Lebanese Republic
Ministry of Public Health
National Mental Health Programme

Contextualizing Consent

A Guide For Health Research

Made with, by and for researchers & communities

Goal supporting mental health systems
LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE
USJ Université Saint-Joseph de Beyrouth جامعة القديس يوسف في بيروت
Beyond TEXT
WAR child
أبعاد abaad

Lebanese Republic
Ministry of Public Health
National Mental Health Programme

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Authors

Emily Oliver (BeyondText), Sandy ElChaar, Imad About Khalil and Rayane Ali.

Creative

Artist: Lena Merhej
Creative Direction: Emily Oliver, BeyondText

Goal supporting mental health systems

London School of Hygiene & Tropical Medicine

Beyond Text

War Child

أبعاد abaad

USJ Université Saint-Joseph de Beyrouth جامعة القديس يوسف في بيروت

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Introduction

Despite legal and ethical requirements for consent to be tailored to an individual in their context, unadapted consent materials and approaches are still routinely used in health research. This can create serious barriers to participation in health research, particularly for underserved communities, both in the West[1] and globally.[2] It also risks failing:

- Fundamental consent principles of autonomy and comprehension.[2]
- World Health Organization recommendations that culturally appropriate consent is fundamental to ethical health research.[3]
- Recommendations for equitable community health partnerships in recent revisions to the Declaration of Helsinki.[6]

Problems

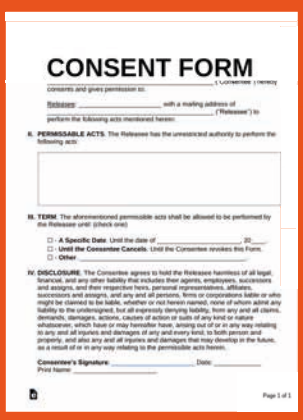
Issues with unadapted, standard consent include the:

- **Legal language and contractual appearance** of consent forms is misleading. Their legal status is ambiguous and they may be distrusted by people underserved by legal institutions.
- **One-sided** nature - drafted by institutions but only signed by participants.
- **Use of western consent** with people from cultures with different understandings of consent.
- **Low levels of understanding** about health consent globally despite decades of standard consent.[7,8,9,10] This even includes Community Advisory Boards (CABs), whose role includes regularly reviewing consent materials on behalf of a community.[11, 6, 12]

Definition

Contextualizing consent means:

- Reflecting the participant's culture, community, gender, age, information processing needs, values, and experience of wider sociocultural dimensions, throughout consent. This includes the design of the materials, processes, and practices.
- Bringing awareness of these contextual factors to the interpersonal relationship between participants and professionals.


CONSENT FORM

- "Pseudo legal contracts"
- One-sided
- Misleading
- Western institutional values

People say they understand consent, but they also say it's like a job contract or even a marriage proposal- that's not the right relationship.

(GOAL researcher, Lebanon)

Aims

This guide aims to support you to:

Diagnose any barriers to contextualizing your consent materials, approaches, and training.

Develop contextualized alternatives (if needed).

Solutions

While there is consensus that consent be conceived of as an ongoing partnership between communities and researchers responding to the context, how to operationalize this is an ongoing debate. Solutions proposed in literature include:

- Meaningful community participation in the co-design of contextualized consent materials and practices including framing the problem and potential solutions.
- Researchers developing ethics reflexivity both individually and collectively.

However, there is a general lack of literature about these topics and effective health research consent practices and materials for research design and delivery more generally. This guide aims to address these gaps.

Benefits

Contextualizing consent may strengthen:

Trust between participants and researchers[14]

Accuracy and relevance of research, policies, and interventions[17]

Participants' understanding of the research and its benefits[15, 16, 5]

Researchers' ability to operationalize ethical reflexive practice[18]

Who is this guide for?

This guide has been designed for health researchers worldwide who already use **consent processes**[12] and are looking to contextualize them with and for communities. The guide may be particularly relevant for researchers co-producing or collaborating on health research with communities - whether through formalized boards such as 'community advisory boards' (CABs) or through other methods.

This guide is best used within a research culture that values and prioritizes the active participation of community members. It can be difficult to begin these conversations if there is not enough commitment to pursue them further.

If you are instead looking for a checklist to confirm which elements should be included in your consent materials the **i-Consent Guidelines for tailoring the informed consent process** may be more relevant. This guide focuses on supporting ethics reflexivity and enabling meaningful community participation through consent from the earliest stages of research and co-design.

Who created this guide?

This guide has been developed by members of the **GOAL** research project working together with CAB participants. GOAL is a partnership between the **National Mental Health Programme of Lebanon**, the **London School of Hygiene and Tropical Medicine**, **ABAAD**, **BeyondText**, **St Joseph's University of Beirut**, and **War Child Lebanon**. GOAL aims to strengthen the mental health system for people living in Lebanon. GOAL sought to embed co-production throughout the research. The guide is underpinned by GOAL's wider consent research in Lebanon.[12]

What research and methods inform this guide?

The GOAL research underpinning this guide[12] included:

- **Narrative literature review** of academic and gray literature on culturally relevant and/or culturally sensitive consent in health research.
- **Survey** of researchers from GOAL (Lebanon and UK) and War Child's global team.
- **Interviews and participatory action research and design thinking workshops** with 22 people from:
  - War Child's CABs in Lebanon
  - Researchers in Lebanon and globally

Tools from ELRHA's **Participation For Humanitarian Innovation Toolkit** were used to develop this guide due to their context-sensitive approach to enable participation in humanitarian innovation.

The Participants

The 22 participants included researchers from academia and NGOs, and members of War Child's CABs with lived experience using health services in Lebanon. The researchers all have significant experience in facilitating health research consent in health and humanitarian contexts with a range of populations including with: women, people who use health services, and people who are refugees. They include researchers from Lebanon and researchers with experience as mental health service users.

Background

The landmark 2015 UK Supreme Court case of Montgomery[5] judged that healthcare practitioners must tailor medical consent information to the person, not use an unadapted approach.[2] As medical consent is routinely applied to health research consent[18] the ruling has repercussions for health research too. So, the summary below includes sources on both medical consent and health research consent.

Standard health research consent materials typically use legal language and look like contracts, however they offer no legal protections. They are drafted by institutions but only signed by the research participants, creating a extractive, asymmetric power relationships. They reflect western institutional values of individualism and legalism. These values may be at odds with people from more collective cultures whose understanding is based on context more than rules.[16] All these factors can create serious barriers to health research participation,[1] particularly excluding underserved communities, including people in humanitarian crisis settings.[18]

While participants typically self-report high levels of understanding of consent, multiple studies across the globe have found the participants in fact have much lower levels of understanding of consent in health research.[8, 9, 19] A 2021 systematic review of medical consent found 'participants' comprehension of fundamental informed consent components was low'.[7 (p. 1)] This chimes with researchers often reporting significant uncertainty about how well participants understand consent materials.[19]

Despite the consensus that consent be conceived of as an ongoing partnership between communities and researchers, the use of standard consent materials actually reduces the focus on this partnership.[20(p373)] Even when health researchers effectively use dialogue to reduce the barriers to participation inherent in standard consent materials, those materials still act as a barrier rather than an enabler of this dialogue. This is particularly problematic in time or resource-limited contexts.

