

Improving Translation and Cultural Appropriateness of Spanish-Language Consent Materials for Biobanks

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Table 1.
Participant Characteristics

	<i>Total</i> <i>n (%)</i>	<i>Traditional form</i> <i>n (%)</i>	<i>Simplified form</i> <i>n (%)</i>
Total participants	39	19 (49)	20 (51)
Gender			
Men	17 (44)	9 (47)	8 (40)
Women	22 (56)	10 (53)	12 (60)
Site			
Los Angeles	19 (49)	10 (53)	9 (45)
New York City	20 (51)	9 (47)	11 (55)
Age group			
≤ 34	12 (31)	8 (42)	4 (20)
35-44	15 (38)	5 (26)	10 (50)
45+	12 (31)	6 (32)	6 (30)
Education			
≤ high school	6 (15)	3 (16)	3 (15)
some college	20 (51)	10 (53)	10 (50)
bachelor's degree	11 (28)	5 (26)	6 (30)
postgraduate education	2 (5)	1 (5)	1 (5)
Place of origin			
Argentina	4 (10)	1 (5)	3 (15)
Colombia	5 (13)	2 (11)	3 (15)
Cuba	2 (5)	1 (5)	1 (5)
Dominican Republic	7 (18)	4 (21)	3 (15)
Ecuador	2 (5)	1 (5)	1 (5)
Guatemala	1 (3)	0 (0)	1 (5)
Honduras	1 (3)	1 (5)	0 (0)
Mexico	6 (15)	3 (16)	3 (15)
Nicaragua	2 (5)	1 (5)	1 (5)
Peru	4 (10)	2 (11)	2 (10)
Puerto Rico	4 (10)	2 (11)	2 (10)
Venezuela	1 (3)	1 (5)	0 (0)

Table 2.
Performance on Comprehension Assessment

<i>Participants who answered the following correctly</i>	<i>Total (n = 39)</i>	<i>Traditional form (n = 20)</i>	<i>Simplified form (n = 19)</i>
	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>
Q1. What is the purpose of this project? [correct: collect and store samples and health information for future research]	33 (85)	16 (84)	17 (85)
Q2. Which of the following is something the biobank will NOT do? [correct: provide me with medical care]	30 (77)	15 (79)	15 (75)
Q3. T/F: You will have blood drawn as part of this project. [correct: true]	39 (100)	19 (100)	20 (100)
Q4. T/F: The biobank will collect information from your medical records. [correct: true]	28 (72)	13 (68)	15 (75)
Q5. T/F: The biobank will let researchers study your samples and information. [correct: true]	36 (92)	18 (95)	19 (95)
Q6. Someone from the biobank might contact you about all of the following EXCEPT [correct: to let me know every time my samples and information are used in a study]	26 (67)	13 (68)	13 (65)
Q7. T/F: If you participate in the biobank, you will get personal health benefits from the research. [correct: false]	33 (85)	18 (95)	15 (75)
Q8. T/F: Unless you decide to stop taking part, there is no limit on the length of time the biobank will keep your samples and information. [correct: true]	36 (92)	19 (100)	17 (85)
Q9. T/F: Some of your genetic and health information might be put into a database outside the biobank. [correct: true]	24 (62)	12 (63)	12 (60)
Q10. The chance that someone could get access to your information or trace it back to you is ____ [correct: small, because the biobank will take many steps to protect my privacy]	35 (90)	18 (95)	17 (85)
Q11. T/F: The biobank will give researchers information that easily identifies you. [correct: false]	36 (92)	17 (89)	19 (95)
Q12. T/F: There are no laws to protect against discrimination based on your information. [correct: false]	36 (92)	18 (95)	18 (90)
Q13. If research using your sample helps lead to any new products or treatments ____ [correct: I will not get any of the profits]	39 (100)	19 (100)	20 (100)
Q14. If the researchers use your sample and information in a study ____ [correct: I should not expect to get my individual results]	39 (100)	19 (100)	20 (100)
Q15. Once you sign up for the biobank, can you change your mind? [correct: yes, but the biobank cannot get back samples and information from studies that have already begun]	38 (97)	19 (100)	19 (95)

