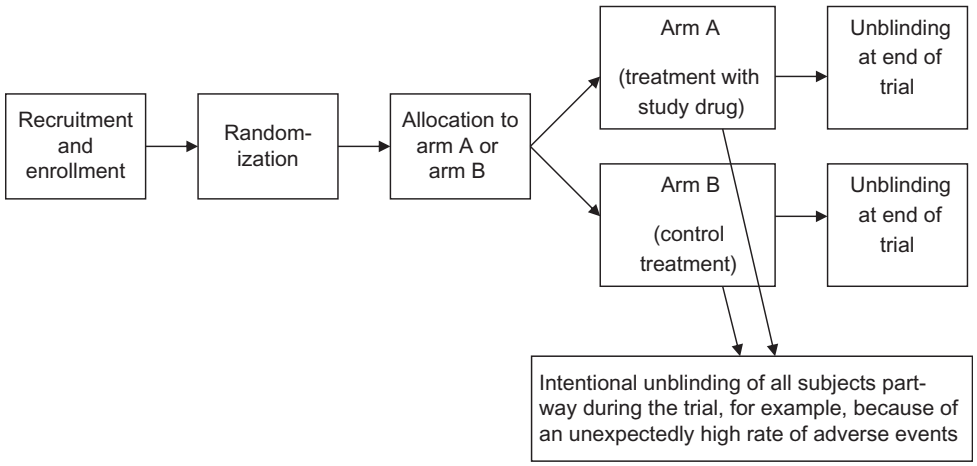

The following definitions provide a context for this chapter.

- *Open-label study.* All parties are aware of treatment being received after randomization. Open-label studies are not blinded.
- *Single-blind study.* The study subject is not aware of the treatment assignment, but the investigator is aware of the treatment assigned to every subject.
- *Double-blind study.* Both the study subject and the investigator are unaware of the treatment assigned to any individual subject.
- *Double-dummy design.* When there is a study drug group, and an active control drug (active comparator drug), blinding can be ensured by the double-dummy design. This design involves two different placebos, one placebo to serve as a control for the study drug, and another placebo to serve as a control for the active comparator drug. The trial involves two active drugs and two matching placebos. For example, in comparing two agents, one in a blue capsule and the other in a red capsule, the investigators would acquire blue placebo capsules and red placebo capsules. Then every subject in the study drug group receives a blue and a red capsule, one active and one inactive. And every subject in the active control group receives a blue and a red capsule.
- *Blinding.* Blinding refers to various features of clinical trial design that, when taken together, prevent the study subjects and most (but not all) study personnel from gaining access to the knowledge over whether any given study subject is receiving the study drug or control. There does not exist any particular moment in a clinical trial that is called "blinding" or that is called a "blinding step."
- *Unblinding.* The disclosure, planned or unintended, of the allocation of one study subject, one group of subjects, or all subjects. Unblinding can take place at a distinct moment, that is, at the moment when information is revealed about whether one or more subjects had received the study drug or control.