

# IRB MINUTES

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*Date | time* 5/5/2022 12:30 PM |

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## In Attendance

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|--------------------|----------------------|-------------|-----------------------|
| Natalie Cruse      | Mary Ellen Wilkinson | John Larson | Eric Riley, D.P.M, MS |
| Marcia Jones, M.D. | Paul Steinke, D.O.   | Lee Fisher  | William Bird, M.D.    |

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## Approval of Minutes

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The meeting minutes from May 13, 2021 were approved by John Larson.

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## Discussion

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The meeting was started at 1231 via Zoom by Natalie Cruse.

The annual meeting is to renew the Biotronik humanitarian device used in the CGH catheterization lab when the patient has a rupture of the vessels in their heart during a cardiac procedure in the catheterization lab. Natalie reported the device has not been used in the last year. Dr. Marcia Jones will sign the letter, for the Biotronick devices, for approval for the next year.

Natalie gave updated information on the 2021 FMT transplants. We did not do any FMT in 2021 due to the FDA regulation with Open Biome during COVID. The FDA wanted the company to screen the donor for COVID as they had not prior to the pandemic and they did not want the samples to be “contaminated” with possible COVID. The FDA allowed only “emergent” cases to be done after Open Biome tested the donors and re-collected samples; physicians had to fill out specific paperwork in order to have approval for FMT. We currently have a credit with Open Biome regarding our outdated product as we had 8 of them outdate during COVID. Currently we have 0 product in our freezer. There was an inquiry as to whether FMT is FDA approved. Natalie will obtain information on this, and report back to the group.

There was an inquiry from the group on the Convaslescent Plasma Therapy, originally discussed at the 2020 meeting, by Dr. Eskandari. It was reported from Paul Steinke that CGH has not received feedback on this study.

Natalie briefly discussed a non-invasive study project from an employee who is obtaining her DNP. The study involves interviewing those 60 years and older, who are taking more than three medications. There was an inquiry regarding some more details of the study, and Natalie will report her findings back to the group.

There being no further business, the meeting ended at 1244.

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## Next Meeting

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The next meeting is tentatively scheduled for Thursday, May 4, 2023.