Increasingly research seeks to enable communities to participate in creating innovative solutions to these issues in standard consent materials. Many of these innovation practices, such as Design Thinking, come from Western, corporate backgrounds[21] and reflect those corporate interests. They are not concerned with power or structural inequalities, and are not designed to address the barriers to participation that underserved communities face.

These innovation practices often limit participation before it begins. The early stages of *framing problems* and *potential solutions* have been identified as priority areas for the meaningful participation of crisis-affected communities in health research.[23] However, these stages are rarely included in these innovation practices. This limits the potential for meaningful participation or change. So, these innovation practices risk exacerbating the issues they seek to address, unintentionally further embedding western corporate values into the process of attempting to re-design consent.[11 (p12)]

This guide seeks to address these issues by facilitating the meaningful participation of communities from the outset in co-designing contextualised consent.

How To Use This Guide & Overview Of The Tools

Stage	Tools and Actions	
Plan	***WHO** will participate?* (This guide is ideally designed for Pathway A) ↓	***Unsure*** if or how a community might participate? First, do step 1 part 2 to decide who will participate. Then work through all the tools in the relevant pathway.
	or	
	PATHWAY A **Researchers designing WITH the community** (co-design)	**PATHWAY B** **Researchers designing FOR the community** (user-centered design)
Step 1 Part 1: **Recognise the problem/s**	**Tool 1.1 Role-play** 60 mins Develops shared experiential understanding of consent approaches in practice.	**Tool 1.2 10-minute survey & follow-up discussion** 70 mins Rapidly surfaces issues and interest in exploring contextualized consent.
Decide	*Is there enough shared interest to continue?* yes ↓ / no → close	
(recommended) **Define participation**	Use **ELRHA's Participation For Humanitarian Innovation Toolkit** to identify the opportunities, roles, and barriers to meaningful community participation.	

*(This framework is adapted from **MIT D-Lab's framework** and ELRHA's **Humanitarian Innovation Guide**)*

Stage	Tools and Actions
Step 1 Part 2 (Pathways A & B) **Define & frame the problem/s**	**1.3 Values identifier** — 90 mins Collectively identify the values present in your consent materials and whether these reflect the values of the population you are working with. **For Pathway B only: use Tool 1.1 here** — 60 mins Develop shared experiential understanding about your consent approaches in practice. **1.4 Common problems** — 45 mins Use research on common issues in consent materials and approaches to rapidly frame any issues in your own materials. Use this to discuss power, participation, and contextual sensitivity. **1.5 Questions & ideas** — 120 mins Collectively reflect on your team's strengths relating to consent, and identify areas in need of improvement.
Step 2: **Identify possible solution/s**	**2.1: Innovation solutions cards** — 90 mins Reflect on real examples of health consent that you could potentially integrate, adapt, or use as inspiration for a full innovation of your consent.
Decide	*Which option to take? (either option is possible for both pathways)*
Step 3: **Develop a solution**	**Strengthen** your existing consent materials, approaches and/or training using findings from the Questions & ideas tool and ongoing individual and group-based ethical reflection to address barriers to consent. or **Adapt or develop** your consent materials, approaches and/or training using ELRHA's **Humanitarian Innovation Toolkit** (HIT) which this guide integrates with (see Appendix 1 for more details).
Step 4: **Test**	We recommend ELRHA's **Humanitarian Innovation Toolkit** for testing.

Facilitation Notes

All the tools are designed for **use by researchers, ideally with community participants.**

Group size: 2-20 people are recommended for all tools. For a larger group, divide into two groups, then share your reflections back to the wider group.

Facilitation level: Medium difficulty
The facilitator needs to have a strong understanding of the process of consent and be comfortable facilitating discussions on issues and potential solutions, including contextual sensitivities and power dynamics, while navigating potential defensiveness.

Comfort zone: Potentially challenging

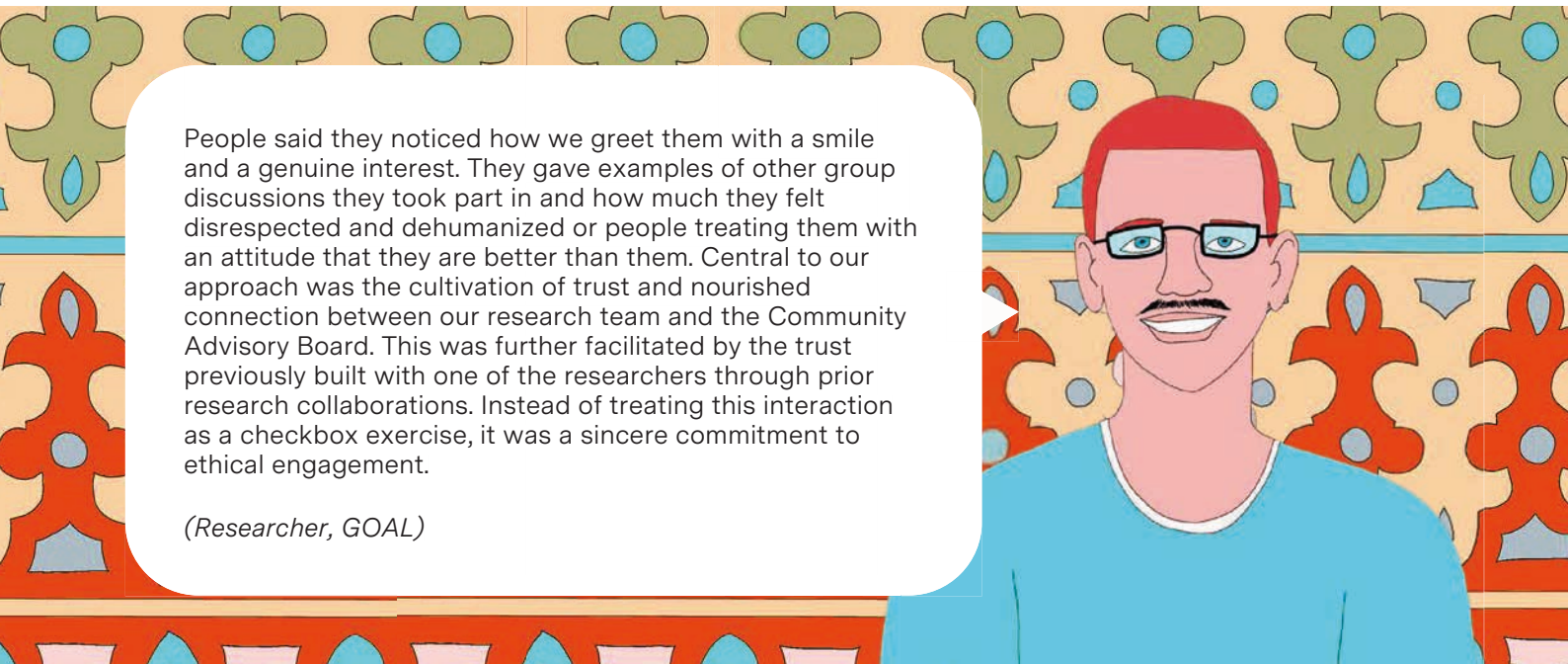
Time frame:

- 1 hour/tool (approximately 7-9 hours for a group to work through all 7 tools)
- Facilitator preparation and follow up: 60-120 minutes / tool

After doing Step 1 Part 1 to decide if there is enough interest to carry out the work, try to keep momentum. For example, as a group you might decide to set aside 1-2 days to work through all the tools, or do one every week or two.

