

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Informazione about randomized manikin study and ethical board
Date: Thursday, November 12, 2015 6:57:23 AM

Good morning --

The study participants are the individuals performing the CPR. This study might need ethic committee (EC) review. I recommend that you consult an EC for further clarification.

Kind regards,

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Office of the Commissioner, FDA

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-----Original Message-----

From: [REDACTED]
Sent: Tuesday, November 10, 2015 3:47 PM
To: OC GCP Questions
Subject: Informazione about randomized manikin study and ethical board

Hi,

I'm [REDACTED], Medical doctor and president of the italian non-profit association [REDACTED].

We are planning to start a randomized controlled manikin trial.

The participants will be lay people who participate to a CPR training course. We will randomized them into 4 groups. Each group will perform 8 minutes of CPR on a manikin connected to a PC following a different protocol for each course.

The endpoint of our study was to assess which type of protocol is better in percentage of compressions performed correctly.

Do this type of study need Ethical Board approval or not?

Thanks a lot

[REDACTED]