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Effect of ethnicity, gender and drug use history on achieving high rates of affirmative informed consent for genetics research: impact of sharing with a national repository

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Abstract

Aim—Genetic research representative of the population is crucial to understanding the underlying causes of many diseases. In a prospective evaluation of informed consent we assessed the willingness of individuals of different ethnicities, gender and drug dependence history to participate in genetic studies in which their genetic sample could be shared with a repository at the National Institutes of Health.

Methods—Potential subjects were recruited from the general population through the use of flyers and referrals from previous participants and clinicians with knowledge of our study. They could consent to 11 separate choices so that they could specify how and with whom their genetic sample could be shared. Rates of affirmative consent were then analysed by gender, ethnicity and drug dependence history.

Results—Of 1416 volunteers enrolled, 99.7% gave affirmative informed consent for studies of addiction conducted in our laboratory. No significant difference was found for participation in genetic studies conducted in our laboratory by gender, ethnicity or drug dependence history. Over all 11 questions, individuals with a history of drug use were more likely to agree to consent to participate in our study than were healthy volunteers.

Conclusion—A high percentage of each category of gender, ethnicity and drug history, gave affirmative consent at all levels. The level of detail in and the amount of time spent reviewing the informed consent, and a relationship of trust with the clinical investigator may contribute to this outcome.

INTRODUCTION

Genetic research is crucial to understanding the underlying causes of many diseases. Genetic influence is just one factor that shapes the manifestation of a disease, but understanding how the many genes and their multiple variants affect phenotype, both directly and through gene

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CJ, BR and SH had full access to all of the data in the study and take full responsibility for the integrity of the data and the accuracy of the data analysis.

Competing interests None.

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environmental interaction, gives valuable insight into pathology. In 1999, in recognition of the important contribution that genetic research lends to an understanding of human disease and its treatments, the US National Institutes of Health (NIH) mandated that each of its Institutes open a DNA repository for sharing of biological specimens and clinical information. The mandate provides that when a subject consents to enrol in a genetic study funded by an Institute of the NIH, he or she should be given a separate option to consent to having his or her lymphocytic DNA shipped to that Institute's DNA repository. Development of such additional components of the written informed consent has been a challenge to investigators, academic institutional review boards and legal counsel for both universities and NIH Institutes.

Working with The Rockefeller University's Institutional Review Board (IRB) and the Office of the General Counsel of the University, as well as with the funding NIH Institute, we developed an acceptable additional component to the informed consent that has been shared with other institutions collaborating with the NIH and its Institutes. This prospective evaluation determines subjects' rate of consent to participate in the genetic research performed locally by the Laboratory of the Biology of Addictive Diseases at The Rockefeller University. It also determines the rate of consent for subjects' DNA to be included in studies conducted with collaborators of this laboratory or shared with the NIH National Institute on Drug Addiction (NIDA) DNA repository for specific types of studies. We examined affirmative informed consent by gender, ethnicity and drug use status.

It has been suggested that women and minorities, as well as any individual with a stigmatising disease, may be less likely to participate in genetic research.[1–4] This issue is addressed in our discussion of the results obtained in this study.

METHODS

This is a prospective evaluation of 1416 volunteers recruited between 26 July 2000 and 25 May 2007 to participate in the genetic research conducted by the Laboratory of the Biology of Addictive Diseases. The Rockefeller University IRB gave final approval to include the possibility of DNA sharing with the NIH-NIDA repository on 26 July 2000.

The volunteers were recruited using a variety of methods. Many of the volunteers with addictive diseases were recruited from well-established addiction treatment clinics in the greater New York or Las Vegas metropolitan areas. IRB approved flyers were posted on public boards of clinics, hospitals and substance abuse treatment centres. Additionally, potential subjects, including healthy volunteers, learnt of our study through previous participants or were referred by clinicians with knowledge of our study.

When a potential subject contacted the laboratory, a member of the clinical research team would describe the study, explain the expectations for the potential subject and make an appointment. The clinical research team consisted of physicians, psychologists, nurse practitioners and registered nurses. When the subject arrived for the study, he or she was led through the informed consent by a member of the clinical research team in a process that could take as long as 2 h. During this time, any questions or concerns the subject had about the study were addressed.

