Title

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Journal

Nature, 620(7975)

ISSN

0028-0836

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Publication Date

2023-08-24

DOI

10.1038/s41586-023-06382-0

Peer reviewed

HHS Public Access

Author manuscript

Nature. Author manuscript; available in PMC 2024 April 26.

Published in final edited form as:

Nature. 2023 August ; 620(7975): 855–862. doi:10.1038/s41586-023-06382-0.

Consent document translation expense hinders inclusive clinical trial enrollment

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Abstract

Patients from historically underrepresented racial and ethnic groups are enrolled in cancer clinical trials at disproportionately low rates in the United States[1–3]. As these patients often have limited English proficiency[4–7], we hypothesized that one barrier to their inclusion is the cost to investigators of translating consent documents. To test this hypothesis, we evaluated more than twelve-thousand consent events at a large Cancer Center and assessed whether patients requiring translated consent documents would sign consent documents less frequently in studies lacking industry sponsorship (for which the principal investigator pays translation costs) than for industry

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Author Contributions:

M.A.V., B.G., and E.B.G. contributed substantially to the conception and design of the work. M.A.V., A.N., Y.R., J.P.L., P.M.B., D.Y.L., M.J.F., M.L., M.H., J.B., T.G., D.E., and E.B.G. contributed to data acquisition, analysis, and interpretation. M.A.V. and E.B.G. drafted the manuscript. B.G., A.L.C., M.G.J, A.G., M.A.T., and E.B.G. contributed substantially to manuscript revision.

sponsored studies (for which translation costs are covered by the sponsor). Here, we show that the proportion of consent events for patients with limited English proficiency in studies not sponsored by industry was approximately half of that seen in industry sponsored studies. We also show that among those signing consent documents, the proportion of consent documents translated into the patient's primary language in studies without industry sponsorship was approximately half of that seen in industry sponsored studies. Results suggest that the cost of consent document translation in trials not sponsored by industry could be a potentially modifiable barrier to the inclusion of patients with limited English proficiency.

Introduction

Cancer clinical trials are the primary means of developing diagnostic and therapeutic strategies, and trial participation associates with improved patient outcomes[8,9]. Patients from traditionally underrepresented racial and ethnic groups participate in clinical trials at disproportionately low rates[10–14], limiting generalizability of results[2,15]. While barriers to inclusion of historically underrepresented racial and ethnic groups have been extensively studied, there has been limited progress toward achieving equity[1,2,7,10,12,16,17]. While many important barriers are not easily addressed by individual clinical trial investigators[16,18], investigator-related barriers to equitable clinical trial enrollment have been less thoroughly studied[18,19].

The non-Hispanic White population in the United States has proportionally decreased, based in part on immigration from Asia and Latin America[20,21]. The percentage of residents speaking a language other than English at home rose from 11% in 1980 to 22% by 2018, with rates above 70% among individuals identifying as Hispanic or Asian[20,22,23]. Consequently, the relative importance of limited English proficiency, an established barrier to trial participation, has likely increased over time. Yet, factors contributing to underrepresentation of patients with limited English proficiency are understudied[7–9].

Ensuring that trial participants are appropriately informed regarding procedures and risks is a cornerstone of ethical research[24]. The Food and Drug administration (FDA) mandates that presented consent documents are in a language understandable to the patient[25–27]. The FDA recommends that Institutional Review Boards (IRBs) ensure that translated consent documents are prepared by a qualified entity with a certification statement for each translation[25,28–30], a potentially costly and time-consuming process[29,31]. Recognizing the importance of timely participation, the FDA allows an alternative approach in which patients sign translated, non-study specific documents to be promptly followed by appropriately translated study specific consent documents (Supplementary Methods).

Whether delays, costs or other aspects of the consent document translation process discourages trial participation among patients with limited English proficiency is challenging to study. As limited data can be collected from patients who do not sign consent documents, it is difficult to establish how these patients differ from those who participate. Since consent documents are often translated only after a prospective participant is identified[32], analyses assessing the impact of available translated consent documents are subject to the bias of reverse causation[33].

Approximately 70% of randomized oncology clinical trials are funded by industry[34], with most studies not sponsored by industry funded by a grant from either industry, philanthropic or governmental groups[36,37]. Industry can offer assistance for a study sponsored by an academic center by providing study drug or device and/or additional financial support, although generally less funding than in industry sponsored studies (Figure 1)[38]. In non-industry sponsored studies, the principal investigator generally operates on a fixed, per patient budget, whereas in industry sponsored studies, the sponsor generally provides additional funds for consent document translation beyond the negotiated per patient budget[39]. Although an investigator can request funds for consent document translation in a proposed grant, many grants have a budget cap, meaning that such a request would limit funds for other study activities[39]. Furthermore, funds intended for consent document translation could often be directed to other study activities if translation costs were below the budgeted amount[39].

Among several barriers to the participation of patients with limited English proficiency in clinical trials, we hypothesized that the additional costs incurred by investigators on studies not sponsored by industry could discourage investigators from offering trial participation to patients for whom consent document translation would be required[4,5,29]. Although prohibited by regulations[25], an investigator who lacks sufficient funds may not offer consent documents to patients with limited English proficiency, (Figure 1) or the investigator may utilize consent documents that are already available in a language in which the patient is not proficient (generally English).

To test our hypothesis, we assessed data from all consent events for studies conducted at the University of California Los Angeles (UCLA) Jonsson Comprehensive Cancer Center over a six-year period to determine patients' primary language, English proficiency, and language of consent documents. We compared studies not sponsored by industry to those sponsored by industry to evaluate potential differences based on participant primary language and English proficiency.

Results

Study Population

Of 13,717 consent events between January 2013 and December 2018, 1,635 were excluded from further analysis based on lack of access to appropriate data (Figure 2). Most of the remaining 12,082 consent events were for patients with English as their primary language (n=11,340, 93.9%). Of the remaining 742, the patient met the definition for limited English proficiency in 481 (64.8%).

Of 200 randomly selected consent events evaluated as a control to ensure English proficiency among patients with English as a primary language, 58 were for children. Need for an interpreter was found in only four consent events, all for pediatric patients with English as their primary language but limited English proficiency among their parents/guardians. Among 247 pediatric consent events for patients with English as their primary language, need for an interpreter was documented in seventeen (6.9%), and these patients

were analyzed as having a primary language other than English and limited English proficiency.

As some patients signed consent documents for multiple studies, the 12,082 consent events occurred in 9,213 patients, 63.4% of whom were non-Hispanic White. While only 1.6% of non-Hispanic white patients had a primary language other than English, 18.3% of members of racial and ethnic groups other than non-Hispanic White signing consent documents had a primary language other than English, including nearly a quarter of Hispanic and Asian or Pacific Islander patients. (Figure 2, Extended Data Table 1).

The most common primary languages other than English were *Spanish* (40.8%, n=231) and *Chinese* (20.8%, n=118) (Extended Data Table 2). The median number of words in the initial English consent document was 7,491.5 (range 598 to 20,382 words), with an estimated cost of $1,498 per translation. Additional costs would be incurred to translate a consent document at the time of protocol amendments, an amount that would vary by trial.

Consent events based on study sponsor

Nearly half of consent events (n= 5,738) were for industry sponsored studies (Extended Data Table 3). Of 758 studies for which patients signed consent documents, 261 (34.4%) had any available IRB-approved translated consent documents. While most studies were sponsored by industry (n = 585), the median number of consent events per study was less as compared to non-industry sponsored studies (5.0 versus 8.0, $p<0.001$). Yet, the proportion of consent events in studies that had translated consent documents available was higher for industry sponsored studies as compared to those not sponsored by industry (51.4% versus 23.9%, $p<0.001$).

Of 758 studies, twelve were pediatric-only studies, none of which were sponsored by industry. Eight of twelve (66.7%) had translated consent documents at any point during the study. In contrast, among 718 adult-only studies, 580 (80.8%) were sponsored by industry, and 241 (33.5%) had translated consent documents at any point during the study. The odds of a consent event for an industry sponsored study having any available translated consent documents were greater than for a non-industry sponsored study [odds ratio (OR) 3.4, 95% confidence interval (CI) 3.1 to 3.6, $p<0.001$] (**data not shown**).

Patients with a primary language other than English represented 8.1% of consent events in industry sponsored studies versus 4.4% in studies not sponsored by industry ($p<0.001$) (Figure 3). Patients with limited English proficiency represented 5.5% of consent events in industry sponsored studies versus 2.8% in studies not sponsored by industry ($p<0.001$). Findings were similar when only interventional studies were analyzed (Extended Data Figure 1).

Consent documents at study opening

Only eighteen studies had translated consent documents available at the time of study opening, 13 industry and 5 non-industry sponsored studies. Twelve of the eighteen had *Spanish* consent documents at study opening, 10 industry and 2 non-industry sponsored (Extended Data Table 4). Patients with *Spanish* as their primary language had higher odds of

signing consent documents for studies that had *Spanish* consent documents at study opening than those without (OR, 5.7, 95% CI, 3.8 to 8.5, p<0.001) (Extended Data Table 4). Patients with a primary language other than English or *Spanish* did not have higher odds of signing consent documents for studies that had *Spanish* consent documents at study opening (OR, 0.9, 95% CI, 0.6 to 1.3).

Consent documents in primary language

Patients with a primary language other than English signed consent documents in a language different than the patient's primary language in 43.8% of consent events for industry sponsored studies versus 72.6% in studies not sponsored by industry (p<0.001). When analyzing patients with limited English proficiency, rates were 31.9% versus 65.9%, respectively (p<0.001) (Figure 4). When only evaluating studies without any translated consent documents, the corresponding results were 42.4% versus 71.9% for patients with a primary language other than English (p<0.001), 30.6% versus 64.9% (p<0.001) in patients with limited English proficiency. This phenomenon appears to be driven by lack of appropriately translated consent documents, as only 3% occurred while available consent documents in the patient's primary language were available (data not shown). Patients with a primary language other than English had lower odds of signing consent documents in a language different than primary for studies with translated consent documents than those without them (OR, 0.02, 95% CI, 0.009 to 0.030) (Extended Data Table 4).

Of 52 patients who signed consent documents for both industry and non-industry sponsored studies, ten signed all in their primary language, 24 signed all in a language different than primary and eighteen signed in their primary language for one study and a language different than primary for the other. Sixteen of these eighteen patients signed consent document in a language different than primary for the non-industry sponsored study (p=0.002) (Figure 4C).

