Recommendations: Community Listening Sessions

The outcomes and recommendations we are sharing today are grounded in three in-depth listening sessions facilitated by the RAGE team with our community partners. In collaboration with the IRB, our community partners reviewed the informed consent form (ICF) template, a minimal-risk study example, and a greater-than-minimal-risk study example. Their feedback was thoughtfully synthesized into three areas: what is working well, opportunities for improvement, and cross-cutting themes across questions and topics.

Our goal has been to elevate community insights in a way that is accurate, respectful, and actionable- so we can drive meaningful improvements to the consent process and strengthen how UCSF engages and shows up for research participants.

For context, this work represents the culmination of an IRB request for RAGE to convene community listening sessions. In early 2024, a RAGE subcommittee conducted an initial review of the template and offered recommendations. Building on that foundation, we convened listening sessions with community partners in October and November of 2025 to review the IRB provided materials and provide recommendations. These recommendations shared today reflect strong alignment and synergy between the subcommittee's earlier work and the perspectives of our community partners.

Bullet Point Format

Things that are working

- Section titles and the occasional bolding support navigation.
- Participants value explicit statements about rights (withdrawal, skipping questions).
- Community partners noted that the consent forms are generally written in language suitable for translation, though some medical and research-specific terms would benefit from clearer, plain-language wording. E.g. "specimens, medical procedures, measurement (tbsp etc.).

Primary Areas Needing Improvement

- Forms are too long, dense, and repetitive—especially concerning risk and privacy.

- Risk information appears in multiple sections (3.3, 3.4, 8), causing confusion.
- Privacy language is difficult to understand; some phrasing is alarming or unclear.
- Organization and flow are not intuitive; key concepts appear late or in unexpected locations.
- Contact information is not up front, and center and community states that it lacks clarity about roles.

High-Priority Structural Changes

- Add a **1–2-page front summary**: purpose, key procedures, compensation, major risks, withdrawal rights, and contact information.
- Create a **table of contents** and include simplified numbering for each section of the consent form (no 1.2/1.3 structure).
- Consolidate all **risk information** into one section with clear subsections for common vs. serious risks.
- Consolidate and rewrite **data privacy and confidentiality** using plain language and concrete examples.
- Place all **contact information** in a standalone section explaining *who* to contact for *what*.
- Add visuals (tables, icons, graphics) to support comprehension and readability.
    - E.g. page 6 of the greater-than-minimal risk example, when it talks about risks. Are there limitations to including visuals? A table listing risks with the potential for pictures can increase access.

Cultural & Accessibility Recommendations

- Encourage research teams to conduct group-consent discussions for communities with lower literacy or collective decision-making norms.
- Replace hard-to-translate terms ("specimens") with simpler alternatives (“samples”).
- Use visuals to support participants with low literacy or limited English proficiency.
- Develop video or audio versions of consent materials; consider accordion-style digital consent.

Operational/Process Recommendations

- Reconsider maximum length expectations; many participants disengage after 1–2 pages without visual breaks.
- Offer a standardized **summary sheet** as a required Supplement to all UCSF ICFs.

- Encourage study teams to explain data privacy verbally to reduce anxiety around the "cannot fully protect" language.
- Add consistent highlighting or underlining for critical participant rights.

Comprehensive Recommendations Report

Summary

Key themes include:

- Length, repetition, and organizational issues that limit comprehension.
- Dense and confusing risk and privacy language.
- Need for clearer structure and visual enhancements.
- Strong support for verbal, group, and multimodal consent processes.
- Recognition of existing plain language strengths.

This report summarizes what is working, what needs improvement, and concrete recommendations to guide IRB revisions and institutional policy.

I. What Community Partners Identified as Working Well

1.Easy to Understand

- Bolded definitions and section headers help anchor understanding.
- Some procedure explanations/descriptions were clear, but this may not be true across more complex and longer ICFs.
- Community partners noted that the consent form examples are generally written in language suitable for translation, though some medical and research-specific terms would benefit from clearer, plain-language wording. E.g. "specimens, medical procedures, measurement (tbsp etc.).

2. Transparency around Participant Rights

- Statements reinforcing voluntary participation and withdrawal rights resonated positively.