The informed consent was constructed to allow subjects to choose with high specificity in which parts of the genetic study they would like to participate. Towards this goal, consent to the use of the subject's sample was divided into four levels to which the volunteer could independently consent. The four levels were: (A) consent to genetic studies of addictive diseases; (B) consent to genetic studies of other medical conditions; (C) consent to other types of genetic studies; and (D) consent to creation of a cell line. Additionally, three

choices were offered to the volunteer as locations where his or her sample could be studied. The three choices were: (1) local, that is, our laboratory; (2) with collaborators from other scientific institutions working with our laboratory; and (3) the NIH-NIDA DNA repository. There were only three levels of consent (A, B, C) possible for sharing of specimens with collaborators, as the informed consent only allows the local laboratory and NIH-NIDA repository, not other individual investigators, to make a cell line. This meant a subject had eleven choices to precisely determine where his or her blood specimen would be sent and for what kind of studies it could be used. Specimens are only stored at the local laboratory and the NIH-NIDA repository.

There are many features that we developed between 1995 and 2000 to include answers which might be raised by potential volunteers, but are not usually covered in informed consents. For example we state, in our informed consent.

> Any sharing that is initiated by researchers at The Rockefeller University of either your coded DNA sample or coded information will involve one or more members of The Rockefeller University research team in order to protect your wishes regarding its use. However, since each individual is unique with respect to the DNA of his or her genes, at some time in the future, it may be possible to determine your identity by use of only the DNA sample you donate.

Also the informed consent includes explicit details gaining permission to re-contact volunteers:

> The researchers may want to contact you to see if you would like to take part in a follow-up study to the research they are doing now. If an investigator wants to follow-up, may we contact you for any and all purposes, including, for research purposes, providing general information about research findings, providing information about tests on your sample that may benefit you or your family members in relation to your or their choices regarding preventive or clinical care?

Subjects were ascertained and blood specimens taken at five sites: The Rockefeller University Hospital (n = 1098); the Adolescent Development Program (n = 57) or the Adult Services Clinic at New York Presbyterian Hospital (n = 4); the Veterans Administration New York Harbor Healthcare System (VANYHHS) Opiate Replacement Treatment Program (ORTP) (n = 97); and The Dr Miriam and Sheldon G Adelson Clinic for Drug Abuse Treatment and Research (The Adelson Clinic) (n = 160) in Las Vegas.

All Rockefeller University subjects were ascertained in the general Outpatient Research Center of The Rockefeller University Hospital, which provides outpatient services to The Rockefeller University clinical research community.

Except for The Rockefeller University site, all other ascertainment sites are primarily methadone maintenance treatment clinics. The subjects that were recruited at these sites were exclusively methadone or buprenorphine maintained opiate dependent patients (all meeting Federal criteria for entry into methadone maintenance treatment).

The informed consent used at the VANYHHS ORTP was approved by the VANYHHS IRB and was slightly modified from the informed consent used at the other sites. The permission for the VANYHHS ORTP to collaborate with our laboratory and with the NIH-NIDA repository was obtained through an agreement signed by the directors of the United States Department of Veterans Affairs and NIH-NIDA. This permission was granted with the stipulation that on the informed consent form administered at the VANYHHS ORTP, permission to make a cell line at the Laboratory of the Biology of Addictive Diseases at The Rockefeller University (local laboratory) and NIH-NIDA repository level were combined

into one question. When a subject at this site chose for which studies their sample could be used, the VANYHHS ORTP consent form had 10 choices, while the informed consent at the other sites had 11.

Subjects were compensated for participation in the genetic study (US$60), regardless of whether or not they agreed to participate at all levels and whether or not they agreed to participate at any level of NIH-NIDA sharing. Refusing to participate in one or more levels did not alter the amount of blood drawn. Each subject was allowed to withdraw at any time from all or any part of the study to which he/she had consented.

After the informed consent process, the drug abuse and psychiatric history of the subject was determined using a series of standardised instruments. At the Rockefeller site, psychiatric history was assessed using the Structured Clinical Interview for (SCID) Diagnostic and Statistical Manual-IV Axis I Disorders version 2, sections A (Mood Episodes), B/C (Psychotic Symptoms), D (Mood Disorders) and F (Anxiety Disorders).[5] Psychiatric assessment of patients at the other sites was based on clinical evaluation. Patients were excluded from the study if they had active psychosis, current intoxication or were unable to read and communicate in English. All other subjects were included.