At Step 2: If you decide you want to adapt or develop your own consent approaches or materials, this will take more time depending on how extensive the redesign is.

Next Steps:
At Step 3: If you choose to re-design your consent materials or approaches, we recommend using ELRHA's **Humanitarian Innovation Toolkit** - unless you have another framework or strong internal existing innovation practices.



People said they noticed how we greet them with a smile and a genuine interest. They gave examples of other group discussions they took part in and how much they felt disrespected and dehumanized or people treating them with an attitude that they are better than them. Central to our approach was the cultivation of trust and nourished connection between our research team and the Community Advisory Board. This was further facilitated by the trust previously built with one of the researchers through prior research collaborations. Instead of treating this interaction as a checkbox exercise, it was a sincere commitment to ethical engagement.

(Researcher, GOAL)

Tools

Step 1: Recognise the problem/s

Tool 1.1 Role-play

(For Pathway B: is it recommended you start with Tool 1.2. See 'How To Use This Guide' for more information)

Experiential workshop including **short role-plays and discussions**
Best done in person.

Aim/s: develop a shared experiential understanding of consent approaches in practice.

Time
60 mins

Participants

3-20+ researchers with community members (for a larger group, divide into 2, then share your reflections back to the wider group)

Materials

- Printed copies of the scripts (2 per group).
- For the follow-up discussion: paper, pens, and/or online collaboration board such as **Miro**

Preparation

- Familiarize yourself with the script and make any adaptations for your context. You may want to adapt or fully revise this role-play to represent the context you are in. Alternatively you could role-play your own consent approaches to enable reflection on them.
- Print out 2 copies of the script for each group.

Steps

1. Introduce the topic and tool by explaining that role-play can be used in participatory research to develop a shared understanding and reflect on ethical issues, including identifying culturally specific areas requiring adaptations.
2. Invite people to get into groups of three and choose their roles: two people will act, and one will observe.
3. Introduce the script using the role-play outline below.
4. Facilitate a reflective discussion with the questions.

Role-play outline

These two scenarios show a *Beginner Cook* approaching an *Experienced Chef* in very different ways. You are invited to reflect on the differences

Scripts

Scenario 1:

- *Beginner Cook:* Hello Chef, I'm planning to start my own food business and I need to improve my cooking skills. I'm looking for honest and clear information from you about the techniques and processes involved. Can you help me learn everything I need to know to succeed?
- *Experienced Chef:* Absolutely! I appreciate your clear goals. I'll make sure to give you detailed explanations and honest feedback on all the techniques and processes you need to know. Let's work together to get you ready for your business.

Scenario 2:

- *Beginner Cook:* Hi Chef, I want to learn how to cook. Can you teach me?
- *Experienced Chef:* "Sure, I'd be happy to teach you. What specifically would you like to learn about cooking? Are there any particular skills or techniques you're interested in, or any concerns you have? It's important to know what you're looking for so I can guide you appropriately.
- *Beginner Cook:* I just want to learn how to cook.

Discussion Questions on Informed Consent

After the role-play, facilitate group reflection on the meaning, ethical, and culturally specific areas with these prompts:

1. Debrief the Role-Play:

   a. What differences did you notice between the two interactions?
   b. How did the participants' roles change based on the information shared?

You can draw out these points:

Scenario 1 the beginner cook uses ***clear effective communication*** to ***explicitly*** express ***clear aims*** to the experienced chef. Through ***dialogue*** it is clear the chef understands those aims. This demonstrates fundamental principles of informed consent in research ethics: ***participants must fully understand what they are agreeing to before they can provide informed consent.*** Consent should be based on a foundation of ***mutual understanding and trust.***

Scenario 2 the beginner cook ***does not communicate*** their real aims or the ***risks***. The chef is ***not informed about the potential risks or benefits*** of the experience. Similarly, in research settings, obtaining consent without adequately informing participants may result in ***a lack of understanding*** or awareness of the study's objectives, procedures, or potential risks. This lack of informed consent can undermine the integrity of the research process and may lead to participants making decisions that are not truly informed or fair.

2. What is / not informed consent?

Suggested features: voluntarily and knowledgeably agreeing to participate in an activity or decision, based on a comprehensive understanding of the risks, benefits, and alternatives without coercion. Consent is an ongoing process and must include: the right to withdraw, having the right to ask questions and have them answered adequately.

a. What is its significance in your context/s?
b. Identify and discuss any sensitivities or specifics e.g. is questioning perceived as disrespectful in this culture? Is collective consent used?

3. Do any aspects of the role-play or this conversation relate or remind you of any experiences you have had?

4. Explore the ethical considerations of informed consent:

a. How does informed consent respect participants' autonomy, protect their rights, and contribute to the overall integrity and validity of research or decision-making processes?
b. What problems might arise without these?

5. Participant Questions and Concerns:

a. Do you have any other questions or perspectives on informed consent?

Next steps:

Discuss with the group if you have enough shared interest to continue with the tools in this guide now? If so, we recommend you use ELRHA's **Participation For Humanitarian Innovation Toolkit** to identify the opportunities, roles, and barriers to meaningful community participation, before moving on to:

Pathway A → Tool 1.2 (optional if you want to define the problem or interest in continuing further) or Tool 1.3
Pathway B (you are completing this tool after Tool 1.2) → Tool 1.5

The role-play transformed participants from passive to active contributors, and left a lasting impression, a memory that continued to resonate as a tangible, experiential understanding of the difference between agreeing to something and providing informed consent. This experience underscored a fundamental truth: theoretical knowledge, while essential, is insufficient when it comes to grasping complex concepts like informed consent. Practical exercises, such as role-play, proved to be crucial for a deeper comprehension.

(Researcher, GOAL)

Tool 1.2: 10 Minute Diagnostic Survey

10-minute survey and **follow-up discussion**

Aim/s:

- Collectively surface perspectives about how effective, context-sensitive, and representative your current consent materials and approaches are.
- Gauge interest in exploring alternative approaches to consent.

Time

70 mins

Participants

5+ researchers (send survey invitations to as many researchers who facilitate consent in your organization as possible)

Alternatively: If you are already collaborating with community participants you might choose to adapt the questions as conversion prompts.

Materials

- Paper and pens,
- or: online survey tool such as **Typeform**

Preparation

Choose one of these options:

- Copy the questions into your preferred online survey tool e.g. Typeform, or:
- Print out the questions below, or:
- Read out the questions in person and ask people to write their answers on paper anonymously. If you are using a paper-based option, decide how you will analyze the results either collectively in person or ahead of the group conversation.

Steps

1. Share the survey
2. Analyze the results
3. Facilitate a group conversation based on the results to embed any shared reflections that may/not be surfaced by the survey, and to agree whether to continue using the tools in this guide to explore whether further training steps or redesigning your consent process may be useful.

10-Minute Survey Questions

This survey is to find out: how effective do you think the current consent process and materials in this organization are? Does this effectiveness vary in different contexts? If or how do you think effectiveness might be improved?

