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Transactional Tools, Transformational Tensions: Piloting the CHIRON Toolkit for Community-Centered Governance of Repository-Enabled Research

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Abstract

Background

There is limited practical guidance for researchers and oversight boards in identifying and addressing group-level risks in the context of repository-enabled research. The Community Health Interests for Researchers & Oversight Networks (CHIRON) Toolkit is a community co-designed, nudge-theory-informed online intervention developed to support repository researchers, ethics boards, and data access committees in systematically considering community-level interests and risks in their work.

Methods

We piloted the CHIRON Toolkit at four sites between October 2024 and June 2025 with eleven participants, including repository researchers, data access committee members, and ethics professionals. We collected qualitative data through semi-structured interviews at three timepoints per site and through participant-completed exploration guides. We used reflexive thematic analysis to examine meanings participants attributed to their experiences, enriched by contextual analysis across four layers and community expert co-analysis of pilot data.

Results

Analysis identified nine parent themes across four contextual layers: transparency, context confusion, "not my job," comfort versus challenge, readability and interpretation, US context, personal and professional identities, nudging versus instructing, and thinking together versus thinking alone. Themes were organized across four contextual layers ranging from toolkit design to societal context. Themes revealed a fundamental tension between transactional change—incremental improvements within existing institutional structures—and transformational change—structural reorientation toward community-centered governance. While CHIRON prompted meaningful reflection among participants, their responses were largely constrained by institutional norms, professional role boundaries, and organizational expectations. Community experts, through co-analysis, identified these shifts as promising but incomplete, consistently prioritizing community interests over institutional convenience.

Conclusions

Transactional governance tools like CHIRON are necessary but insufficient to ensure communities benefit from repository-enabled research. Complementary structural reforms—in oversight committee mandates, funder requirements, researcher training, and the redistribution of decision-making power—are needed to move from incremental improvement toward transformational, community-centered governance of biorepository research.

Introduction

The reuse of large-scale health data has become a central feature of contemporary biomedical research.[1] Data collected from clinical care, research studies, and public health initiatives are increasingly made available for secondary analysis via data repositories, enabling research at scales that would be infeasible through primary data collection alone.[2] Repositories have enabled research advances across genomics, epidemiology, and population health, including studies that seek to better understand and address health disparities.[3] At the same time, the widespread reuse of health data raises ethical and governance questions that extend beyond those traditionally addressed in human subjects research.[4,5]

Existing research oversight frameworks largely emphasize the protection of *individual* participants, focusing on issues such as privacy, confidentiality, and informed consent.[6] However, the research enabled by repositories frequently produces findings that implicate *groups* rather than individuals.[4,7] As a result, potential harms may arise at a collective level, affecting groups defined by shared characteristics such as ancestry, disease status, geographic location, or social identity. These "shared characteristics" may extend beyond characteristics recognized by, or even recognizable to, individuals, spanning from unfortunate clinical shorthand (e.g., "non-compliant" patients[8]), to nuanced, and even proprietary, combinations of health data.[9,10] Moreover, research discoveries may instantiate new groups, such as those with shared genetic variants or risk profiles (e.g., "previvors").[11,12]

Although group-level harms have been discussed in the literature, there is limited practical guidance for identifying and addressing these risks in the context of repository-enabled research.[9] In this study, we use the term *group harm* to refer to the adverse effects of research practices or findings that impact a group of people collectively, whether directly or indirectly, as a result of shared attributes or affiliations.[4,9] These effects may include stigmatization, misrepresentation, or exposure to social, economic, or legal risks, even when individual-level risks are minimal. Group harms are particularly challenging to anticipate in repository-enabled research, where investigations may explicitly be exploratory or hypothesis-generating and data can be analyzed without the direct engagement with the populations represented.[9]

An additional challenge to integrating community voice into repository-enabled research arises directly from the diversity and fluidity of the communities implicated by repository research themselves.[9,13] For example, while some communities (e.g., Native American tribes) are formally organized and have established governance structure, others are loosely defined and/or lack clear leadership structures.[14] Communities also evolve over time, merging, dividing or otherwise changing in their composition, with new priorities and/or capacity for collective decision-making complicating assumptions about representation and consent.[13]

Together, these factors point to a gap between the ethical issues raised by repository-enabled research and the tools currently available to researchers and oversight bodies to address them.[9,11] There is a need

for empirically grounded approaches that clarify how group-level risks are understood and how such considerations might be integrated into existing research processes. Community Health Interests for Researchers & Oversight Networks (CHIRON) is a multi-year initiative to integrate community voice in repository-enabled research.[9] We previously reported on the community co-creation process;[15] here we report piloting outcomes from October 2024 through June 2025. We interpret findings through organizational change theory and bounded justice, examining the tension between transactional and transformational approaches to research governance reform.[16,17]

Materials and Methods

The CHIRON Toolkit

The Community Health Interests for Researchers and Oversight Networks (CHIRON) Toolkit is an online, self-directed resource developed to support biorepository researchers, ethics boards, and data access committees in systematically considering community-level interests and potential group harms in repository-enabled research.[18,19] The Toolkit is organized into ten modular components that map to key stages of the repository-research lifecycle: study planning, data access and analysis, and reporting and dissemination (Fig. 1). Each module was designed as a self-contained exercise, allowing users to engage with components based on their role, institutional context, and stage of research activity.