Drug abuse history was ascertained using the SCID section E (Substance Use Disorders), the Kreek-McHugh-Schluger-Kellogg Scale and the Addiction Severity Index.[67] The diagnoses in this evaluation included dependence on opiates, cocaine and alcohol as ascertained by SCID criteria. For this evaluation of informed consent, if a subject was codependent, he or she was categorised as follows: a diagnosis of opiate dependence took precedence over any other dependence diagnosis and cocaine dependence took precedence over alcohol dependence. Subjects who did not qualify as dependent on or abusing any drug of abuse or alcohol by SCID criteria were categorised as healthy volunteers.

Our laboratory obtains a rigorous family origin history, which includes country and region of birth, race, ethnicity or cultural group and nationality of subject, parents, maternal and paternal grandparents and great-grandparents, if known. For this evaluation, gender and ethnicity were determined by self-report.

To determine if there was a significant difference in consent rates between groups we performed χ^2 analyses. In order to correct for multiple testing we used Bonferroni with a correction factor of 33 which includes gender, drug use and ethnic groups (3) by the number of questions (11).We present experiment-wise p values in this paper.

RESULTS

Affirmative informed consent rates for all 1416 subjects ranged from 99.7% for studies of the genetics of addiction to be conducted within our laboratory, to 87% for samples and clinical information to be sent to the NIH-NIDA repository for similar studies (tables 1 and 2).

Difference between males and females

Of the 1416 subjects in our evaluation, 62% were male and 38% were female (table 1). For each of the individual choices offered there was no significant difference in affirmative informed consent rates between males and females. When the overall consent rates for all questions were compared, there was no significant difference for each of the individual choices in affirmative informed consent rates between males and females ($p = 1.0000$, table 3).

Difference between ethnic groups

In our evaluation, 38% of our subjects were African American, 37% were Caucasian, 18% were Hispanic, and 7% were 'Other', which included Native Americans, Asians, persons of mixed ethnicity or not specified (table 1). Due to the heterogeneity and low overall percentage of the 'Other' group, analysis of this group was not conducted. There was no significant difference among the ethnicities for studies of addiction, studies of other medical conditions, and other types of genetic studies conducted within our laboratory (table 1). Over all levels of consent possible in the study, there was a difference between ethnic groups ($p<0.0001$, table 3). African Americans had a lower affirmative informed consent rate than the combined group of Hispanics and Caucasians ($p<0.0001$).

The greatest difference between African Americans and the other two ethnicities in affirmative informed consent rates was seen with the choices pertaining to the sharing of specimens with the NIH-NIDA repository. The overall consent rate for Hispanics is 90%, Caucasians 89% and African Americans 82% (table 2).

Differences among the different drug dependence diagnoses

Of the total, 35% of the subjects in the study were classified as opiate dependent, 15% were cocaine dependent, 21% were alcohol dependent, 28% were healthy controls and 1% were unclassified (table 1). Due to missing information on the 'unclassified' group, analysis of this group was not conducted.

Overall, subjects with an addictive disease diagnosis were significantly more likely to consent to all eleven levels of consent than were healthy controls ($p<0.0001$, table 3).

For studies conducted within our laboratory, subjects with a drug dependence diagnosis were just as likely to participate as healthy controls for studies of addiction ($p = 1.000$), studies of other medical conditions ($p = 1.000$) and other types of genetics studies ($p = 1.000$).

For choices pertaining to the sharing of specimens with collaborators, there was a significant difference among the four diagnostic categories (table 4).

When subjects with a drug dependence diagnosis were compared to healthy controls, the subjects with a drug dependence diagnosis were found to be significantly more likely to consent to participate in studies of addiction ($p = 0.0051$) and other types of genetic studies ($p = 0.0160$), but not for studies of other medical conditions ($p = 0.2211$) (not shown in tables).

For choices pertaining to the sharing of specimens with the NIH-NIDA repository, there was a significant difference among the four diagnostic categories (table 2). Subjects with a drug dependence diagnosis were significantly more likely to consent to participate in studies of addiction ($p<0.0001$), studies of other medical conditions ($p = 0.0011$) and other types of genetic studies ($p = 0.0014$) than were healthy controls.

Differences between choices pertaining to studies conducted within our laboratory, the sharing of specimens with collaborators and sharing of specimens with the NIH-NIDA repository

There was a significant difference overall in the affirmative informed consent rates ($p<0.0001$): 96% of subjects consented to studies conducted within our laboratory; 92% to the sharing of specimens with our collaborators; and 87% to sharing of specimens with the NIH-NIDA repository, (table 3) ($p<0.0001$). A post-hoc comparison showed a significant difference for the overall level of consent between local studies and studies involving

collaborators ($p<0.0001$), between local studies and consent rates to share specimens with the NIH-NIDA repository ($p<0.0001$), and between studies involving collaborators and consent rates to share specimens with the NIH-NIDA repository ($p<0.0001$).

