From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Wednesday, September 25, 2002 2:33 PM
To: [purged]
Subject: RE:

Yes. While informed consent is generally required, there are a few exceptions. One relates to the emergency use of a test article in a life-threatening situation, with no satisfactory alternatives--basically, a last ditch effort to save the life of the individual. See 21 CFR 50.23(a)-(c). Another is related to emergency research; see 21 CFR 50.24. The last applies to military personnel only; see 21 CFR 50.23(d). The regulations can be found on our website at: http://www.fda.gov/oc/gcp/default.htm. I hope this is helpful to you.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Office for Good Clinical Practice
OSCC, Office of the Commissioner
5600 Fishers Lane, HF 34
Rockville, MD 20857
Phone: 301-827-3340
Fax: 301-827-1169

-----Original Message-----
From: [purged]
Sent: Monday, September 16, 2002 10:58 AM
To: gcpquestions@oc.fda.gov
Subject:

Are there any studies on FDA regulated products which do not require informed consent from study participants?