This survey needs around 10 minutes to complete. The results will be used by ***[ADD]*** to explore the topic and/or develop tools aiming to facilitate more informed consent.

1. From 1 to 10 how would you rate your level of satisfaction with your organization's current way of facilitating consent? (1 = completely unsatisfied, 10 = completely satisfied)

   1 2 3 4 5 6 7 8 9 10

2. From 1 to 10 how well do you feel that participants generally understand the information sheet? (1 = no understanding, 10 = complete understanding)

   1 2 3 4 5 6 7 8 9 10

3. From 1 to 10 how well do you feel that the participants generally understand the consent form? (1 = no understanding, 10 = complete understanding)

   1 2 3 4 5 6 7 8 9 10

4. What, if any, differences do you think there are between different populations' levels of understanding the consent process?

5. Have you faced any of these challenges in administering informed consent procedures, including completing consent forms?

	No challenge	Somewhat a challenge	Significant challenge
• Language barriers			
• Poor communication techniques			
• Long consent process			
• Lack of time to administer consent			
• Inability to detect participant's full comprehension			
• Literacy			
• Challenges with vulnerable people and groups (e.g. children, elderly, refugees, people with disabilities and/or visual impairments etc)			
• Participants perceive it as an unnecessary burden			
• Difficulty clarifying false expectations on the study outcome			

6. From 1 to 10 how would you rate your level of satisfaction with your organization's current way of facilitating consent? (1 = completely unsatisfied, 10 = completely satisfied)

1 2 3 4 5 6 7 8 9 10

7. If you'd like to expand on your answers, in your own words how would you describe the current process of facilitating consent?

8. In your experience, how appropriate are the current consent materials and processes for the participants' cultures, values, and contexts?

1	2	3	4	5
Very complimentary		*Somewhat complimentary*		*Not at all complimentary*

9. If you'd like to expand on your answers, in your own words how complementary are the current consent materials and processes with participants' cultures, values, and contexts?

10. In your experience, approximately how many people have refused to consent to research you have carried out? *(Please circle)*

- None
- 1-2%
- 3-10%
- 11-20%
- 21+%

11. Which statement best describes your perspective of using participatory, culturally, or contextually sensitive approaches in the consent process? (*please only choose one answer)

A I have used participatory, culturally or contextually sensitive approaches for consent and would ***not*** use them again
B I would ***not*** be interested in using more participatory, culturally or contextually sensitive approaches for consent
C I ***would*** be interested in using more participatory, culturally or contextually sensitive approaches for consent
D I ***am*** actively planning on using more participatory, culturally or contextually sensitive approaches for consent
E I have used more participatory, culturally or contextually sensitive approaches for consent and ***would*** be interested in using them again
F Other

12. If you have seen any helpful participatory, culturally, or contextually sensitive approaches for consent before please can you describe them?
(*Please share links to examples or further information if possible)*

13. What do you see as being the potential risks of using participatory, culturally, or contextually sensitive approaches in the consent process? And why?
(Please share links to examples or further information if possible)

14. How significant do you think each of the following risks are in participatory, culturally or contextually sensitive approaches to consent?

	no risk	**moderate risk**	**significant risk**
• Reducing participant comprehension			
• Reducing participant willingness to participate			
• Reducing participant trust in the research			
• Needing additional time to administer the tool			
• Requiring additional time to learn any tool			
• Cost to develop a tool for each setting/study			
• Cost to administer per participant			
• The tool being perceived negatively by participants			

15. What do you see as being the potential benefits of using participatory, culturally, or contextually sensitive approaches in the consent process? And why?
(Please share links to examples or further information if relevant.)

16. How significant do you think any of the following potential benefits in using participatory, culturally, or contextually sensitive approaches in the consent process are?

	significant benefit	moderate benefit	no benefit
• Improves participant understanding			
• Increases participant willingness to participate			
• Increases participant trust in the research			
• Reduces time to administer			
• Perceived positively by participant			

17. Are there any populations or contexts where you think participatory, culturally or contextually sensitive approaches would be particularly appropriate or inappropriate - and why?

18. If you could have a wish list of characteristics or components that you would like to see in any new tool developed to try to improve consent processes, what would be on it? (e.g. low cost, video components, etc).

Analyzing the survey results

You may want to analyze these results as a group or delegate that role to group members.

- Questions 1-3: Calculate average ratings for each question to gauge overall satisfaction and understanding levels.
- Question 4: Analyze open-ended responses to identify perceived differences in understanding across populations.
- Question 5: Categorize responses to identify the most common challenges in administering informed consent procedures.
- Question 6: Analyze the distribution of responses on the sliding scale to understand the perceived meaningfulness of current consent procedures.
- Question 7: Identify common themes or issues raised in the open-ended responses about the current consent process.
- Questions 8-9: Analyze responses to understand the perceived compatibility of current consent materials and processes with participants' cultures, values, and contexts.
- Questions 11-13: Analyze responses to understand attitudes toward participatory, culturally, or contextually sensitive approaches, as well as perceived risks and benefits.
- Question 14: Analyze responses to understand perceptions of the significance of risks associated with participatory approaches.
- Questions 16-17: Analyze responses to understand perceived benefits and their significance in using participatory approaches.
- Question 18: Identify common characteristics or components desired in new consent tools.

Here are some questions that the group, or people analyzing the results, could ask themselves:

- What are the key themes or patterns that emerge from the responses?
- Are there any unexpected findings or outliers that need further investigation?
- How do the quantitative and qualitative findings complement each other?
- What is the group’s current appetite for redesigning consent procedures?
- What are the main challenges identified in administering informed consent procedures?
- What are the perceived benefits and risks of using participatory, culturally, or contextually sensitive approaches?
- How do participants' levels of satisfaction and understanding align with their attitudes toward the consent process?
- What are the implications of the findings for developing tools to improve consent processes?
- Are there any specific populations or contexts where tailored approaches to consent may be particularly beneficial or challenging?
- If you find it useful to review some literature, how do the findings align with existing literature or best practices in informed consent?
- Do the potential risks outweigh the benefits?

Next Steps

- Is there enough shared interest in the group to continue the guide at this time, or in the future?
- If you have not done so already, we recommend you use ELRHA's **Participation For Humanitarian Innovation Toolkit** to identify the opportunities, roles, and barriers to meaningful community participation before moving on to:
  - Pathway A & B → Tool 1.3
- Note: keep the 'wish list' of characteristics or components from answers to question 18. You may need this later if you choose to adapt or co-design approaches to consent. These characteristics can form the beginning of a specification or list of requirements for the design statement and specification (see **Appendix 1**).

Step 1 Part 2: Recognise, frame & define the problem/s

Tool 1.3: Values Identifier

Interactive workshop

Aim/s:

- Identify values that might be overlooked in consent materials
- Assess whether the materials enable good practice, or may act as a barrier to your team's values

Time

90 mins

Participants

2-20+ researchers, ideally with community members (for a larger group, divide into 2, then share your reflections back to the wider group)

Materials

- paper, pens, or:
- online collaboration board such as **Miro**

Preparation

1. Set up one of these options:
   - post-it notes, pens, paper, or
   - an online discussion board to facilitate discussion.
2. Familiarize yourself with the materials and have copies of them for each group.

