From: OC GCP Questions
To: [redacted]
Subject: Medicare language in Research ICF
Date: Friday, June 05, 2020 10:46:42 AM
Attachments: [redacted]

Good morning

Thank you for your query. 21 CFR 50.25 - Elements of informed consent, in the guidance document link below, says the following. Please note – there is no mention of Medicare identifier sharing.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent It states -

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
Informed consent documents should describe any compensation or medical treatments that will be provided if injury occurs. If specific statements cannot be made (e.g., each case is likely to require a different response), the subjects should be informed where further information may be obtained. The consent should also indicate whether subjects will be billed for the cost of such medical treatments. When costs will be billed, statements such as "will be billed to you or your insurer in the ordinary manner," "the sponsor has set some funds aside for medical costs related to.... Here's how to apply for reimbursement if you think you might be eligible" or "no funds have been set aside..." are preferred. Statements such as: "will be the responsibility of you or your insurance company" or "compensation is not available," could appear to relieve the sponsor or investigator of liability for negligence, see 21 CFR 50.20.

Since we are not familiar with the Medicare rules for billing, you might want to visit the Medicare website. https://www.medicare.gov/

You can also negotiate with the sponsor as to what language you are comfortable with in the IC document. You can also seek advice from your reviewing IRB. The ICD must be reviewed and approved by your IRB.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Clinical Policy and Programs
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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, June 04, 2020 5:24 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Medicare language in Research ICF

Good Afternoon:

We have see a few Clinical Research Informed Consents with added language by the sponsor that we have not seen previously and would like some guidance and/or feedback. Below is the language regarding Medicare.

"To pay medical treatment costs for study-related injuries, the study Sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the study Sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare."

Is this a new requirement? As a site, can we push back on this if we do not feel it is appropriate or necessary?

I appreciate your response and guidance.

Thank you.

Warm Regards,

[redacted]