

GRSSM Code of Reasonable Expectations for Human Research Subjects

Caution: Expectations deemed reasonable in the GRSSM Code are not necessarily the same as current law, regulations and/or policies. Existing legal protections and local practices vary. **Compare the GRS Code with protections in your situation.**

Despite *existing* limits to mandatory applicability, it is reasonable for subjects to want (i.e., expect) protections from risk that involve (1) not less than the **procedural protections** of existing federal standards that are suited to the circumstance (i.e., [Subpart A of 45 CFR 46](#) [identical with the Common Rule] for basic procedural protections, [Subparts B-D of 45 CFR 46](#) for vulnerable populations and/or related [regulations](#) of the Food and Drug Administration (FDA) for any drug, biologic or medical device study, such as 21 CFR 50/56/312/812), and (2) the following **ideals**, especially when the degree of risk ordinarily requires prior consent by or for the subject:

- Dignity** - Participation does not lessen the **self-esteem** of the subject, before, during, or after participation (“anything goes” is not acceptable and mere politeness is not a substitute for ethical behavior) and the timing, setting, and circumstances associated with any required consent for participation are **free of avoidable pressure and disadvantage inspired by the interests of others**.
- Respect** - Participation is conditioned on (a) initial access to self-administered **guidance** (e.g., see [Checklist](#)) or access to **counseling** from sources outside the research, (b) **consent** (or consent on their behalf under certain circumstances) prior to participation, unless legitimately waived, (c) continued **self-control** during participation (subject refusals, withdrawals, and/or questions are honored unless abrupt withdrawal would be perilous), and (d) payment of otherwise uncovered research-related **expenses** is offered by the investigator.
- Knowledge** - Provision of sufficient and understandable information essential to a self-responsible decision about participation, to include (a) the added **risks** of harm and any **benefits** that may be expected from the research, (b) **precautions** to minimize and **safeguards** to deal with risks and consequences during or after participation, (c) all material investigator and institution **conflicts of interest**, and (d) how to **contact persons** outside the research for advise or to pursue a complaint (e.g., private physician or appropriately skilled counselor).
- Honesty** - Information **neither fails to disclose** all anticipated risks and consequences **nor leaves the impression** that benefits exist or are greater than justified (information and guidance must serve the best interests of subjects).
- Well-being** - Research **risks are minimized, benefits (if any) maximized**, and the resultant level of risk is **independently confirmed as justified** when compared with the benefits, if any (some research, by design, has no direct benefit to subjects), and suitable **precautions** to prevent and **safeguards** to deal with possible harms are in place for the safety of subjects.
- Fairness** - Invitation and/or selection to **participate does not** (a) **bias** by targeting some for the benefit of others, (b) **deny** the opportunity to participate, if eligible, (c) **require repeated or sequential participation** in follow-on studies without option to decline, or (d) **insist upon indefinite retention of identifiable private information** for undisclosed future use without additional consent.
- Security** - Participation honors the **privacy** of identifiable private information already in existence about the subject and ensures the **confidentiality** of that which is to be collected by barring access by others without explicit consent.
- Recourse** - Investigator provides for emergency and/or other treatment, counseling, and financial or other **compensation** for otherwise unresolved research-related injury (i.e., through insurance, mediation, arbitration, and/or otherwise).

ASKSM (*Assume nothing, Speak up, and Know then decide!*)