INFORMED CONSENT FOR CLINICAL TRIALS

INFORMED CONSENT FOR CLINICAL RESEARCH SHOULD BE OBTAINED FROM ALL SUBJECTS AND SHOULD CONTAIN THE FOLLOWING ELEMENTS:

1. That the trial involves research.

2. The purpose of the trial.

3. The trial treatment(s) and the probability for random assignment to each treatment.

4. The trial procedures to be followed, including all invasive procedures.

5. The subject's responsibilities.

6. Those aspects of the trial which are experimental.

7. The foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus or nursing infant.

8. The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.

9. That the monitor(s), the auditor(s), the IRB/Ethics Committee, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.

10. Those records, identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, it will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

11. That the findings of the study will be recorded in a publicly available databank maintained by the National Institutes of Health/National Library of Medicine, available at http://wwwClinicalTrials.gov.[i]

12. That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.

13. The person(s) to contact for further information regarding the trial and the rights of the trial subjects and whom to contact in the event of a trial-related injury.

14. The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.

15. The expected duration of the subject's participation in the trial.

16. The approximate number of subjects involved in the trial.

17. The alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks.

18. The compensation and/or treatment available to the subject in the event of a trial-related injury.

19. The anticipated prorated payment, if any, to the subject for participating in the trial.

20. The anticipated expenses, if any, to the subject for participating in the trial.

21. That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.

Source: *The Trial Investigator's GCP (Good Clinical Practice) Handbook: a practical guide to ICH requirements.*

Note about ICH: Because of differences in GCP procedures in Europe, the USA and the 3rd largest pharmaceutical market, Japan, regulatory authorities and representatives of the pharmaceutical companies of these regions, together with observers from Scandinavia, Australia, Canada and the WHO – collectively known as ICH – held a series of meetings to develop a set of universally-accepted GCPs. In May, 1996, the ICH GCPs were finalized and these have now become the standard by which all clinical trials have to be performed in order to achieve universal recognition.

[i] *FDA Requires Statement on Clinical Trial Informed Consent Documents,* ECRI, Healthcare Risk Control, HRC Alerts, January 11, 2011.