From: Toth-Allen, Jean
Sent: Thursday, November 30, 2006 9:36 AM
To: **[Redacted]**
Subject: RE:
[Redacted],

As far as I can see, there is nothing on the 1571 that requests such information, either initially or as a change in the protocol. This form is basically the coversheet for submitting a request for a new IND and/or information related to an on-going IND. The proper place for submission of a change in sample size may well depend on the initial purpose for the study and the rationale for changing subject numbers at the particular point in time. In any case, discussion with the reviewing division would seem in order. They might want to discuss this immediately before allowing the sponsor-investigator to proceed any further with the study rather than waiting to learn of this after the fact, for example in the annual report as you suggest.

Hope this is helpful.

Jean

From: **[Redacted]**
Sent: Wednesday, November 22, 2006 9:53 AM
To: OC GCP Questions
Subject:

I was hoping that you may answer a general question that I have concerning investigator initiated INDs. Do changes in the sample size because recruitment is a problem require a new 1571 submitted, or is that something that can be provided in the annual report?
[Redacted]