Health Resources and Services Administration
SUPPORTING STATEMENT
HRSA Division of Transplantation Research on Customer Information Needs Related to Vascularized Composite Allographs Transplants

A. Justification

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA) currently has approval under the generic clearance, Office of Management and Budget (OMB) Control No. 0915-0212, to conduct customer satisfaction surveys and focus groups. This collection of information helps fulfill the requirements of:

a. Executive Order 12862, "Setting Customer Service Standards," which directs Agencies to continually reform their management practices and operations to provide service to the public that matches or exceeds the best service available in the private sector.

This is a request for OMB approval of a voluntary customer satisfaction survey and focus groups under HRSA's generic clearance.

New advances have allowed for vascularized composite allographs (VCAs), such as faces and hands, to be transplanted. In July 2013, HRSA published a Federal Register notice, announcing that effective July 3, 2014, VCAs would be added to the definition of organs covered by federal regulation, 42 CFR 121 (the OPTN Final Rule).

This policy change gives new responsibilities to HRSA's Division of Transplantation (DoT) in terms of educating and informing its customers about this treatment. Specifically, DoT needs to develop communication products and tools that inform and educate customers and potential customers about donation and transplantation of VCAs. In response to this need, HRSA/DoT is requesting approval to obtain information from customers and potential customers on information needs and preferences related to VCA outreach and education.

Executive Order 12862 directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." This data collection activity is designed to collect information to allow DoT to fulfill this objective.

Key questions to be addressed by this research include:

- What information do customers and potential customers need on VCA donation?
- What impact, if any, will learning about VCA donation have on willingness to consent for organ, eye, and tissue donation?
- What is the best way to present information on VCA donation so as to not negatively impact organ donor and tissue consent rates?

- What is the best format to deliver information to customers and potential customers on

VCA?

2. Purpose and Use of the Information

As a vital part of its ongoing mission, DoT produces outreach and information materials on organ donation and transplantation for numerous audiences, including both consumers and professionals. These materials are designed to respond to and anticipate customer needs and requirements, including providing information about new developments in organ donation and information on how to register to become an organ donor.

To develop effective new outreach materials and strategies related to VCA, DoT is seeking to gather pertinent information on customer information needs related to this new medical technology. Feedback will relate to the topic of communications (what information are customers seeking), format (what is the best method to convey the information), message design (what types of messages/stories move people to take desired actions), delivery method (how to reach customers with information), and appropriateness. Responses will directly inform the communications DoT is developing on this topic. This vital, formative research, will enhance DoT's ability to efficiently and effectively communicate on this topic.

Hand and face transplants are a relatively recent and still rare development in the transplant field. Most people in the U.S. are familiar with—and accept—the concept of organ donation. But the idea of hand and face transplants is new and unfamiliar. While VCA is an exciting technology, initial feedback from DoT's partners indicates that for some consumers it may be seen as "icky" or unappealing. Customers have many questions and concerns regarding the surgery and donation. These concerns, if not properly addressed, have the potential to discourage individuals from agreeing to VCA donation or even registering as organ, eye, and tissue donors even though registering as an organ donor does not automatically include consent to VCA donation.

If consumers decline to register as organ donors because they are concerned about VCA donation, lives could be lost as the supply of organs is decreased. Therefore, DoT is seeking permission to collect data that will inform its internal efforts to develop these new materials.

The collection of this information will be voluntary and non-controversial. Collection will be targeted to the opinions of customers who are registered organ donors as well as to those who support organ donation and would consider registering as donors but have not yet done so (aged 21-64).

DoT is requesting generic clearance to conduct qualitative research to improve its service delivery through:

- Focus groups of potential customers to inform product development and
- A satisfaction and preference survey of customers and potential customers to determine how message framing impacts attitudes and intentions related to organ donation.

These research approaches will provide DoT with the information it needs to improve its materials and service delivery. Data from the focus groups will be exploratory in nature, and

will address how VCA donation is perceived overall. Data from the survey will focus on the impacts of different communication approaches. For example, are consumers more receptive to VCA donation when information is presented in a facts-based style or embedded as a part of a personal story? Do they react differently to a story about hand donation versus one about a face transplant? All collected data and information will be used strictly for internal program planning purposes and are not intended to be statistically representative of donor or non-donor populations.

DoT will use the information collected as it develops new communications on this topic, currently planned for development in the spring/summer of 2015. Without this research, vital feedback from customers on the Agency's services will be unavailable.

3. Use of Improved Information Technology

The survey will be conducted electronically to reduce burden.

The focus groups will not employ information technology but will be conducted in-person, which is the most appropriate and cost-effective methodology to obtain feedback from these respondents. We have limited the design to the smallest number of respondents possible (two groups) to further reduce the overall burden. In-person data collection is more appropriate for formative research such as this, so that we can interact with participants to better understand their reactions. A focus group also allows participants to discuss ideas with one another.

4. Efforts to Avoid Duplication

The Department of Health and Human Services (HHS) is the only Cabinet Department with statutory responsibility for organ donation. Within HHS, responsibility for implementing efforts to increase organ donation is delegated to HRSA's DoT. VCA transplantation is a recent development and has only recently become defined as an organ under Federal authority, so it is unlikely other work is proceeding in this area. To the best of our knowledge, no other entity within the Federal Government or the private sector has gathered or is planning to gather similar data. The attached research instruments have been reviewed carefully to avoid potential duplication of data collection.

