

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Exempt IVD Collection Study Question
Date: Wednesday, August 19, 2015 6:26:52 AM

Good morning –

It is best to contact the FDA person/office that requested an equal number of subjects across all three vaccines. I cannot specifically answer your question. Please see the contacts below if you don't know the specific FDA office.

For vaccines -- ocod@fda.hhs.gov Phone: 1-800-835-4709

For devices -- DICE@fda.hhs.gov Phone: 1-800-638-2041

Kind regards,

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Office of Good Clinical Practice
Office of the Commissioner, FDA

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: [REDACTED]
Sent: Tuesday, August 18, 2015 4:46 PM
To: OC GCP Questions
Subject: Exempt IVD Collection Study Question

We are in the process of performing an Exempt IVD Clinical collection study for subjects who are receiving one of the three approved Hepatitis B vaccinations on the market. We are simply collecting serum pre and post vaccination (subjects are already receiving the vaccination as their standard of care).

The FDA requested that we collect an equal number of subjects across all three vaccines that are available. Two of the three vaccines are close in cost for the medical group providing the vaccine, while the third vaccine is significantly higher. This has resulted in a very low enrollment on subjects who have received the third vaccine.

To mitigate this we have a few ideas but need to know if one of these is acceptable. If we offer to pay the medical group the cost of the third vaccine would that

- introduce bias and/or
- change the study type from exempt to interventional and/or
- could this be misconstrued as coercion?

We appreciate your assistance with this matter.

Kind regards,

[REDACTED]