From: OC GCP Questions
To: [redacted]
Subject: Total number of enrollmed
Date: Tuesday, June 03, 2014 3:30:28 PM

Good morning –

You should follow the randomization scheme that is detailed in the protocol. As far as the number of individuals who sign the ICD, we would consider these subjects as screening subjects. Please see the guidances on recruitment and screening. If you are still unsure please consult your reviewing IRB and sponsor.
Guidances > Recruiting Study Subjects - Information Sheet

Guidances > Screening Tests Prior to Study Enrollment - Information Sheet

Additionally, I cannot specifically address your over-enrollment question. Sometimes over-enrollment is not advisable. I recommend that you report the information you have to the FDA Review Division that you are working with on your specific study (e.g. your assigned FDA Project Manager for the IND).

The ICH E-6 Good Clinical Practice Consolidated Guidance, an FDA official guidance, addresses Randomization Procedures inSection 4.7

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf

4.7 Randomization Procedures and Unblinding

The investigator should follow the trial's randomization procedures, if any, and should ensure that the code is broken only in accordance with the protocol. If the trial is blinded, the investigator should promptly document and explain to the sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the investigational product(s).

The randomization scheme should be detailed in the protocol.

Other guidances that might be helpful are below.

ICH E9, "Guidance for Industry Statistical Principles for Clinical Trials," available at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073137.pdf

ICH E10, "Guidance for Industry Choice of Control Group and Related Issues in Clinical Trials," available at
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073139.pdf

I hope this information is useful to you. If you need further information and/or have additional questions, please feel free to contact us at gcp.questions@fda.hhs.gov.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

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, June 02, 2014 4:54 PM
To: OC GCP Questions
Subject: Total number of enrollmed

Dear Sir / Madam,

Is there a limitation to the number of patients who can sign inform consent form to reach the estimated randomized sample size? For example, we calculated we need 20 randomized subjects for a study, can we have 80 subjects sign an informed consent to reach this number? Although, we limit the number of enrollment to 20 in the protocol and ICF.

Regard
[redacted]