Differences in the proportion of consent events by sponsor type were largely driven by a difference in consent events in the patient's primary language. The proportion of consent events for patients with a primary language other than English who signed consent documents in the patient's primary language was 4.6% versus 1.2% (p<0.001) in industry versus non-industry sponsored studies, and 3.7% versus 1.0% (p<0.001) for those with limited English proficiency (Figure 3). However, the proportion of consent events for patients with a primary language other than English who signed consent documents in a language different than primary was similar between industry and non-industry sponsored studies (3.5% versus 3.2%, p=0.391) and patients with limited English proficiency (1.8% versus 1.8%, p=0.643). Patients with a primary language other than English had a higher proportion of consent events in which the patient signed consent documents in a language different than primary in studies not sponsored by industry across Departments (Extended Data Table 5).

Consent odds based on language

A multivariable analysis evaluated whether associations were confounded by other factors. After adjusting for age at consent, gender, race, ethnicity, histology, and study type (observational versus interventional), patients with a primary language other than English

(OR, 0.74, 95% CI, 0.63 to 0.94, p=0.005) and limited English proficiency (OR, 0.74, 95% CI, 0.58 to 0.95, p=0.021) had lower odds of signing consent documents for non-industry sponsored studies than patients with English as their primary language. Younger age, women and Asian and Pacific Islander and Hispanic (both compared to non-Hispanic White) patients also had lower odds of signing consent documents for non-industry sponsored studies. The odds of signing consent documents for observational studies was higher in studies not sponsored by industry (Table 1).

The odds of signing consent documents in the patient's primary language for a non-industry sponsored study were considerably lower for patients with a primary language other than English (OR, 0.38, 95% CI, 0.28 to 0.52, p<0.001) and limited English proficiency (OR, 0.35, 95% CI, 0.25 to 0.50, p<0.001) compared to patients with English as their primary language. Results were similar when evaluated by bivariable analysis (Extended Data Table 6). Patients with a primary language other than English, including those with limited English proficiency, had lower odds of signing consent documents for non-industry than industry sponsored studies across Departments (Figure 5). When looking at the distribution of patients with a primary language other than English the proportion of those signing consent documents and signing consent documents in their primary language was decreased across non-industry sponsored studies (Extended Data Figure 2)

Additional potential confounders

The potentially confounding interactions between Medi-Cal status and language interaction terms were evaluated, but not significant (Extended Data Table 7). Therefore, interaction terms were not included in the final model. While nesting consent events within studies led to p-values that were somewhat higher for some analyses, the general trends seen were similar (Extended Data Table 8). Findings also remained consistent when studies that could have received some industry support for consent document translation were grouped with those that were sponsored by industry. The odds of signing consent documents for studies not sponsored or supported by industry were 0.61 (95% CI, 0.52 to 0.72, p<0.001) for patients with a primary language other than English and 0.64 (95% CI, 0.53 to 0.79, p<0.001) for patients with limited English proficiency compared to patients with English as their primary language (data not shown)

The safety net insurer Medi-Cal insured 48.8% of patients with a primary language other than English versus 6.9% among patients with English as their primary language (p < 0.001) (Extended Data Table 1). When Medi-Cal insurance status was added as a variable in the multivariable model, results remained consistent (Extended Data Table 7).

Discussion

We found that the proportion of consent events for patients with a primary language other than English was lower in non-industry versus industry sponsored studies. For non-industry sponsored studies, patients with a primary language other than English frequently signed consent documents in a language different than their primary language. Findings persisted when analyses were restricted to patients with limited English proficiency.

Standard economic theory argues that increasing the expense faced by an individual for an activity discourages the individual from engaging in that activity[40]. So, we tested the hypothesis that patients requiring translated consent documents would be less likely to sign consent documents for studies not sponsored by industry, studies for which the investigator would generally be responsible for the cost of consent document translation. While a retrospective study cannot prove causation, consistent associations across analyses support the hypothesis that patients requiring translated consent documents were selectively missing from studies not sponsored by industry.

Our observations were unlikely driven by differential enrollment by sponsor type, as the odds of having any translated consent documents available for non-industry sponsored studies was substantially lower despite a greater median number of consent events per study when compared to industry sponsored studies. Observations were also unlikely to be driven by differences in the patient population by sponsor type, as when the same patient signed consent documents for both an industry and non-industry sponsored study, nearly all patients who signed consent documents in discrepant languages signed in a language different from their primary for the non-industry sponsored study.

An approach that increases the participation of patients with a primary language other than English in non-industry sponsored to the level seen in industry sponsored studies would be expected to lead to a modest increase in the representation of patients from ethnic or racial groups other than non-Hispanic White. If either efficacy or toxicity substantially differed in these populations as compared to non-Hispanic White patients, in aggregate, this increased representation could facilitate recognizing such a difference. Moreover, as patients with limited English proficiency may form a distinct subpopulation more likely to have poor social determinants of health within traditionally underrepresented racial and ethnic groups, differential clinical outcomes observed in this subpopulation could be even more pronounced than in an unselected population from that racial or ethnic group[41,42].

Increased representation could be particularly important in pediatric studies since approximately 30% of the Hispanic population living in the United States are children[43]. While patients with *Spanish* as their primary language were more likely to sign consent documents for studies with *Spanish* consent documents available at study opening, this result should be interpreted cautiously. First, the presence of translated consent documents at the time of study opening in a single study in less common languages, such as *Thai*, suggests that this analysis is subject to the bias of reverse causation. Second, it is possible that a study anticipated to enroll a disproportionate number of Hispanic patients would be more likely to have *Spanish* consent documents available at study opening. The potential for translated consent documents at study opening facilitating increased inclusion in clinical trials should be an area for future investigation.

While most industry sponsored studies have a therapeutic intent, non-industry sponsored studies often focus on biobanking, assessing screening/prevention strategies and survivorship/quality of life issues[45], study types in which the inclusion of a diverse patient population is highly relevant. Although our analysis focused on cancer studies,

investigators studying other diseases face similar pressures. Whether our findings extend beyond oncology studies should be investigated.

Our results raise concern about the quality of information conveyed to patients with limited English proficiency. The NIH Policy and Guidelines on the Inclusion of Women and Minorities clearly indicates that cost of inclusion of participants with limited English proficiency in clinical research should not hinder their participation[46]. However, no additional resources are typically provided to investigators to cover the cost of consent document translation on studies not sponsored by industry, which are typically funded through federal grants or cooperative groups[29,47]. We are not aware of data to date that has explored whether the cost of consent document translation is commonly requested in NIH grant applications, but it would be helpful if that data could be made available.

The FDA does not specifically mandate who should perform consent document translation, and IRB requirements vary across institutions[48,49]. At some institutions, IRBs require that consent documents be translated by a professional translation service, while others rely on investigators to determine what constitutes an adequate translation[26]. Investigators at some institutions could have members of the research team fluent in another language translate consent documents, especially for minimal risk studies, at a lower cost than professional translation services. This could potentially decrease the barrier of cost of consent translation.

Strengths of the current dataset include a large number of consent events based on six years of heavily curated data, the high number of translated consent documents, and the large number of patients signing consent documents for studies not sponsored by industry. Additionally, inclusion of all consent events for which the appropriate data was available increases confidence in our results and reduces potential biases. The primary weakness of our analysis is its single center nature. Sensitivities regarding patient health information, study-related data, and differences in regulatory structures make cross-center studies difficult. The general consistency across Departments suggests that these findings are widespread. However, data from additional Cancer Centers would enhance confidence in our findings. While Southern California has particularly high racial and ethnic diversity[50], increasing non-Hispanic White populations are not limited to this region.

Significant findings for the Asian and Pacific Islander race and Hispanic ethnicity in multivariable analyses suggests that our models may not have optimally separated the effects of race and ethnicity from language. The effect of language in the multivariable analysis may have persisted for Asian and Pacific Islander and Hispanic patients based on perceived limited English proficiency. This will be an important topic for future research. Another limitation is the retrospective nature of our study and reliance on electronic health record data. For instance, Medi-Cal status, a dynamic variable, was gathered retrospectively and may not accurately reflect insurance status at the time of the consent event. Furthermore, some data, such as language proficiency, may not be documented accurately in the electronic health record.

As all data included were from patients who signed consent documents for Cancer Center studies, important barriers preventing patients from participating in any Cancer Center study

were not assessed. Barriers such as delays associated with consent document translation and lack of training for research staff on appropriate consent practices for patients with limited English proficiency may have played important roles. As such, additional impediments should be explored to inform possible future interventions.

Conclusion

Our findings suggest that an important barrier for patients with limited English proficiency to participate in cancer studies may be the cost that consent document translation presents to investigators, particularly in studies not sponsored by industry. This work identifies a potentially modifiable barrier to enrolling these patients on studies, which is of particular importance in an increasingly multicultural and multilingual population.

Methods

Study population

After approval by the UCLA IRB, data were collected for all patients signing consent documents for studies conducted at the Cancer Center from January 1, 2013, to December 31, 2018, and data on consent events and investigator-reported patient demographics were extracted from the clinical trials database, OnCore (OnCore Enterprise Research, Advarra Inc, Columbia, MD) (Supplementary Methods). Patient characteristics, including primary language, need for a translator, insurance provider, and date of birth were obtained from the demographic section of the Epic (Epic Systems Corporation, Verona, WI) electronic health record. Using each patient's medical record number, patient data were matched to consent event data retrieved from OnCore. Study data was collected and managed using the Research Electronic Data Capture (REDCap) system, and protected health information was manipulated by a third party through the UCLA Department of Biostatistics[1,2].

Language designations

Definitions for primary language can be found in Supplementary Methods. Patients were considered to have limited English proficiency if the demographic section of the electronic health record indicated the need for an interpreter or medical record review indicated need for an interpreter during any encounter within six months of the consent date. Chart review on 200 randomly selected consent events for patients with English as their primary language evaluated whether there was an identifiable group requiring an interpreter six months before or after the consent date. Based on this analysis, adult patients with English as a primary language were considered proficient in English, while English proficiency in pediatric patients was evaluated regardless of the patient's primary language. Pediatric patients with limited English proficiency included those for whom the electronic health record indicated that the patient or parents/guardians required an interpreter within 6 months of the consent date, as the parents/guardians sign the primary consent documents. When a pediatric patient had a primary language documented as English but limited English proficiency (based on the parents/guardians), the patient was considered to have a primary language other than English and limited English proficiency.

