

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Criteria for entering Country or Nationality Information
Date: Monday, April 28, 2014 7:42:33 AM

Good morning –

FDA regulations are not specific when it comes to preparing eCRFs. When the regulations are silent, institutions and/or sites are free to develop their own procedures.

I've listed below a few FDA guidance documents that you may find helpful in answering your question:

FDA's Guidance for Industry – Computerized Systems Used in Clinical Investigations found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf>

FDA's Draft Guidance for Industry – Electronic Source Data in Clinical Investigations found at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf>

FDA's Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application found at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf>

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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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: FYXUMXQ
Sent: Friday, April 25, 2014 12:31 PM
To: OC GCP Questions
Subject: Criteria for entering Country or Nationality Information

To Whom it May Concern:

We are preparing an eCRF for a retrospective collection study. We have come across a data item identified as a nationality, listed as 'Zimbabwe'.

Since this data isn't technically an ethnicity or race, is it possible for us to list as: it as
Ethnicity (Citizenship)
- Zimbabwe

Please share your thoughts.]tgf cevfg _