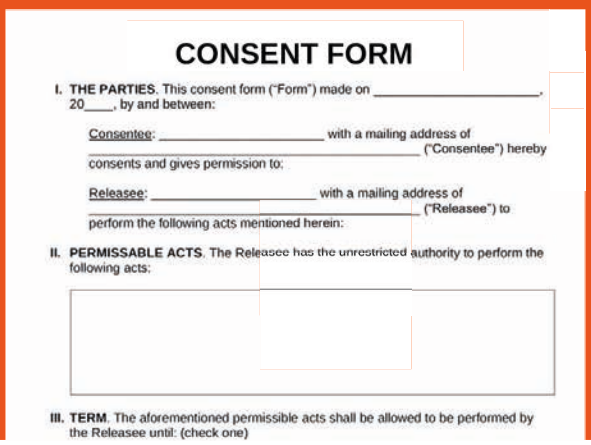
Steps

1. Introduce the topic using the prompt cards below.
2. In groups of three, invite people to review the consent materials that are used by the organization.
3. Discuss the questions below.
4. Facilitate a group conversation based on the results to embed any shared reflections.

Questions

Reviewing your organization's consent materials and approaches, discuss:

- How contextually sensitive are the language and format?
- How effectively does the format suggest consent is ongoing or a one-off event?
- How effectively does the format invite questions? Do the questions in the materials genuinely invite deliberation, or seek to persuade the participant to consent?



CONSENT FORM

I. **THE PARTIES.** This consent form ("Form") made on _____, 20____, by and between:

Consentee: _____ with a mailing address of _____ ("Consentee") hereby consents and gives permission to:

Releasee: _____ with a mailing address of _____ ("Releasee") to perform the following acts mentioned herein:

II. **PERMISSABLE ACTS.** The Releasee has the unrestricted authority to perform the following acts:

III. **TERM.** The aforementioned permissible acts shall be allowed to be performed by the Releasee until: (check one)

- Legalist
- Individualist
- Contractual

= western, rules-based values

- Reflecting on the above image, are any of these values represented in your consent materials or approaches?
- Are these values complimentary to participant's context and culture?
- How might these values affect power dynamics in consent?
- Whose interests are represented by the values represented in your consent materials?
- Are there any other un/intentional effects of these values being present in the consent materials?
- What do you think are the strengths and weaknesses of your materials?

Group discussion:

- What similarities and differences are there in your group's answers?
- What can you learn from this?

Optional additional values discussion

Most groups will find this is enough discussion to surface any issues about values in your consent materials. If you want to explore this further:

- If you want to reflect on your shared values as a group you could use **ELRHA's Participation For Humanitarian Innovation Values tool**.
- If your organization already has a shared set of values you could reflect on how effectively these reflect the community/s? Is this reflected in your consent approaches?

Next Steps

Now that you have identified any issues in your consent materials, you are ready to move on to the next tool which explores how your materials are used in practice:

Pathway A → Tool 1.4
Pathway B → Skip back to do Tool **1.1** now

Tool 1.4: Common problems with standard consent approaches

Interactive workshop using research on common consent issues in health research to frame discussions about your own consent materials and processes.

Aim/s: rapidly identify issues with your own consent materials and approaches relating to power, participation, and contextual sensitivity

Time

60 mins

Participants

2-20+ researchers, ideally with community members (for a larger group, divide into 2, then share your reflections back to the wider group)

Alternatively: if group dynamics might prohibit people from speaking freely, these sheets can be printed for each participant to answer, before sheets being shuffled and distributed back to the group to analyze and discuss.

Materials

- paper, pens, or:
- online collaboration board such as **Miro**

Preparation

1. Set up one of these options:
   - post-it notes, pens, paper, or
   - an online discussion board to facilitate discussion.
2. Familiarize yourself with the materials and have copies of them for each group.

Steps

1. With your group, briefly review any notable findings so far on your organization's consent materials and approaches.
2. Display all the Common Problems using an on/offline board and read them aloud. Invite all participants to reflect on whether they think each Common Problem Card is relevant to your organization's consent materials or processes and mark them with the below if you think:
   - Tick = your organization addresses this effectively
   - Cross = your organization does not address this effectively
   - Star = your organization does not address this effectively *and* it is a priority to address
3. Use the blanks to add cards for any other issues you think are missing.
4. First, group together the cards with ticks and discuss them using the Suggested Questions, going from the card with the highest number of ticks down. Repeat with Stars, and then Crosses. After discussion highlight any cards or other ideas you think are a priority to address.
5. Facilitate a group reflection with the Suggested Questions below.

Suggested Questions:

- Does anything particularly stand out or surprise you?
- What similarities and differences do you recognize with these problems and your consent materials and approaches?
- Is there any agreement or disagreement about this amongst the group?

Common problems with typical consenting approaches
(composite quotes from GOAL research)

Researchers say:

- ‘Consent is a boring tick box exercise’
- ‘It takes so long to carry out consent, we don’t even include it in the time we tell participants the interview will take.’
- ‘People say they understand consent, but they also say it’s like a job contract or a marriage proposal. That’s not the right relationship.’
- ‘Only one person has ever refused to consent in my experiences, how meaningful can it be?
- ‘Are people participating because they think they will benefit? How fully informed are people really about the research and their rights?’
- ‘Current processes exacerbate unequal power dynamics and feel very hard to change’
- ‘Consent is a microcosm of all the issues in research: all the power dynamics, cultural issues, extractive nature, you can see them all in consent. Maybe it’s also a way to address those issues - but any change feels impossible to get through ethics review boards, even if we had time!’
- ‘Does consent really protect the participant? Or does it protect the institution?’
- ‘Making consent relevant to each person’s culture, context and language takes time and effort. It can be a big burden on researchers and is rarely recognized.’
- Legal-looking forms suggest consent is a legal contract and a one-off event, not ongoing.
- Even high literacy groups may not understand key concepts like the right to withdraw or therapeutic misconception.

Participants say:

- ‘Sometimes the time, topics or anything else being proposed surprises you and things don’t get performed according to the plan and here trust decrease and you wouldn’t want to continue’
- ‘The information sheet contains conditions for the short-term, not the long-term and does not inform the participants of the burden their participation in research will be put on them.”
- ‘Hopefully one day it’ll bring me some benefit’ Participants may hope there are direct benefits for them in participating, even if researcher/s say there are not:

Next Steps

Now that you have identified any issues in your consent materials, you are ready to move on to the next tool which explores how those materials are used in practice:

Pathways A & B → Tool **1.5**

Tool 1.5: Questions and Ideas exercise

Interactive workshop

Aim/s: collectively reflect on your team's strengths relating to consent materials, approaches, and training, and identify areas in need of improvement

Time
120 mins

Participants

2-20+ researchers, ideally with community members (for a larger group, divide into 2, then share your reflections back to the wider group

Materials

- In-person: paper, pens, sticker dots in Blue, Red and Green, or:
- Online: collaboration board

Preparation

Set up one of these options:

- Cut out pre-made 'question and ideas' cards, or:
- Set up an online discussion board to facilitate discussion and copy 'question and ideas' cards

Steps

1. Introduce the exercise by reading the introductory rationale and overall question below.
2. Read the question on the first card.
3. Give everybody some colored sticker dots, coloured pens (or digital dots online).
4. Everyone in the team marks on the idea card if they think:
   - Green = strength: an area in which you are fully reflecting good practice
   - Red = an area that could be improved
   - Blue = an area where you're unsure
5. As a group, reflect on any differences in opinion, and see if that changes based on discussion.
6. Prioritize the red ideas and decide which ones you might want to improve.
7. Reflect on the green cards that represent your top strengths. What might you need to do to ensure you stay strong here?
8. Facilitate a discussion to make the Decision in the Next Steps.

