

Instructions for Using the Electronic Human Cell and Tissue Establishment Registration System (eHCTERS)

Establishments that manufacture Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) regulated solely under Section 361 of the Public Health Service (PHS) Act (361 HCT/Ps) and the regulations in 21 CFR Part 1271 are required to register and list their HCT/Ps electronically with the FDA for the manufacturing steps they perform using eHCTERS (§1271.1(b)(1) and §1271.22(a)).

Establishments that manufacture HCT/Ps regulated as devices, drugs, and/or biological drugs under Section 351 of the PHS Act and/or under the Food, Drug, and Cosmetic Act can no longer register in eHCTERS. Such establishments must register and list their products, after approval, in accordance with 21 CFR Part 207 or 807, rather than 21 CFR Part 1271. Please refer to [Drug Establishment Registration and Listing](#) or [Device Registration and Listing](#) websites for additional information.

FDA does not require establishments that manufacture drugs and devices under an investigational new drug application (IND) (21 CFR Part 312) or an investigational device exemption (IDE) (21 CFR Part 812) to register and list their HCT/Ps until the HCT/P is approved through a biologics license application (BLA), a new drug application (NDA), or a premarket approval application (PMA); or cleared through a premarket notification submission (510(k)). Therefore, establishments that only manufacture HCT/Ps currently under an IND or IDE may deactivate or change their registration in eHCTERS as indicated.

FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (§1271.27(b)).

The following instructions describe how to use eHCTERS to submit an initial registration, update registration annually, change information, and/or deactivate registration.

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General Instructions

- We recommend that you print these instructions for reference.
- Complete all sections that apply to your establishment.
- Dates should be entered as MM/DD/YYYY (e.g., December 1, 2018 = 12/01/2018).
- All fields marked with an asterisk (*) are required fields and must be completed.
- The reporting official e-mail address is required to facilitate obtaining additional information when necessary.
- Complete a separate registration for each establishment. If an establishment manufactures more than one HCT/P Type, only one registration should be completed.
- The **Tab** key or a **mouse** can be used for screen navigation. Other keys are enabled to ensure that the system is totally navigable via keyboard. Please [contact us](#) if you have any **accessibility problems**.
- The following are **buttons** located on most screens:
 - **Next:** Go to next screen
 - **Previous:** Go to previous screen
 - **CBER On-Line Main Menu:** returns to CBER's listing of on-line applications
 - **Select New Establishment:** exits the current registration and returns to the Activity Selection screen
 - At the top of most screens is a '**speed**' bar that will allow you to go directly to a screen in the application.
 - Click the associated **links** located at the bottom of each page:
 - To log off the system
 - Help with filling out this form - provides the Instructions for using eHCTERS
 - For email help from the eHCTERS Registration Coordinator - [Contact us](#)
- After logging into the system, you have 20 minutes to enter information and continue to the next page (use the **Continue** button located at the bottom of each page). When you have been on a page for 17 minutes, a message will appear asking if you need more time. If you click 'yes' you will be given an additional 20 minutes. If you do not respond when the message appears, and you have been on the page for more than 20 minutes, your session will be lost. If you have a pre-confirmation number, you can re-log in and continue

entering data.

- It is highly recommended that you do not use the back and forward buttons on your browser. Unexpected results may occur. Only use the buttons on each screen for form navigation.

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Activity Selection Screen

eHCTERS - Activity Selection

Welcome UserName

All establishments that manufacture human cells, tissues, or cellular or tissue-based products (HCT/Ps) regulated solely under Section 361 of the Public Health Service Act and 21 CFR Part 1271 must use eHCTERS to register and list their HCT/Ps with FDA. Manufacture means any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any HCT/P, and the screening or testing of a cell or tissue donor. After we receive your registration and HCT/P listing information, we will update our records.

[Electronic Form Instructions](#)

Select the activity you wish to complete from the list below. If this is your establishment's first time submitting an HCT/P registration, please select Initial Registration. If you would like to edit previously submitted registration and HCT/P listing information, please select Edit Registration Information. If you are returning to work on a previously saved but not submitted registration, select Complete Unfinished Registration and enter the corresponding Pre-Confirmation number. When you have made your selection and entered the requested information, press the Continue button to proceed.