Consent language and sponsor assessment

For all patients with a primary language other than English, consent documents were reviewed to determine whether the patient signed consent documents in their primary language. When this information was not available, all IRB-approved translated consent documents were reviewed. We considered patients to have signed consent documents in their primary language if IRB-approved consent documents were available at the time of consent or within the subsequent 30 days (Supplementary Methods).

An additional analysis was restricted to consent events for which there were no translated consent documents at the time of consent or within the subsequent 30 days to identify patients who definitively signed English consent documents. Another analysis evaluated the odds of patients with *Spanish* as their primary language signing consent documents to studies that had *Spanish* consent documents at study opening.

Study type and sponsor assessment

The Cancer Center labels studies as interventional when a clear pharmacologic, dietary, lifestyle intervention, procedural, or diagnostic intervention was performed with other studies labeled as observational. We lacked access to complete budgetary data, but the study sponsor was documented. Studies considered industry sponsored had a biopharmaceutical company that evaluated a drug, device or procedure, serve as the principal funding sponsor. All other studies were considered non-industry sponsored. An additional analysis was performed, dividing studies based on whether any funds for consent document translation could have been provided by an industry partner (i.e. the study did not receive funding from industry beyond study drug or device) versus studies in which funds for consent document translation from industry could not be ruled out. Studies including only patients younger than 18 were considered pediatric-only, while studies that included only patients 18 or older were considered adult-only. Studies were also reviewed to assess whether they included a single solid or hematologic malignancy, multiple histologies or healthy patients.

Assessment of cost of consent document translation

For simplicity, we assumed that every study had the initial consent document translated at twenty cents per word, the median cost for translation paid by the Cancer Center during the evaluated period. (Supplementary Methods).

Statistical Analyses

Patient characteristics were summarized using frequency (%) and compared using Pearson Chi-square tests (Supplementary Methods). The median number of consent events between studies sponsored and not sponsored by industry were compared using the Wilcoxon Rank Sum test.

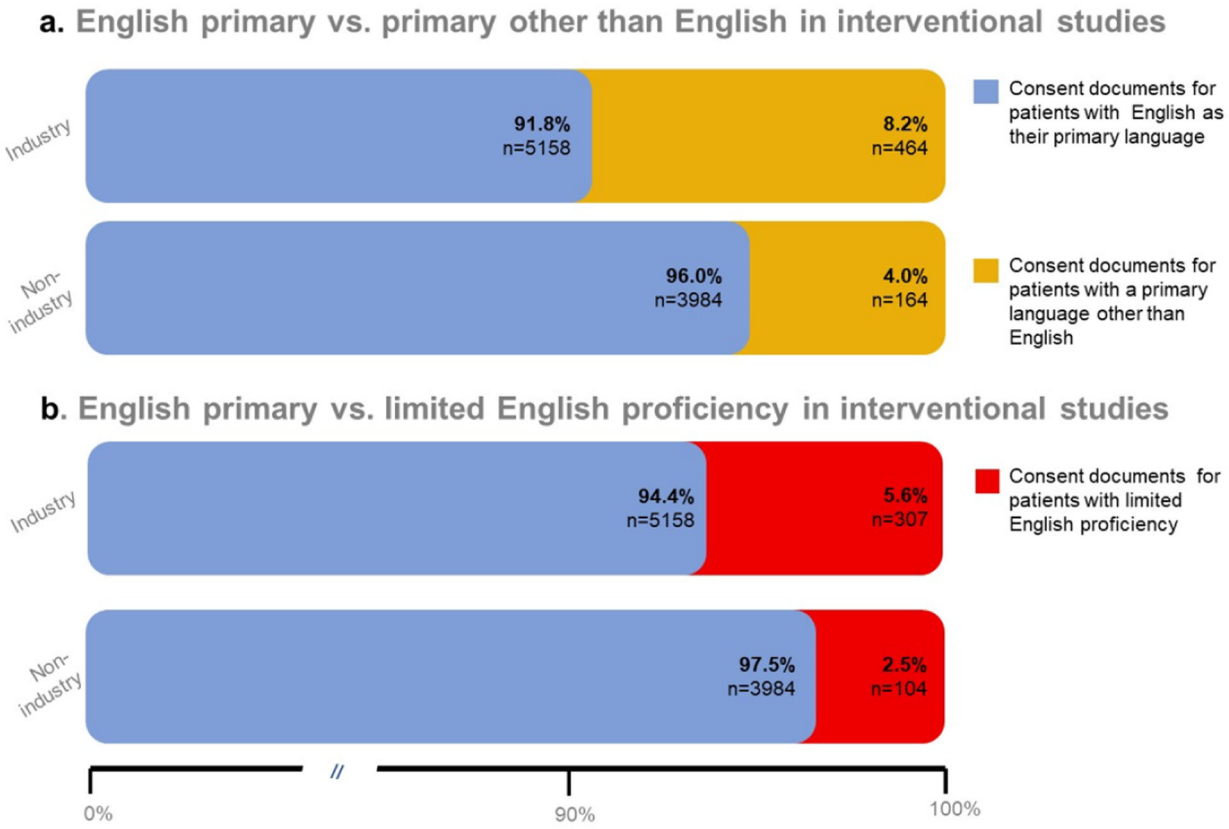
Logistic regression models with Generalized Estimating Equations clustered by patient unique identifier to adjust for repeated measures compared consent events for non-industry versus industry sponsored studies. As a sensitivity analysis, the same Generalized Estimated Equation models were run specifying patients nested within each study as the repeated effect. Models were constructed in two consent event groupings: all consent events and the

subset in which patients signed consent documents in their primary language. The main explanatory variable was a language grouping variable (English primary versus primary other than English or limited English proficiency). Additional covariates were prospectively identified: age at consent, a single category for race and ethnicity in which Hispanic patients were coded as such regardless of race [i.e., Hispanic, Black, Asian or Pacific Islander, other (which included race or ethnicities in whose proportion in the evaluated population was less than 4.0%), non-Hispanic White], female versus male, interventional versus non-interventional, and the study's included histologies (single hematologic malignancy, solid malignancy, multiple histologies or healthy patients). A variable evaluating whether each patient had Medi-Cal as their payor was subsequently added for specific analyses (patient with Medi-Cal as their payor, Yes versus No). For each set of models, we first constructed bivariable and then multivariable models. Additional analyses estimated the effect of the language grouping variable within subgroups based on the Department conducting the study and interventional studies. Consent events missing primary language were excluded from all analyses. Other methods for handling missing data are described in Supplementary Methods.

The McNemar's test compared the subset of patients who signed consent documents for both industry and non-industry sponsored studies to identify the probability of signing translated consent documents for a study based on whether or not the study had industry sponsorship (Supplementary Methods).

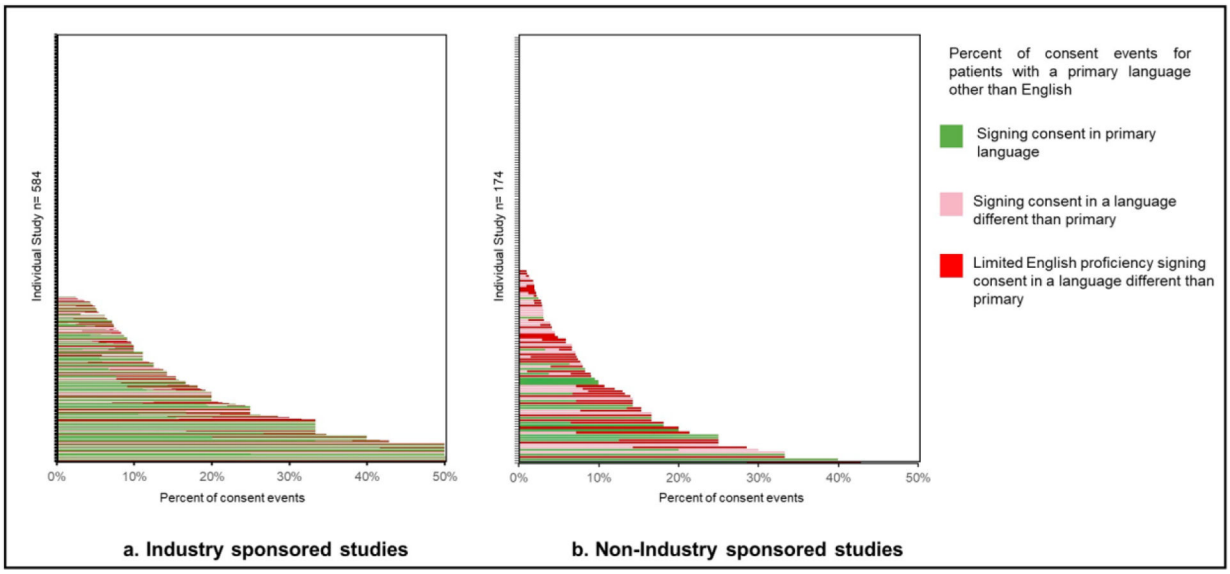
For all tests, a two-tailed P-Value <0.05 was considered statistically significant. Data were analyzed using SAS software, version 9.3 (SAS Institute) and JMP Pro 16.0 (SAS Institute Inc., Cary, NC, USA).

Extended Data



Extended Data Figure 1.

Comparison of the proportion of consent events based on primary language and English proficiency in interventional industry versus non-industry sponsored studies. **A**. Blue indicates the proportion of consent events for patients with English as their primary language. Yellow indicates the proportion of consent events for patients with a primary language other than English in industry sponsored studies (top bar) versus non-industry sponsored studies (bottom bar) (8.2% versus 4.0%, $p<0.001$). **B.** Blue indicates the proportion of consent events for patients with English as their primary language. Red indicates the proportion of consent events for patients with limited English proficiency in industry sponsored studies (top bar) versus non-industry sponsored studies (bottom bar) (5.6% versus 2.5%, $p<0.001$). Logistic regression models with Generalized Estimating Equations clustered by patient unique identifier were used to test comparisons above, p-values reported are two-tailed.



Extended Data Figure 2.

