

General Questions:

1. Why is the pilot limited to kidney and liver donations?

The majority of living organ donations are livers and kidneys. The Organ Procurement and Transplantation Network (OPTN) policy for follow-up also focuses only on the liver and kidney living donors.

2. How were the pilot sites selected?

Pilot sites were selected on a volunteer basis. The Scientific Registry of Transplant Recipients (SRTR) chose sites that would also reflect the diversity of sites and organ donation candidates throughout the OPTN network.

3. What outcomes are of interest to the program in deciding whether to continue the registry? What does a “successful” pilot look like?

A successful pilot would demonstrate that collecting initial screening data on donor candidates does not impose an excessive burden to the transplant centers, and candidates are willing to be contacted for follow up. Additionally, a successful pilot would show the benefit of collecting data on candidates who do not donate by allowing for accurate risk analysis of living donation.

4. If successful, does HRSA have plans to expand the scope of the registry to include additional organs?

Since the majority of living donations are liver or kidney, there are no plans to expand the scope of the registry beyond these two organs.

5. What types of data analysis are planned?

SRTR will analyze the characteristics of donors and controls at the initial screening. Specifically, continuous variables (e.g., age at screening) will be summarized by a mean and standard deviation, whereas categorical variables (e.g., sex) will be summarized by frequencies and percentages. The characteristics of the donors who do not donate will be stratified by the reasons for non-donation. Finally, the descriptive statistics for both donors and potential donors who do not donate will be stratified by year of initial screening to determine how the characteristics of donors and potential donors who do not donate change over time.

In addition, Living Donor Collective (LDC) data will be linked to available registries to provide potential and past donors and caregivers with the most up-to-date information on risks that may be attributable to donation, such as lifetime risk of end-stage renal disease (ESRD) and mortality. Links to registry data may include Centers for Medicare and Medicaid Services data to determine which donors develop ESRD or to the National Center for Health Statistics and National Death Index to obtain data on deaths and causes of death among donors.

SRTR will also link LDC data to the Pharmaceutical Claims Data clearinghouse. These records will allow us to examine comorbid conditions related to specific medication usage, e.g., hypertension, diabetes, gout, and depression.

6. Is the program using the following SORN for the pilot: 09-15-0055? If so, did/does it need to be modified to cover the pilot?

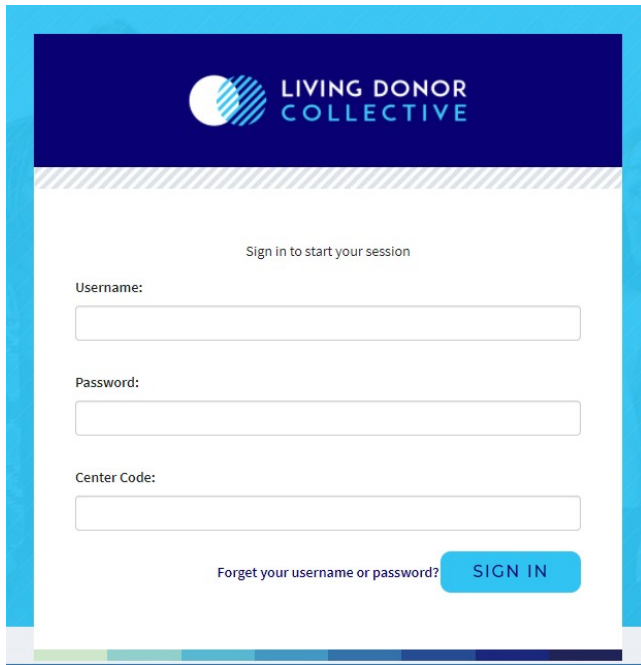
No, system of record notice 09-15-0055 will not be used for this pilot program. The program is developing a separate secure online data collection system to allow transplant programs to submit data collected at the time of initial in-person evaluation, and at the time of donation or at the time of reporting reasons for not donating.

7. Related to the question above, please check the following two RISC and OIRA Consolidated Information System fields for accuracy (this is how they were submitted in the system):

- a. Does this Information Collection Request (ICR) request any personally identifiable information (see OMB Circular No. A-130 for an explanation of this term)? Please consult with your agency's privacy program when making this determination.
 - i. Yes, personally identifiable information will be collected.
- b. Does this ICR include a form that requires a Privacy Act Statement (see 5 U.S.C. §552a(e)(3))? Please consult with your agency's privacy program when making this determination.
 - ii. No, SRTR is recognized as a public health authority under the HIPAA Privacy Rule (42 CFR 164.512(b)).

