

Gene Therapy Update

Our last newsletter featured an article pertaining to the death of a subject participating in a gene therapy study for inflammatory arthritis. The FDA determined that the research was not related to the death of the participant, but specific events and the timeline associated with these events cause researchers and IRBs to take a look at how we can take a proactive approach to protecting human subjects. The following information provides a timeline of events and notations by an IRB professional who reviewed the case study.

Timeline

2/26/07: Injection 1
7/2/07: No complications and received Injection 2
7/3 & 7/4: temperature of 101, vomiting
7/7/07: ER visit; temp of 104; investigator determines this is not drug related – was a virus
7/12/07 – admitted to hospital and then moved to different hospital on 7/19/07
7/20/07 – hospital contacts FDA and study suspended
7/24/07 – Death of subject

Notations

- Subject was already taking 3 potent arthritis drugs
- No mention of animal test results for two injections.
- Consent was not taken home and considered
- Consent was 15 pages
- Questionable method of recruitment
- Personal physician consented subject
- Serious adverse event report was submitted more than 20 days after first sign of the problem

INSIDE THIS ISSUE

Gene Therapy in the News	1
Harrison IRB Q&A - FDA 1572	1

Minimum Considerations/Requirements

As an IRB, there are various requirements that can be put into place to minimize danger to subjects when participating in genetic research. Recruitment by personal physician and not allowing ample time to review the study in detail were noted as elements of concern in a Washington Post article published on August 6, 2007.

Harrison IRB Q&A

Question: if a subject's personal physician is performing routine follow-up procedures associated with a clinical study, must the personal physician be listed on the Form FDA 1572 as a sub-investigator?

Answer: The FDA will allow a study subject's personal physician to perform a specific test or activity if the subject lives a long distance from the trial site and it is inconvenient for him/her to return to the site for routine follow-up procedures as dictated by the study protocol. "In such cases, the FDA does not view the personal physician as a sub-investigator, and does not expect him/her to be listed on the FDA Form 1572. Instead, study records should describe the types of tests/activities that may be performed by the subject's personal physician(s) and note that the results will be provided to the clinical investigator. Each subject's case history should also indicate the contact information for the person who performed the test/activity and the results"¹.

GCP Q&A: Focus on 1572s, First Clinical Research