Patient Attitudes on the Use of Clinical Biospecimens for Medical Research

An independent, US-based population survey

Commissioned by:

Conducted by:

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BACKGROUND

Studying patient attitudes regarding the use of their clinical biospecimens and/or associated data in medical research is not new. Hundreds of studies have been conducted on patient preferences regarding this practice, including both use of clinically-derived remnant samples (samples collected for medical testing that are leftover once testing is complete) as well as research-derived samples (collected for purpose from patients enrolled in a specific research study). Investigators have looked at factors such as patient willingness, patient concerns, and various social and demographic factors that may or may not influence behavior, such as religion, health status, and ethnicity[1,2]. The type of research for which specimens may be used has also been assessed as a possible driver or dissuader of patient participation[3]. While some studies have surveyed a representative US population, many have focused on localized patient populations, and surveys of the *broad US population* have not been plentiful or recent.

A 2007 analysis conducted by Public Responsibility in Medicine and Research (PRIM&R) of 14 different studies on these topics deduced that 53-90% of individuals were willing to consent for research to be conducted with their biological samples[4]. However, two points stand out: First, the 14 studies on which this analysis was conducted were published between 1995 and 2003, long before the rise of precision medicine and genomics as we know them today. Second, only a handful of these studies were representative of the general US population. A similar literature review, published last month this year, also showed high rates of willingness but reviewed a series of studies that included data back to 1990[5].

In looking at other patient studies, outside of these analyses, the same limitations hold true – many are years old and many not representative of the US population as a whole, having been conducted on discrete patient populations in a specific geographic area, sometimes outside of the United States, or by specific medical conditions. These practices are understandable as a specific medical facility's patient population or a particular clinical population may be more readily available to study or of interest to the organization. Or, a particular institution or medical specialist might want to know how their specific patients would react.

Given the nature of iSpecimen's work, which involves procuring patient biospecimens for use in research from healthcare providers across the country, particularly *remnant* biospecimens, iSpecimen sought out to conduct a new 2015 study that would be representative of attitudes of the US population, particularly during the current explosion of precision medicine.

OBJECTIVES

iSpecimen commissioned research by an independent third party with the primary goal of understanding how willing Americans are to participate in medical research and specifically to allow their remnant clinical specimens to be used in medical research, provided the specimens and all associated data are de-identified and cannot be traced back to the patient. Further, as iSpecimen also offers specimens collected for research use purposes, an additional goal was to look at willingness to allow an extra tube of blood to be drawn at the point of care. Patient willingness was to be examined across variables including demographics, interaction with the healthcare system, health status, the nature of the research to be

conducted, and pre-existing medically philanthropic behavior, such as registering as an organ donor or giving blood, in order to understand if and how patients differ in terms of willingness to donate their specimens. The survey also sought to identify primary emotional drivers for donation and preferences around disclosure and consent. The latter piece is relevant because currently, under federal law, the Department of Health & Human Services' Common Rule dictates that patients need not be informed of use of *remnant* specimens in research as long as they are de-identified. But, this law is under review for changes regarding this clause, among others, as of September 2015[6].

Another objective of the study was to understand these patient attitudes *today*, when precision medicine holds more promise than ever before, and the drug and diagnostic industries are booming. As researchers seek to solve more and more medical mysteries, segmenting them by individual patient characteristics, the need for human biospecimens on which to conduct the research has greatly proliferated. Finding well-qualified and richly-annotated biospecimens has long been difficult for scientists, who are often unable to find enough, or the right type, or the right quality to meet their needs[7]. With demand dramatically increasing, specifically during an age of unprecedented genomic research, it is important to understand drivers of supply. After all, some of the most important diagnostic and therapeutic discoveries have been made – and will be made – through initial research using human biospecimens. Breast cancer drug Herceptin®, for example, which has demonstrated a proven life-saving benefit and been credited with changing the breast cancer treatment landscape since its arrival in 1998, was developed through initial research using human biospecimens[8,9,10].

iSpecimen hypothesized that the majority of the study population would be willing to donate their remnant biospecimens to medical research. We also expected willingness to donate for research use only, as opposed to the use of remnants, to be lower but still primarily supported. We remained curious about understanding factors that affect willingness to donate.

