## **RESEARCH FOR BGU INSTITUTIONAL REVIEW BOARD**

If your research includes **any** of the following criteria, it must be reviewed by the Institutional Review Board.

### 1. Research on *sensitive.* stressful, or highly personal topics, including but not limited to:

* AIDS issues
* Drug or alcohol use
* Sexual attitudes or behavior
* Personal issues such as family relations, marriage, and similar topics
* Financial status
* Illegal conduct
* Religious, political, or racial attitude

(See 45 CFR 46

### 2. Research involving *vulnerable* populations. These populations include children under the age of 18, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons [see [Federal Code, 45 CFR 46.111(a)(3) ].](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html)

### 3. Research involving the use of instruments to measure personality characteristics, traits, structure, or disorders (e.g., MMPI, Myers-Briggs, BDI, or others in the public domain), which require adequate training for proper interpretation.

### 4. Research such that *if a participant's responses became known* outside the research it could reasonably place him/her at risk in the following ways:

* Criminal or civil liability
* Damage to the participant's financial standing
* Damage to the participant's employability or employment status
* Damage to the participant's standing at an academic institution

### 5. Research in which data are collected through *videotape, audio tape, or photographs,* since it is impossible to completely remove or disguise identifying information in such materials.

### 6. Research conducted by investigators external to BGU who would possible need approval of the BGU IRB.

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\* Federal Code 45 CFR 46,Subpart D, permits IRBs to approve three categories of research involving children as research subjects summarized as follows.

**45 CFR 46.404 - Research not involving greater than minimal risk to the children. To approve this category of research, the IRB must make the following determinations:**

* the research presents no greater than minimal risk to the children; **and**
* adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

**45 CFR 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research. To approve research in this category, the IRB must make the following determinations:**

* the risk is justified by the anticipated benefits to the subjects;
* the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; **and**
* adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

**45 CFR 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition. In order to approve research in this category, the IRB must make the following determinations:**

* the risk of the research represents a minor increase over minimal risk;
* the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
* the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; **and**
* adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

Adapted from materials produced by the Institutional Review Board of Bethel University in December 12, 2010.