



Convalescent Plasma for the Treatment of COVID-19 and Donation of Convalescent Plasma April 13, 2020

1. Use of convalescent plasma to treat COVID-19 patients

COVID-19 convalescent plasma has not yet been demonstrated to provide clinical benefit in patients affected by this disease. It is not known if this treatment will or will not help those with COVID-19 or if it will have any harmful effects. Based on preliminary data from small series of patients it appears safe and historical precedent with other respiratory infections the antibodies in convalescent plasma may provide therapeutic benefit.

The following pathways are available for the use of COVID-19 convalescent plasma:

a. **Clinical Trials:** Information regarding clinical trials involving use of convalescent plasma is available at clinicaltrials.gov. Not every clinical trial is registered on the clinicaltrials.gov website¹; other clinical trial options may be available.

b. **Single Patient Emergency IND:** The FDA is facilitating access to COVID-19 convalescent plasma for use in patients with COVID-19 infections through a single patient emergency IND (eIND) for the individual patient. For more information, see: www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma.

c. **Expanded Access Treatment Protocols:** Currently, the Mayo Clinic is the lead institution for the only expanded access protocol approved by the FDA. This protocol targets adults admitted to the hospital with severe² or life-threatening illness:

[National Expanded Access Treatment Protocol \(www.uscovidplasma.org/\)](https://www.uscovidplasma.org/)

Physicians must register their institution in Mayo Clinic's database in order to obtain access to convalescent plasma for their patients under this protocol. To participate, your hospital can rely on the Mayo Clinic IRB. A separate IRB reliance agreement is not required. Hospitals can

¹ Note: Not all clinical trials are registered on the clinicaltrials.gov website.

² Severe COVID-19 is defined by > 1 of the following: shortness of breath, respiratory rate ≥ 30 /min, blood oxygen saturation $\leq 93\%$, partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300 , lung infiltrates $> 50\%$ within 24 to 48 hours.

designate one physician/PI for this Expanded Access Program OR multiple physicians/ PIs can register for each site.

As of April 13, 2020, over 50 Illinois hospitals have registered to participate in this protocol. [Expanded Access Treatment Protocol](#) links:

- [Site Registration Form](#) (first step, also includes IRB information)
- [Physician/PI Registration Form](#) (use only after registering your hospital)
- [Patient Enrollment Form](#)(use only after the above steps have been completed and patient has consented)

For more information, go to the [Expanded Access Program website](#), or contact the PI at uscovidplasma@mayo.edu.

2. Donation of convalescent plasma by recovered COVID-19 patients

Convalescent COVID-19 Plasma will be widely available under the above programs only if there is robust participation of recovered patients in the plasma donation process. Hospitals may choose to support donation by contacting and referring recovered patients.

Donors may donate as 14-27 days after they have recovered to donate if they have a negative nasal, nasopharyngeal or blood molecular assay. If donors wait for ≥ 28 days after recovery repeat testing to document a negative specimen is not typically required, and higher antibody levels are usually present.

Alphabetic list of links to current information regarding donation of convalescent plasma through blood donation centers:

1. Central Illinois Community Blood Center
Community Blood Services of Illinois
Mississippi Valley Regional Blood Center:
(Patients must be referred by a provider, hospital or healthcare system for the present to be sure of adequate documentation of infection.)
<https://www.bloodcenter.org/hospitals/patient-services/convalescent-plasma/>
2. Red Cross:
Patient self-referral: <https://www.redcrossblood.org/donate-blood/dlp/plasma-donations-from-recovered-covid-19-patients.html>
3. Versiti:
<https://www.versiti.org/home/convalescent-plasma-donations>
4. Vitalant Patient Self-Referral:
<https://www.vitalant.org/COVIDFree>

A complete list of blood donation centers in IL is here: <https://ilabb.org/Donation.html>.

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Additional information regarding facilitation of donation by recovered patients will be provided in a forthcoming memo.

Reference:

Bloch, Evan, et al. (April 7, 2020). Deployment of convalescent plasma for prevention and treatment of COVID-19. *The Journal of Clinical Investigation*. Retrieved at <https://www.jci.org/articles/view/138745/pdf>