Differences between sites of ascertainment

When the subjects were classified by site of ascertainment, the methadone maintenance treatment sites had an overall affirmative informed consent rate that was significantly higher ($p<0.0001$) than subjects ascertained at The Rockefeller University Hospital. Since subjects at the methadone maintenance treatment sites were exclusively individuals with a history of opiate dependence, this comparison was made with only those subjects with a history of opiate dependence ascertained at The Rockefeller University Hospital site.

COMMENT

There are certain risks associated with research that may lead subjects to be wary of participation. A subject may have a general distrust of researchers because the subject has no guarantee that the researcher will adhere to the limitations imposed by the informed consent. Also, they may fear that the study will be used to cast aspersions on a group with which the subject identifies.[8–10]

There are also risks that are unique to genetic studies. Even with the passage of the 2008 Genetic Information Nondiscrimination Act, H.R.493, there is concern that the discovery of a genetic predisposition for a disease will have a negative impact on a subject's life.[10] There is no guarantee that the new legislation will be sufficient to protect against discrimination from employers, healthcare providers, health insurers, or misuse by any group. Subjects may also be apprehensive that such information will have an effect on their family. A genetic predisposition discovered in a subject is also likely to be present in family members. When family studies are performed, concerns about the ability of genetic markers to reveal paternity, identify consanguinity, and confirm fraternal relationships are another factor that may cause subjects to avoid these types of studies. However, this is not a concern since we do not ascertain family members.

It is often thought in the research community that individuals with a stigmatised disease will be less likely to participate in research.[1311] These individuals may be concerned that they will suffer social, familial or job discrimination if their disease status became known. If subjects desire to keep their disease status as private personal information, they would be less likely to participate in a study where their disease state could be revealed to anyone other than the investigator, let alone be the focal point of research.

The wish to keep a stigmatised disease secret is compounded by the fact that a person's entire genome is a unique identifier. The technology to identify individuals using their entire genome is available, but expensive. However, this technology may soon become readily available. Should the results of a genome-wide study be made available from a repository to military and law enforcement data bases, it would no longer be possible for the researcher to guarantee anonymity. Since properly stored DNA will last indefinitely, the fear that participation in genetic studies, with linked drug use and psychosocial history, will not be permanently anonymous is a realistic fear that may preclude people from participation in genetic studies.

Evaluation-wide results

This prospective evaluation of affirmative informed consent rates obtained by the Laboratory of the Biology of Addictive Diseases and its collaborators shows that, despite the above concerns, it is possible to conduct a genetic study with very high affirmative informed

consent rates. It was also found that, at each level, rates of affirmative consent were higher for studies conducted within our laboratory than they were for sharing with our collaborators, which in turn were higher or equal to rates for choices pertaining to the sharing of specimens with the NIH-NIDA repository.

We, like others, conclude that the level of detail contained within the informed consent and the amount of time spent ensuring that the subject understood the informed consent contributed to the high overall consent rates found in the study.[1812–15] This trend may be seen because, during the consent process, the subject develops a sense of confidence in the clinician/researcher. We think these are factors responsible for the high rates of consent because they create a relationship between the subject and the researcher, thus engendering mutual trust.

The consent rate for the choices pertaining to working with collaborators is higher than the consent rate for the choices pertaining to the sharing of specimens with the NIH-NIDA repository because it is probably perceived that more control is maintained while sharing with collaborators. A collaborator is an individual with whom our laboratory has chosen to work, while the NIH-NIDA repository may be seen as a remote government sponsored facility.

Differences between genders

Unlike the findings from the National Health and Nutritional Examination Survey, and the Action for Health in Diabetes (Look AHEAD), in which females were significantly less likely to provide affirmative informed consent to genetic studies, the differences between the genders in affirmative informed consent rates in our study were not significant, for any of the 11 choices offered.[12]

Differences among the ethnicities

The finding that there is an overall trend of lower rates of affirmative informed consent among African American participants, as has been found in other genetic studies, is in no way meant to imply that African Americans will not participate in genetic studies.[1–312] A high percentage of subjects of each ethnicity agreed to each level of consent. Though there was an overall trend for African Americans to consent to fewer levels than Hispanics or Caucasians, this was not the case for all levels of consent, as African American affirmative informed consent rates for studies conducted by our laboratory were not significantly different from those of Hispanics or Caucasians.