Initial Registration: Select this if your establishment is submitting registration information for the first time.

Edit Registration Information: Select this if you have the FEI number assigned to your establishment.

Reason for Submission: Annual Registration/Listing Change in Information In-Activate Registration

Select from your existing user establishments:

If your establishment does not appear in the above drop down list, press the User Establishments button below to add your establishment to the list

Complete Unfinished Registration: Pre-Confirmation Number must be provided.

Select one of the following:

- **Initial Registration** - Select this if your establishment has never registered with CBER for manufacturing HCT/Ps. When the Initial Registration radio button is selected, the system will display a page to help confirm that "initial registration" is the appropriate selection.
 - Press **Continue** to confirm that your establishment has never registered with CBER for manufacturing HCT/Ps.
 - Press **Search** to see if your establishment has previously registered or to check your registration status.
 - Press **Cancel** if you have already registered.
- **Edit Registration Information** - Select this if you have previously registered and an FDA

Establishment Identifier (FEI) number has been assigned by the agency. Select a **Reason for Submission (Annual Registration/Listing, Change in Information, or In-Activate Registration)** and select the establishment you wish to edit from “your existing user establishments” dropdown list. If your establishment does not appear in the “Select from your existing user establishments” dropdown list, press the **User Establishments** button to add your establishment to the list.

- **Complete Unfinished Registration** - Enter an eHCTERS assigned pre-confirmation number if you are completing an unfinished (not submitted) entry that you saved earlier (within the past 30 days).
- When you have made your selection and entered the requested information, press the **Continue** button to proceed.
- Button Descriptions:
 - **Continue** - Navigates to the next screen based on the Activity selected (Initial Registration, Edit Form, Complete Unfinished Form)
 - **User Establishments** - Navigates to the User Establishments screen where you associate your account to one or more establishments
 - **Active Users** - Navigates to the Active Users screen, which displays a list of all users associated with the same establishments
 - **CBER On-Line Main Menu** - Exits eHCTERS, returns to CBER's listing of on-line applications

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User Establishments Screen

eHCTERS - User Establishments

Enter the FEI number of the establishment to which you are requesting access..

*FEI:

*Last Registration Receipt Date (MM/DD/YYYY):

* Required

This Profile is currently subscribed to the following establishments:

Current Establishments	Location	FEI
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You can access this page by clicking the **User Establishments** button on the **Activity Selection** screen. On this page, you may add the establishment(s) to your eHCTERS account to view or update registration through eHCTERS.

In the upper portion of the screen, you are required to enter the FDA Establishment Identifier (FEI) number of the establishment with which you wish to be associated and the **Last Registration Receipt Date** for this establishment. The **Last Registration Receipt Date** is located in the upper-right corner of the Registration Summary Report that we send by email to the establishment's Reporting Official.

Once you have entered an **FEI** number and a **Last Registration Receipt Date**, press the **Add This Establishment** button. If your FEI number and Last Registration Receipt Date are accurate, eHCTERS will immediately grant you access to the establishment's registration. If your FEI number and Last Registration Receipt Date do not match our records, eHCTERS will immediately notify you. If you feel that the information you supplied is correct and eHCTERS should have accepted it, please contact eHCTERS Technical Support located at the bottom of the web page.

Once you have successfully associated your user account with the establishment, the establishment name will appear in the lower portion of this screen.

The lower portion of the screen lists the establishments to which you have access. Each establishment listing is prefaced with two buttons **Edit** and **Remove**.

To view and/or update an establishment, click on the Edit button next to the establishment name. If you have already started making changes to an establishment's information through eHCTERS or have recently submitted changes being reviewed by the FDA, the system will display the **Submissions Pending** screen.

To revoke your access to an establishment, click on the **Remove** button next to the establishment name. This will NOT delete any registration information about this establishment. It will simply remove your access to this establishment's registration.