Table 3.
Amount of Information Provided

	<i>Total (n = 39)</i>	<i>Traditional form (n = 19)</i>	<i>Simplified form (n = 20)</i>	<i>P-value</i>
	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>
Amount of Information				0.03
Way too little	2 (5)	1 (5)	1 (5)	
Too little	2 (5)	1 (5)	1 (5)	
About right	24 (62)	9 (47)	15 (75)	
Too much	9 (23)	3 (16)	6 (30)	
Way too much	2 (5)	2 (11)	0 (0)	

Table 4.
Willingness to Participate in Hypothetical Biobank

	<i>Total (n = 39)</i>	<i>Traditional form (n = 19)</i>	<i>Simplified form (n = 20)</i>	<i>P-value</i>
	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>	<i>n (%)</i>
Definitely willing	12 (31)	9 (47)	3 (15)	0.02
Probably willing	16 (41)	7 (37)	9 (45)	
Probably not willing	6 (15)	1 (5)	5 (25)	
Definitely not willing	3 (8)	1 (5)	2 (10)	

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SUPPLEMENT: ORIGINAL SPANISH QUOTATIONS AND ENGLISH TRANSLATIONS

Comprehension of Consent Materials	
The benefit to your health would be to be told, “Look, you have something.”	El beneficio para tu salud sería que te dijeran, “Mira, tienes algo, tienes algo.” (LA, 18, traditional)
Reassuring Consent Form Information	
They are letting you know that if you want you can join the study or not and that if you join and one day say, “I don’t want to be a part anymore,” then you can quit. I like it—I like it a lot; it’s very important.	Te está diciendo que si quieres puedes ser parte del estudio, si quieres no, y si empiezas a ser parte, si algún día dices, “Ya no quiero ser parte.” Entonces puedes parar. Me gusta, me gusta mucho, es muy importante. (LA, 04, traditional)
Well, this kind of helps with the previous part [describing privacy risks], it’s like you get scared and then you get all the information we need to calm down again: that [the data are stored in a] building apart from where the medical records are—that is huge, gives me lots of peace of mind, because it means that it’s its own thing, with its own protection, and that they change the specific information with the number [code], and	Bueno, eso como que ayuda con lo último, como que asustaste y después nos da toda la información que necesitamos para calmarnos otra vez, que esté en un edificio que esté separado de los registros médicos, eso es enorme, que me da mucha tranquilidad, porque quiere decir que es su propia cosa, que tiene su propia protección y que cambian la información específica con el número y que la gente, los investigadores no

that people, the researchers don't know our name, nothing; this makes one feel very protected. So, I like it.	sepan nuestro nombre, nada. Eso sí lo hace sentir como que muy protegido. Así que me gusta. (NY, 08, traditional)
If you look at it, it is very professional, very legal too.	Si tú ves, es algo muy profesional, muy legal también. (NY, 04, simplified)
They tried to be as transparent as they could be. They did not mention that "oh, you do not have to worry, nothing bad will happen." They mentioned the possibility that in the future a more sophisticated, easier way to obtain information from a specific person may be invented. What caught my attention was that they did not deny the possibility that this could happen in the future; they let you know.	Trataron de ser lo más transparente que pudieran ser. No mencionaron que "oh no tienes que preocuparte, nada malo pasará." Mencionaron la posibilidad que puede que suceda que en el futuro se invente una manera más sofisticada, más fácil para obtener información de una persona específica. Lo que me llamó la atención fue eso que no negaron la posibilidad que en el futuro, te lo dejaron saber. (NY, 01, simplified)
[I like that participating in other studies is] voluntary—you can decide to participate or not. And that they won't contact you about more than two studies a year, which is also excellent, because you don't want for them to be calling you every week. No.	Y voluntario—puedes decidir si participas o no. Y que no te van a avisar por más de dos al año. Lo que también es excelente, porque no quieres que ellos te estén llamando todas las semanas, no. (NY, 06, simplified)
Concerning or Confusing Consent Form Information	
<i>Data sharing</i>	
[The form] is saying that they will give [biobank data] to who they want to, so it's like a huge network. It's a little like, I don't know, like who's deciding that?	Está diciendo que se lo van a dar a quien quieran, así que es como una red enorme. Es un poquito, no sé, como ¿quién está decidiendo eso? (NY, 08, traditional)
The people who are going to have this access to my information, how can I trust them?"	Las personas que van a tener este acceso a mi información, ¿cómo puedo confiar en ellas? (LA, 03, simplified)
The government is very big, and you never know how it'll use it, right?	El gobierno es muy grande y no se sabe nunca para que lo use, ¿no? (LA, 02, simplified)
I like the part of universities. I like everything that has to do with the public service because they are studies, but the pharma-	Me gusta la parte de universidades. Me gusta todo lo que tenga que ver con el servicio público porque son estudios, pero las farmacéuticas no porque pues, ya estamos hablando de una

