Example checklist

**Worksheet: Criteria for Approval**

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This worksheet is used to determine whether non-exempt <Human Research> can be approved.

1. Criteria for approval

1.1 Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk (see Footnotes 3 and 4). The risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for other purposes.

1.2 Risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for other purposes.

1.3 Risks to subjects are acceptable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (see Footnote 3).

1.4 Selection of subjects is equitable (see Footnote 4).

1.5 The research involves no more than 

- Minimal Risk to subjects.
- There are adequate provisions for monitoring the data collected to ensure the safety of subjects (see Footnote 5).
- There are adequate provisions to maintain the confidentiality of data.
- There is a legal requirement for the submission of information (see Footnote 6).
- Subjects are not likely to be vulnerable to coercion or undue influence.
- Additional safeguards are included to protect the rights and welfare of subject vulnerable to coercion or undue influence.

1.6 The consent process will be voluntary (see Footnote 7).

1.7 The document is clear and complete.

1.8 The investigator will follow the principles of 

- Respect for persons (including the right to autonomy, informed consent, and confidentiality), and the right to privacy.
- Consent: an informed judgment by the subject or his legal representative about the value of the information to be obtained from the research.
- Confidentiality: the right of the subject to privacy and the obligation of the investigator to respect the confidentiality of private information about the subject.
- Respect for autonomy: the right of the subject to make informed decisions about the research.
- Informed consent: the right of the subject to make informed decisions about the research.
- Protection of data: the right of the subject to have the data collected from the research protected from misuse.
- Protection of confidentiality: the right of the subject to have their information protected from misuse.
- Protection of privacy: the right of the subject to have their information protected from misuse.
- Respect for persons: the right of the subject to have their information protected from misuse.
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