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Active Users Screen

Current Establishments	FEI	User Name	Real Name
10162018 Test	4005550091	UserName	

By clicking the **Active Users** button located at the bottom of the **Activity Selection** screen, the Active Users screen will appear. This page displays a list of all establishments you have access to and the current user(s) to such establishments. For each establishment listed you

will see Establishment Name, FEI, User Names associated with the establishment, and the First and Last name of those users.

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Submissions Pending Screen

eHCTERS - Submissions Pending

Current User: **UserName**

This page is being displayed because Other submissions are pending for this facility. [If you experience problems with this Web Site Contact: HCT/P Registration Coordinator.](#)

10162018 Test
FEI: 4005550091

<input type="button" value="Edit P-36410"/>	Created By: (10/18/2018) Not Submitted, Last Modified by: (10/18/2018)
<input type="button" value="View P-36411"/>	Created By: (10/18/2018) Submitted By: (10/18/2018)

The **Submissions Pending** screen will appear when you attempt to create an electronic registration submission, and the system finds a record created for that establishment within past 30 days or a record submitted within past 7 days.

Your options for proceeding are as follows:

- To edit a record that you have created but not yet submitted to the FDA, click the **Edit** button next to the record.
- To view a recently submitted record, click the **View** button next to the record.
- To create a new registration submission based on your current registration, click the **Create a New Registration Submission** button.
- To return to the main eHCTERS screen, click the **Return to Activity Selection Screen** button.

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Initial Establishment Registration Information Screen

FEI: Pre-Confirmation Number: 37148										
Legal Name: Todays Date: 10/24/2018										
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save
eHCTERS - Initial Establishment Registration Information										
* Reason for Submission										
<input checked="" type="radio"/> Initial Registration				Other FDA Registrations for the entered FEI Number						
				<input type="checkbox"/> Blood		<input type="text"/>				
				<input type="checkbox"/> Devices		<input type="text"/>				
				<input type="checkbox"/> Drug		<input type="text"/>				
* Required										
Next			Select New Establishment				CBER On-Line Main Menu			

The **Initial Establishment Registration Information** screen will appear if you attempt to create an initial registration by selecting **Edit Registration** on **Activity Selection** screen follow by clicking **Continue** button on **Initial Registration Selection** Screen. You should create an initial registration only if your establishment has never registered with the FDA as a 361 HCT/P establishment.

If your establishment is already registered with the FDA as a Blood, Medical Device, or Drug establishment, please provide the FEI number in the appropriate field. To move forward, please press **Next** button and continue to fill out information as the subsequent screens indicate.

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Edit Establishment Registration Information Screen

FEI: 3003003000 Pre-Confirmation Number: 37151										
Legal Name: FDA Tissue Test Todays Date: 10/24/2018										
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save
eHCTERS - Edit Establishment Registration Information										
* Reason for Submission										
<input checked="" type="radio"/> Annual Registration/Listing <input type="radio"/> Change in Information				Tissue FEI# 3003003000 Other FDA Registrations for the entered FEI Number						
				<input type="checkbox"/> Blood		<input type="text"/>				
				<input type="checkbox"/> Devices		<input type="text"/>				
				<input type="checkbox"/> Drug		<input type="text"/>				
* Required										
Next			Select New Establishment				CBER On-Line Main Menu			

The **Edit Establishment Registration Information** screen will appear if you attempt to update an existing registration by selecting **Edit Registration Information** on **Activity Selection** screen.

Reason for Submission: Select the reason for your submission, Annual Registration/Listing or Change in Information. Please note that the annual registration period is from November 15 through December 31 each year.

Other FDA Registrations: If your establishment is registered with FDA as a Blood, Medical Device, or Drug establishment, please provide the FEI number in the appropriate field.

To move forward, please press **Next** button and continue to update your information on subsequent screens as needed.