<p>ceutical companies I don't like because then we are talking about a private company. They can profit.</p>	<p>empresa privada, ahí como que ellos pueden lucrarse. (LA, 19, simplified)</p>
<p>Well, when you think that the data are going to be studied not only in the United States but also in other countries, you say, "Okay, well, in this country I can guarantee certain things, but outside of it, I do not know what can happen." That is something that can cause concern.</p>	<p>Bueno, cuando tú piensas que los datos van a ser investigados no solamente en los Estados Unidos sino en otros países, tú dices, "Okey, bueno, en este país yo puedo garantizar ciertas cosas, pero fuera de él no sé qué pueda pasar." Eso sí es algo que puede generar preocupación. (LA, 01, traditional)</p>
<p><i>Genetic Information Nondiscrimination Act</i></p>	
<p>Okay, in this section I don't get what life or disability insurance has to do with this project. What do they have to do with the study?</p>	<p>OK, en esta no entiendo qué tiene que ver un seguro de vida o de incapacidad con este proyecto. ¿Qué tienen que ver? (LA, 03, simplified)</p>
<p>Yeah, I'm a little bit confused with the last section because it says, "GINA will not protect you against genetic discrimination from companies selling life insurance." I don't get it because it says we will protect you, but later it says that we won't. That confused me a bit.</p>	<p>Sí, estoy como un poquito confundida en la última sección porque dice, "GINA no lo protege de la discriminación genética de compañías que venden sus seguros de vida." No entiendo porque está diciendo como que sí te protegemos pero después dice que no te protegemos. Eso me confundió un poco. (LA, 04, traditional)</p>
<p>This alarms me, because, why are you going to tell me this when before you told me that my information wasn't going to be exposed to insurance companies?</p>	<p>Eso me hace ruido, ¿por qué me vas a explicar eso si antes me dijiste que esto no iba a ser expuesto ante las compañías de seguros? (LA, 01, traditional)</p>
<p>GINA will not protect me against life or disability insurance companies. This worries me, because how can they access that information?</p>	<p>GINA no me protege para seguros de vida o incapacidad, o me preocupa de que porque ¿cómo ellos pueden tomar esta información? (LA, 08, traditional)</p>
<p><i>Medical records access</i></p>	
<p>What leaves me a bit confused is this that says, "We will get information from your medical records, such as test results, medical procedures, x-ray images, the medicine you take." So,</p>	<p>Lo que deja un chin confuso es esto que dice, "Obtendremos información de sus registros médicos, como resultado de pruebas, procedimientos médicos, imágenes como rayos X, la medicina que toma." So, ¿cómo harían eso? ¿Sería ellos</p>

