

From: OC GCP Questions
To: [REDACTED]
Subject: Question regarding US clinical trial
Date: Monday, July 31, 2017 8:46:00 AM
Attachments: [REDACTED]

Good morning –

As far as I know generally FDA regulations do not prohibit enrolling foreign study participants. However some specific studies might require only US citizens from a practical standpoint. (Availability for trial treatment and follow-up). This would not be a problem if you were a non US citizen living in the US.

Additionally, FDA does have foreign sites studies (Clinical trials outside the US) and non US citizens are enrolled in these studies.

Kind regards,

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From: [REDACTED]
Sent: Sunday, July 30, 2017 11:14 PM
To: OC GCP Questions
Subject: Question regarding US clinical trial

Dear Sir/Madam

I have a question regarding the eligibility to enrol in a US clinical trial as a foreigner. I was told that I MUST be a US citizen in order to enrol, is this correct?

I know of a precedent of an Australian woman who was successfully enrolled in a US trial 5yrs ago. I was wondering if the eligibility is strictly dictated by the FDA?

Your prompt reply will be much appreciated.

Regards

[REDACTED]