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Establishment Registration Address Information Screen

FEI:										Pre-Confirmation Number: 37152	
Legal Name:										Todays Date: 10/24/2018	
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save	
eHCTERS - Establishment Address Information											
Physical Location											
* Legal Name <input type="text"/>											
* Street Address <input type="text"/>											
<input type="text"/>											
<input type="text"/>											
* City <input type="text"/>											
* U.S. State <input type="text" value="None"/>										* Postal Code <input type="text"/>	
* Country <input type="text" value="United States"/>											
* Phone(xxx-xxx-xxxx) <input type="text"/> ext. <input type="text"/>											
Foreign Phone(Country Code-City Code-Telephone Number)											
Satellite Recovery Establishment <input type="checkbox"/> If checked, please enter Parent Manufacturing Establishment FEI											
Parent Manufacturing Establishment FEI No. <input type="text"/>											
Testing For Micro-Organisms Only <input type="checkbox"/>											
* Required											
Next			Previous			Select New Establishment			CBER On-Line Main Menu		

Physical Location: Provide information about the physical location of the establishment such as **Legal Name**, **Street Address**, **City**, **Country**, **Phone**, etc. Please note that **State** and **Postal Code** are only required for U.S. establishments.

Satellite Recovery Establishment: Indicate (with a check) if you are a satellite recovery establishment that supports recovery personnel in the field by providing temporary storage for recovered HCT/Ps prior to shipment to your parent manufacturing establishment, but you do not perform any other activities or manufacturing steps.

Parent Manufacturing Establishment FEI Number: Provide the FEI number of your parent manufacturing establishment only if you have selected Satellite Recovery Establishment.

Testing For Micro-Organisms Only: Indicate (with a check) if you are an establishment that performs testing of HCT/Ps for microorganisms if that is the only HCT/P processing function that you perform. On the HCT/P listing information screen, you must also list the HCT/Ps for which you perform microbiological testing.

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Possible Establishment Matches Found Screen

FEI:	Pre-Confirmation Number: 37152
Legal Name: FDA Tissue Test	Today's Date: 10/24/2018

eHCTERS - Possible Establishment Matches Found

Your establishment may already be registered. Please review the list of possible matches below. You may view detailed information about each establishment by clicking the establishment name.

- If your establishment is not listed, continue with the initial registration.
- If your establishment is listed below as:
 - **Pre-Registered**, your establishment registration is still under review. Please discontinue the initial registration and contact tissuereg@fda.hhs.gov regarding the status of your registration.
 - **Registered**, your establishment is already registered. Please discontinue the initial registration and follow the instructions on the Activity Selection page if you wish to edit your registration.
 - **Inactive**, your establishment information is in the system but your establishment is not currently registered. Please discontinue the initial registration and follow the instructions on the Activity Selection page if you wish to "edit and reactivate" your registration.
- If Registered or Inactive: After discontinuing your initial registration the system will navigate to the Activity Selection page. If you wish to edit your registration, select Edit Validated Form, select Change in Information, select your establishment and then press continue.

Establishment Name	City, State/Zip	FEI	Establishment Status
FDA Tissue Test	Rockville, MD / 20852	3003003000	Pre-registered

The **Possible Establishment Matches Found** Screen displays when the initial registration Legal Name and one of these fields: City, Postal Code, Address Line 1, or Address Line 2 are identified to an existing establishment. To verify that your establishment is not already registered, please review the detailed information about each establishment in the table by clicking the establishment name.

If the establishment you are trying to register is not listed, press the **Continue With Initial Registration** button to return to the **Establishment Registration Address Information** Screen and continue entering your initial registration.

If the establishment you are trying to register is listed, the establishment status can be found as:

- **Pre-Registered** - this status means that the establishment has submitted their initial registration to the FDA, but assignment of an FEI number is still pending. After the establishment's registration is processed by the FDA and an FEI number is assigned to the establishment, the status will be changed to "registered" from "pre-registered".

Please discontinue the initial registration you are working on to avoid duplicate registration.

- **Registered** - this status means that the establishment has submitted their registration information to the FDA and an FEI number has been assigned to the establishment. Please discontinue the initial registration you are working on to avoid duplicate registration.
- **Inactive** - this status means that the establishment's registration with the FDA is not active because the establishment is no longer manufacturing 361 HCT/Ps. Please discontinue the initial registration.

By clicking the **Discontinue Initial Registration** button, the system will navigate to the **Activity Selection** page. If you wish to edit or reactivate your existing registration (select the establishment from the dropdown list), please select **Edit Registration Information** and **Change in Information** as the reason for submission. If your establishment does not appear in the "Select from your existing user establishments" dropdown list, press the **User Establishments** button to add your establishment to the list.