how would they do that? Would they be contacting my doctor? Are they contacting my health insurance?	contactándose con mi doctor? ¿Ellos contactándose con mis seguros médicos? (NY, 14, simplified)
It says, "We'll get information from your medical records." Is that information I provide, or will they contact the doctors?	Dice, "Obtendremos información de sus registros médicos." ¿Es [la] información que uno provee, o ellos van a contactar a los médicos? (NY, 06, simplified)
I guess [my medical record is] in a national database, right?	Eso me imagino que esté en un database nacional, ¿verdad? (NY, 11, simplified)
[Why are x-rays needed?] For studies? For research? To confirm that the person is sick? It doesn't say specifically the reason that x-rays will be needed.	¿Por qué razón' [los rayos X se necesitarán].¿Para pruebas del estudio? ¿Para confirmar que la persona esté enferma? No se dice, específicamente, la razón de por qué los rayos X se necesitarán. (NY, 09, simplified)
It seems to me that as they collect the medical information, and if I have something, they will contact me.	Me parece de que al ellos colectar la información médica, y si yo tengo supongo algo, van a contactarse conmigo. (LA, 08, traditional)
Well, it would give me peace of mind if they find anything. Something that is affecting my health and I do not know. That they would contact my regular doctor.	Bueno, me daría tranquilidad si ellos encuentran algo. Algo que me esté afectando a mi salud y que yo no sé. Que contactarían a mi médico regular. (LA, 18, traditional)
<i>Certificates of Confidentiality</i>	
It does not make it very clear to know if this [Certificate] is good or bad or how you are benefiting—like it is not very clear.	Sí, como que no deja muy claro saber si eso está bien o está mal o en qué le está beneficiando. Como que no queda muy claro." (NY, 09, simplified)
I'm a little confused because it talks about how they can't hand over information even at the request of a judge. But in another part, it also says that they are obligated to give the information to the government when they ask for it. So I kind of don't understand how they are—what do they base it on if they decide to do it or not?	Me confunde un poco porque habla de que no pueden entregar la información aunque sea a la petición de un juez. Pero en otra parte también dice que si tiene—tienen la obligación de entregar la información al gobierno cuando se lo pide. Entonces como que no entiendo cómo se—en qué se basan si deciden hacerlo o no? (NY, 02, traditional)
This part has me a little confused. . . . I'm not sure whether they do or do not share information with the government. I don't understand this a bit.	Esta parte me tiene un poco confusa No sé si es que sí o que no se comparte la información con el gobierno. No entiendo un poco. (NY, 05, traditional)

<p>It says, “In addition, we will disclose your information without your consent”—how—it should be, “In addition, we will <i>not</i> disclose your information without your consent.” I don’t know; maybe you have to be clearer in this part.</p>	<p>Dice, “Además revelaremos su información sin su consentimiento”—como—o sería, “Además, no revelaremos su información sin su consentimiento.” No sé si; tal vez, hay que ser más claros en esta parte. (LA, 18, traditional)</p>
<p>If you discover that there’s domestic violence, or abuse of someone, I don’t understand how. How would you know if there is domestic violence through the blood?</p>	<p>Si ustedes descubren que hay violencia doméstica, abusa de alguna persona, no entiendo cómo. ¿Cómo podrían saber si hay violencia domestica a través de la sangre? (LA, 16, traditional)</p>
<p><i>Description of quantity of blood to be drawn</i></p>	
<p>“Spoonful” doesn’t seem very appropriate. Because the spoon is related to food, no? So no one eats blood.</p>	<p>“Cucharada” no me parece muy apropiado. Porque la cuchara está relacionada a la comida, ¿no? Entonces, nadie come sangre. (LA, 17, simplified)</p>
<p>It sounds weird. I wouldn’t know how to give an example of what you could put instead, but three tablespoons sounds like you’re going to get the spoon out, and they’re going to put it there so that you bleed [onto the spoon]. I mean, I don’t know.</p>	<p>Suena raro. No sabría dar un ejemplo de lo que podrías poner, pero como que tres cucharadas suena como que te van a sacar la cuchara del, y la van a poner para que te desangres así, o sea no sé. (NY, 07, traditional)</p>
<p>It sounds more like food—like you’re cooking a recipe.</p>	<p>Suena como más a alimento—como que está haciendo una receta de cocina. (LA, 05, traditional)</p>
<p>the equivalent of about three tablespoons of blood</p>	<p>el equivalente de a tres cucharadas de sangre (LA, 19, simplified)</p>
<p><i>Concerns about tone and formality</i></p>	
<p>Promises are never . . . It’s like no, that word isn’t used for that. I can’t think of the appropriate word now—but it would have to be some more legalistic term.</p>	<p>Las promesas nunca se—es como que no, esa palabra no se usa para eso. No me vendría ahora la palabra correcta, pero tendría que ser como, algún término más legal. (NY, 07, traditional)</p>
<p>No, I don’t like “promise.” It’d be more like a “privacy policy.” That’s what you are trying to say, right?</p>	<p>No, no me gusta “promesa.” Sería como una “póliza de privacidad.” Algo así es lo que intentan decir, ¿verdad? (LA, 14, traditional)</p>
<p>It sounds like I’m reading a story to a five-year-old—a promise. The word “promise” does not give me a sense of security. In fact, it could be even best to get rid of this phrase . . . [If it said]</p>	<p>Como que le estoy leyendo un cuento a un niño de cinco años—una promesa. La palabra “promesa” no me da seguridad. Más bien a lo mejor hasta eliminar esto . . . “bajo un contrato</p>