The more distant the consent from our investigators at the local level, the lower the level of African American affirmative informed consent. This lower level of African American affirmative informed consent to participate in the sharing of specimens with collaborators and the NIH-NIDA repository may be, in part, traced to the troubling history of scientific research in the USA, of which the Tuskegee Syphilis Experiment is just one example. (In 1932, a study of untreated syphilis was begun in Macon County, Alabama by the venereal disease branch of the United States Public Health Service. The study enrolled 399 African American males with latent untreated syphilis and 201 African American males without syphilis. The purpose was to study the untreated patient with syphilis from the beginning of the disease until the death of the patient. Even though penicillin became the treatment of choice for syphilis in 1945, the researchers did not offer treatment to the 399 infected males, and continued the study until 1972).[16–19] Another factor possibly contributing to the lower rates may be that African Americans have a strong sense of cultural identity and are more sensitive to the possibility of mishandled research being used to malign their ethnicity.[920] The comparable levels of consent for each ethnicity at the local level may indicate that this

can be overcome. We think that the level of detail in the informed consent, the accessibility of the investigator and the time spent interacting with the subject during the consent process helped to increase affirmative consent rates among African Americans.

Differences among the different drug dependence diagnoses

An interesting finding from this study is that the subjects with a stigmatised disease—current or past heroin, cocaine or alcohol dependence—were, at each level of consent, just as likely or significantly more likely to participate in genetic research than were healthy controls. This finding is of interest because, as mentioned above, individuals with a stigmatised disease are thought to avoid situations in which their disease status would become known. We actually found the reverse; the overall affirmative informed consent rates of subjects with a history of drug or alcohol dependence was significantly higher than affirmative informed consent rates of healthy controls. This may be due, in part, to the fact that subjects with addictive diseases recognise the need for research in this area.

Differences between sites of ascertainment

The informed consent was conducted at two different types of sites: methadone maintenance treatment clinics which had a prior long-term relationship with the subject and The Rockefeller University Hospital which did not have a prior relationship with the subject. The finding that the methadone maintenance treatment sites had significantly higher overall affirmative informed consent rates than did The Rockefeller University Hospital site may indicate that conducting the consent process where the investigator is known to the potential subject and/or in an environment in which he/she is comfortable may increase affirmative informed consent rates.[82122]

CONCLUSION

A high percentage of individuals agreed to participate in studies conducted within our laboratory, to the sharing of specimens with our collaborators and to choices pertaining to the sharing of specimens with the NIH-NIDA repository. We believe that the level of detail, the amount of time spent reviewing the informed consent document and the relationship with the clinical investigator contributed to our high consent rates.

African Americans have enrolled in studies conducted in our laboratory at a high rate comparable to other ethnicities. Although they were found to have lower rates of affirmative informed consent for the choices pertaining to the sharing of specimens with collaborators and the NIH-NIDA repository, a high overall rate of affirmative informed consent was still found.

Our prospective evaluation indicates that persons with the stigmatised disease of addiction were more likely, not less likely, to consent to participate in genetic studies than were healthy volunteers. Also, we found that subjects with addictions were more likely to consent to sharing their specimens with the NIH-NIDA repository for genetic studies of addiction than were healthy controls.

An efficacious plan to end the disparities in healthcare must include provision for inclusion of minorities in sufficient numbers in health/medical research.[23] In agreement with others, this evaluation shows that when the researcher develops a relationship of trust with the potential volunteer and actively involves the participant in the consent process, the inclusion of all groups, including African Americans and women, in genetic research studies can be successfully accomplished.[18121421]

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Table 1

Affirmative informed consent rates at our laboratory, by gender, ethnicity and drug dependence status

	N	Percentage	Addiction	Other medical diseases	Other types of studies	Cell line	Overall
All subject	1416	100%	99.7%	96%	97%	92%	96%
By gender							
Female	534	38%	99.8%	97%	97%	91%	96%
Male	882	62%	99.6%	96%	97%	92%	96%
p Value			1.00	1.00	1.00	1.00	1.00
By ethnicity							
African American	536	38%	99.4%	94%	95%	89%	94%
Caucasian	526	37%	99.8%	98%	98%	94%	97%
Hispanic	258	18%	100%	98%	98%	94%	98%
Other	96	7%	N/A	N/A	N/A	N/A	N/A
p Value			1.00	0.0514	0.1064	0.5236	<0.0001
By drug dependence							
Alcohol	291	21%	100%	97%	97%	89%	96%
Cocaine	219	15%	99.5%	94%	95%	90%	95%
Healthy volunteer	397	28%	99.2%	95%	97%	88%	95%
Opiate	493	35%	99.8%	98%	98%	98%	98%
Unclassified	16	1%	N/A	N/A	N/A	N/A	N/A
p Value			1.00	0.5365	1.00	<0.0001	<0.0001

The lowest overall affirmative informed consent rate, 85%, was for permission for the NIH National Institute on Drug Addiction repository to create a cell line (table 2).