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Establishment Reporting Official Information Screen

FEI: Pre-Confirmation Number: 37158
Legal Name: Todays Date: 10/24/2018

Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save
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eHCTERS - Establishment Reporting Official Information

Reporting Official Information

*First Name M.I.
*Last Name
Credentials
*Title
*E-Mail Address
*Phone(xxx-xxx-xxxx) Ext.
Foreign Phone(Country Code-City Code-Telephone Number)

Mailing Address

*Institution Name
*Street Address

*City
*State *Postal Code
*Country

* Required

Reporting Official Information: The Reporting Official is the person appointed by the owner or operator to register the firm and answer all the correspondence and inquiries relative thereto. Reporting Official's **First Name, Last Name, Title, Email Address** and **Phone** are required fields.

Mailing Address: Provide Reporting Official's **Institution Name, Street Address, City, State, Postal Code**, and **Country**. Please note that **State** and **Postal Code** fields are only required for U.S. establishments. You may copy such information from the **Establishment Registration Address Information** screen to the Reporting Official screen by pressing the **Copy From Address Info Screen** button.

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Establishment U.S. Agent Information Screen

FEI: Pre-Confirmation Number: 37156

Legal Name: Today's Date: 10/24/2018

RegistrationAddressReporting OfficialU.S. AgentImporterHCT/P ListingFunctionDonorAdditional InfoReportSave

eHCTERS - Establishment U.S. Agent Information

U.S. Agent Information

*First Name M.I.

*Last Name

Credentials

Title

*E-Mail Address

*Phone(xxx-xxx-xxxx) Ext.

Foreign Phone(Country Code-City Code-Telephone Number)

Mailing Address

Organization Name

*Street Address

*City

*State *Postal Code

* Required

This section should ONLY be filled out for non-U.S. establishments. U.S. Agent means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent (§1271.3(n)). Provide your U.S. Agent's **First Name,**

Last Name, Title (optional), **Email Address** and **Phone Number**.

Mailing Address: Provide the U.S. Agent's mailing address with **Organization Name** (if applicable), **Street Address**, **City**, **State** and **Postal Code**.

Press **Add Another U.S. Agent** button to add another U.S. Agent, if applicable. After finishing adding all the U.S. Agent to your registration, press **Next** button to move to the **Establishment Importer Information** screen.

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Establishment Importer Information Screen

FEI: Pre-Confirmation Number: 37156
Legal Name: Todays Date: 10/24/2018

Registration | Address | Reporting Official | U.S. Agent | **Importer** | HCT/P Listing | Function | Donor | Additional Info | Report | Save

eHCTERS – Establishment Importer Information

Your establishment is located outside the United States. Please provide information on any importer (defined in 21 CFR 1271.3(mm)) that is known to you. Otherwise, you may advance to the HCT/P Listing tab.

Importer Organization

*Importer First Name M.I.

*Importer Last Name

*Street Address

*City

*State *Postal Code

*Phone(XXX-XXX-XXXX) Ext.

*E-Mail Address

* Required

Non-U.S. establishments must provide information on each importer that is known to them. Importer means a company or individual in the United States that is the owner, consignee, or recipient, at the time of entry, of the foreign establishment's HCT/P that is imported into the United States (§1271.3(mm)).

Provide your Importer's **Organization Name** (if applicable), **First Name**, **Last Name**, **Street Address**, **City**, **State** and **Postal Code**, **Email Address** and **Phone Number**.

Press **Add Another Importer** button to add another Importer, if applicable. After finishing adding all the Importers to your registration, press the **Next** button to move to the **HCT/P Listing** screen.