METHODS

Lab42, an independent market research firm headquartered in Chicago, IL, surveyed 400 English-speaking US-based adults over the age of 18, balanced to the national population census in terms of gender, age, income, and ethnicity. By surveying 400 individuals, the population was deemed large enough to maintain a 95% confidence interval that could be maintained even in several subgroup comparisons.

The survey itself consisted of 30 multiple choice and interval-scale questions, nine of which were demographic. Answer choices were randomized as appropriate and the survey was quality-checked by Lab42 for bias, readability, and question order so as not to produce leading inquiries.

Outside of demographics, substantive questions were asked across seven main categories: interaction with the healthcare system, health status, nature of intended research, pre-existing philanthropic behavior, emotional drivers, thoughts on disclosure or consent, and concerns.

Table I: Substantive Question Categories

Category of Question	Example Responses
Use of healthcare system	Doctor's appointment, ER visit, inpatient admission, blood test, or urine test within the last year
Health status	Chronic or serious medical condition experienced by self or close family member or friend
Research type	Clinical specialty of the research as well as commissioner of the research, including academics or biopharma companies
Philanthropic behavior	Registered organ donor, past blood donor, past medical research participant
Emotional drivers	Helping others, moral obligation, feels good to help, advancing medicine, monetary compensation, etc.
Disclosure or consent	From no need to disclose, to disclose, to asking for consent at varying levels of frequency
Concerns	Privacy, who may be profiting, insurance company or physician notification concerns

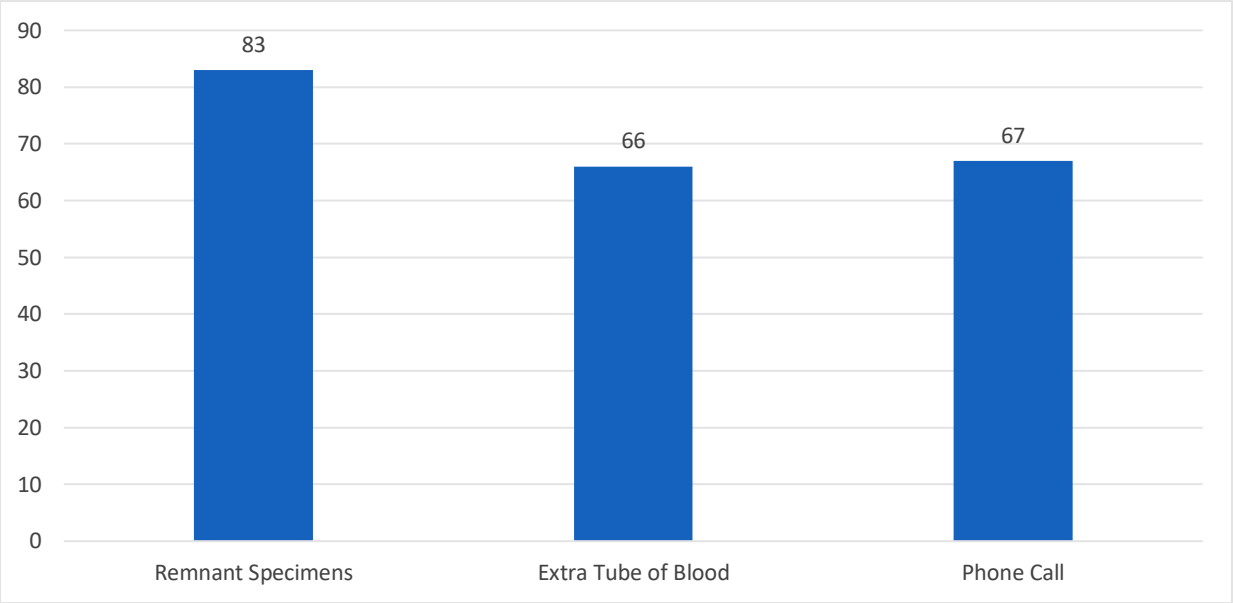
Upon completion of the study, Lab42 performed data analysis, including crosstab comparisons and indication of statistical significance to the 95% confidence level where achieved.

