HUMAN RESEARCH PROTECTION

Informed consent for Investigational COVID-19 Convalescent Plasma - Emergency INDs

Number 118 Version date 31 MAR 2020

Resource type Guidance

FDA SUPPORTING DOCUMENTS

Investigational COVID-19 Convalescent Plasma - Emergency INDs

FDA fillable form 3926 (PDF)

Form 3926 Instructional Supplement

HENNEPIN HEALTHCARE IRB SUPPORTING DOCUMENTS

323 FORM Independent physician certification

602 TEMPLATE Informed consent for emergency use of a test article

Informed consent scenarios

The following scenarios describe the informed consent process in order of most preferred method:

1. Informed consent is obtained from patient
    1.a. patient is able to provide signature
    1.b. patient is unable to provide signature
2. Informed consent is obtained from a legally-authorized representative (LAR)
    2.a. LAR is able to provide signature
    2.b. LAR is unable to provide signature
3. Informed consent is unable to be obtained from the patient or LAR

Scenarios in which signature on the ICF is not obtained is not considered a waiver of documentation. This assessment relies upon the FDA information sheet Informed Consent.

1. Informed consent obtained from patient

- Informed consent is obtained from the patient following a presentation and discussion of the investigational treatment
- The clinical team may conduct the consent process if it is documented that they were educated in what the investigational treatment involves; this helps ensure the clinical team can knowledgeably obtain consent
- Clinicians should review and discuss the ICF with the patient and answer their questions
- The entire consent process must be documented

The **patient** agrees to the investigational treatment and **is able to provide signature** on the ICF If the signed ICF can't be taken out of the unit, it can be scanned and uploaded to an electronic storage system If it is not possible to obtain a digital image of the signed page, the clinician must: ▪ Document that an imaging device was not available ▪ Establish a witness to the process ▪ Obtain witness signature and date on the ICF Note: For FDA regulated research, the ICF must also be dated by the signer	The **patient** agrees to the investigational treatment but **is unable to provide signature** on the ICF, e.g., the ICF is being read to the patient because a copy could not be taken into the patient's space, the clinician must: ▪ Document the method used for communication with the patient ▪ Means by which agreement was communicated ▪ Establish a witness to the process ▪ Obtain witness signature and date on the ICF

2. Remote informed consent obtained from LAR

- Informed consent is obtained from the LAR following a telephone conversation of the investigational treatment
  - Provide the LAR with an electronic version of the ICF (e.g., email attachment, fax)
    OR
- The clinical team may conduct the consent process if it is documented that they were educated in what the investigational treatment involves; this helps ensure the clinical team can knowledgeably obtain consent
- Clinicians should review and discuss the ICF with the LAR and answer their questions
- The entire consent process must be documented

The **LAR** agrees to the investigational treatment on behalf of the patient and **is able to provide signature** on the ICF	The **LAR** agrees to the investigational treatment but **is unable to provide a signature** on the ICF
The clinician must: ▪ Document how the ICF was transmitted to the LAR (e.g., email, fax) ▪ Document the method used for communication with the LAR ▪ Document how the LAR's signature was obtained. For example: – Electronic signature – Signature page scanned and emailed back to the clinician – Photo image of signature page sent to the clinician ▪ Upload signed ICF to an electronic storage system Note: For FDA regulated research, the ICF must also be dated by the signer	The clinician must: ▪ Document how the ICF was transmitted to the LAR (e.g., email, fax) ▪ Document the method used for communication with the LAR ▪ Means by which agreement was communicated ▪ Document that no imaging technology was available to capture a signed consent form ▪ Establish a witness to the process ▪ Obtain witness signature and date on the ICF

3. Inability to obtain informed consent

If no option to obtain patient or LAR consent exists, both the clinician and a physician who is not otherwise participating in the investigational treatment must certify in writing all of the following:

(1) The patient is confronted by a life-threatening situation necessitating the use of the test article.
(2) Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.
(3) Time is not sufficient to obtain consent from the patient's legal representative (LAR).
(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

If immediate use of the test article is, in the clinician's opinion, required to preserve the life of the patient, and time is not sufficient to obtain an independent physician's determination of these 4 criteria in advance of using the test article, the determinations of the clinician shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the investigational treatment.