

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: clinical trial
Date: Monday, May 11, 2015 1:39:39 PM

Good afternoon –

Thank you for your email. Your wife may be eligible for expanded access or compassionate use. This route provides a pathway for patients to gain access to investigations drugs, biologics and medical devices for serious diseases or conditions. However, you will need to discuss this situation with her medical staff or the clinical investigator of the clinical trial. I am providing you web links below that give you more information on expanded access. Again please note that I am not sure if your wife would be eligible for this access. Additionally you may wish contact the Center for Drugs (CDER) directly at druginfo@fda.hhs.gov for additional information. The expanded access program originates from this Center. This office may need to refer you to the review division that is overseeing your wife's clinical trial.

[Expanded Access: Information for Patients](#)

[Learn About Expanded Access and Other Treatment Options](#)

[Expanded Access \(Compassionate Use\)](#)

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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Senior Health Policy Analyst
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: Monday, May 11, 2015 12:37 PM
To: OC GCP Questions
Subject: clinical trial

Sir/Madam:

My wife recently signed a consent form to enter into clinical trial [REDACTED]. The trial offered two paths, [REDACTED] or three standard chemotherapies. The hope was that she would be randomized into the [REDACTED] as she recently had a severe reaction to her last chemo-treatment (i.e., pancolitis and a 3 1/2 week hospital stay). Unfortunately, she was selected for another chemo-treatment.

Do we have any options, appeals, etc. She, as well members of her medical staff, are nervous about the ability of her body to tolerate another round of chemo. While we can understand the need to address bias through randomization, it seems unthinkable that this alone would prevent her from receiving what is quickly becoming one of her few remaining options.

Thanks for your time and consideration.

[REDACTED]