Comparison of the percentage of patients signing consent documents per study between industry and non-industry sponsored studies. The X axis depicts the percentage of patients signing consent documents for each study who had a primary language other than English in industry (a) and non-industry sponsored studies (b). Each study is represented by a row in the Y axis. The rows are taller for non-industry sponsored studies compared to industry sponsored studies as there are fewer of them. Green denotes the percentage of patients who signed consent in their primary language, pink represents the percentage of patients signing consent documents in a language different than their primary language and red represents the percentage of patients with limited English proficiency signing consent document in a language different than primary.

Extended Data

Extended Data Table 1.

Characteristics of patients who signed consent documents to Cancer Center studies.

Characteristic, n (%)	Total n=9213	English Primary n=8636 (93.7)	Primary Other than English n=577 (6.3)	P Value[a]	Limited English Proficiency n=376 <4.0)	P Value[b]
Gender [c]						
Female	3513 (38.1)	3255 (37.7)	260 (45.1)	<0.001[d]	175 (46.5)	<0.001[e]
Male	5686 (61.7)	5368 (62.2)	316 (54.8)		201 (53.4)	
Race and Ethnicity [f]				<0.001[g]		<0.001[h]
Asian or Pacific Islander	901 (9.8)	680 (7.8)	221 (38.3)	<0.001	139 (37.0)	<0.001
Black	389 (4.2)	389 (4.5)	0	<0.001	0	<0.001
Other[i]	279 (3.0)	262 (3.0)	17 (3.0)	0.725	13 (3.5)	0.804
Hispanic	902 (9.7)	687 (7.9)	215 (37,2)	<0.001	160 (42.5)	<0,001

Characteristic, n (%)	Total n=9213	English Primary n=8636 (93.7)	Primary Other than English n=577 (6.3)	P Value[a]	Limited English Proficiency n=376 <4.0)	P Value[b]
Non-Hlspanlc White	5840 (63.4)	5744 (66.5)	96 (16.6)	<0.001	50 (13.3)	<0.001
Medi-Cal as payor [j]						
Yes	879 (9.5)	597 (6.9)	282 (48.8)	<0.001[k]	206 (55.1)	<0.001[l]
No	8270 (89.8)	7983 (92.4)	287 (49.7)		162 (43.3)	

[a]Comparison between patients with primary language other than English and English as primary language.

[b]Comparison between patients with limited English proficiency and English as primary language.

[c]Unknown Total: 14 (0.2%).

[d]Comparison of the proportion of female and male patients between patients with a primary language other than English and English as primary language.

[e]Comparison of the proportion of female and male patients between patients limited English proficiency and patients with English as primary language.

[f]Unknown Total: 902 (9.7%).

[g]Comparison of the proportion by racial and ethnic groups among patients with primary language other than English and English as primary language.

[h]Comparison of the proportion by racial and ethnic groups among patients with limited English proficiency and English as primary language.

[i]Other: American Indian; 16 (0.2%), Multiracial; 28 (0.3%), Other; 235 (2.5%).

[j]Unknown Total: 64 (0.7%).

[k]Comparison of the proportion of patients with Medi-Cal as their payor between patients with a primary language other than English and patients with English as primary language.

[l]Comparison of the proportion of patients with Medi-Cal as their payor between patients with limited English proficiency and patients with English as primary language. All statistical comparisons were performed using Pearson's chi-squared test, no adjustments were made for multiple comparisons. Abbreviations: n, number. Racial and ethnic groups representing less than 4.0% of the study population were included as "other".

Extended Data Table 2.

Primary languages spoken by patients with a primary language other than English.

Language	Number of patient	Percent
Spanish	231	40.8%
Chinese[a]	118	20.8%
Korean	63	11.1%
Farsi, Persian	33	5.8%
Armenian	30	5.3%
Russian	20	3.5%
Viebiamese	19	3.4%
Japanese	12	2.1%
Arabic	8	1.4%
Other	6	1.1%
TS93I03	6	1.1%
Hindi	<5	<0.4%
Hungarian	<5	<0.4%

Language	Number of patient	Percent
Lithuanian	<5	<0.4%
Thai	<5	<0.4%
Afar	<5	<0.4%
Burmese	<5	<0.4%
Cambodan	<5	<0.4%
Danish	<5	<0.4%
Ethiopian	<5	<0.4%
French	<5	<0.4%
Greek	<5	<0.4%
Hebrew	<5	<0.4%
Indonesian	<5	<0.4%
Italian	<5	<0.4%
Laotian	<5	<0.4%
Ukrainian	<5	<0.4%

[a]Chinese includes Mandarin, Cantonese, and Simplified Chinese

Extended Data Table 3.

Characteristics and distribution of consent events in non-industry and industry sponsored studies.

	Non-industry Sponsored Study	Industry Sponsored Study	P Value
Studies, N (%)	173 (22.9)	585 (77.1)	
Studies with at least one translated consent document, N (% per sponsor type)	39 (23)	222 (38)	<0.001[a]
Consent events, N (%)	6344 (52.5)	5738 (47.5)	
Consent events for studies that translated at least one consent document, N (%, per sponsor type)	1513 (23.9)	2951 (51.4)	<0.001[a]
Median number of consent events per study (range)	8.0 (1–791)	5.0 (1–206)	<0.001[b]
Median number of consent events for studies that translated at least one consent document (range)	9.5 (1–510)	8.0 (1–206)	0.577[b]
Median number of consent events for studies that did not translate at least one consent (range)	8.0 (1–791)	4.0 (1–93)	<0.001[b]
Number of Interventional studies, N (%)	143 (19.8)	577 (80.2)	
Median number of consent events for interventional studies (range)	8.0 (1–585)	5.0 (1–206)	<0.001[b]

[a]Statistical comparisons were performed using Pearson's chi-squared.

[b]Statistical comparisons were performed using the Wilcoxon Rank Sum Test. P-values reported are two tailed. No adjustments were made for multiple comparisons. Abbreviations, OR; odds ratio, CI; confidence Interval.

Extended Data Table 4.

Analysis of studies with translated consent documents in Spanish and odds of signing consent based on consent document translation availability at study opening.

	Non-Industry Sponsored Study	Industry Sponsored Study
Studies with translated consent documents in Spanish available at the start of study opening, N [a]	2	10
Consent events for studies with Spanish consent documents available at the start of study opening, N (%, per sponsor type) [b]	127 (2.0)	142 (2.4)
Consent events for patients with a primary language other than English[c]	10 (3.6)	31 (6.7)
Consent events for patients with limited Enqlish proficiency[d]	5 (2 .8)	26 (8.4)
Consent events for patients with Spanish as their primary language[e]	9 (6.9)	23 (13.0)
Consent events for patients with Spanish as their primary language who had limited English proficiency[f]	5 (5,7)	20 (16.1)
At study opening	**OR**	**95% Cl**
Odds for patients with Spanish as their primary language of signing of consent to studies with Spanish translation compared to studies without them.	5.7	3.8–8.5
Odds for patients with a primary language other than English or Spanish of signing consent to studies with a Spanish translation compared to studies without them.	0.9	0.6–1.3
At any time dunng the study		
Odds for patients with a primary language other than English of signing consent in a language different than primary to studies that had translated consent documents.	0.02	0.009–0.030
Odds for patients with limited English proficiency of signing consent in a language different than primary to studies that had translated consent documents.	0.02	0.009–0.037

[a] Other languages in which studies had available translated consent documents at study opening included: Chinese (n=1), Farsi (n=1), Hebrew (n=1), Japanese (n=1), Korean (N=1), Thai (n=1).

[b] Denominator is consent events per sponsor type (non-industry sponsored studies n=6344, industry sponsored studies n=5738).

[c] Denominator is consent events for patients with a primary language other than English within that sponsor type (non-industry sponsored studies n=278, industry sponsored studies n=464).

[d] Denominator is consent events for patients with limited English proficiency within that sponsor type (non-industry sponsored studies n=174, industry sponsored studies n=307).

[e] Denominator is consent events for patients with Spanish as their primary language within that sponsor type (non-industry sponsored studies n=129, industry sponsored studies n=176).

[f] Denominator is consent events for patients with Spanish and limited English proficiency within that sponsor type (non-industry sponsored studies n=88, industry sponsored studies n=124).

Odds ratios (with 95% CI) were estimated from a logistic regression model with Generalized Estimating Equations clustered by patient identifier. P-values reported are two tailed. No adjustments were made for multiple comparisons. Abbreviations, OR; odds ratio, CI; confidence Interval.

Extended Data Table 5.

Proportion of consent events in which patients with a primary language other than English and limited English proficiency who signed consent documents in a language different than primary in industry sponsored and non-industry sponsored studies across Departments.

Department	Proportion (%)	95% CI	P Value
Primary language other than English			
Medicine			<0.001
Industry Sponsored Study	39.5	34.8 – 44.4	
Non-Industry Sponsored Study	62.5	53.5–70.9	
Radiology and Molecular Pharmacology			0.003
Industry Sponsored Study	60.0	26.2–87.8	
Non-Industry Sponsored Study	98.4	91.2–99.9	
Pediatrics			NA[a]
Industry Sponsored Study	0.0	0.0–84.1	
Non-Industry Sponsored Study	19.2	6.5–39.5	
Radiation Oncology			NA[b]
Industry Sponsored Study	100.0	63.0–100	
Non-Industry Sponsored Study	100.0	79.4–100	
Surgical specialties			0.082
Industry Sponsored Study	82.6	6.1.2–95.5	
Non-Industry Sponsored Study	97.3	85.8–99.9	
Other			NA[C]
Industry Sponsored Study	100	54.0–100	
Non-Industry Sponsored Study	44.4	13.7–78.8	
Limited English Proficiency			
Medicine			<0.001
Industry Sponsored Study	27.4	22.2–33.0	
Non-Industry Sponsored Study	58.2	46.5–69.2	
Radiology and Molecular Pharmacology			0.013
Industry Sponsored Study	55.6	21.2–86.3	
Non-Industry Sponsored Study	97.4	86.1–99.9	
Pediatrics			NA[a]
Industry Sponsored Study	0.0	0.0–84.2	
Non-Industry Sponsored Study	19.2	6.6–39.4	
Radiation Oncology			NA[b]
Industry Sponsored Study	100.0	54.0–100	
Non-Industry Sponsored Study	100.0	66.3–100	
Surqical specialties			0.112
Industry Sponsored Study	69.2	38.5–90.9	
Non-Industry Sponsored Study	93.7	69.7–99.8	

Department	Proportion (%)	95% CI	P Value
Other			NA[C]
Industry Sponsored Study	100.0	29.2–100	
Non-Industry Sponsored Study	40.0	5.3–85.3	

[a] P-value could not be generated because there were no patients who signed consent documents in a language different than primary in industry sponsored studies.

