The following definitions provide a context for this chapter.

1. **Open label study.** All parties are aware of treatment being received after randomization. Open label studies are not blinded.
2. **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.
3. **Double-blind study.** Both the study subject and the investigator are unaware of the treatment assigned to any individual subject.
4. **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.
5. **Unblinding.** The disclosure, planned or unintended, of the allocation of one study subject, one group of subjects, or all subjects.

a. Allocation and allocation concealment

Allocation refers to the act, decision-making process, or automated process of assigning each subject to one of the study arms. In short, allocation means the act of connecting a given subject to a given treatment. Allocation is not the same thing as randomization. Allocation can either be random or non-random. According to Schultz (3), "[t]o ensure unpredictability of that allocation sequence, investigators should generate it by a random process (e.g., computer generated numbers, random number tables, or coin flipping)."

Allocation concealment seeks to prevent selection bias, and protects the allocation sequence before and until assignment to one of the study arms. Without the protection provided by allocation concealment, investigators have been known to change who gets assigned to a particular treatment, for example who gets assigned to study drug arm or placebo arm (4). To provide a hypothetic example, where there is no allocation concealment, the clerk who admits participants could ascertain the upcoming treatment allocations and then route participants with better prognoses to the experimental group and those with poorer prognoses to the control group, where the clerk's goal is to make the study drug appear to have greater efficacy. Allocation concealment is not

[3] Schulz KF. Assessing allocation concealment and blinding in randomised controlled trials: why bother? *Evid Based Nurs.* 2001;4:4–6.

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