

Study Eligibility and the Principle of Justice

By Norman M. Goldfarb

The principle of justice requires that any qualified and interested person have an equal opportunity to participate in a study. Not everyone who meets a study's eligibility criteria is, however, equal; each person remains a unique individual. Study personnel should therefore take a broad perspective of this individuality when enrolling subjects.

For example, most of the following criteria are never found in a protocol, but may bear on the decision to enroll a potential subject. They may indicate that a candidate would not, in the judgment of the investigator, be a good subject because of potential issues such as safety, welfare, compliance, adverse events, and data quality:

- Difficulty scheduling initial visit
- Reluctant agreement to participate
- Excessive interest in stipends
- Unstable or excessively demanding home, family or work life
- Evidence of unreliability
- Unreliable or expensive transportation
- Reliance on third-party for transportation or compliance
- Long-distance travel to visits
- Out-of-town trips
- Difficult to contact by telephone
- Difficulties in understanding, learning or communicating; cognitive impairment
- Negative personal interactions
- Excessively time-consuming interactions
- Unsupportive family or friends
- History of problematic or marginal medical conditions, drug allergies, psychological conditions, lab results or medications
- Untreated illness, infection or skin disease
- Frailty
- History of medication non-compliance
- Lack of primary care provider (may expect free primary care from investigator)
- Uncoordinated care from multiple physicians
- Fear or anxiety related to study procedures
- Poor venous access for phlebotomy
- Religious concerns, e.g., accepting blood transfusions during an SAE
- Requirements for special treatment
- Substance abuse

- Poor personal hygiene
- Personal safety of study team

In the United States, at least, “equal opportunity” implies that reasonable efforts be made to accommodate each individual. Some of the above issues can be accommodated with extra effort by the site. The definition of “reasonable effort”, however, may boil down to an economic decision: Can the site and sponsor afford the time and money to enroll the subject? Unfortunately, there is no general answer to this question.

The answer depends on the circumstances. For example, should a subject be enrolled who does not speak English? To answer this question, we must first know if the cost of translating the informed consent form is justified by the number of potential subjects who speak only that language. We must also know the cost to arrange interpretation services, including availability for serious adverse events. The answers to these questions depend on the sponsor, the site, the study, and the subject.

The answer also depends on whom the burden will fall. How much time and money does the site have to accommodate the subject? What is the sponsor willing to pay? What cost or inconvenience will the subject accept? Are there ancillary benefits, such as the site’s mission to serve a particular population? What other purposes could that time and money address?

The principle of justice does not specify a “right” answer, but it does require each site and sponsor to thoughtfully ask the right questions.

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