Introductory rationale

A review of MHPSS researchers[18] found broad support to:

- 'conceive of consent as a partnership between researchers and participants' [18 (p8)]
- 'prioritizing cultural context and attainment of moral duties over quasi-legal standards through a more flexible and nuanced approach in practice'.[18 (p15)]
- Researchers reflecting on the ethics of consent may lead to more effective consent that can address barriers to participation in health research.[18]

Overall question:

How can we create the conditions for a trustworthy, equitable, and ongoing partnership between participants and researchers through consent?

Note:

* = relevant further resources or literature available after the question and ideas cards

Q1. Does your consent *planning* reflect the community's interests in long-term research partnerships?

Rationale: *meaningful collaboration by communities in research includes participation throughout research. That includes participation at the earliest stages: setting research aims, framing solutions, and potential solutions.*[23] *How can the barriers to participation in consent planning be addressed? What benefits might this bring?*

1.1: Meaningful community participation from the outset including in setting the research aims and, in the ethics application, defining ethical issues and consent.

Idea

1.2: Recruit trusted community members as outreach staff to build trust, dialogue, and mutual understanding so participants can freely ask questions, express their concerns, and decline to consent.

Idea

1.3: Carefully evaluate benefits & incentives with the community. Including: how they influence participants' autonomy to consent; if the research is sufficiently aligned with the community's interests not to need further incentives; and if additional incentives influence people's ongoing consent and participation.

Idea

1.4: Consider community concerns with community members, including cultural stigma and any community fears that participants risk "losing" benefits from other NGOs by consenting (or not consenting) to research.

Idea

1.5: Involve the community in participant selection to avoid asking people to consent to multiple studies and potential burnout.

Idea

1.6: Include the time to consent in communicating how long the research will take.

Idea

1.7 Co-design consent sessions with community members. This could include: planning to share refreshments; encouraging conversation; how to foster ongoing dialogue about these topics beyond sessions; and other contextually appropriate and relational dimensions.

Idea

1.8 Co-design security with community members including ensuring that issues such as a participant's anonymity (or right to be named) are clear and understandable.

Idea

1.9 Promote inclusion and diversity in community engagement to ensure the reviewing of consent materials represents marginalized groups.

Idea

What else do you do to address the barriers to participation in the consent planning stage? What else could you do at this stage?

Q2. Do the *language and format* of consent complement the participants' values?

Rationale: *typical consent reflects western values as* ***legal-looking*** *contracts, signed by an* ***individual****. Even in cultures that share these values, studies find people have low levels of understanding about what they are consenting to. If participants do not share these values, are the materials causing unintended consequences? If yes, how could this be addressed?*

2.1: Co-design materials and approaches with community members to ensure the language and format are culturally appropriate, inclusive, understandable, and engaging for participants. (These could include audio and/or visual materials by community members, or more interactive formats)*

Idea

2.3: Consider alternatives to signatures for different literacies and cultures e.g. fingerprint, audio recorded, etc.

Idea

2.2: Consider self-selection options for people to choose group and/or individual consent.

Idea

What else do you do to address the barriers to participation in the language and format of consent to complement the participants' values? What else could you do?

Q3. Does your approach to consent contribute to developing *understanding of research* at an individual and community level?

Rationale: *the process of deciding whether to consent to research may be affected by: 'individual-level awareness of the purpose, processes, and importance of research; community-level acceptance of research; and individual and community perceptions of the ease of access to research activities'.* [15 (p. 2)]

3.1 See consent as an opportunity for shared learning to develop shared understanding between participant/s and researchers about one another's perceptions of research and priorities for research.

Idea

3.3. Feedback research findings, including those related to consent, to the community in a timely and meaningful manner.

Idea

3.2 Use context-sensitive participation tools to improve understanding and participation between communities and researchers about consent-related topics.*

Idea

What else do you do to develop ***understanding of research*** through consent at an individual and community level? What else could you do?

Q4. Is the *ongoing nature* of consent clear?

Rationale: *the ongoing nature of consent throughout the research must be clearly understood for meaningful understanding of the potential to withdraw consent.*[18] *However, consent materials that look like legally-binding contracts are are only seen once may suggest consent is a one-off, binding event. How can the ongoing nature of consent be meaningfully communicated in a way that participants can understand? How can potential mixed signals between what researcher's state, and how consent materials are perceived, be addressed?*

4.1: Include communication channels for questions during consent consideration time to balance community members' need for consideration with potential negative consequences if they do not feel they can ask questions immediately.*

Idea

4.4: Contextualize the ongoing nature of consent and the right to withdraw in appropriate language and concepts, including addressing any concerns the participant may have.

Idea

4.2: Give participants a copy of the consent for ongoing reference.

Idea

What else do you do to meaningfully ***convey the ongoing nature*** of consent? What else could you do?

4.3: Consider whether more interactive formats support more active participation*.

Idea

Q5. Does the ***researcher's approach*** meet the individual and community's needs?

Rationale: *consent is an ongoing partnership between the researcher and participants.*[18] *The researcher needs to tailor consent to the individual's context to meet the legal, ethical, and relational requirements of consent. As part of this they must also ensure consent is culturally appropriate. This is a fundamental aspect of ethical health globally, as advocated for by the World Health Organization.*[4]

5.1 Tailor consent to participant/s culture and context, including: their gender, disability, socioeconomic factors, culture, age, language, perception of risk, personality, level of education, and other relevant wider sociocultural factors. This should be done with an awareness of the interpersonal relationship between the researcher and the participant/s.

Idea

5.2 Contextualize key elements of consent using clear language and building understanding, including: the ongoing nature of consent, the right to withdraw, the purpose of research and its potential benefits for individuals/community, etc.

Idea

5.3 Build ethical rapport including: balancing professionalism and approachability from the initial outreach contact; encouraging open dialogue, and address any misconceptions that may affect consent.

Idea

5.4 Use reflexive facilitation including: attending to power dynamics, encouraging active questioning, facilitating dissent, thanking participants, and clearly explaining the next steps.

Idea

5.5 Effectively validate participants' understanding potentially using reflexive tools and methods that are culturally appropriate*.

Idea

What else do you do to ensure the ***researcher's approach*** meets the individual and community's needs? What else could you do?

Q6. Do your *consent measurement* and evaluation practices support *ongoing learning*?

Rationale: *measurement and evaluation of consent is crucial to improving understanding of consent. There is consensus that ethical issues, including consent, should be evaluated throughout research to avoid and address ethical issues.[18] Measuring consent presents specific challenges; while participants typically self-report high levels of understanding of consent, multiple studies across the globe have found the participants in fact have much lower levels of understanding of consent in health research.[8, 9, 19] A 2021 systematic review of medical consent found "participants' comprehension of fundamental informed consent components was low".* [7 (p. 1)]
This chimes with researchers often reporting significant uncertainty about how well participants understand consent materials.[19]

6.1 Seek dissent feedback.

Idea

6.2 Seek consent feedback from participants and researchers on what enabled their informed consent (and any barriers they perceived).