II. Areas that could use Improvement

1. Length, Density, and Repetition

Community members described the documents as:

- “Too long”
- “Too repetitive”
- “Difficult to stay engaged with after two pages”

Repeated information, especially regarding risks and data privacy, makes the forms harder to follow and can heighten anxiety.

2. Confusing Organization and Section Order

- Critical information (purpose, study steps, compensation, major risks) appears later than participants expect.
- Numbering systems (e.g., 1.2, 1.3) are perceived as unnecessarily complex.
- Readers want a logical, “walk-through” sequence that mirrors what they will actually experience in the study.
- Tables, graphics, and bolding were viewed as culturally inclusive and extremely helpful for comprehension.
- Visuals are especially valuable for communities with low literacy or limited health education.

3. Risk Section Issues

- Risk information appears in multiple locations (3.3, 3.4, Section 8).
- Participants struggle to differentiate common vs. serious risks.
- Repetition increases confusion and mistrust.
- Community members strongly recommend consolidating all risk information in one place.

4. Privacy and Data Use Language is Dense and Alarming

- Phrases like “your privacy cannot be guaranteed” create fear when placed early or repeated.
- Sections 11 and 12 (privacy, confidentiality, and data access) require multiple readings to interpret. Some suggestions include:

    - We might gather information from your existing medical records or generate new ones for you.
    - Your signed consent and some research results will be added to your medical record, potentially visible to those involved in your future care or insurance.
    - Study information will be part of your research records and may also be added to your medical record
    - We may share your personal information if legally required (e.g., if you pose a risk to yourself or others).
    - While UCSF has agreements with service providers, like email, to protect your information, complete privacy cannot be guaranteed.
    - Study results may be published or presented, but your name and personal details will not be used.
- Lack of concrete examples makes the text feel abstract and unclear.

5. Contact Information needs to be Standalone and Clear

- Contact details are often embedded within paragraphs.
- Participants want explicit explanations of **who** each contact is and **why** they should be contacted.
- The role of the IRB is unfamiliar to many and needs plain-language explanation.

6. Cultural and Linguistic Considerations

- Some terms do not translate well (e.g., “specimens”).
- People prefer visuals, examples, and simplified language.
- Many communities benefit from group or verbal consent processes.
- Videos or audio explanations would significantly improve accessibility.

Area for Improvement	Key Feedback for Adjustment	Informed Consent Implication	Suggestion
Length, density, and repetition	• “Too long” • “Too repetitive” • “Difficult to stay engaged with after two pages”	Repetition, especially regarding risks and privacy, makes the forms harder to follow and increases anxiety. As a result, participants may not finish reading the	• Plain-language summary before the full form. • Clear bullets: purpose, procedures, risks, compensation,

		consent form before they sign.	privacy basics, rights, contacts.
Confusing organization and section order	• Numbering system is confusing. • Critical information appears later.	If critical information is later in the document, a participant that feels overwhelmed and anxious about the length would not finish the consent form before signing.	• Participants want a logical "walk through" order that mirrors the experience of the participant. • Community members recommend that each consent form have a navigational tool (table of contents).
Tables, graphics, and bolding	• Use of tables, graphics, and bolding was culturally appropriate. • Lack of graphics showing side effects, etc.	By not having graphics, the consent form is leaving out those that are visual learners and those with lower literacy levels.	Accessible visuals are especially valuable for communities with low literacy levels. Participants pointed to: • Icons (e.g., dizziness, headaches, injections) • Tables for design elements (e.g., timelines, study arms, risks) • A more spacious layout • Bolded definitions • Highlights for critical rights ("you may

