

**New York Chiropractic College
Institutional Review Board**

The Researcher's responsibility includes:

1. Providing a written annual report of research progress, and/or a final report. The annual report constitutes an application for a one-year extension of the research application. The report must include 2 complete copies of recent subject consent forms, a description of any adverse subject reactions that may have occurred during the study period, and the actions you took to address those reactions. If no data was collected during the final year of the study period, a written statement to this effect should be included with the final report in lieu of the consent forms.
2. Depending upon the nature of the research project, and its potential hazards or benefits, the IRB may require reports on a more frequent basis.
3. Prompt notification of any change in research methods, procedures, and key personnel. This notification must be accompanied by an appropriately revised IRB application.
4. Prompt notification, in writing, about subjects that reacted negatively to the research procedure. Not every adverse reaction needs to be reported immediately, only the severe or unexpected ones. As a general guideline, you should report to the IRB
 - (A) Anytime a subject has a strong negative reaction to the research procedure, whether or not this type of reaction was listed as a potential negative side effect in the informed consent form. A strong negative reaction includes anything that causes a reasonable concern about the health and welfare of the subject.
 - (B) Anytime a subject specifically contacts you about a negative reaction to the research procedure (no matter how minor this reaction may seem).
 - (C) Anytime a subject exhibits a negative reaction that was not documented as a possible side effect in the original IRB proposal.
5. The researcher must allow the subject a minimum of 24 hours to read, and review, the informed consent form before data collection begins. This requirement will be waived only when the IRB is convinced that it would seriously undermine the goals of the research project without creating unacceptable risk for the subjects.
6. The researcher must keep all consent forms on file, and available for inspection, for a period of a least three years from the date of acceptance of the final report.
7. The researcher must make all current research results available for inspection by the IRB, or its appointed representatives, while data is being collected.
8. The researcher must allow on site inspection of the laboratory, data, and data collection procedures by the IRB, or its appointed representatives.

Primary Investigator Signature

IRB Number

Date

*Please sign this form to indicate your understanding of the Researcher's Responsibilities.
Return signed form to the Research Department, and keep a copy for your records.*