KEY FINDINGS

Top-Level Findings

Consistent with the hypotheses, the majority of Americans (83%) are willing to allow use of their de-identified clinical remnants and associated data for medical research. Also consistent with our hypotheses, nearly two-thirds were willing to donate an extra tube of blood expressly for research purposes. Two-thirds of the study population also indicated that they would agree to be contacted at a later date by their healthcare provider about potential specimen donation requests should they arise. Following are other key findings that emerged.

Chart I: Population Willingness to Donate Remnants, Give a Tube of Blood, or Take Call (%)



Emotional Drivers & Research Type

Primary emotional drivers for allowing specimen use were altruistic and progressive. In fact, the least selected reason was financial compensation. Of ten presented choices, the top three reasons were, "Others may benefit", "I would like to help sick people", and "It feels good to help." In terms of what individuals hoped to accomplish by supporting research, the top three answers included "help medical researchers learn about disease", "help improve patient care", and "help medical researchers develop new diagnostics or treatments". Interestingly, when the term "medical researchers" was switched out with "pharma/biotech companies", respondents' willingness fell about 25%, indicating a difference in perspective depending on who conducted the research. This indicates a change in emotional response due to a perceived change in research motive. In line with this, when people were asked about concerns regarding donation, the largest subset had no concerns (37%). But, for those who did, the top concerns were "I don't know who may be profiting" (24%) and "My identity may accidentally be revealed" (24%). When we dug deeper, respondents seemed to take issue with research conducted by for-profit biopharma companies, as 63% of respondents thought it was okay for a hospital or lab to receive compensation for biospecimens. This is further discussed in the "concerns" section.

Table II: Top Three Emotional Drivers for Allowing Remnant Specimen Use

1	Others may benefit
2	I would like to help sick people
3	It feels good to help

Use of the Healthcare System & Medically Philanthropic Behavior

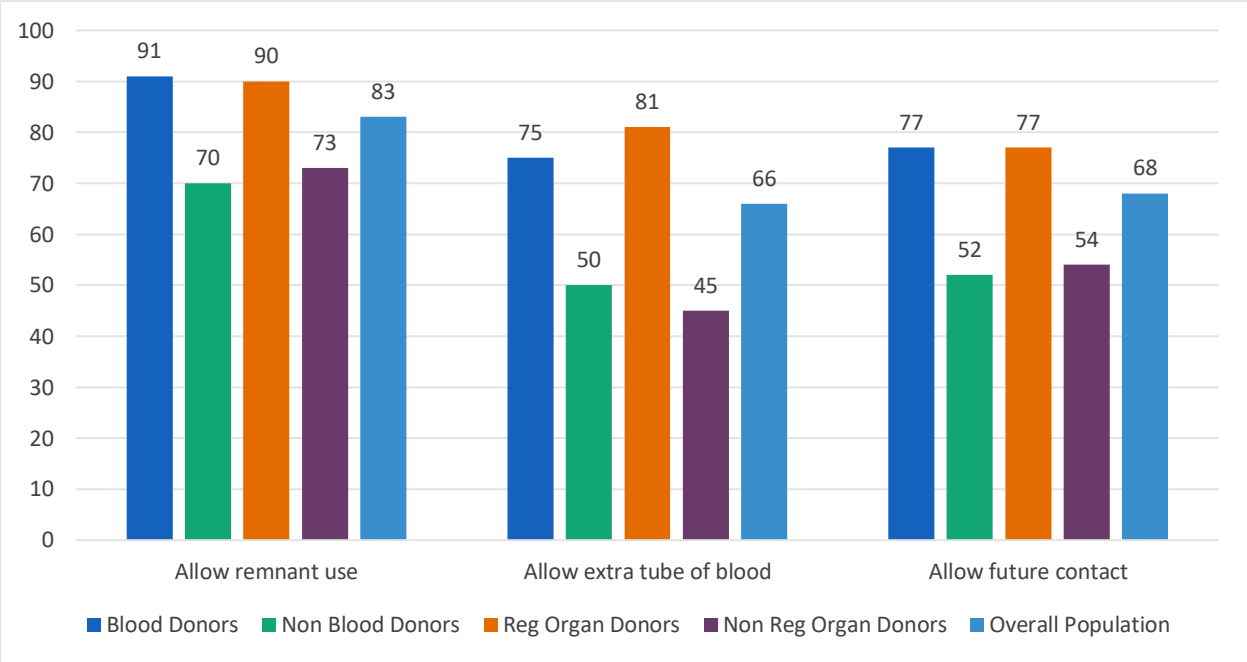
Table III: Use of the Healthcare System and Willingness to Allow Remnant Use

