

From: OC GCP Questions
To: [REDACTED]
Subject: Can a study use patient locator service?
Date: Tuesday, May 09, 2017 11:24:00 AM
Attachments: [REDACTED]

Good morning –

I am not sure what you mean by patient locator service. However the information below is language we have used in the past regarding clinical data after a subject withdraws from a clinical study.

FDA has a guidance document titled “Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials” (see www.fda.gov/downloads/regulatoryinformation/guidances/ucm126489.pdf) which describes the FDA's longstanding policy that already-accrued data, relating to individuals who cease participating in a study, are to be maintained as part of the study data. The guidance document also discusses key points regarding FDA's policy on the withdrawal of subjects from a clinical investigation, whether the subject elects to discontinue further interventions or the clinical investigator terminates the subject's participation in further interventions. The last bullet under section IV. (FDA Policy) says:

If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and **may consult public records, such as those establishing survival status. [Emphasis added]**

The guidance indicates that the investigator must not access the subject's medical records or other confidential records for purposes of the study (i.e., clinical outcome information such as survival) because the subject has not provided their consent for this, or has withdrawn their consent. However, as the guidance indicates, this does not preclude investigators from looking at public records (e.g., public records establishing survival status).

Kind regards,

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Office of Good Clinical Practice
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From: [REDACTED]
Sent: Thursday, May 04, 2017 4:50 PM
To: OC GCP Questions
Subject: Can a study use patient locator service?

Dear GCP Questions,

Are there any regulations or laws in the US that would forbid the use of patient locator services to locate subjects once they have withdrawn their consent?

[REDACTED]

Kind Regards,

[REDACTED]

[REDACTED]