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HCT/P Listing Information Screen

FEI:		Pre-Confirmation Number: 37156								
Legal Name:		Todays Date: 10/24/2018								
Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save

eHCTERS - HCT/P Listing Information

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names
Amniotic Membrane	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Blood Vessel	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Bone	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Cardiac Tissue - non-valved	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Cartilage	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Cornea	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Dura Mater	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Embryo	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Fascia	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Heart Valve	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
HPC Apheresis	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
HPC Cord Blood	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Ligament	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Nerve Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Oocyte	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Ovarian Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Pancreatic Islet Cells - autologous	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Parathyroid	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Pericardium	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Peripheral Blood Mononuclear Cells	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Peritoneal Membrane	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Sclera	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Semen	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Skin	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Tendon	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Testicular Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Tooth Pulp	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	
Umbilical Cord Tissue	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	

Please list all the 361 HCT/Ps that your establishment manufactures by checking (indicate with an X) the **HCT/Ps Described in 21 CFR 1271.10** column. Each HCT/P must meet all the following criteria described in §1271.10(a):

- (1) The HCT/P is minimally manipulated,
- (2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent,
- (3) The manufacture of the HCT/P does not involve the combination of the cell or tissue component with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of the water, crystalloids, or a sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and
- (4) Either:
 - (i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
 - (ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
 - (a) Is for autologous use;
 - (b) Is for allogeneic use in a first-degree or second-degree blood relative; or
 - (c) Is for reproductive use.

Notes:

- The intent of the HCT/P list on this screen is to capture the types of HCT/Ps that are generally regulated solely under Section 361 of the PHS Act, provided that they meet all the criteria in 21 CFR 1271.10(a). Each product must be evaluated individually with respect to the criteria in §1271.10(a), and the manufacturers of these products are responsible for appropriately applying these regulations. To facilitate stakeholders' understanding of how the regulatory criteria in §1271.10(a) apply to their HCT/Ps, FDA has published several guidance documents that can be found on [FDA's Tissue Guidance webpage](#).
- If your HCT/P Type is not listed on the screen and your product is not regulated as a drug, device, and/or biological product, you may contact a Tissue Registration Coordinator at tissuereg@fda.hhs.gov.
- You should only list HCT/Ps that are intended for implantation, transplantation, infusion, or transfer into a human recipient (§1271.3(d)).

For changes to an HCT/P listing such as discontinuance (indicate with a **D**), or for resumption (indicate with an **R**) of an HCT/P manufacturing, or other changes described in §1271.25(c), update the HCT/P listing with the new information at the time of the change or in June and December, whichever month occurs first after the change in accordance with §1271.21. **Date of Discontinuance** or **Date of Resumption** must be provided.

Proprietary Names: Provide any applicable proprietary name(s) for the HCT/Ps you list, such as a trademark.

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Function Information Screen

FEI:
Legal Name:
Pre-Confirmation Number: 37156
Today's Date: 10/24/2018

Registration	Address	Reporting Official	U.S. Agent	Importer	HCT/P Listing	Function	Donor	Additional Info	Report	Save
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eHCTERS - HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane								
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament								
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin								
Tendon								
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue								

Next
Previous
Select New Establishment
CBER On-Line Main Menu

Function Information: Indicate (with a check) the manufacturing step(s) performed by the establishment for the types of HCT/Ps listed. Check boxes will display only for HCT/Ps which were selected on the **HCT/P Listing Information** screen.

Please note that “Screen” refers to the donor, not the HCT/P. If your establishment performs testing of HCT/Ps for microorganisms, you must check “Process” as one of your establishment’s manufacturing functions for each type of HCT/P that you list. If testing of HCT/Ps for microorganisms is the only HCT/P processing function that you perform, you should also check **Testing For Micro-Organisms Only** on the **Establishment Registration Address Information** screen.

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Donor Information Screen

FEI: Pre-Confirmation Number: 37156
 Legal Name: Todays Date: 10/24/2018

Registration | Address | Reporting Official | U.S. Agent | Importer | HCT/P Listing | Function | Donor | Additional Info | Report | Save

eHCTERS - HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

For reproductive HCT/Ps, including embryo, semen, and oocyte, indicate whether such HCT/Ps are from a **SIP** (sexually intimate partner), **Directed** (defined in §1271.3(l)), or **Anonymous** donor. For HCT/Ps such as HPC Apheresis (hematopoietic progenitor cells, apheresis), HPC Cord Blood (hematopoietic progenitor cells, cord blood), and Peripheral Blood Mononuclear Cells (e.g., donor lymphocytes for infusion (DLI)), indicate whether the HCT/P is from an autologous or family related donor.