91%	of blood donors were willing *
90%	of registered organ donors were willing *
87%	of those who had an ER visit within the last year were willing
87%	of those who had a urine test within the last year were willing
86%	of those who had a blood test within the last year were willing
86%	of those who had a hospitalization within the last year were willing
83%	of the overall population was willing

*Statistically significant in relation to overall population result

The table above reflects respondent differences in their willingness to allow use of de-identified remnant specimens and associated data based upon their different levels of healthcare system use. Overall, there is a clear trend towards increased willingness to donate specimens when respondents interacted with the healthcare system (86-91% in contrast to the overall population result of 83%). Statistically significant increases in willingness to allow use were seen in blood donors and registered organ donors (relative to people who didn't exhibit these philanthropic behaviors). A case could be made that these respondents are already pre-disposed to give something of themselves to help advance healthcare. Blood and registered organ donors were also statistically significantly more likely to show other assenting behaviors, including giving an extra tube of blood or allowing future contact for specimen donation needs, as depicted on the following chart.

Chart II: Blood Donors and Registered Organ Donors Show Greater Willingness to Donate (%)

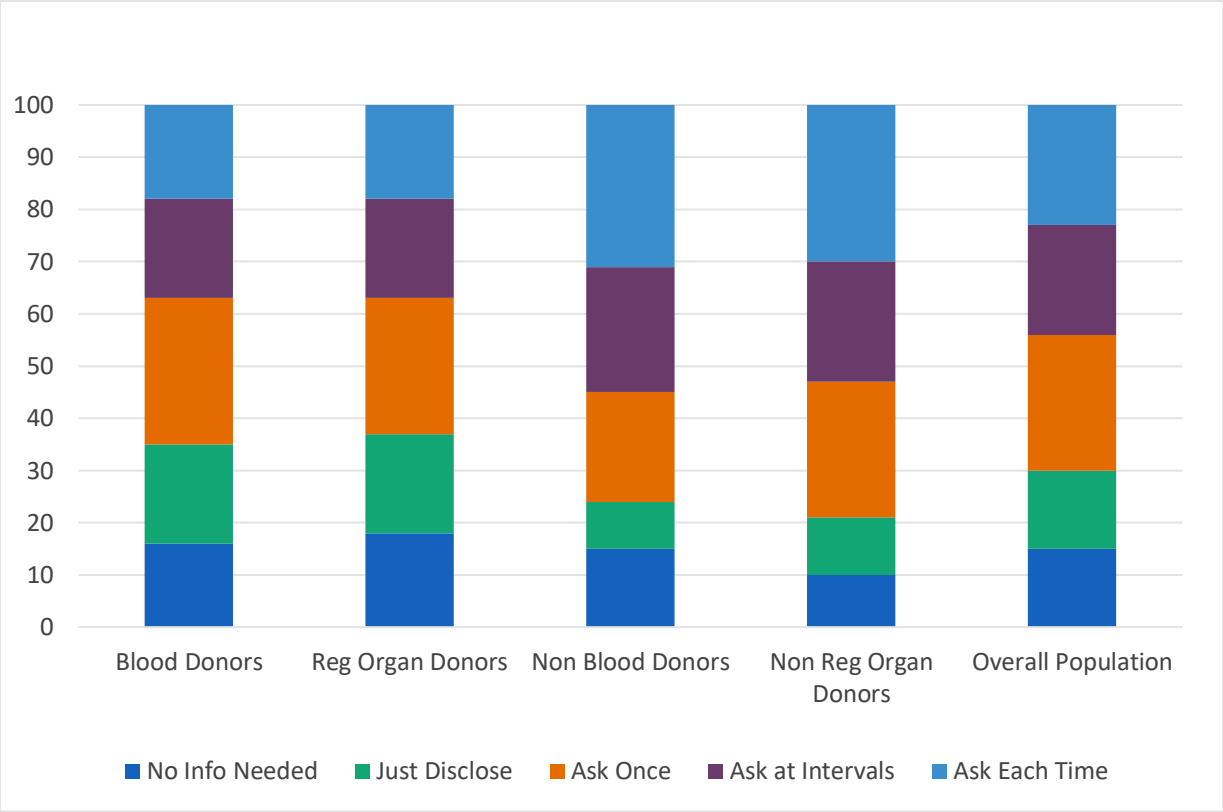


Disclosure or Consent

As previously stated, current federal law does not require healthcare institutions to disclose the use of remnant specimens for medical research as long as the specimens are de-identified and cannot be traced back to the patient. When specimens are collected with research use in mind, however, the law changes, and patient consent is needed. Nevertheless, we thought it important to ask study participants about whether or not they would like to be informed or asked about remnant use.

Sixty-nine percent of the population said they want to be asked about remnant use. This group was split about equally in terms of frequency, with 26% of this group needing only to be asked one time and having their decision persist; 23% wanting to be asked at each point of care interaction when specimens might be used in research; and 21% indicating that being asked at a regular interval – say once a year – would be okay. The remaining 31% of the population (outside of the 69% who desire to be asked) were split between just needing the practice to be disclosed (16%) and not needing any information at all (15%). Most people, therefore, would like to know about the practice and be part of the decision. People are willing, but they prefer to be informed and part of the process. Not surprisingly, blood donors and registered organ donors were more lenient in terms of how frequently they would want to be asked as displayed in the chart below.

Chart III: Blood Donors and Registered Organ Donors Need Less Frequent Asking (%)