[b] P-value could not be generated because there were no consent documents translated.

[c] P-value could not be generated because there were no patients who signed consent documents in a language different than primary in industry sponsored studies. A logistic regression model with Generalized Estimating Equations

clustered by patient unique identifier was used to compare the proportions above. P-values reported are two tailed. No adjustments were made for multiple comparisons.

Extended Data Table 6.

Bivariable analysis odds ratio for the association between various factors and signing consent into a non-industry sponsored study.

	Bivariable Analysis for signing consent documents			Bivariable Analysis for signing consent documents in patient's primary language		
Variable	**OR**	**95% CI**	**P Value**	**OR**	**95% CI**	**P Value**
Age						
Age at consent (per year)	0.99	0.98–0.99	<0.001	0.99	0.98 0.99	<0.001
Language						
Enqlish Primary		**Reference**			**Reference**	
Primary Other than English[a]	0.50	0.43–0.59	<0.001	0.25	0.19–0.32	<0.001
Limited English Proficiency[b]	0.47	0.38–0.57	<0.001	0.24	0.18–0.32	<0.001
Race and Ethnicity						
Non-Hispanic White		**Reference**			**Reference**	
Asian or Pacific islander	0.61	0.53–0,69	<0.001	0.61	0.53–0.70	<0.001
Black	1.22	0.92–1.36	0.250	1.13	0.93–1.37	0.215
Hispanic	0.81	0.71–0.92	0.002	0.79	0.69–0.90	<0.001
Other	1.44	1.13–1,83	0.004	1.44	1.13–1.85	0.004
Unknown	3.34	2.89–3.94	<0.001	3.36	2.84–3.97	<0.001
Study Type						
Interventional		**Reference**			**Reference**	
Observational	32.4	25.1–41.8	<0.001	31.1	24.1–40.1	<0.001
Gender						
Male		**Reference**			**Reference**	
Female	0.37	0.34–0.40	<0.001	0.36	0.33–0.39	<0.001
Histology						
Single Solid Malignancy		**Reference**			**Reference**	

	Bivariable Analysis for signing consent documents			Bivariable Analysis for signing consent documents in patient's primary language		
Variable	**OR**	**95% Cl**	**P Value**	**OR**	**95% Cl**	**P Value**
Healthy	1.62	1.23–2.14	<0.001	1.70	1.28–2.27	<0.001
Multiple Histology	0.46	0.42–0.50	<0.001	045	0.41–0.49	<0.001
Single Heme Maliqnancy	0.07	0.05–0.09	<0.001	0.07	005–0.09	<0.001

[a]Patients with a primary language other than English compared to patients with English as their primary language.

[b]Patients with limited English proficiency compared to patients with English as their primary language. Odds ratios (with 95% CI) were estimated from a logistic regression model with Generalized Estimating Equations clustered by patient identifier. P-values reported are two tailed. No adjustments were made for multiple comparisons. Abbreviations, OR; odds ratio, CI; confidence Interval.

Extended Data Table 7.

Multivariable analysis for odds ratio for the association between various factors including Medi-Cal status and signing consent into a non-industry sponsored study nested by individual patient.

	Multivariable Analysis for patients with a primary language other than English signing consent documents			Multi variable Analysis for patients with a primary language other than English signing consent documents in patient's primary language			Multivariable Analysis for patients with limited English proficiency signing consent documents			Multivariable Analysis for patients with limited English proficiency signing consent documents in patient's primary language		
Variable	**OR**	**95% Cl**	**P Value**	**OR**	**95% Cl**	**P Value**	**OR**	**95% Cl**	**P Value**	**OR**	**95% Cl**	**P Value**
Age												
Age at consent (per year)	0.97	0.97–0.98	<0,001	0.98	0.97–0,98	<0.001	0.97	0.97–0.98	<0.001	0.98	0.97–0.98	<0.001
Language												
English Primary	**Reference**			**Reference**			**Reference**			**Reference**		
Primary Other than English[a]	0.78	0.63–0.98	0.033	0.39	0.29–0.54	<0.001	-			-	-	
Limited English Proficiency[b]	-		-	-		-	0.80	0.62–1.00	0.105	0.38	0.27–0.54	<0.001
Race and Ethnicity												
Non-Hispanic White	**Reference**			**Reference**			**Reference**			**Reference**		
Asian or Pacific Islander	0.64	0.54–0.76	<0.001	0.66	0.56–0.79	<0.001	0.65	0.55–0.77	<0.001	0.66	0.55–0.79	<0.001
Black	1.03	0.81–1.29	0.833	1.03	0.81–1.30	0.787	1.03	0.82–1.30	0.805	1.03	0.81–1.30	0.776
Hispanic	0.75	0.63–0.89	0.001	0.76	0.63–0.91	0.003	0.74	0.62–0.88	<0.001	0.75	0.63–0.90	<0.002
Other	1.16	0.87–1.54	0.306	1.16	0.87–1.56	0.306	1.15	0.87–1.54	0.323	1.16	0.87–1.56	0,304
Unknown	3.36	2.83–3.98	<0.001	3.36	2.83–3.99	<0.001	3.40	2.86–4.04	<0.001	3.39	2.89–4.04	<0.001
Study Type												

	Multivariable Analysis for patients with a primary language other than English signing consent documents			Multi variable Analysis for patients with a primary language other than English signing consent documents in patient's primary language			Multivariable Analysis for patients with limited English proficiency signing consent documents			Multivariable Analysis for patients with limited English proficiency signing consent documents in patient's primary language		
Variable	**OR**	**95% Cl**	**P Value**	**OR**	**95% Cl**	**P Value**	**OR**	**95% Cl**	**P Value**	**OR**	**95% Cl**	**P Value**
Interventional		**Reference**			**Reference**			**Reference**			**Reference**	
Observational	36.3	28,4–46,5	<0.001	35.2	27.4–45.1	<0.001	35.5	27.7–45.4	<0.001	35.0	27.3–45.8	<0.001
Gender												
Male		**Reference**			**Reference**			**Reference**			**Reference**	
Female	0.38	0.34–0.42	<0.001	0.37	0.33–0.41	<0.001	0.37	0.34–0.42	<0.001	0.37	0.38–0.45	<0.001
Histology												
Single Solid Malignancy		**Reference**			**Reference**			**Reference**			**Reference**	
Healthy	1.73	1.30–2.3	<0.001	1.82	1,38–2.43	<0.001	1.77	1.34–2.30	<0.001	1.83	1,38–2.40	<0.001
Multiple Bistoloqy	0.38	0.35–0.43	<0.001	0.38	0.34–0.42	<0.001	0.39	0.35–0.43	<0.001	0.38	0.35–0.42	<0.001
Single Heme Malignancy	0.06	0.04–0.09	<0.001	0.06	0.04–0.09	<0.001	0.06	0.04–0.09	<0.001	0.06	0.04–0.09	<0.001
Medi-Cal [c]												
No		**Reference**			**Reference**			**Reference**			**Reference**	
Yes	0.81	0.68–0.97	0.021	0.81	0.67–0.98	0.034	0.78	0.66–0.95	0.015	0.83	0.66–0.97	0.025
Unknown	3.66	1.73–7.64	<0.001	3.73	1,97–8.12	<0.001	3.42	1.61–7,2	<0.001	3.49	1,55–7.72	<0.001

[a] Patients with a primary language other than English compared to patients with English as their primary language.

[b] Patients with limited English proficiency compared to patients with English as their primary language.

[c] The p-value for the overall interaction between Medi-Cal and primary language other than English or English as primary language was p=0.163, and the overall p-value for the interaction between Medi-Cal and limited English proficiency, English as primary language was p=0.275. Odds Ratios were estimated with a Generalized Estimating Equation Model clustered by patient. P-values reported are two tailed. No adjustments were made for multiple comparisons. Abbreviations, OR; odds ratio, CI; confidence Interval.

Extended Data Table 8.

Multivariable analysis for odds ratio for the association between various factors and signing consent into a non-industry sponsored study nested by study.

	Multivariable Analysis Tor patients with a primary language other than English signing consent documents			Multivariable Analysis for patients with a primary language other than English signing consent documents in patient's primary language			Multivariable Analysis for patients with limited English proficiency signing consent documents			Multivariable Analysis for patients with limited English proficiency signing consent documents in patient's primary language		
Variable	OR	95% Cl	P Value	OR	95% Cl	P Value	OR	95% Cl	P Value	OR	95% Cl	P Value
Age												
Age at consent (per year)	0.97	0.97–0.98	<0.001	0.98	0.97–0.98	<0.001	0.97	0.97–0.98	<0.001	0.98	0.97–0.98	<0.001
Language												

