From: Toth-Allen, Jean
Sent: Friday, March 03, 2006 10:29 AM
To: **[Redacted]**
Subject: RE: Question

Dear Ms. **[Redacted]**:

Thank you for your inquiry regarding the recording of the gender of a study subject.

Neither FDA regulation nor guidance discuss this topic. However, since it is well known that gender differences can affect an individual's response to a pharmaceutical, it would be important information to capture, if this individual is accepted as a study subject. It would seem that the entire set of facts regarding this individual's gender needs to be captured. If there is only a small space to initially capture gender on the case report form (CRF), entering the subject's presently recognized gender, female, would seem appropriate, with an asterisk to denote that there is further information. Where room is otherwise available on the CRF, an explanation of the asterisk should be included. While this subject will be provided female hormones, more than hormones are involved in gender-specific responses to pharmaceuticals and this individual's response to the investigational product may need to be uniquely assessed.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

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: Monday, February 27, 2006 10:34 AM
To: OC GCP Questions
Subject: Question

To whom it may concern:

Can you please tell me what gender is recorded on the case report form for a transgender subject? For example, a subject is currently a female but was born a male.

Is there a guidance document that speaks to how record the gender?

Thanks for your assistance.

[Redacted]