Draft Guidance - Use of Electronic Informed Consent in Clinical Investigations

Author: Research Compliance and Administration Committee

Published Date: 05/12/2015
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Dear Dr. Stith-Coleman,

The Council on Governmental Relations (COGR) is an association of 190 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

We and our members appreciate the opportunity that the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) has offered to provide comment on the above subject Draft Guidance to enhance human subject protection and reduce regulatory burden. We also appreciate the engagement effort both OHRP and FDA have made to harmonize the agencies’ regulatory requirements and guidance for human subject research. However, we do not think it’s appropriate to apply the draft guidance regulated under multiple parts of 21 CFR to all research regulated under 45 CFR Part 46 for the reasons cited below.

While we applaud the efforts of the FDA to improve efficiency, reduce burden and minimize duplicity, particularly for clinical trials that support IND or IDE submissions, the Draft Guidance for FDA should stay with the FDA. In other words, applicability of this guidance for all research studies such as non-clinical biomedical, social and behavioral research subject to 45 CRF Part 46 would only add burden to more than minimal or not more than minimal risk studies, the plethora of studies conducted at many research institutions that the FDA Draft Guidance does not address.

Furthermore, the FDA Draft Guidance does not address waivers or alterations of documentation or consent as permitted under 45 CFR Part 46 §46.116 and §46.117, respectively. Due to the types of studies (e.g. survey, on-line), coupled with the volume and differing CFR’s pertaining to them, over policing the verification process of informed consent would be impracticable thereby creating unintended consequences of what we believe the FDA and OHRP set out to achieve.

We appreciate your efforts to work together and to harmonize regulations where harmonization makes sense, but strongly encourage OHRP to develop guidance that would be suitable for the types of studies covered under 45 CFR Part 46.