			withdraw at any time")
Risk section issue	• Risk information appears in multiple locations (3.3, 3.4, Section 8). • Participants struggle to differentiate common vs. serious risks. • Repetition increases confusion and mistrust.	If participants do not understand all the risks, or if they mistrust the study, they will not understand the consent form or may not finish the consent form.	• Combine risk sections into one. • Distinguish common vs serious risks using tables or icons. • Streamline privacy language, emphasize key points in bold/underline, use concrete examples.
Privacy and data use language is dense and alarming	• Phrases like "your privacy cannot be guaranteed" create fear when placed early or repeated. • Sections 11 and 12 (privacy, confidentiality, and data access) require multiple readings to interpret • Lack of concrete examples makes the text feel abstract and unclear.	Repetition, especially regarding risks and privacy, makes the forms harder to follow and increases anxiety. As a result, participants may not finish reading the consent form before they sign.	• Community members provided alternative language to use in Section 4. • **Rewrite and streamline privacy language** with concrete examples.
Contact info needs to be standalone and clear	• Contact details are often embedded within paragraphs. • The role of the IRB is unfamiliar to many.	If participants do not know to contact for different issues, they may not report significant side effects, incidental findings, etc.	Participants want explicit explanations of **who** each contact is and **why** they should be contacted.

			Explain the role of the IRB in plain language.
Cultural and linguistic considerations	• Some terms do not translate well (e.g., "specimens"). • The consenting process is primarily written. • The consenting process is done alone.	• By focusing on a written consent process, we are leaving out the participants that are aural, visual (in terms of graphics), and kinesthetic learners. • Consenting alone feels overwhelming and the power dynamics in the room shift to the CRC or researcher.	• People prefer visuals, examples, and simplified language. • Many communities benefit from group or verbal consent processes. • Videos or audio explanations would significantly improve accessibility.

III. Themes Across Listening Sessions

1. Need for a Front One- to Two-Page Summary

Participants overwhelmingly recommended:

- A plain-language summary before the full form
- Clear bullets: purpose, procedures, risks, compensation, privacy basics, rights, contacts
- A navigational tool (table of contents)

2. Risk and Privacy Sections Require Redesign

- Combine risk sections into one.
- Distinguish common vs serious risks using tables or icons.
- Streamline privacy language, emphasize key points in bold/underline, use concrete examples.

3. Visuals and Formatting are Critical

Participants pointed to:

- Icons (e.g., dizziness, headaches, injections)
- Tables for design elements (e.g., timelines, study arms, risks)
- A more spacious layout
- Bolded definitions
- Highlights for critical rights ("you may withdraw at any time")

4. Consent should be a Conversation, not just a Form

- Strong preference for verbal explanation.
- Group settings improve question-asking.
- Videos can support individuals with low literacy or visual learning styles.

5. Build Trust through Clarity and Transparency

- Minimizing repeated alarming phrases supports trust.
- Clearly explaining why research matters helps participants understand the value to their community.

IV. General Recommendations

1. Structural & Formatting Recommendations

1. **Develop a 1–2-page required summary sheet** for all ICFs.
2. **Add a table of contents** with simplified numbering.
3. **Use visual aids** (icons, graphics, tables) consistently.
4. **Break up long paragraphs** using bullets and spacing.

2. Content Recommendations

1. **Consolidate all risk information** into a single section divided into:
    a. Common risks
    b. Serious risks
    c. Procedure-specific risks

2. **Rewrite and streamline privacy language** with concrete examples.
3. **Clarify the study purpose** at the beginning of the form.
4. **Remove unnecessary repetition.**

3. Cultural and Accessibility Improvements

1. Replace terms like “specimens” with “samples.”
2. Highlight participant rights using bold or underlining.
3. Collaborate with community partners to ensure translations retain meaning.
4. Include visuals to support lower-literacy participants.

4. Contact Information Revisions

1. Make a dedicated, clearly labeled section: **Who to Contact and Why**.
2. Explain the IRB’s oversight role in simple terms.
3. State availability of interpreters in multiple languages.

5. Process Recommendations

1. Encourage and standardize **verbal consent explanations**.
2. Support **group consent** models where appropriate.
3. Provide **video/audio consent** as supplemental tools.
4. Consider checkboxes or initials instead of multiple signatures.

Conclusion

Thank you to UCSF’s IRB and RAGE Program for collaborating on moving forward these community listening sessions. Community reviewers provided clear, consistent, and actionable guidance. Their input highlights both strengths of UCSF’s existing informed consent and opportunities to make the consent document and process more accessible, culturally respectful, and aligned with participants’ needs.

Implementing these recommendations will:

- Improve participant comprehension
- Increase trust
- Support equity in research participation

- Strengthen UCSF's commitment to community-informed, human-centered research practices