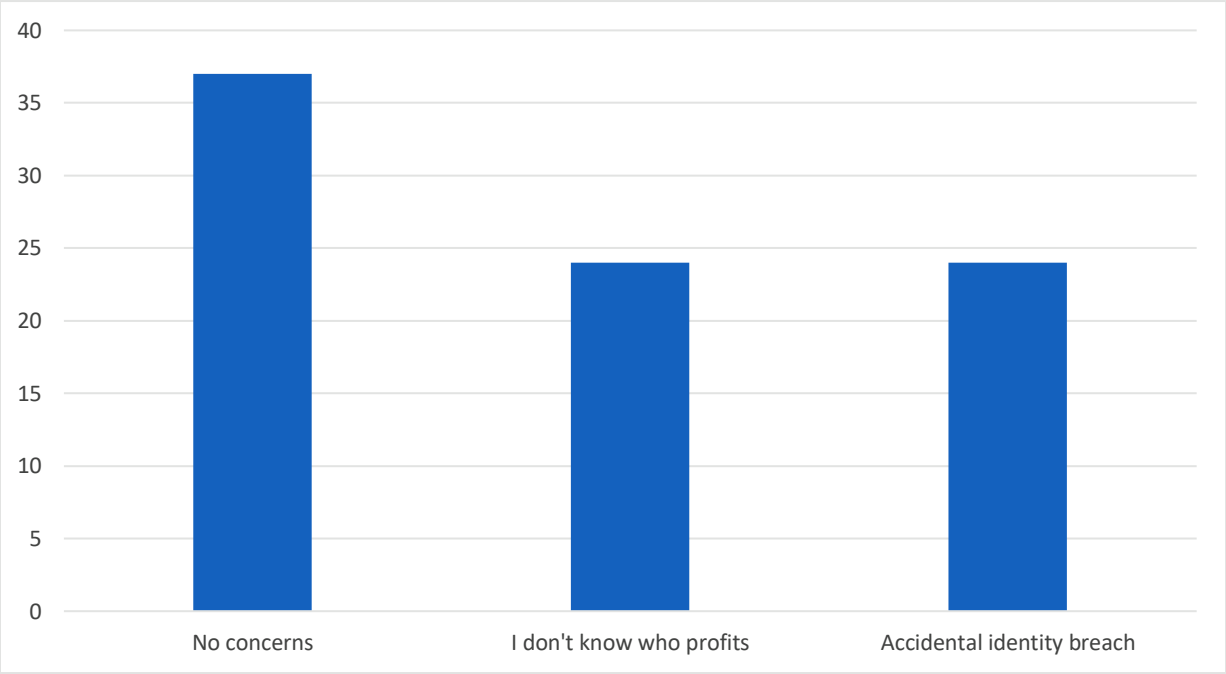
Concerns

In terms of concerns about donation, as previously discussed, about a quarter of the population expressed concern that their identity might accidentally be revealed and about a quarter expressed concern that they did not know who would be profiting. Data showed that respondents want to further advancements in diagnostics, treatments, and patient care, but sided much more closely with hospitals and academic researchers than biopharma companies. Remedies to these concerns include:

a) Making sure that any specimen procurement process be conducted with the highest standards of data privacy and protection, as mandated by the Health Insurance Portability & Accountability Act (HIPAA) and information technology security practices, and

b) Educating the public that the very same types of diagnostics and treatments that they support being created by academic researchers are also born out of biopharma companies. Regardless of where the breakthrough originates, the result is better care. Overall, researchers are working towards the same goal of lessening the burden of disease regardless of whether the research originates in a non-profit organization or for-profit corporation.

Chart IV: Top Three Reported Concerns Regarding Remnant Specimen Donation (%)



Health Status

No specific trends emerged regarding willingness to donate based on health status of participants or their family or friends.

RECAP & DISCUSSION

Based on this study, 83% of Americans are willing to allow the use of their remnant clinical specimens in medical research, provided the specimens and associated data are de-identified and cannot be traced back to them. Close to two-thirds of Americans are even willing to donate an extra tube of blood explicitly for research purposes. This readiness of people to give of themselves to help the health and well-being of others is representative of what can be termed today's "philanthropic patient". People want to help – and give of themselves, quite literally. Motivation to help was largely altruistic and forward-thinking, with respondents wanting to advance medicine and help other people. Such medical philanthropy can be seen in other altruistic behaviors, such as giving blood or registering for organ donation, and not surprisingly, respondents who reported displaying these behaviors in the past were even more willing to allow remnant use, coming in at 91% and 90% respectively.

A condition of remnant specimen use emerged as important to patients – they want to be asked about their willingness to give. While blood and organ donors expressed a less frequent need to be asked, the majority of the population did want to be informed and part of the process. Consistent with this finding is the fact that just a few months ago, in September 2015, HHS announced proposed changes to the nearly 25-year-old Common Rule that if adopted into law would require a change in the patient consent requirement for the use of de-identified clinical remnants.

CONCLUSION

In the age of precision medicine, the bounds of healthcare's potential seem limitless. The general public is reached on a daily basis with news about genetics, new treatments, and customization. Overwhelmingly, Americans want to help support the acceleration of healthcare advancements. Remnant biospecimen donation is a way that US adults can give back, and the findings here show that doing so is copacetic with the majority.

For more information about iSpecimen or this study, please contact partners@ispecimen.com.

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