From: OC GCP Questions
To: [redacted]
Subject: no safety net for humans in clinical trials
Date: Wednesday, April 22, 2015 2:42:56 PM

Good afternoon --

The information regarding injury should be found in the informed consent document.

In particular, the required basic element of informed consent found in the regulations at 21 CFR 50.25(a)(7) requires that each subject be provided with information regarding an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject

Please see the link below to A Guide to Informed Consent –
Search for FDA Guidance Documents > A Guide to Informed Consent - Information Sheet Please see "Compensation v. Waiver of Subject's Rights" section.

I cannot specifically comment on the advertisement link. However you can report problems to FDA. Please be aware that the contact information is product specific – drug, biologic, or device. Please see the information below.

Reporting Complaints Related to FDA-Regulated Clinical Trials

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional information.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Tuesday, April 21, 2015 10:12 PM
To: CBER OCOD Consumer Account; CDER-OSI-GCP Referrals; OC GCP Questions; ohrp@hhs.gov
Subject: no safety net for humans in clinical trials

I am a patient in a clinical trial. Why is there no safety net to care for human trial participant if they are injured during a clinical trial? Why are we told we can "SUE"?

[redacted]

thank you

[redacted]