

## Investigational COVID-19 Convalescent Plasma - Emergency INDs Frequently Asked Questions

April 3, 2020

### What is convalescent plasma?

- Convalescent plasma is the liquid part of blood that is collected from patients who have recovered from an infection.
- Antibodies present in convalescent plasma are proteins that might help fight the infection.

### Why is convalescent plasma being investigated to treat COVID-19?

- Convalescent plasma is being investigated for the treatment of COVID-19 because there is no approved treatment for this disease and there is some information that suggests it might help some patients recover from COVID-19.
- Further investigation is still necessary to determine if convalescent plasma might shorten the duration of illness, reduce morbidity, or prevent death associated with COVID-19.

### Is convalescent plasma safe and effective against COVID-19?

- It is not known if convalescent plasma will be an effective treatment against COVID-19.
- Plasma transfusions are generally safe and well-tolerated by most patients, but can cause allergic reactions and other side effects. It is also not known if patients with COVID-19 might have other types of reactions to convalescent plasma.
- While it is not known if convalescent plasma is safe and effective against COVID-19, there is anecdotal evidence that convalescent plasma might be for some patients.
- Because there are no approved treatments, FDA is permitting the emergency investigational use of convalescent plasma to treat COVID-19 under the criteria of the emergency IND.

### How can a physician obtain access to convalescent plasma to treat COVID-19?

- **A physician should contact their local blood center to inquire about obtaining convalescent plasma from a recovered donor.**
- Licensed physicians can request the use of convalescent plasma through a single-patient Emergency Investigational New Drug (eIND). Please see information about how to request an eIND [posted on FDA's web site](#).

### What is an emergency IND?

A physician may decide to request use of an investigational product through a single-patient Emergency Investigational New Drug (eIND) application if:

- the physician considers the product may be urgently needed for the patient's serious or immediately life-threatening disease or condition;
- no satisfactory alternative therapy is available;
- the probable risk from the investigational drug is not greater than the probable risk from the disease or condition; and
- the patient cannot receive the product through any existing clinical trials or expanded access protocols

### Where can a physician obtain convalescent plasma for a patient with COVID-19?

- Convalescent plasma is not yet widely available from blood centers, although many are starting to collect it.
- Hospitals should contact their blood supplier to discuss possible options for obtaining convalescent plasma.
- FDA does not provide convalescent plasma to hospitals.

**I recently recovered from COVID-19, can I donate convalescent plasma?**

- COVID-19 convalescent plasma must only be collected from recovered individuals if they are eligible to donate blood.
- Individuals must have had a prior diagnosis of COVID-19 documented by a laboratory test and meet other laboratory criteria.
- Individuals must have fully recovered from COVID-19, with complete resolution of symptoms for at least 14 days before donation of convalescent plasma.

**I think I had COVID-19, but I did not get a test. Can I still donate convalescent plasma?**

- Yes. Please refer to the information in “Considerations for eligibility of plasma donors” on the investigational COVID-19 convalescent plasma web page.

**Who should I contact if I want to donate convalescent plasma?**

- Not all blood centers collect convalescent plasma, but some have started to collect it.
- You can ask your local blood center if there are options to donate convalescent plasma in your area. FDA included contact information for blood organizations in its [March 19, 2020 statement on blood donations](#).
- FDA does not collect convalescent plasma.