From: OC GCP Questions
To: [redacted]
Subject: RE: Question on how to complete gender in CRF
Date: Wednesday, November 26, 2014 10:06:17 AM

Dear [redacted],
Thank you for your inquiry regarding the recording of gender of a study subject in the situation of gender reassignment surgery. Unfortunately, FDA does not have any formal guidance on this topic so my advice is from my own perspective. Gender is often a significant issue considered when assessing and assuring the risks and potential benefits of a research intervention. Gender differences can often affect an individual's response to a research intervention so it would be important information to correctly record when enrolling (and retaining) a subject into research. How important gender is to assessing and assuring safety and efficacy of a given intervention is study specific, so for each of the scenarios you describe in your question I recommend contacting the sponsor for advice or, if you are the sponsor, contacting the specific FDA review divisions responsible for the study. However, in general, I recommend the entire set of facts regarding an individual's gender be recorded. If there is only a small space to initially capture gender on the case report form (CRF), entering the subject's presently recognized gender would seem appropriate with an asterisk to denote that there is additional information to consider. Where room is otherwise available on the CRF, an explanation of the asterisk should be included. In all cases, the primary goal should be to assure the safety of the individual participating in research.
I hope this information is helpful to you. If further assistance is needed, please contact us again at the official GCP mailbox, gcp.questions@fda.hhs.gov.
Sincerely,

Kevin

Kevin A. Prohaska, D.O., M.P.H., Captain (USPHS)
Senior Medical Policy Analyst
Office of the Commissioner
Office of Good Clinical Practice
301-796-3707

From: [redacted]
Sent: Tuesday, November 25, 2014 7:47 AM
To: OC GCP Questions
Subject: Question on how to complete gender in CRF

Dear Madam, Dear Sir,

Could you please be so kind clarifying if there is a FDA guidance on how to proceed in the following cenarios:
1) Under CRF gender filed it was completed as male while under medical history the subject was refered as "she", surgical history included and concomitant medication was
estrogen and progesterone as hormonal replacement therapy. How should this matter be handled? Should we consider the new gender or the chromosomal gender?
2) How to proceed if the gender change surgery is performed during a trial?
3) Could the subject be included in the trial in case of gender change surgery in trial involving genetic studies or the data obtained should be excluded?
4) In a breast cancer study. Should we consider male breast cancer or female breast cancer taking into account the gender change surgery.
Thank you very much in advance for your support.

Best regards,

[redacted]