

The Carle Foundation

IRB Policy 402

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| Subject | Initial Review – Criteria for IRB Approval | | | | |
| Approval | Dec 2006 | Review | Jun 2009 | Revision | Jun 2009 |
| Scope | These policies and procedures apply to all research submitted to the IRB. | | | | |
| Purpose | To state the procedures for initial review of research. | | | | |

Statement of Policy

1. All research proposals that intend to enroll human subjects must meet certain criteria before study-related procedures can be initiated. The criteria are based on the principles of justice, beneficence and autonomy as discussed in the Belmont Report and are specified below. In addition, certain other criteria that are unique to Carle Foundation Hospital's system may apply and must be met as well.

Specific Policies

1. Minimal Criteria for Approval of Research – In order for a research project to be approved, the IRB must find that:
 - a. Risks to Subjects are Minimized
 - By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
 - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - b. Risk Assessment – Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may 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 that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research benefits that fall within the purview of its responsibility
 - c. Selection of Subjects is Equitable
 - In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons. (IRB Reviews Requiring Special Consideration Policy 501 Vulnerable Populations).
 - d. Unless waived by the IRB, 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 appropriate local, state and federal regulations.
 - e. Informed consent will be appropriately documented as required by local, state and federal regulations.
 - f. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
 - g. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
 - h. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or for subjects found at international sites, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.
 - i. Studies are reviewed at periods appropriate to the degree of risk research subject are exposed to due to their participation in the study, but at least annually.
2. Other Criteria
 - a. The IRB may require verification of information submitted by an Investigator. The need to verify any information will be determined by the IRB at a convened meeting. The purpose of the verification will be to provide necessary protection to subjects when deemed appropriate by the IRB.
The criteria used to determine whether third-party verification is required may include:
 - Investigators that conduct studies that involve a potential high risk to subjects,
 - Studies that involve vulnerable populations,
 - Investigators that conduct studies that involve large numbers of subjects, and

Specific Policies (cont.)

- Investigators selected at the discretion of the IRB.
 - Projects that need third party verification from sources other than the Investigator that no material changes have occurred since previous IRB review is determined, will have such assessment performed as necessary.
- b. The IRB may require that the Investigator attend the IRB meeting.
3. Use of Consultants
- a. The IRB Chairperson can request individuals with particular expertise in matters under review to provide information to the IRB relevant to consideration of the research in question.
4. Permitted IRB Actions
- a. The IRB may approve as submitted, require changes, table, or disapprove a research project. If the research project is approved, a letter will be sent to the Investigator indicating approval, and specifying the requirements for continuing review. Informed consent documents will be dated as of the date of IRB approval. All IRB actions will be communicated to the Investigators in writing.
- b. The IRB shall advise the Investigator of any changes or additional information required prior to approval. Changes or additional information shall be reviewed by the convened IRB, unless the change(s) requested are minor, in which case the Chairperson or an IRB member designated by the Chairperson may review submitted changes and approve them.
- c. The IRB may decline to approve a research project. If the IRB declines to approve a study, the Investigator must so advise the Sponsor, and any other IRBs which are currently exercising oversight, or whose approval of the project is sought. (IRB Review of Research Policy 406 Categories of Action)

Reference

45 CFR 46.111

Approval On File

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