Responsible Clinician Notification:

From: Mayo Clinic IRB
To: Michael Joyner
Cc: Amy Amsbaugh
    Kylie Andersen
    Brenda Anderson
    Machiko Anderson
    Sarah Baker
    Philippe Bauer
    Supriya Behl
    Lori Bergstrom
    Lisa Brumble
    Katelyn Bruno
    Zachary Buchholtz
    Matthew Buras
    Michelle Burtis
    Brian Butterfield
    Rickey Carter
    Frances Cayer
    Andrew Clayburn
    Kristin Cornwell
    Joshua Dennis
    Juan Diaz Soto
    Grant Dubbels
    Adam Eggert
    Ree Erickson
    DeLisa Fairweather
    Robert Frye
    Daniel Gaz
    Winston Guo
    Maira Gutierrez Rascon
    Starr Guzman
    Walter Hellinger
    Vitaly Herasevich
    Karina Hex
    David Hodge
    Patrick Johnson
    Christopher Johnson
Vidhu Joshi
Michael Joyner
Stephen Klassen
Allan Klompas
Megan Knudson
Tessa Kroeninger
Katie Kunze
Kathryn Larson
Elizabeth Lesser
Claudia Libertin
Ilana Logvinov
Jaime Long
Jorge Mallea
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William Morice
Brenna Murphy
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John O'Horo
Amy Olofson
Shauna Overton
Laura Pacheco-Spann
Sumedha Penheiter
Michaela Pletsch
Robert Rea
Riley Regimbal
Jennifer Rich
Juan Ripoll Sanz
Shelly Roberts
Nicolas Saikali
Paula Santrach
Jonathon Senefeld
Matthew Sexton
John-Roger Shepherd
Jason Siegel
Pamela Skaran
Lindsay Stromback
Edward Swaray
Morgan Swope
Lisa Tebay
Elitza Theel
Kristine Tree
Camille Van Buskirk
Matthew Vogt
Mark Wentworth
Re: IRB Modification #: Mod20-003312-33  
Title: Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19  
IRB#: 20-003312

Modification Approval Date: 6/11/2020

The above referenced modification is approved by expedited review procedures. The modification includes: 1) Addition of Note to File, dated June 9, 2020, describing external (Non-Mayo Clinic) collaborators from whom de-identified data (information) about patients hospitalized with COVID-19 will be received at Mayo Clinic; and 2) Appendix 1: Modification to the US Convalescent Plasma Program to create a control group for Efficacy Analysis. The modification constitutes a minor change to previously approved research, and therefore was eligible for expedited review in accordance with 45CFR46.110(b)(2) & 21CFR56.110(b)(2). The Reviewer determined the modification(s) pose no more than minimal risk to subjects.

AS THE PRINCIPAL INVESTIGATOR OF THIS PROJECT, YOU ARE RESPONSIBLE FOR THE FOLLOWING RELATING TO THIS STUDY.
1) When applicable, use only IRB approved materials which are located under the documents tab of the IRBe workspace. Materials include consent forms, HIPAA, questionnaires, contact letters, advertisements, etc.
2) Submission to the IRB of any modifications to approved research along with any supporting documents for review and approval prior to initiation of the changes.
3) Submission to the IRB of all Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and major protocol violations/deviations within 5 working days of becoming aware of the occurrence.
4) Compliance with applicable regulations for the protection of human subjects and with Mayo Clinic Institutional Policies.

Mayo Clinic Institutional Reviewer