

## GRS<sup>SM</sup> Checklist\*

### Questions to ask before those who are invited to participate in research make a decision.

- \_\_\_ Do I understand what the investigator hopes to learn?
- \_\_\_ Do I understand what I will experience or receive and if it is available outside the study?
- \_\_\_ Is there any benefit to me? If so, what and under what circumstances (e.g., chance)?
- \_\_\_ What risk of harm, discomfort, or inconvenience is there to me? Under what circumstances?
- \_\_\_ What precautions (i.e., planning that is designed to prevent risks) and safeguards (i.e., plans to deal with risks that cannot be totally prevented) are in place to lessen risks?
- \_\_\_ Do I understand what commercial and/or professional gain may be had by the investigator, his or her employer, and/or the study's financial supporters beyond completion of the study?
- \_\_\_ Will I have to pay extra to be in the study or to receive treatment for injuries? If so, why?
- \_\_\_ If I'm injured (i.e., physically, psychologically, socially, and/or economically) because of the study, and treatment is insufficient to return me to health, will compensation be volunteered by the investigator? If not, inquire further.
- \_\_\_ Will the findings of the study be made available to me by the investigator at the time of publication in scientific journals or, if my identity will not be known to the investigator at that time, do I know how to contact the investigator and/or are there plans to publicly announce availability of the findings (e.g., through the news media)?
- \_\_\_ Will private information about me that is collected during the research be linked to me by name, or by a code that can be connected to my name, beyond the point needed to answer the research question(s) of this specific study? If so, for what purpose?
- \_\_\_ If private information can still be traced to me beyond the point it is needed for this study, will I be given a choice to prohibit further use of it without my prior written permission?
- \_\_\_ Do I know how private information during this study, while still traceable to me, will be protected from unauthorized access, voluntary sharing with others, or involuntary release to others (e.g., by subpoena)?
- \_\_\_ Do I know and/or has the investigator arranged how I might inquire of research participants in other similar studies so I can consider their experience before I decide?
- \_\_\_ Has it been made clear to me that participation is totally voluntary and withdrawal will not result in bad feelings or other adverse consequences of any sort? If not, inquire further.
- \_\_\_ With whom can I discuss the value of the research, my interests as a participant, or complaints about my experience who is *not* involved in the research (sometimes called an ombudsman)?
- \_\_\_ If invited to participate in a clinical trial, will I have access to my own treating doctor or other uninvolved clinician who can help me understand terminology, compare options outside the study, and/or advise on the possible impact to my health during the study?
- \_\_\_ Has an opportunity that is as free as possible of immediate pressure and sufficient time been planned for me to consult with my significant others and advisors prior to making a decision (e.g., at home, when possible, and/or over a few days)?

***Answers to the above questions should be acceptable to you! If in doubt, wait until sure!***

\* Issues concerning populations that are especially vulnerable to invitation, the potential for risk, and/or consequences from which they are relatively or absolutely defenseless exceed the scope of these fundamentals.