Please note that family related means allogeneic use in a first-degree or second-degree relative.

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Additional Information to Complete HCT/P Information Listing Screen

FEI: Pre-Confirmation Number: 37157
 Legal Name: Todays Date: 10/24/2018

Registration | Address | Reporting Official | U.S. Agent | Importer | HCT/P Listing | Function | Donor | Additional Info | Report | Save

eHCTERS - Additional Information to Complete HCT/P Listing

If necessary, this screen exists to add additional information in completing the HCT/P Information Listing (e.g., proprietary names that are too long). You may also use this section to provide information related to change in establishment ownership when there is no change to the establishment name or physical location. Please note that if there is a change in the

establishment name or physical location, you must update your registration using those fields.

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Preview your Establishment Registration Information Screen

The purpose of this report is to review your information prior to submitting the information to FDA/CBER. Without a submission, the information is still saved as a record in the system with an Pre-Confirmation Number, and user can return to this record and continue editing the information within 30 days after creating the record.

Submit to FDA button: Once you have completed a review, press the **Submit to FDA** button located at the bottom of this page to complete the submission.

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Reporting Official Signature Screen

eHCTERS - Reporting Official Signature

Current User:
Date: 10/24/2018

By entering your Reporting Official E-Mail Address and continuing with your submission of this information to FDA/CBER, you are certifying that:

1. You are the Reporting Official as listed in this form ()
2. As a Reporting Official, you are the person appointed by the owner or operator to register the firm and answer all correspondence and inquiries relative there to.
3. All information contained in this form is true and accurate to the best of your knowledge.

Under 21 CFR 1271.25 (a)(4), a dated signature by the reporting official affirms that all information contained in the establishment registration and HCT/P listing form is true and accurate, to the best of his or her knowledge.

Additionally, under 21 CFR 1271.25(b), you state that each listed HCT/P meets the criteria set out in section 1271.10.

Under 18 USC 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation to the U.S. Government is subject to criminal penalties.

If you understand and agree to the above statements, re-enter your Reporting Official E-Mail Address then press the Continue button. You may press the Cancel button if you do not wish to continue.

Confirm Reporting Official E-Mail Address:

The Reporting Official is the person appointed by the owner or operator to register the firm and answer all correspondence and inquiries relative thereto. By entering your Reporting Official email address and then continuing with your submission of this information to FDA/CBER, you are certifying that:

1. You are the Reporting Official as listed in this form.
2. As a Reporting Official, you are the person appointed by the owner or operator to register the firm and answer all correspondence and inquiries relative thereto.

3. All information contained in this form is true and accurate to the best of your knowledge.

Under 21 CFR 1271.25 (a)(4), a dated signature by the Reporting Official affirms that all information contained in the establishment registration and HCT/P listing is true and accurate, to the best of his or her knowledge.

Under 21 CFR 1271.25(b), you state that each listed HCT/P meets the criteria set out in §1271.10.

Under 18 USC 1030, anyone who intentionally accesses a protected computer without authorization and, as a result of such conduct, causes damage and a threat to public health or safety is subject to criminal penalties.

Under 18 USC 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement or representation to the U.S. Government is subject to criminal penalties.

If you understand and agree to the above statements, re-enter your Reporting Official email address and then press the **Continue** button.

You may press the **Cancel** button if you do not wish to continue.

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Submitted Establishment Registration Information Screen

PLEASE NOTE:

The changes submitted today will not be reflected in the electronic Tissue Establishment Registration (eHCTERS) until they are validated by the FDA. This process varies in time. Please Contact the Tissue Establishment Registration coordinator if you have any questions.

Print information submitted for HCT/P establishment registration

Close

The purpose of this screen is for you to print the report so you can have a copy of what you submitted should any questions arise. You will not be able to make any other changes until FDA/CBER has received the submitted changes. The Reporting Official may request an updated copy of the registration by email once FDA has received the changes. You may then make additional changes, if needed.

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