5. Involvement of Small Entities

No small business will be involved in this study.

6. Consequences if Information Collected Less Frequently

DoT is proposing to implement this research study only once. If this study is not conducted, DoT will not have timely information to create new outreach materials and strategies to inform its work related to this emerging transplant specialty. Customers will be asked to participate one time and participation is voluntary. There are no legal obstacles to reduce the burden.

7. Consistency With the Guidelines in 5 CFR 1320.5(d)(2)

These surveys will be implemented in a manner fully consistent with 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

In accordance with 5 CFR 1320.8(d), on April 24, 2009, a 30-day notice was published in the Federal Register for HRSA's generic clearance, OMB Control No. 0915-0212 (Vol. 74, Page 18726). No public comments were received.

9. Remuneration of Respondents

This request involves a survey and focus groups. Survey participants will not receive a stipend for participation. DoT will provide a stipend of $85 for participants in the 2-hour focus groups. DoT offered a similar stipend when it last conducted consumer focus groups in 2012. While DoT would like to obtain viewpoints from a cross section of society, not offering a stipend may discourage those of less financial means from study participation, thereby limiting the quality of the data. Additionally, paying stipends reduces the government's overall cost, as recruiting without incentives takes considerably longer thereby raising costs.

10. Assurance of Confidentiality

To date, the HRSA customer satisfaction surveys have not collected personally identifiable information from respondents. This effort also will not involve the collection of personally identifiable information. HRSA will be provided with first names only of focus group participants. HRSA will not receive the IP addresses or other identifying information from those who participate in the survey.

Participation is fully voluntary and information will be kept private to the extent permitted by law. Tape recordings of the groups will be conducted only with respondent permission. These recordings will be used solely to verify notes taken for accuracy and then destroyed. Respondents will be assured that neither their participation/non-participation nor any of their responses to items will have any effect on their participation in Agency programs.

11. Questions of a Sensitive Nature

As a part of the screening process for selecting research participants, DoT will collect information on race and ethnicity. This information is necessary because several racial and ethnic groups are disproportionately represented on transplant waiting lists and have well documented health disparities. DoT will use the information to ensure that the research includes participants of diverse racial and ethnic backgrounds so that VCA materials and strategies can effectively speak to these audiences.

12. Estimates of Annualized Hour Burden

Respondents:

Respondents will be individuals who support organ donation and include both registered organ donors and those who are not registered. The annual burden hour estimate (174) is based on the number of collections we expect to conduct over the requested period for this clearance.

Annual burden estimates:

Type of Collection	Number of Respondents	Responses per Respondent	Total Responses	Hours per Respondent	Total Burden Hours	Wage Rate	Total Hour Cost
Focus groups	24	1	24	2.25	54	$20	$1,080
Online survey	700	1	700	.17	119	$20	$2,380
Total	724	1	724	.2	174	$20	$3,480

Each focus group participant will take part in a 2-hour study plus a 15-minute individual discussion to answer screening questions and to provide informed consent. Each survey participant will take part in a 10-minute study, which includes screening and informed consent.

Planned frequency of information collection:

Each respondent will participate one time.

13. Estimates of Annualized Cost Burden to Respondents

No appreciable costs are anticipated for focus group respondents. Any out-of pocket expenses (phone minutes, mileage to focus group facility, etc.) would be more than offset by the stipend.

No appreciable costs are anticipated for survey respondents.

14. Estimates of Annualized Cost to the Government

The anticipated cost to the Federal Government is approximately $35,712. These costs are comprised of:

Contractor payment (which includes recruitment of participants, participant stipends, facility rental, survey hosting, analysis, and reporting): $35,000 (based on estimate provided by contractor to the government)

Government cost (including supervision of contractors and observing focus groups): $712 (0.3 percent FTE @ $139,523 = $405 per year and 0.3 percent FTE @ $105,960 = $307 per year)

15. Change in Burden

Not Applicable. This is a new activity under HRSA's generic clearance and will be included in the total burden currently approved by OMB under OMB Control No. 0915-0212.

16. Plans for Analysis and Timetable of Key Activities

Data will be collected within 3-4 weeks of OMB approval, estimated May 2015. Analysis and reporting will occur in June 2015.

Survey findings will be analyzed to make comparisons across groups. Findings will be used to inform DoT communication approaches, but will not be generalized to the overall population nor will they be used for publication or public release. DoT will use findings to develop new outreach content and strategies related to VCA.

Focus group findings will be analyzed using qualitative research approaches to inform DoT's communication efforts. They will not be generalized to the overall population nor will they be used for publication or public release.

Although DoT does not intend to publish its findings, DoT may receive requests to release the information (e.g., congressional inquiry, Freedom of Information Act requests). The Agency will disseminate the findings when appropriate, strictly following the Agency's "Guidelines for Ensuring the Quality of Information Disseminated to the Public," and will include specific discussion of the limitation of the results discussed above.

17. Exemption for Display of Expiration Date

No exemption is being requested. The expiration date will be displayed.

18. Certifications

This information collection activity will comply with the requirements in 5 CFR 1320.9.

Attachments:
1. Informed consent for focus groups
2. Focus group screener
3. Focus group guide
4. Survey questionnaire