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COVID-19 Convalescent Plasma: Sample Information Sheet

HRP is providing the following information as part of its ongoing responsibility to assist clients in navigating their research programs through the COVID-19 pandemic. This sample information sheet describes the pathways currently available for providers to study or otherwise access COVID-19 Convalescent Plasma. Organizations should modify this sample so that it incorporates the organizations processes and requirements. Please note that this information sheet was last updated on April 10, 2020 and reflects information available on that date. Information is rapidly evolving; organizations should consult the FDA Investigational COVID-19 Convalescent Plasma Website and other resources regularly to ensure that their information remains up to date.

INTRODUCTION:
Currently there are no proven vaccines or therapies for the prevention or treatment of COVID-19. One investigational treatment being explored for COVID-19 involves the use of convalescent plasma collected from recovered COVID-19 patients. Per the FDA, the current regulatory pathways for COVID-19 convalescent plasma include:

- **Clinical Trials** conducted under the traditional IND regulatory pathway including the three National COVID-19 Convalescent Plasma Project protocols (Asymptomatic, Mild/Moderate, and Severe/Critical). Other clinical trials can be identified by searching ClinicalTrials.Gov.
- The National Expanded Access Treatment Protocol – for patients with, or at risk of severe or life-threatening COVID-19 disease who are not eligible or are other unable to participate in a clinical trial.

  The Mayo Clinic IRB serves as the IRB of record for this protocol. IRB reliance is documented via a combination of the site registration and the physician enrollment form. This streamlined reliance agreement process was developed in consultation with the FDA to facilitate timely access given the urgency of the situation. Organizations may need to document (e.g., via a memo or note to file) an exception to their standard IRB reliance policies and procedures for this protocol.
- Single patient emergency IND (eIND) – when neither of the above options is possible. Single patient eINDs require FDA authorization and IRB Chair Concurrence (when time permits, otherwise the emergency use exemption from prospective IRB approval may be used so long as the requirements are satisfied).

The American Red Cross and other blood centers are currently seeking plasma donations from recovered COVID-19 patients who are eligible to donate blood. Information about donor eligibility and labeling of COVID-19 plasma units is available on the FDA Investigational COVID-19 Convalescent Plasma Website.

Providers considering the use of COVID-19 Convalescent Plasma should carefully consider the current medical condition of their patient and any underlying health conditions or risk factors as well as what is known about the potential risks and benefits of COVID-19 plasma administration. Transfusions should only be performed by appropriately qualified persons in settings equipped to handle potential complications of transfusion such as an allergic reaction or systemic transfusion reaction. Providers participating in any of the above IND pathways (as the local PI, registered physician, or holder of an eIND) must maintain records about the use of convalescent plasma, including the unique identification number of the plasma unit.

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Use this section to insert local information about institutional requirements, IRB review, etc. The following is sample language should be modified to appropriately reflect each organizations' processes and requirements.

CLINICAL TRIALS:
The following clinical trials involving COVID-19 Convalescent Plasma are available at [Organization Name]. Please contact the study contact identified below for more information:

- [Protocol title, PI, study contact, brief description or link to additional information]

[Organization Name] has established a **COVID-19 Research Triage Process** to vet and prioritize requests for research investigating COVID-19. Investigators interested in developing or participating in a clinical trial investigating the use of COVID-19 Convalescent Plasma for the prevention or treatment of COVID-19 should contact [Contact Information] to initiate the triage review process. [Organization Name] has established fast-track processes for COVID-19 research identified as high-priority through the triage process. Once approved for initiation, contact the [HRPP/IRB Office] at [Contact Information] to discuss IRB review options. [Insert information about other administrative or support units that may be involved (e.g., sponsored programs, a clinical trials support unit, biosafety, etc.]

