**FORM 5.1D CHECKLIST** – **REQUIREMENTS FOR RESEARCH INVOLVING HANDCAPPED PARTICIPANTS**

**(MENTALLY & PHYSICALLY), MENTALLY ILL AND BEHAVIORALLY DISORDERED**

**INVESTIGATOR: IDI REC #**

**STUDY TITLE**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** |
| Does the IDI REC need to include a member knowledgeable about and experienced with the handicapped (mentally and/or physically), mentally ill and behaviorally disordered research participants? | [ ]  | [ ]  | [ ]  |
| Does the research pertain to the handicapped so that it is necessary to involve persons who are handicapped, mentally ill and behaviorally disordered as participants? |[ ] [ ] [ ]
| If the investigator proposes to involve institutionalized individuals, has he or she provided sufficient justification for using that population? Are non-institutionalized participants appropriate for the research and reasonably available? Does the research pertain to aspects of institutionalization? | [ ]  | [ ]  | [ ]  |
| Are adequate procedures proposed for evaluating the mental status of prospective participants to determine whether they are capable of consenting? Are these procedures appropriate both to the participant population and the nature of the proposed research? | [ ]  | [ ]  | [ ]  |
| Is more than minimal risk involved? If so, is the risk justified by anticipated benefits to the participating participants and the importance of the knowledge that may reasonably be expected to result? | [ ]  | [ ]  | [ ]  |
| Is it possible to identify persons authorized to give legally valid consent on behalf of any individuals judged incapable of consenting on their own behalf? Should assent of the prospective participants also be required? If incapable of giving valid consent, can participants' objection to participation be overridden? Under what circumstances? | [ ]  | [ ]  | [ ]  |
| Should an advocate or consent auditor be appointed to ensure that the preferences of potential participants are elicited and respected? Should someone ensure the continuing agreement of participants to participate, as the research progresses? | [ ]  | [ ]  | [ ]  |
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Comments:

Primary Reviewer Date