Table 2

Affirmative informed consent rates to share specimens with NIH National Institute on Drug Addiction, by gender, ethnicity and drug dependence status

	N	Percentage	Addiction	Other medical diseases	Other types of studies	Cell line	Overall
All subjects	1416	100%	88%	87%	86%	85%	87%
By gender							
Female	534	38%	87%	86%	84%	84%	85%
Male	882	62%	89%	87%	86%	86%	87%
p Value			1.00	1.00	1.00	1.00	1.00
By ethnicity							
African American	536	38%	85%	82%	80%	82%	82%
Caucasian	526	37%	91%	90%	89%	87%	89%
Hispanic	258	18%	93%	90%	89%	89%	90%
Other	96	7%	N/A	N/A	N/A	N/A	N/A
p Value			0.0137	0.0017	0.0012	0.2107	<0.0001
By drug dependence							
Alcohol	291	21%	89%	86%	84%	84%	86%
Cocaine	219	15%	87%	82%	81%	83%	83%
Healthy volunteer	397	28%	82%	81%	80%	78%	80%
Opiate	493	35%	95%	94%	94%	93%	94%
Unclassified	16	1%	N/A	N/A	N/A	N/A	N/A
p Value			<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

There was no significant difference in the consent rates by gender, ethnicity, or drug use status for studies of the molecular genetics of addictive diseases conducted within our laboratory (table 1).

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Table 3

Overall affirmative informed consent rates, by gender, ethnicity and drug dependence status

	N	Percentage	Local	Collaborator	NIH-NIDA	All 11 questions
All subjects	1416	100%	96%	92%	87%	92%
By Gender						
Female	534	38%	96%	92%	85%	91%
Male	882	62%	96%	93%	87%	92%
p Value			1.00	1.00	1.00	1.00
By ethnicity						
African American	536	38%	94%	89%	82%	86%
Caucasian	526	37%	97%	90%	89%	94%
Hispanic	258	18%	98%	94%	90%	94%
Other	96	7%	N/A	N/A	N/A	N/A
p Value			<0.0001	<0.0001	<0.0001	<0.0001
By drug dependence						
Alcohol	291	21%	96%	92%	86%	91%
Cocaine	219	15%	95%	88%	83%	89%
Healthy volunteer	397	28%	95%	88%	80%	88%
Opiate	493	35%	98%	98%	94%	97%
Unclassified	16	1%	N/A	N/A	N/A	N/A
p Value			<0.0001	<0.0001	<0.0001	<0.0001

NIH-NIDA, National Institutes of Health National Institute on Drug Addiction.

Table 4

Affirmative informed consent rates to share specimens with our collaborators, by gender, ethnicity, and drug dependence status

	N	Percentage	Addiction	Other medical diseases	Other types of studies	Cell line	Overall
All subjects	1416	100%	94%	92%	91%	N/A	92%
By gender							
Female	534	38%	93%	92%	91%	N/A	92%
Male	882	62%	95%	92%	91%	N/A	93%
p Value			1.00	1.00	1.00	N/A	1.00
By ethnicity							
African American	536	38%	91%	88%	88%	N/A	89%
Caucasian	526	37%	91%	90%	89%	N/A	90%
Hispanic	258	18%	97%	93%	93%	N/A	94%
Other	96	7%	N/A	N/A	N/A	N/A	N/A
p Value			0.0160	0.0009	0.0081	N/A	<0.0001
By drug dependence							
Alcohol	291	21%	94%	91%	90%	N/A	92%
Cocaine	219	15%	91%	85%	87%	N/A	88%
Healthy volunteer	397	28%	90%	88%	87%	N/A	88%
Opiate	493	35%	99.0%	98%	98%	N/A	98%
Unclassified	16	1%	N/A	N/A	N/A	N/A	N/A
p Value			<0.0001	<0.0001	<0.0001	N/A	<0.0001

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