Idea

6.3 Audit ethics *following* a study, including reflections on consent, to improve the organization's approach to consent.

Idea

6.4 Identify and evaluate any differences between researcher and participant/s understanding of, or perceived understanding of, consent.

Idea

6.5 Develop effective feedback loops on consent to improve practice, relationships, and policies.

Idea

6.6 Develop effective co-learning about consent between Ethics Review Boards, researchers, and communities.

Idea

What else do you do to ***measure, evaluate and enable ongoing learning*** to improve consent? What else could you do?

Q7. Is *training* needed in any of these areas?

Rationale: *A review of MHPSS ethics in emergencies found 'One proposal for enhancing ethical research conduct is active reflection upon implementing ethical principles with a view to refining ethical research practice in specific contexts, and building transferable knowledge for application across settings.'* [18 (p16)]

7.1 Reflexive questioning as a transformative consenting skill.* (Reflexive questioning is a facilitative approach to questioning that invites the participant to consider their beliefs or thoughts, carried out by a researcher who has also reflected on their own beliefs and positionality)

Idea

7.2 Researcher reflexivity including reflecting on researcher biases, community perspectives, non-verbal communication, and even values coded by the researcher's presentation.*

Idea

7.3 Cultural competence in consent-related areas, including respecting local cultural norms and values, perceptions of signatures, overcoming barriers presented by legal-looking documents, and individualistic approaches.

Idea

7.4 Relational dynamics including ensuring consent is effectively contextualized, group dynamics are considered, and awareness of fear-based responses.

Idea

7.5 Psychological safety to facilitate trust from the outset in organisations, teams and with communities. This can encourage open questioning of consent, and promote an open research culture throughout.

Idea

7.6 Trauma-informed approaches for consent due to the likelihood that people who have experienced trauma will necessarily have experienced something against their wishes or consent, therefore recognising how this can effect people.*

Idea

7.7 Psychological first aid to help treat issues at the earliest stage to try to prevent these becoming a barrier to meaningful consent and participation.

Idea

7.8 Effective communication including plain language, active listening and non-verbal communication.*

Idea

7.9 Context-sensitive innovation and co-design in order to adapt and develop consent with community members.

Idea

Would any other training be useful?

Q8: What additional tensions do you face in consent? Do you have any ideas of how to address these?

A GOAL researcher's example: Are the tensions and burdens of translating and tailoring consent materials fully understood by all stakeholders and appreciated?

"The process of translating materials between languages in advance, and tailoring them to the individual's dialect, level of understanding, and wider sociocultural context, requires careful attention. This can place a considerable burden on researchers. It is not enough to just have linguistic skills; a deep understanding of the technical concepts involved is also necessary for accurate translation. To ensure that the content resonates with the participants while maintaining technical accuracy, it is important to have a culturally-appropriate translation. This raises the question of whether it is better to translate the tool or create it from scratch in the local language.

Cultural-appropriateness involves understanding and respecting the cultural norms, values, and sensitivities of the target audience. This extends to: design choices, color palettes, iconography, naming conventions, and more. For example, certain colors or symbols may have specific meanings in Arabic culture, and it is important to understand these nuances to avoid unintended misunderstandings.

The ultimate goal is to create materials that not only function effectively but also connect with participants by acknowledging their cultural context and specific needs. This may require collaboration with experts in language, culture, and design to achieve a successful and culturally appropriate outcome."

If any of the cards you marked red or blue were asterisked* consider if you want to explore any of the below corresponding resources or literature for more information and ideas.

- **3.2 Context-sensitive tools:** see ELRHA's **Participation For Humanitarian Innovation Toolkit**
- **4.1 Literature on balancing time and offering communication channels** see 'Report on gender and age-related issues associated with the acquisition of informed consent'[24]
- **4.3 Ideas for alternative formats** see Tool **2.1**
- **4.7 Validating understanding** consider using **iConsent**[25] or a contextually suitable alternative
- **6.6 Co-learning** between ERBs, researchers and participants[18]
- **7.1 Reflexive questioning** see 'Reflecting on three creative approaches to informed consent with children under six'[26]
- **7.6 Trauma-Informed** see **'Integrating a key trauma-informed element: consent'**
- **7.8 Effective Communication** see **iConsent**[25]

Other resources you may find useful:
Guidelines For Tailoring The Informed Consent Process in Clinical Studies[25]

We were able to identify power dynamics, not just between researchers and participants but also among participants from different nationalities. We also conducted regular check-ins and asked for feedback from the participants to motivate them to share any concerns or issues related to power dynamics.

(Researcher, GOAL)

Next Steps

Now you have identified your strengths and any specific issues you want to address, you might want to research whether any of the resources or literature above, in the **references**, or more broadly could address your needs.

Then:

Pathways A&B → tool **2.1** to consider further redesign

Step 2: Identify Potential Solution/s

Tool 2.1: Innovative Solutions Cards

This is an **interactive workshop** drawing on real-life examples.

Aim/s: Decide if you want to:

- *Adapt* aspects of your consent materials or approach
- *Develop* a fuller innovation of your consent materials or approach

Time
150 mins

Participants

2-20+ researchers and community member/s (for a larger group, divide into 2, then share your reflections back to the wider group)

Materials

Choose either:

- In-person: pre-made inspiration cards, sticker dots, pens, paper, or:
- Remote: collaboration board e.g. **Miro**

Preparation

Cut out the Cards or open up the digital version. Then set up one of these options:

- post-it notes, pens, paper, or
- an online discussion board to facilitate discussion

Steps

1. Introduce the exercise using the rationale below.
2. Read through the cards as a group.
3. Invite the group to put stickers on the cards that resonate most with the community/ies you work with.
4. Discuss using these conversation prompts:

   A. What aspects resonate most with the community/ies?

   B. What aspects could be adapted or contextualized?

Rationale

There are an increasing number of innovative approaches to consent emerging that you could adapt and contextualize using the **Next Steps** pathways in this guide. Notably all the approaches are more interactive and engaging than standard approaches to consent. More interactive forms of consent may be more effective[26] and it is hypothesized these may encourage active participation, and enable reflection on the relational and ethical dimensions of consent.

Cards

Community-engaged consent training

Example: Tufts Clinical and Translational Science Institute's developed training for research staff by working with community members as simulated patients for role-playing exercises.

