

OHRs Information Sheet Sponsor Requests for PHI related to Adverse or Severe Adverse Events

Recently study teams have received requests from clinical trial industry sponsors or their designated agents seeking protected health information ("PHI"), as defined by Health Insurance Portability and Accountability Act ("HIPAA"), for subjects who experienced an adverse event ("AE") or severe adverse event ("SAE") while enrolled in the sponsor's protocol at a DF/HCC institution.

These PHI requests are required by the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA), Section 111 Reporting Obligations and Research Related Injuries clause.

Under this federal law, clinical trial industry sponsors are now responsible for reporting to Centers for Medicare & Medicaid Services ("CMS") all payments made to Medicare beneficiaries for such AEs or SAEs and related complications. MMSEA permits disclosing PHI, including social security numbers, to verify such payments.

Many industry sponsors have hired businesses as designated agents to perform this MMSEA-required reporting function. Letters from such businesses typically state that the industry sponsor is collecting information on all patients who experienced AEs and SAEs, as required by MMSEA to verify whether payments for such injuries have been made.

Providing PHI in this context to the sponsor or their designated agents is permissible *as long as the request is limited to the following circumstances:*

- i) information requests are only regarding subjects who experienced an AE or SAE as defined under the protocol and as a result of participation in the trial and the industry sponsor is requesting the information;**
- ii) the sponsor is paying for medical care for such AE or SAE;**
- iii) the sponsor is considering whether to pay for such medical care; or**
- iv) the sponsor has agreed to make such payments after consultation with the study team**

The Clinical Trial Agreements ("CTA") between DF/HCC institutions and sponsors permit obtaining and using a subject's PHI for study purposes and as required by law. Since this PHI is required by MMSEA (i.e. by law), and permitted both under the CTA and informed consent form, it is permissible to provide a subject's PHI to the industry sponsor or its designated agent for this limited purpose of reporting to CMS. CMS is required under law to protect the confidentiality of the PHI reported to comply with MMSEA.

If you have any questions about the scope of the MMSEA reporting requests, please contact the Clinical Research Agreements Office staff:

Mary Melloni at mary_melloni@dfci.harvard.edu or
Moirra Hayes Waligory at moira_waligory@dfci.harvard.edu.