	Multivariable Analysis Tor patients with a primary language other than English signing consent documents			Multivariable Analysis for patients with a primary language other than English signing consent documents in patient's primary language			Multivariable Analysis for patients with limited English proficiency signing consent documents			Multivariable Analysis for patients with limited English proficiency signing consent documents in patient's primary language		
English Primary	**Reference**			**Reference**			**Reference**			**Reference**		
Primary Other than English[a]	0.79	0.65–0.96	0.019	0.40	0.30–0.54	<0.001	-	-				-
Limited English Proficiency[b]	-	-		-	-		0.78	0.61–0.99	0.045	0.38	0.27–0.53	<0.001
Race and Ethnicity												
Non-Hispanic White	**Reference**			**Reference**			**Reference**			**Reference**		
Asian or Pacific Islander	0.55	0.48–0.66	<0.001	0.58	0.49–0.69	<0.001	0.63	0.53–0.73	<0.001	0.58	0.49–0.69	<0.001
Black	0.95	0.76–1.28	0.608	0.94	0.76–1.17	0.605	1.05	0.84–1.30	0.660	0.94	0.76–1.18	0.600
Hispanic	0.67	0.58–0.78	<0.001	0.68	0.58–0.80	<0.001	0.75	0.64–0.88	<0.001	0.68	0.57–0.80	<0.001
Other	0.99	0.77–1.28	0.972	1.00	0.77–1.29	0.996	1.13	0.87–1.45	0.358	1.00	0.77–1.29	0.996
Unknown	1.12	0.86–1.41	0.315	1.12	0.89–1.40	0.318	3.31	2.78–3.94	<0.001	1.12	0.89–1.40	0.318
Study Type												
Interventional	**Reference**			**Reference**			**Reference**			**Reference**		
Observational	30.3	24.8–37.2	<0.001	29.2	23.8–35.9	<0.001	31.3	25.6–28.8	<0.001	29.1	23.7–35.8	<0.001
Gender												
Male	**Reference**			**Reference**			**Reference**			**Reference**		
Female	0.36	0.33–0.39	<0.001	0.36	0.32–0.39	<0.001	0.38	0.35–0.42	<0.001	0.35	0.32–0.39	<0.001
Histology												
Single Solid Maiignancy	**Reference**			**Reference**			**Reference**			**Reference**		
Healthy	1.73	1.30^2.3	<0.001	1.83	1.37–2.44	<0.001	1.78	1.37–2.52	<0.001	1.84	1.41–2.45	<0.001
Multiple Histology	0,33	0.30–0.37	<0.001	0.33	0.30–0.36	<0.001	035	0.32–0,39	<0,001	0,33	0.30–0.37	<0.001
Single Heme Malignancy	0.06	0.04–0.09	<0.001	0.06	0.04–0.09	<0.001	0.06	0.04–0.09	<0.001	0.06	0.04–0,09	<0.001

[a]Patients with a primary language other than English compared to patients with English as their primary language.

[b]Patients with limited English proficiency compared to patients with English as their primary language. Odds ratios (with 95% CI) were estimated from a logistic regression model with Generalized Estimating Equations clustered by study, P-values reported are two-tailed. Abbreviations, OR; odds ratio, CI; confidence Interval.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments:

Figure 1. was created using BioRender.com. We would like to thank Jeff Allen and Rebecca Flores Stella for their assistance.

This work was funded by E.B.G.'s UCLA Jonsson Comprehensive Cancer Center Seed Grant.

Competing Interest Declaration:

E.B.G. was funded by NIH-NCI R01 CA276917, the Cancer Center Support Grant P30 CA016042, and NIH-NCATS UL1TR001881, CLIN-10784. A.L.C. was funded by a Specialty Training and Advanced Research (STAR) Award. A.L. was funded by NIH-NCI K08 CA245249-01A1 and a LUNGevity 2019 Career Development Award. E.B.G. is also funded by CLIN-10784. M.A.T. was funded by P30CA016042- Cancer Center Support Grant, UCLA Jonsson Comprehensive Cancer Center. D.E., was funded by the National Center for Advancing Translational Science (NCATS) of the National Institutes of Health under the UCLA Clinical and Translational Science Institute grant number UL1TR001881. M.A.V, B.A.G., M.G.J., A.N., Y.R., J.P.LP., P.M.B., D.Y.L., M.J.F.T., A.G., M.L., M.H., J.B., T.G., have no funding to disclose and no competing interests.

E.B.G., has been a consultant and/or Advisor for Abbvie; ABL-Bio; AstraZeneca, Boehringer-Ingelheim; Bristol Myers Squibb; Dracen Pharmaceuticals; EMD Serono; Eisai; Eli Lilly; Gilead; GlaxoSmithKline; Ipsen; Merck; Natera; Novartis; Personalis; Regeneron; Sanofi; Shionogi; and Xilio. E.B.G., has received Grant/Research Support from ABL-Bio; AstraZeneca; Bristol Myers Squibb; Dynavax Technologies; Eli Lilly; EMD Serono; Genentech; Iovance Biotherapeutics; Merck; Mirati Therapeutics; Neon; and Novartis. A.E.L has received commercial research grants from Daiichi Sankyo, Calithera Biosciences, AstraZeneca, Dracen Pharmaceuticals, WindMIL, eFFECTOR Therapeutics. A.E.L. has served as a consultant/Advisory Board for, AstraZeneca, Bristol-Myers Squibb, Leica Biosystems, Jazz Pharmaceuticals, Novocure, Pfizer, MorphoSys, Eli-Lilly, Oncocyte, Novartis, Regeneron, Janssen oncology, Sanofi group of companies.

Data Availability statement:

All consent event data associated with this study and data contained in Extended Data tables are freely available at: https://doi.org/10.5281/zenodo.7992491

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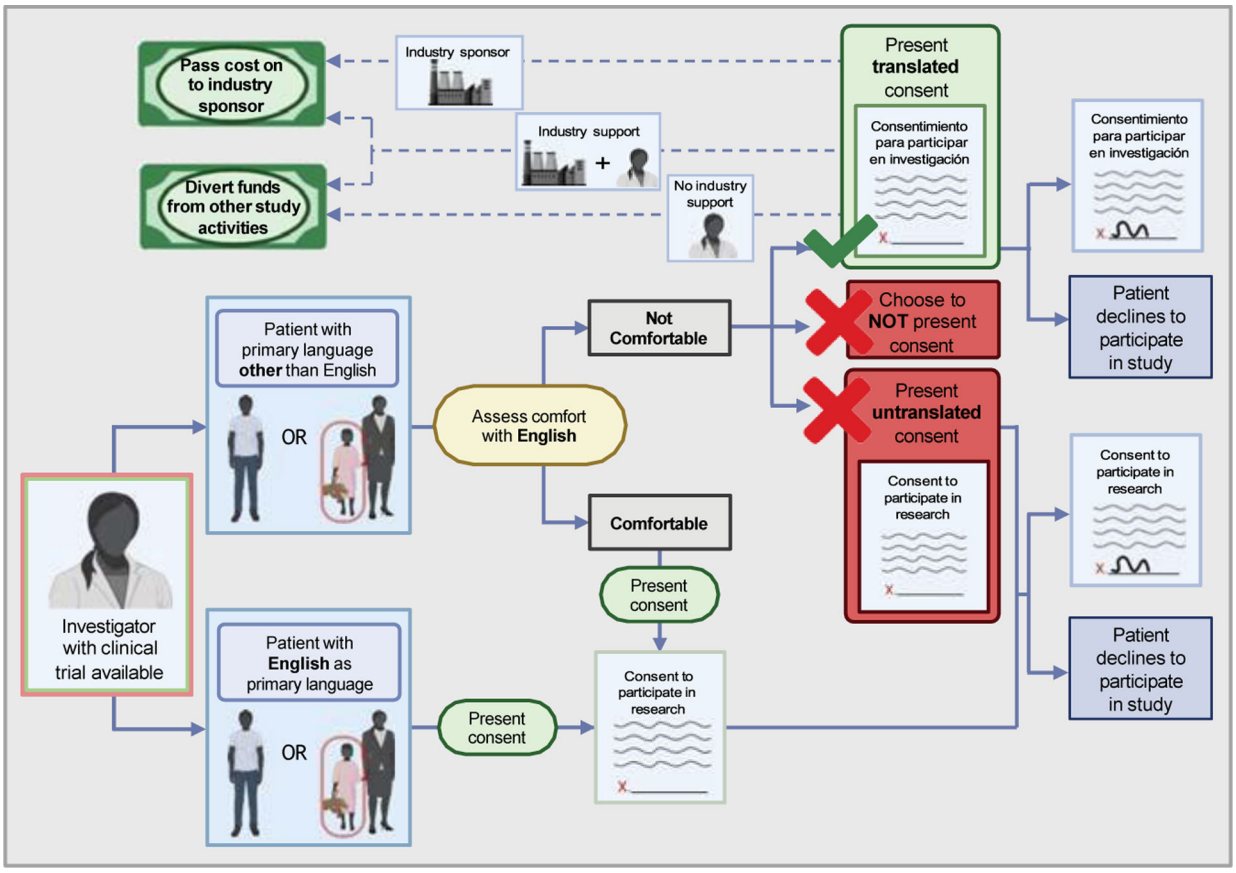

Figure 1.

Consent process and cost allocation of consent document translation. An investigator meeting an eligible patient for a clinical trial should assess the patient's (or parent/guardian's) comfort with signing an English consent document. If patient (or parent/guardian) is not comfortable signing consent documents in English, the investigator should translate the consent documents. Depending on the study funder, this cost can be either completely passed on to the industry sponsor, potentially covered by the industry sponsor or covered completely by the investigator.