<p>“under a signed contract” that would be different, not with a promise.</p>	<p>firmado” eso sería diferente, no bajo una promesa. (LA, 06, simplified)</p>
<p>Yeah, this business that we will contact you “no more”—this of “no more” you use it too much. I think it is negative.</p>	<p>Sí, esto de que lo contactaremos “no más”—eso del “no más” lo usan mucho. Creo que es negativo. (NY, 03, simplified)</p>
<p>There has to be a way of softening this a bit. I think that this line, “We will contact you no more than once a year to use this information,” you use a negative, not a positive [way] of communicating the information. It [should be] “In the future we will contact you once a year to update this information. Sure. Stating, “no more,” already indicates a bit of a defensive[ness].</p>	<p>Tiene que haber alguna forma de amortiguarlo un poco eso. Creo que esta línea, "Le contactaremos no más una vez al año para usar esta información," usar es un negativo, no positiva de comunicarla. Es "En el futuro le contactaremos una vez al año para actualizar esta información." Claro. El poner, “no,” ya indica un poquito de defensa. (LA, 05, simplified)</p>
<p>I would put this part about risks later because you’re always telling me about risks first, and you’re not showing all that you’ll do to protect my data. I’m worried in this regard about the order in which this information is presented That phrase you put in all caps so that you highlight “WE ARE GOING TO DO EVERYTHING TO PROTECT YOU IN ANY WAY WE CAN.”</p>	<p>Esta parte de riesgos yo la pondría después de esto porque siempre que tú me estás platicando primero riesgos, y no me estás mostrando todo lo que vas hacer por mí. Me preocupa en ese sentido el orden. . . . Esa frase la pones en mayúsculas así como que le resaltas “VAMOS A HACER TODO POR PROTEGERLOS EN LA MEDIDA QUE PODAMOS.” (LA, 14, traditional)</p>
<p>When it says, “We cannot [guarantee],” it’s like they are leaving you all alone. I think that it should say, “<i>There are no guarantees.</i>”</p>	<p>Cuando dice, “no podemos” es como que están, te están dejando solo. Yo pensaría que podía decir, “No existe, no hay garantía.” (LA, 05, traditional)</p>
<p>The phrases you use [referring to “you should not expect”], it can be that no—they can even be a bit aggressive. Instead of saying, “you shouldn’t expect,” simply say, “there are no direct benefits.”</p>	<p>Las frases que usan, puede ser que no—sea un poco hasta agresivo. En vez de decir, "no debe esperar," simplemente decir, "no hay beneficios directos." (NY, 02, traditional)</p>
<p>Well, I understand what the project is about and all that, but still, as a human being, it’d be nice maybe if there was some benefit, not that the first thing says, “You will not obtain any direct benefit.” Maybe that can go at the end. First, maybe it could read something like, “The benefit is great because it is a benefit in the future for humanity, for our kids,” maybe starting</p>	<p>Pues yo entiendo lo que es el proyecto y todo eso, pero aún así, como un ser humano pues que soy, sería bonito tal vez que si hay algún beneficio que no sea primero decir, “Usted no obtendrá un beneficio directo.” Tal vez eso que sea al final. Primero más bien poner como, “El beneficio es grande porque es un beneficio para el futuro de la humanidad, de nuestros hijos,” tal vez comenzarlo de esa forma más bien. Y después al final</p>

<p>this section like this. And then at the end perhaps adding, “No direct benefits will be obtained from participating.”</p>	<p>poner tal vez, “No se obtendrá un beneficio directo por participar.” (LA, 06, simplified)</p>
<p>“The main benefit is that you wish to participate and collaborate in research and reach discoveries that could benefit others in the future. There is no monetary reward.” And there, leave it like that. Just don’t write that there is no benefit.</p>	<p>“El principal beneficio es que usted desea participar y colaborar en las investigaciones y alcanzar el descubrimiento que podría beneficiar a otras personas en el futuro. No existe ninguna recompensa económica.” Y ya, así déjalo. Nada más no le pongas que no tienes ningún beneficio. (LA, 14, traditional)</p>