

RISK ASSESSMENT CHECKLIST FOR RESEARCH STUDIES

Note: This checklist will be attached to all new protocols (excluding device studies) to assist in determining risk level and frequency of review

RR 402-B

01/01/07

STUDY NAME (IRB #): _____

IRB MEETING DATE: _____

_____ **High:** Activities in medical or behavioral research that may induce a potentially harmful altered physical or mental state of condition or forms of personal invasion and, as such are considered to be in a “high risk” category. Examples:

- biopsy procedures
- the administration of experimental drugs or radiation
- the use of indwelling catheters or electrodes
- the requirement of strenuous physical exercise
- hypnotism
- subjection to deceit, public embarrassment and humiliation

In these cases there must be especially care documentation to show that the benefits outweigh the risks.

_____ **Intermediate:** Activities involving a wide range of medical and behavioral projects, in which there is no immediate physical risk to the subject. Examples:

- personality inventories
- activities that may involve possible physical or mental stress
- activities that may involve medical intervention
- herbal supplements with unknown risks
- collection of data for registries
- activities that may involve gathering of genetic information or data

Since some of these procedures may impose a varying degree of demeaning or dehumanizing conditions, prior written informed consent is required. However, since this type of activity does not involve physical invasion but is where voluntary consent on the part of the subjects is desirable, a more simplified consent may be requested.

_____ **Low:** Certain activities classified as “low risk” may not require an informed consent. Examples:

- the use of a completely anonymous questionnaire
- interviews
- information-gathering conducted in classrooms, elsewhere or group therapy sessions
- the use of photographs, taped records, and stored data
- retrospective chart reviews
- all expeditable categories

If a written informed consent is deemed unnecessary or undesirable in a particular instance, a waiver of written consent may be requested.

Low risk involves situations in which there is no conceivable physical or mental discomfort, and measurements made on subjects can be considered to be reasonably unobtrusive. In these situations, written informed consent may be waived.

Approved 12/11/06

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