



## Subjects With Impaired [Decision-Making

## \$ E L Checklist

Research Involving Adult Subjects with Impaired [Decision-Making Skills with Anticipated [Direct Benefit to the Subject (all must be checked)

- Making

One of the following is true:

Subjects have a disease / condition for which the research provides the prospect of direct benefit that is not available outside the research context

The objectives of the research cannot be met by studying subjects who have the decision-making ability to provide consent

The investigator is knowledgeable about the condition and any level of impairment that is likely to be present in the subject population

The risks to subjects are reasonable in relation to anticipated benefits to subjects

The ratio of anticipated benefits to risks is at least as favorable to the subject as that presented by available alternative approaches

The research procedures are not prohibited by law

The subjects will be closely monitored

Subjects will be withdrawn if they appear to be unduly distressed

Subjects will be informed about the research to the extent compatible with their understanding

Assent will be documented and obtained from some or all of the subjects to the

future research procedures (the consent of the LAR would become invalid)

