HHS COVID-19 Research Project Q & A
Project Title: Investigating the Immunology of Convalescent Plasma as a Therapy for COVID-19
Updated 6/25/2020

Q: Why is HHS doing this research?

A: Early access to promising new therapies are initially only available through research studies. This project is a great example of this. Convalescent plasma appears to be of benefit for the treatment of certain infectious diseases, including infections from respiratory viruses. The rationale for use of convalescent plasma for patients with COVID-19 illness is that plasma from recovered patients contains antibodies that may help fight the disease.

Our entire community can benefit if we discover ways to treat and respond to this unprecedented virus. We have an urgent need to protect and treat our community and this research is one way we can help get to possible solutions.

Q: What is the purpose of this study?

A: This study is a national multi-site project being coordinated by Mayo Clinic. The purpose of this study is two-fold: the primary objective is clinical – to provide a treatment option to patients with COVID-19 using plasma from patients who have recovered from the virus (referred to as 'convalescent plasma'). While the safety profile of plasma administration is well established for other indications, the secondary objective of the project is to study the safety of this treatment specifically in patients with COVID-19. Our research team is also conducting studies on blood specimens from patients with COVID to characterize immune responses to the virus, with the goal of developing additional immune therapy strategies.

Q: Will patients be able to decide if they do or do not want to be in the study?

A: Yes. If they are able to consent, we will ask them directly. If they are too sick to consent themselves, we will ask their legally authorized representative to provide consent on their behalf. If a patient is too ill to provide informed consent and their legally authorized representative is unavailable, federal regulations allow for an emergency exception to informed consent, in order to provide potentially life-saving treatment to the patient. This action requires documentation of the specific clinical circumstances that meet these federal requirements, both by the study investigator and a second physician, not involved in the study. This documentation must be submitted to the IRB within 5 working days after the therapy is administered.

Q: What are the possible risks to patients of this treatment?

A: Blood and plasma have been used as a treatment for many other conditions, and in general are considered very safe. However, there are the risks associated with the administration of plasma (including allergic reactions), and there is also a theoretical risk

that convalescent plasma could interfere with a recipient's long-term immune response to SARS-CoV-2. This risk will be assessed as part this project.

Q: How will outcomes be measured?

A: Outcomes will be measured by looking at a patient's medical records to assess how quickly they recovered and assessing their hospitalization status 7 days after they received the plasma.

Q: Is there a cost to patients to be in the study?

A: No. Patients will not need to pay for the convalescent plasma. However, their insurance will need to pay for all other tests and procedures that they would normally have as part of their clinical care, including co-payments and deductibles, and any costs not covered by their insurance.

Q: What is the status of IRB Approval?

A: This study has been reviewed and approved by the IRB at the Mayo Clinic in Rochester, MN. This study is multi-site and Mayo's IRB is the central IRB overseeing the project for all sites that are participating.

Q: Where can I get more detailed information about this study?

A: The study has a website that can be found at https://www.uscovidplasma.org/.