NATIONAL EXPANDED ACCESS TREATMENT PROTOCOL:
(The following sample language is for organizations who have already registered with the expanded access program. Organizations who have not should replace this sample information with information about whom to contact if they would like to seek access for a patient under the national expanded access program.)
[Organization Name] has registered as a participating site with the National Expanded Access Treatment Protocol. Hospitalized patients are eligible to receive COVID-19 convalescent plasma under this protocol if they have severe or life-threatening COVID-19 or are judged by a healthcare provider to be at high risk of progression to severe or life-threatening disease. Patients must meet the protocol's inclusion criteria, be electronically registered, and provide informed consent (patient or health care proxy, as appropriate) using an approved consent form. Certain safety data, demographics, and other information (e.g., days in ICU, length of stay) will need to be submitted via the program's secure website.

For more information on the National Expanded Access Treatment Protocol, including the protocol, consent form, and registration form, please visit the programs website: https://www.uscovidplasma.org/.

[Describe any local requirements (e.g., sign-off by a clinical leader, independent medical opinion, etc.)]

SINGLE PATIENT EMERGENCY IND:
When patients are confronted with severe or life-threatening COVID-19 and unable to participate in a clinical trial or the National Expanded Access Treatment Protocol, providers may seek authorization from the FDA for a Single Patient Emergency IND (eIND). To facilitate the FDA's review process, FDA suggests that providers consider the following eligibility criteria prior to initiating a request:

- Laboratory confirmed COVID-19
- Severe or life-threatening COVID-19:
    - Severe disease is defined as:
        - Dyspnea,
        - Respiratory frequency ≥ 30/min,

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        - Blood oxygen saturation ≤ 93%,
        - Partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300, and/or
        - Lung infiltrates > 50% within 24 to 48 hours
    - Life-threatening disease is defined as:
        - Respiratory failure,
        - Septic shock, and/or
        - Multi-organ dysfunction or failure
- Informed consent provided by the patient or legally authorized representative [if a template consent is available link to it here]

[Describe any local requirements (e.g., sign-off by a clinical leader, independent medical opinion, etc.)]

The FDA **does not** collect or provide COVID-19 convalescent plasma for eINDs. Providers will need to seek access to the plasma from the American Red Cross or another FDA-registered blood establishment that follows the donor criteria described on the FDA website. [insert information about any hospital-vetted suppliers]

Information about eINDs for COVID-19 convalescent plasma, including the submission form (Form FDA 3926) and process, is available on the FDA Investigational COVID-19 Convalescent Plasma Website. Please be certain to check the box at 10.b. on the FDA 3926 form, this permits review by the IRB Chair (or their designee) in lieu of convened IRB review and will save significant time.

Please contact the [HRPP/IRB office] at [Contact Information] as soon as possible when considering a single patient eIND so that we may facilitate the process. [Organization] has established fast track processes for high-priority requests related to COVID-19 and can initiate the IRB review process while you are working with the FDA on the eIND. When IRB Chair review cannot be obtained in advance of the use, an emergency use exemption may be able to be invoked. [link to or provide information about emergency use requirements and procedures]

Providers who obtain an eIND from the FDA are considered "sponsor-investigators" and must submit any proposed modifications to the treatment plan or safety monitoring plan to the FDA and IRB for approval. Follow-up reports are also required. Modifications, safety reports, and other follow-up reports can be submitted to the FDA using Form FDA 3926 the same form used for the original submission). Reporting requirements are summarized on this FDA website: Follow-up Expanded Access Reports. [Describe follow up IRB requirements, for example: Modifications can be submitted to the IRB by submitting a Modification Request Form to [instructions] with the FDA form attached. Copies of the follow-up reports to the FDA should be submitted to the IRB as soon as possible, these can be submitted by [instructions].]

Note: *Because single patient INDs are frequently submitted by providers who may not have much experience with the IRB (or FDA), HRP encourages organizations to offer as much support as possible. While the eIND must be personally requested by the treating physician, regulatory staff may be able to help facilitate the process and assist with follow-up requirements. If the IRB uses an electronic submission system, consider allowing the provider to submit materials via encrypted email or another simple but secure means (PHI is included on the FDA Form) for later upload into the IRB electronic system by staff.*