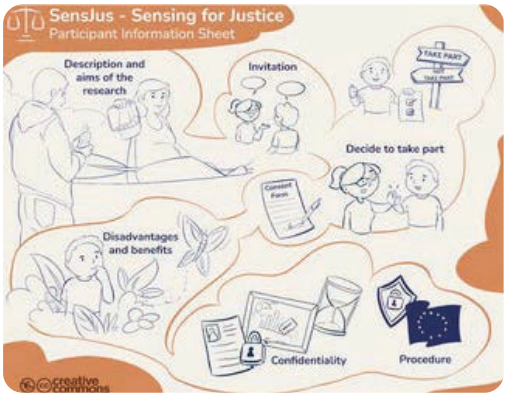
"...by embedding community members in the trainings, clinical research coordinators get to hear diverse perspectives, experience a range of patient responses, and learn from the lived experience of the communities that research tries to serve. Utilizing community members as trainers also helps to dismantle traditional power dynamics by demonstrating the organization's commitment to inclusiveness and community engagement"[29 (p1)]

Physical, equitable research agreements

Example: In one study the participant and researcher co-created a physical research agreement by both selecting different statements and physically placing them together to make each of their aims and responsibilities clear, ongoing, and therefore negotiable. The participants and researchers could return to this agreement throughout the research as part of an ongoing negotiation of consent.[26(p793)] The researchers hypothesize that the visual and manipulable characteristics of these formats may support more engaged, reflexive questioning from participants - if the researcher is attuned to the individual.[26]

Audio visual consent forms

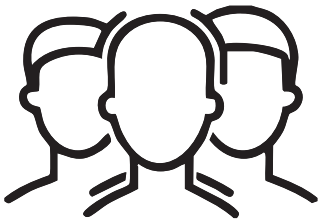
Example: Sensing For Justice Visual Consent published with a Creative Commons license enabling the format and visuals to be freely adapted to different research contexts.



Role- play & Community assemblies

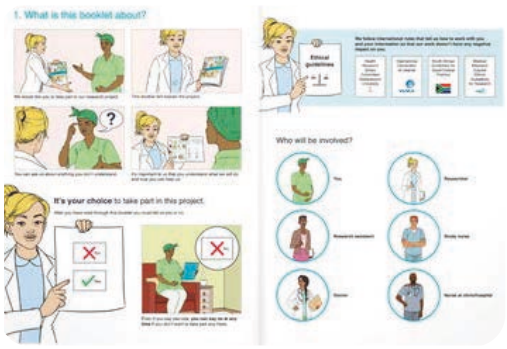
These formats can be highly effective and engaging in a range of contexts and stages in consent (from researcher training to community decision-making).

Example: Traditional community assemblies were found to be effective in investigating community perspectives on informed consent and research participation in Western Kenya.[30]



Visual research information

The ***Cherish Medical Research Information booklet*** by Dr. Amy Slogrove is a researcher at the University of Stellenbosch and Creative Contracts (Pty) Ltd and ComiContracts™ ©

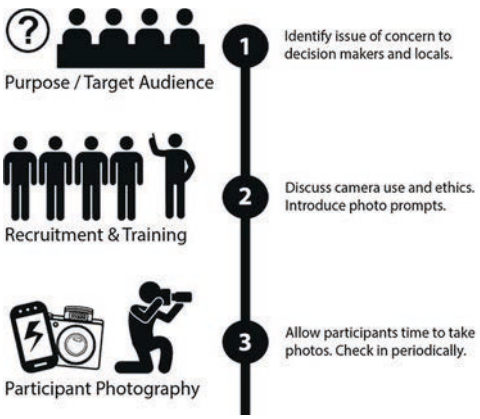


Audio visual consent education

Informed Consent Video by Kaiser Permanante for their Research Bank highlights the rights and aims of consent.

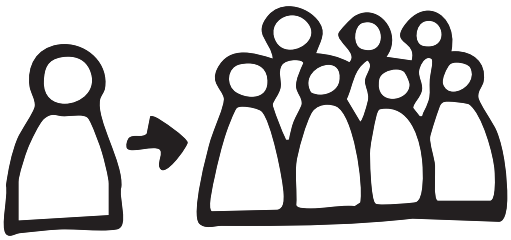
Integrating consent throughout research methodology

Consent can be interwoven into the research methodology. For example, photovoice provides multiple options for considering consent and has been used in global health research projects.



Self-select individual and/or collective forms of consent

Example: one study enabled participants to self-select whether to consent individually and/or collectively.[26(p795)]



Consent memory aids

Example: UK-based anesthetists developed a memory aid sticker to facilitate consent conversations between patients and consultants, and found:
'Based on early feedback, it has been seen to help stimulate discussions on the nature and purpose of anesthesia, common side effects, and rare but serious complications, which otherwise may have been overlooked as part of the consent process.'[32 (p3147)]

Likewise, co-created research agreements were also found to act as memory aids that participants and researchers could return to throughout the research as part of an ongoing negotiation of consent.[26(p793)]

The GOAL Community Advisory Board were really interested in audio visual formats about consent created with, by and for local communities, representing their language and values. These could provide a comprehensive insight into how the project aligns with their cultural backgrounds and community needs. This proactive approach may promote inclusivity, empower participants to make informed decisions, and establish a respectful foundation for their future engagement with the researchers.

GOAL Researcher

Next Steps

You should now have a clearer sense of:

- The values in your consent materials, approaches and training.
- Your team's strengths, weaknesses, and ideas to improve your consent approaches, materials, and training.

There are two options for next steps:

A: Ongoing individual and group-based ethical reflection

These are key to addressing barriers to research consent.[18] So you may want to simply reflect on whether there are any ways you want to strengthen your reflection and/or use your responses to the Questions & Ideas analysis to strengthen your existing practices. You could use the list of resources to address specific areas or search for more specific existing resources.

If your consent materials, practices or trainings are an ongoing barrier to participation that you are ready to address, you could also use the below:

A+B: *Adapt or develop* context-sensitive consent alternatives

Ideally this is done in partnership between community members, and researchers. We recommend you use:

ELRHA's Participation For Humanitarian Innovation Toolkit (PHIT)

To be used if you are a group of researchers and community members to identify: the barriers and enablers to participation; and the type of relationship and decision-making that is most appropriate between co-developers. Then you are ready to use ELRHA's Humanitarian Innovation Guide (HIG). ⟶

ELRHA's Humanitarian Innovation Guide (HIG)

To adapt or innovate new consent materials, approaches, or trainings. By completing this guide, you have already completed up to step two of the HIG, because the Contextualizing Consent (CC) tools in this guide have been designed as consent-specific alternatives for the HIG tools. (See **Appendix 1** for more details on how to continue).

You can find more GOAL research and let us know how you get on with this guide - we would love to hear from you!

Appendix 1: Next Steps Pathways To Innovate

The Contextualizing Consent (CC) tools in this guide are consent-specific alternatives for the **Humanitarian Innovation Guide (HIG)**. So, by completing this guide you have already completed all of HIG Stage 1 (Recognition) except finalizing the Challenge Brief, and part of HIG Step 2 (Identify) and the first part of Step 2.2. Use HIG to finish the Challenge Brief, and then you can begin at HIG Step 2.3 to continue the HIG pathway for adapting or innovating new materials, approaches, or training. CC uses the same broad Steps as HIG. Below is a list of the tools you have already completed.

STEP	HIG TOOL	CC REPLACEMENT TOOL
1. Recognition / Defining the problem	1.1A Learn from evalutions and reports	✓ Introduction, Background and bibliography 1.2 Survey
	1.1 C Observe the problem	✓ 1.1 Role-play
	1.1 B Assess strengths and weaknesses	✓ 1.4 Common problems ✓ 1.5 Questions and Ideas
	1.4 HIG Challenge Brief	✓ Use the criteria from the CC 'survey wishlist'
2. Identify the possible solution/creating an approach	2.1-2.2 Search for ideas	✓ 2.1 Examples
	2.3 Then carry on with the HIG, starting here	

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*Cited references are below. You can find further reading in the **full bibliography**.*

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