

# Clinical Trials Community eNewsletter

Winter 2020

CLINICAL TRIALS  
Community   
CROHN'S & COLITIS  
FOUNDATION

Can you believe it? The year is almost over! It's time for reflection, renewal, and for reading our Winter eNews. Stay safe and read on!

## Addressing poor sleep quality to improve IBD health outcomes

Have you ever noticed that when you get a good night's sleep, you feel better physically and emotionally? That is because there is a connection between your sleep and intestinal inflammation. In an [IBDVisible blog post](#), we explore two new research articles that look at the impact of poor sleep quality on IBD and one approach to addressing insomnia, one of the most common sleep disturbances among patients with chronic illnesses.

## Meet our Clinical Trials Ambassadors: Jill



After experiencing symptoms of fatigue, stomach pain, and diarrhea, Jill was diagnosed with ulcerative colitis at 15. Jill's doctor recommended a maintenance medication as part of her treatment plan. During the months following Jill's diagnosis, she slowly regained her strength and quality of life; however, her symptoms returned after two years, and the medications stopped working. Then, Jill's gastroenterologist approached her about being in a year-long clinical trial. [Read more about Jill's journey here.](#)

## Meet our Clinical Trials Ambassadors: Kristen

Kristen first observed her daughter Kira's symptoms during a family trip, which caused Kira to be confined to their room, missing most of the activities. After returning home, Kira's symptoms continued to worsen as they spent more and more time visiting her pediatrician. After a referral for an endoscopy, Kira was diagnosed with Crohn's disease. During the following months, Kira modified her diet and increased medications, hoping to get to remission. At an infusion center, Kristen and Kira met a research study nurse who approached them about participating in a clinical trial. Kira declined to participate in the initial study the nurse approached her about, but eventually changed her mind and agreed to participate in a different study. [Learn more about Kristen and Kira's decision and experience in a clinical trial here.](#)



## Interested in a clinical trial for your child?

Did you know there are clinical trials for children with IBD? Pediatric clinical trials allow researchers to determine what the best dosage and frequency of treatment is for children and teens. These trials allow the medical community to test the effects of these new treatments with the overall goal of providing safe and effective therapies specifically tailored for children with IBD. Learn more in our comic, [Nicole Learns about Clinical Trials](#).

## Phrase of the Quarter: Informed Assent

**Informed assent** is a term to express willingness to participate in research by people who are too young to consent, or minors, but old enough to understand the proposed research, expected risks, possible benefits, and activities expected of them as participants. Assent by itself is not sufficient, as informed consent must still be obtained from the minor's parent or guardian.

## Clinical Trials Quiz:

### Who monitors and approves clinical trials?

- A. U.S. Food and Drug Administration (FDA)
- B. A committee made up of patients and doctors
- C. IRB (Institutional Review Board)
- D. A group of selected patients

See the answer at the bottom of this email.

## COVID-19 Guidance for the Holidays

Holidays and celebrations look different this year as we continue to adjust to life during the COVID-19 pandemic. It's important to protect yourself and your loved ones by observing social distancing measures, wearing a mask in public, and washing your hands frequently. [Learn more about how you can safely celebrate religious events and special moments](#).

Stress and anxiety can be part of daily life for patients with IBD. Uncertainty around the pandemic and social distancing during the holidays can add an additional layer of concern. It is important to address your emotions and concerns. [Read more to learn some of the ways to help you or loved ones cope with these challenges](#).

## Thank You

As we near the end of the year, we want to extend gratitude to you for being part of our Clinical Trials Community. We look forward to bringing you more news, updates, and helpful clinical trials resources in 2021. If you have ideas of what you'd like to read about next year, we'd like to hear from you! Share your feedback with us via email: [clinicaltrials@crohnscolitisfoundation.org](mailto:clinicaltrials@crohnscolitisfoundation.org).

Again, thank you for engaging with us throughout the year. We wish you a safe and happy holiday season!

Quiz Answer: B. IRB (Institutional Review Board) [Learn more about the IRB's role in clinical trials here](#).