8. The supporting statement mentions an electronic system – please provide screenshots of the system.

Log in page:



The login page features a dark blue header with the Living Donor Collective logo. Below the header is a light blue background with a white box containing the login form. The form includes fields for Username, Password, and Center Code, along with a 'SIGN IN' button and a link for 'Forget your username or password?'.

Sign in to start your session

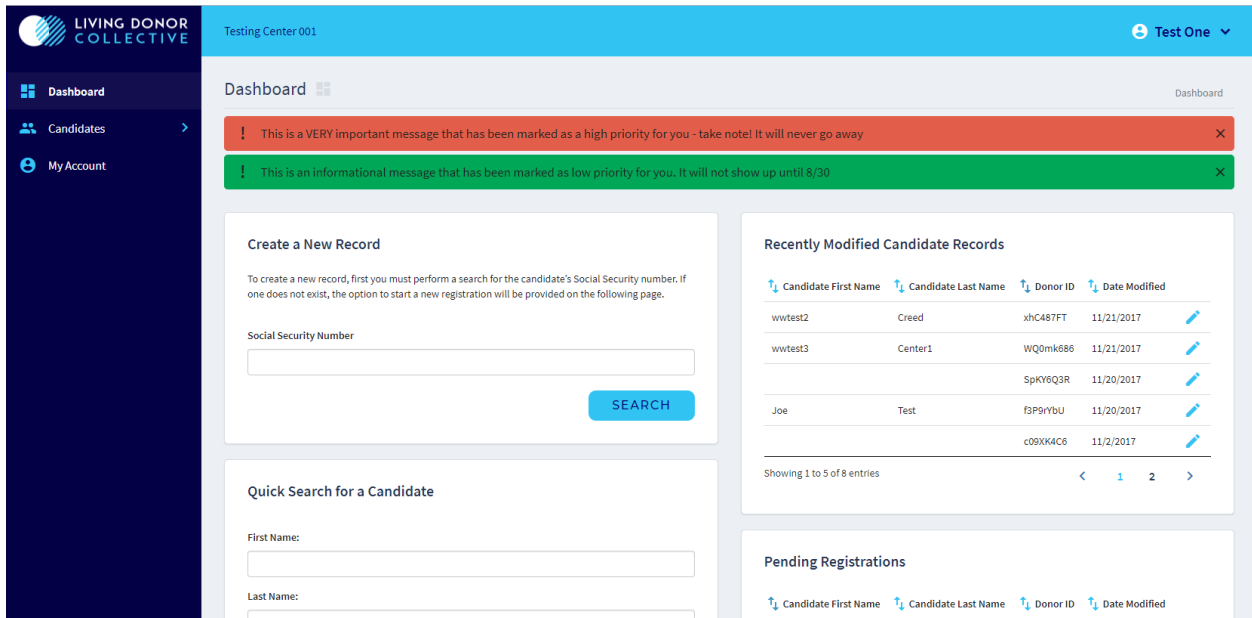
Username:

Password:

Center Code:

Forget your username or password? [SIGN IN](#)

Dashboard (test environment):



The dashboard is titled 'Testing Center 001' and includes a 'Test One' button. It features a sidebar with 'Dashboard', 'Candidates', and 'My Account'. The main content area has a 'Dashboard' header and two notification banners: a red one for a high-priority message and a green one for a low-priority informational message. Below the notifications are three main sections: 'Create a New Record' with a Social Security Number search field and a 'SEARCH' button; 'Quick Search for a Candidate' with 'First Name' and 'Last Name' search fields; and 'Recently Modified Candidate Records' with a table of records. A 'Pending Registrations' section is also visible at the bottom.

Testing Center 001 Test One

Dashboard

! This is a VERY important message that has been marked as a high priority for you - take note! It will never go away

! This is an informational message that has been marked as low priority for you. It will not show up until 8/30

Create a New Record

To create a new record, first you must perform a search for the candidate's Social Security number. If one does not exist, the option to start a new registration will be provided on the following page.

