ESSENTIAL ELEMENTS OF A RESEARCH PROTOCOL – WHAT DOES THE IRB LOOK FOR?

In addition to required elements of a research protocol such as the hypothesis, objectives-primary/secondary, statistical analysis, etc; the IRB's responsibility is to determine that all of the following 8 requirements are satisfied, even when the study is minimal risk (as outlined in 45CFR46.111):

I. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

II. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

III. **Selection of subjects is equitable**: The protocol should cover: number of subjects ("N"), gender of subjects, age, racial and ethnic origin and inclusion/exclusion criteria). In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

IV. **Informed consent will be sought from each prospective subject or the subject's legally authorized representative**, in accordance with, and to the extent required by §46.116 (see IRBCo.'s separate guidance document, titled 'Required Elements of an Informed Consent Form' for more details).

V. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117 (See IRBCo.'s separate guidance document, titled 'Required Elements of an Informed Consent Form' for more details).

VI. When appropriate, the research plan makes adequate provision for **monitoring the data** collected to ensure the safety of subjects.

VII. When appropriate, there are adequate provisions to protect the **privacy of subjects** and to maintain the **confidentiality of data**.

VIII. When some or all of the subjects are likely to be **vulnerable to coercion** or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, employees, students; the IRB will look for whether additional safeguards have been included in the study to protect the rights and welfare of these subjects.