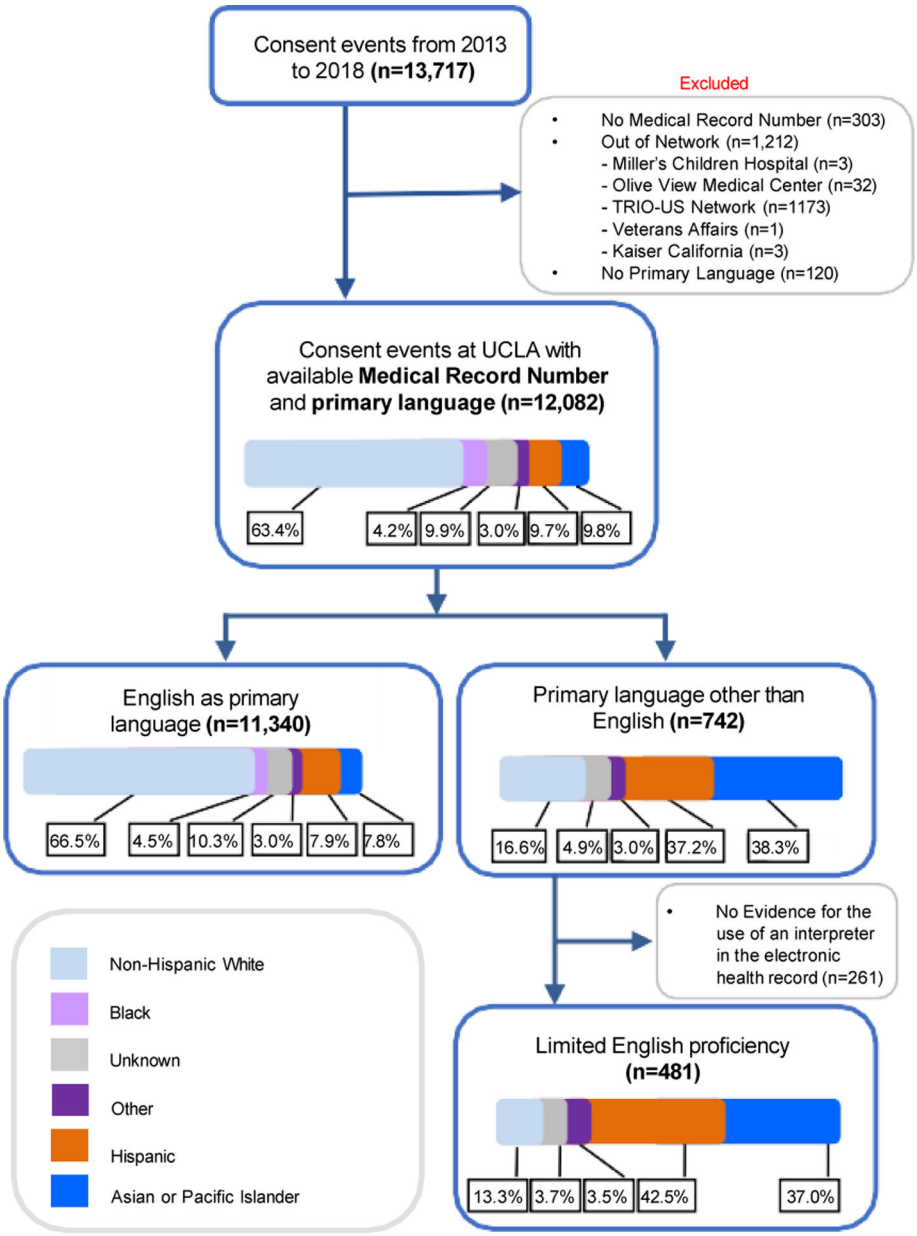

Figure 2.

Consent events included in the study. Consent event data for patients who signed consent documents for Cancer Center studies from 2013 to 2018 were included in our analysis if they had a medical record number in our electronic health system as well as a documented primary language (n=12,082). Patients were considered to have English as their primary language (English Primary, n=11,340) or to have a primary language other than English (n=742). Patients with a primary language other than English were considered to have limited English proficiency if there was evidence for the use of an interpreter in the electronic health record. The racial/ethnic distribution of patients is depicted by color with the representative colors described in the box on the lower left.

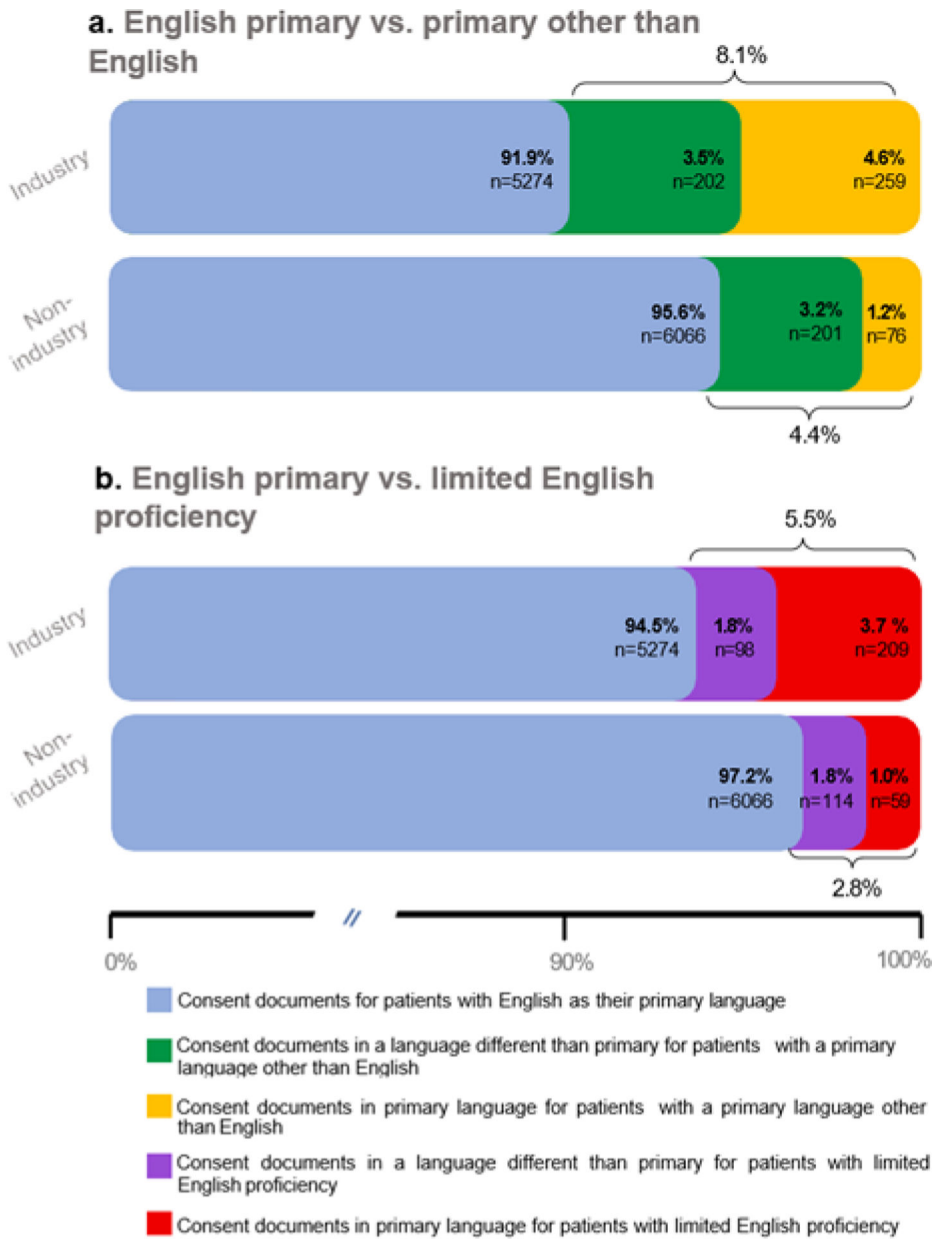

Figure 3.

Comparison of the proportion of consent events based on primary language and English proficiency in industry versus non-industry sponsored studies. **a**. Blue indicates the proportion of consent events for patients with English as their primary language. The bracketed areas indicate the proportion of consent events for patients with a primary language other than English in industry sponsored studies (top bar) versus non-industry sponsored studies (bottom bar) (8.1% versus 4.4%, $p<0.001$). Green indicates the proportion of consent events for patients with a primary language other than English signing consent documents in a language different than their primary in industry sponsored studies (top bar) compared to non-industry sponsored studies (bottom bar) (3.5% versus 3.2%, $p=0.391$). Yellow indicates the proportion of consent events for patients with a primary language other

than English signing consent documents in their primary language in industry sponsored studies (top bar) compared to non-industry sponsored studies (bottom bar) (4.6% versus 1.2%, p<0.001). **b.** Blue indicates the proportion of consent events for patients with English as their primary language. The bracketed areas indicate the proportion of consent events for patients with limited English proficiency in industry sponsored studies (top bar) versus non-industry sponsored studies (bottom bar) (5.5% versus 2.8%, p<0.001). Purple indicates the proportion of consent events for patients with limited English proficiency signing consent documents in a language different than their primary in industry sponsored studies (top bar) compared to non-industry sponsored studies (bottom bar) (1.8% versus 1.8%, p=0.643). Red indicates the proportion of consent events for patients limited English proficiency signing consent documents in their primary language in industry sponsored studies (top bar) compared to non-industry sponsored studies (bottom bar) (3.7% versus 1.0% p<0.001). Logistic regression models with Generalized Estimating Equations clustered by patient identifier compared the proportions above, p-values reported are two-tailed.

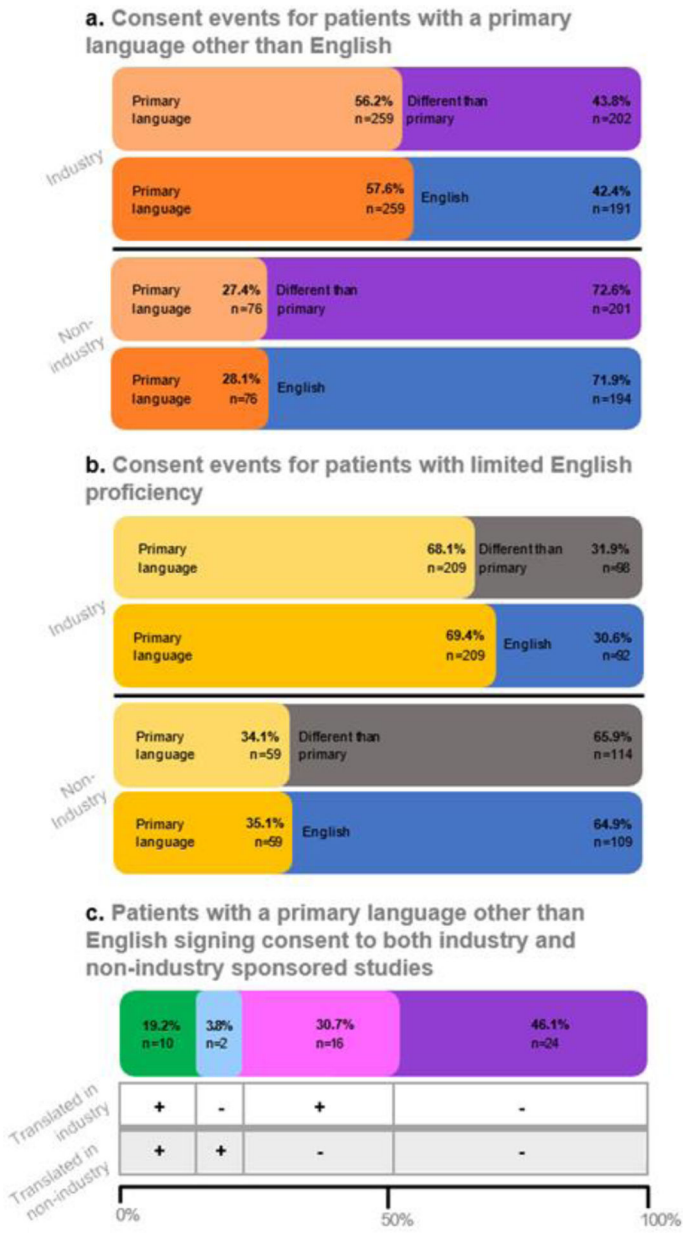

Figure 4.