Social Security Number

[SEARCH](#)

Quick Search for a Candidate

First Name:

Last Name:

Recently Modified Candidate Records

Candidate First Name	Candidate Last Name	Donor ID	Date Modified	
wwtest2	Creed	xhC487FT	11/21/2017	Edit
wwtest3	Center1	WQomk686	11/21/2017	Edit
		SpKY8Q3R	11/20/2017	Edit
Joe	Test	fSP9Y1bU	11/20/2017	Edit
		c09XK4C6	11/2/2017	Edit

Showing 1 to 5 of 8 entries < 1 2 >

Pending Registrations

Candidate First Name	Candidate Last Name	Donor ID	Date Modified
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Data Entry Screen (dummy data):

Testing Center 001 Test One

Candidate Record Dashboard / Forms

Form Status: In Progress

54 Errors Found View Errors Print

Living Donor and Potential Living Donor Initial Registration Worksheet

Provider Information Finished ✓

Donor Candidate Information Finished ✓

Pre-Donation Clinical Information Not Started

43. Pre-Donation Height - Feet ft
Pre-Donation Height - Feet is required

44. Pre-Donation Height - Inches in
Pre-Donation Height - Inches is required

45. Pre-Donation Weight lb
Pre-Donation Weight is required

46. History of Cancer
 Yes
 No
History of Cancer is required

Left Sidebar:
 Dashboard
 Candidates
 My Account
 Candidate
 LDC ID: mGm4v24V
 Last modified 11/21/17 by test001
 Summary
 Form Status: In Progress
 54 Errors Found
 Not Saved
 Protocol
 Registration
 Donation Status
 Follow Up

All Candidate Overview (dummy data):

Testing Center 001 Test One

View All Candidates Dashboard / View All Candidates

First Name	Last Name	Donor ID	DOB	Center	Last Modified	Status
		c09XK4C6	None	Testing Center 001	11/2/2017	PENDING
		SpKY6Q3R	None	Testing Center 001	11/20/2017	PENDING
		mGm4v24V	None	Testing Center 001	11/21/2017	PENDING
Jane	Doe	78u70p6L	None	Testing Center 001	11/20/2017	PENDING
Joe	Test	f3P9rYbU	None	Testing Center 001	11/20/2017	PENDING
Test	User	b2sp4aG8	None	Testing Center 001	10/5/2017	PENDING
wwtest1	creed	8s1c5nm8	None	Testing Center 001	11/19/2017	PENDING
wwtest2	Creed	xhC487FT	None	Testing Center 001	11/21/2017	PENDING
wwtest3	Center1	WQ0mk686	None	Testing Center 001	11/21/2017	PENDING

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Left Sidebar:
 Dashboard
 Candidates
 My Account

Living Donor and Potential Living Donor Initial Registration Worksheet

- 1. Will potential donors be filling this form out or will the provider be asking questions and recording responses?**

The transplant center will be collecting this information from potential living donors who are evaluated at their centers and will be recording them in electronic data collection system.

- 2. What is the rationale for requesting SSN? We generally discourage the collection of this identifier.**

The SRTR's responsibilities of providing analytic support to the OPTN also include linkages of the OPTN data set with other databases such as the Social Security Death Master File for purposes of validation and enhancement. There are currently no viable alternatives to using SSN. The major obstacle is the OPTN/SRTR needs to identify patients across the nation in independent data systems with no other common identifiers.

- 3. If asking for race/ethnicity, the questions should be asked separately - ethnicity (Hispanic/Latino) first, followed by race.**

Where possible, questions align with the OPTN data collection formats. The race/ethnicity question corresponds with how OPTN asks this question.

- 4. What is the rationale for asking about citizenship?**

This question also corresponds with the OPTN data collection forms for living donors.

Potential Living Donor Follow-up Form

- 1. Who will be conducting the follow-up call? Suggest making the affiliation clear in the introduction.**

Follow-up information will be collected by SRTR and not by the transplant programs. SRTR will establish procedures for maintaining contact with participants by using a brief survey instrument. Participants will be contacted via postal mail, email, social media, or phone approximately 1 year after donation or 1 year after determination not to donate and approximately every 1 to 2 years thereafter.