Comparison of the proportion of consent events by language. **a.** Orange bars indicate the proportion of consent events for which patients with a primary language other than English signed consent documents in their primary language in industry versus non-industry sponsored studies (light orange, 56.2% versus 27.4%, p<0.001; dark orange, 57.6% versus 28.1%, p<0.001). Purple bars indicate the proportion of consent events for which patients signed consent documents in a language different than primary in industry versus non-industry sponsored studies (43.8% versus 72.6%, p<0.001). Blue indicates the proportion of consent events for which patients signed consent documents in English in industry versus non-industry sponsored studies (42.4% versus 71.9%, p<0.001) **b.** Yellow bars indicate the proportion of consent events for which patients with limited English proficiency signed

consent documents in their primary language in industry versus non-industry sponsored studies (light yellow, 68.1% versus 34.1%, p<0.001; dark yellow, 68.1% versus 35.1%, p<0.001). Grey bars indicate the proportion of consent events for which patients signed consent documents in a language different than primary in industry versus non-industry sponsored studies (31.9% versus 65.9%, p<0.001). Blue bars indicate the proportion of consent events for which patients signed consent documents in English in industry versus non-industry sponsored studies (30.6% versus 64.9%, p<0.001). Logistic regression models with Generalized Estimating Equations clustered by patient unique identifier compared the proportions above, p-values reported are two-tailed. **c**. Among patients with a primary language other than English signing consent documents for both an industry and a non-industry sponsored study, 10 (green) signed in their primary language and 24 signed in a language different than primary for both (purple). Of the 18 patients who signed consent documents in discrepant languages, 16 (pink) signed in their primary language in the industry sponsored study versus 2 (blue) in the non-industry sponsored study (McNermar's test, p=0.002).

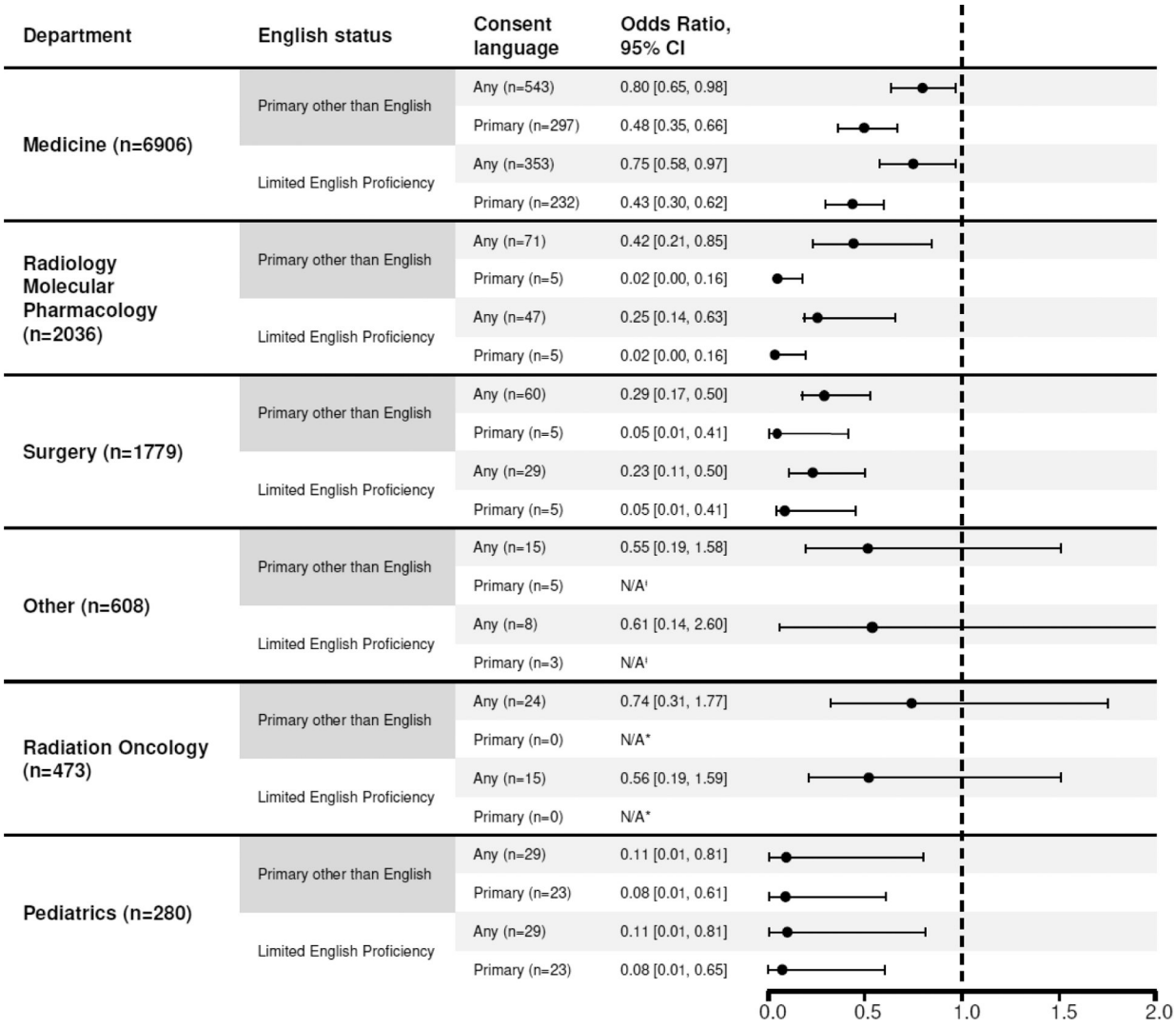

Figure 5.

Odds Ratios for patients with a primary language other than English and with limited English proficiency signing consent documents in non-industry sponsored studies compared to patients with English as their primary language across the different Departments. Odds Ratios for patients with a primary language other than English (dark grey cells) and limited English proficiency (white cells) of signing consent document in any language (light grey cells) and in the patient's primary language (white cells) were calculated using a logistic regression model with Generalized Estimating Equations clustered by patient unique identifier. Dot denotes odds ratio and bars represent 95% CI. *OR could not be calculated as no consent documents were translated into patient's primary language. ‡OR could not be calculated because there were no patients with a primary language other than English or limited English proficiency who signed consent documents in their primary language in industry sponsored studies. Abbreviations; OR, Odds Ratio, CI; confidence Interval.

Table 1.

Multivariable analysis for odds ratio for the association between various factors and signing consent documents into a non-industry sponsored study.

	Multivariable Analysis for patients with a primary language other than English signing consent documents			Multivariable Analysis for patients with a primary language other than English signing consent documents in patient's primary language			Multivariable Analysis for patients with limited English proficiency signing consent documents			Multivariable Analysis for patients with limited English proficiency signing consent documents in patient's primary language		
Variable	**OR**	**95% CI**	**P Value**	**OR**	**95% CI**	**P Value**	**OR**	**95% CI**	**P Value**	**OR**	**95% CI**	**P Value**
Age												
Age at consent (per year)	0.97	0.97–0.98	<0.001	0.97	0.97–0.98	<0.001	0.97	0.97–0.98	<0.001	0.97	0.97–0.98	<0.001
Language												
English Primary		**Reference**			**Reference**			**Reference**			**Reference**	
Primary Other than English[a]	0.74	0.63–0.94	0.005	0.38	0.28–0.52	<0.001	-	-	-	-	-	-
Limited English Proficiency[b]	-	-	-	-	-	-	0.74	0.58–0.95	0.021	0.35	0.25–0.50	<0.001
Race and Ethnicity												
Non-Hispanic White		**Reference**			**Reference**			**Reference**			**Reference**	
Asian or Pacific Islander	0.64	0.54–0.75	<0.001	0.66	0.55–0.79	<0.001	0.65	0.55–0.77	<0.001	0.66	0.55–0.79	<0.001
Black	1.00	0.80–1.26	0.978	1.01	0.80–1.28	0.916	1.06	0.80–1.27	0.972	1.01	0.80–1.27	0.921
Hispanic	0.75	0.63–0.89	<0.001	0.76	0.63–0.90	0.002	0.73	0.62–0.88	<0.001	0.74	0.62–0.90	0.002
Other	1.15	0.87–1.54	0.324	1.16	0.87–1.56	0.321	1.15	0.86–1.53	0.345	1.2	0.87–1.55	0.320
Unknown	3.38	2.86–4.01	<0.001	3.39	2.86–4.02	<0.001	3.43	2.89–4.06	<0.001	3.41	2.87–4.05	<0.001
Study Type												
Interventional		**Reference**			**Reference**			**Reference**			**Reference**	
Observational	36.2	28.3–46.4	<0.001	35.1	27.3–45.0	<0.001	35.7	27.7–37.3	<0.001	34.9	27.3–44.9	<0.001
Gender												
Male		**Reference**			**Reference**			**Reference**			**Reference**	
Female	0.38	0.35–0.42	<0.001	0.37	0.33–0.42	<0.001	0.38	0.35–0.42	<0.001	0.37	0.34–0.41	<0.001
Histology												
Single Solid Malignancy		**Reference**			**Reference**			**Reference**			**Reference**	
Healthy	1.78	1.35–2.35	<0.001	1.87	1.41–2.48	<0.001	1.86	1.37–2.52	<0.001	1.89	1.41–2.51	<0.001
Multiple Histology	0.38	0.34–0.42	<0.001	0.38	0.34–0.42	<0.001	0.36	0.33–0.40	<0.001	0.38	0.35–0.43	<0.001
Single Heme Malignancy	0.06	0.04–0.08	<0.001	0.06	0.04–0.09	<0.001	0.06	0.04–0.09	<0.001	0.06	0.04–0.09	<0.001

[a]Patients with a primary language other than English compared to patients with English as their primary language.

[b]Patients with limited English proficiency compared to patients with English as their primary language. Odds ratios (with 95% CI) were estimated from a logistic regression model with Generalized Estimating Equations clustered by patient identifier, p-values reported are two-tailed. Abbreviations, OR; odds ratio, CI; confidence Interval.