We applied nudge theory to CHIRON Toolkit development to increase the likelihood that researchers and oversight boards would consider community interests.[20] Nudging influences behavior by targeting cognitive biases and heuristics.[21–23] Critics highlight two key concerns: nudges may obscure problem complexity and may not drive policy change.[24–26] We mitigated the first through deep community engagement in design. For the second, research governance policy is circumscribed, and many argue risks are better addressed through guidance and education.[4,27] By addressing cognitive bias through nudges, we hoped to increase uptake and educational impact.

In addition to the structured reflective modules, the Toolkit includes several types of supporting materials. Accompanying documentation, covering topics such as cases of group harm in biorepository research, priority setting literature, demographic labeling considerations, and approaches to contextualizing findings, provides background knowledge and best-practice guidance that is linked from within the relevant modules but can also be accessed independently as standalone readings. How-to guides offer more pragmatic support for specific tasks such as communicating findings to communities and addressing conflicts of interest, complementing the reflective exercises without requiring completion of those exercises. The Toolkit also includes the CHIRON Trustworthiness Calculator, an embedded interactive tool that prompts users to reflect on their research practices in relation to represented communities, generates a benchmarking score, and suggests relevant modules for further reflection.

The Pilot of the CHIRON Toolkit

Ethics

The pilot protocol was reviewed and approved by an external IRB (WIRB #20170371); participants provided verbal informed consent.

Study team

The pilot study team was composed of two host scholars from the grant-receiving institution, six external scholars, and eleven community experts from the CHIRON project team.[15] Collectively, the pilot study team was responsible for designing procedures, data collection, and analysis activities for the CHIRON pilot.

Given that the CHIRON toolkit itself foregrounds positionality and the relationship between researchers and communities, we describe our own positions and how they shaped this work. The host scholars are based at Sage Bionetworks, a non-profit open science organization. This institutional position is directly relevant: Sage Bionetworks is not a neutral observer of the repository research governance landscape the CHIRON Toolkit seeks to influence but an active participant in it. External scholars are all dual space holders: both academic professionals with expertise in a variety of fields related to repository research, as well as members of marginalized communities that have been impacted by group harm. Community experts were all members of marginalized communities that have been impacted by group harm (i.e., American Indian, Alaska Native, Native Hawaiian, Pacific Islander (AIANNHPI); Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual, Two-Spirit (LGBTQIA2S+); Black/African American; and individuals with high-penetrance genetic variants); experts served as paid consultants to the CHIRON project, as described in depth in our earlier manuscript.[15]

We note several implications of our positions for this study. First, as designers of the CHIRON Toolkit, the pilot study team was both part of the development of the intervention as well as its evaluator.[15] We sought to manage this through structural safeguards such as community expert co-analysis, the involvement of external scholars in theme review and refinement, and the deliberate retention of tensions between analytic perspectives rather than resolution by consensus. Second, host scholars' institutional location within a non-profit organization that builds open access data governance tools means we are professionally invested in the premise that governance interventions can advance the practice of research. We attempted to counterbalance this by centering our analysis on pilot participants' own accounts and by foregrounding findings that challenge the sufficiency of toolkit-based approaches. Third, the pilot study team is enriched for individuals who identify as members of communities historically affected by the harms CHIRON addresses, as well as including individuals who do not. This range of proximity and distance shaped our analytic conversations and is reflected in the tensions we chose to preserve rather than resolve.

Recruitment

We used purposive and convenience sampling to recruit participants. The pilot study team predefined eligible stakeholder groups: (1) investigators conducting repository-enabled research; (2) members of data access or other repository oversight committees; and (3) research ethics professionals, including human subjects research staff and ethics committee members. A brief pilot description was circulated through professional networks via email, direct outreach, and social media. Sixteen groups across ten institutions expressed interest. Ultimately, four pilot sites were selected based on variation in institutional role, organizational structure, and anticipated focus of Toolkit use, conditional on confirmation of institutional approval and prospective participants' availability. Participants included repository-enabled researchers, repository directors, individuals responsible for developing and/or implementing data access procedures, and human subjects research professionals, with some holding multiple relevant roles.

Research focus and activities

The CHIRON Toolkit pilot was designed to address three primary research foci: (1) to characterize patterns of Toolkit use across participating sites; (2) to assess whether pilot participant experiences aligned with the Toolkit's intended purpose, including promoting meaningful consideration of community interests and avoiding unintended counterproductive effects; and (3) to examine how contextual factors, such as pilot participant roles or the format or timing of piloting, influenced user experiences. The pilot also sought opportunities for refinement, including evaluation of user experience and barriers to adoption. Toolkit evaluation was designed to capture use in situ rather than under controlled conditions, reflecting the modular and context-dependent nature of Toolkit usage. Pilot sites participated on a rolling basis between fall 2024 and late spring 2025 **(**Table 1**)**. Pilot participants were asked to commit one hour per week to exploring each component of the Toolkit in turn over a minimum pilot period of 12 weeks.

Table 1
CHIRON pilot site details

Pilot site	**Site's pilot focus**	**# Pilot participants**	**Time period**	**Engagement (weeks)**
International researcher-administrator at biobank (single institution)	Toolkit utility for data use/access policies	1	Oct 2024 - April 2025	12
US-based HSRP (single institution)	Toolkit utility for IRB processes	4	Nov 2024 - March 2025	12
US-based researchers / ethics professionals (single institution)	Toolkit utility establishing DAC	4	Nov 2024 - Feb 2025	Planned 12, completed 9
US-based researchers (separate institutions)	Toolkit as addition / substitute for existing procedures	2	Feb 2025 - June 2025	16

Data sources and types

We interviewed each site's participants at pilot initiation, at the approximate midpoint of their pilot period, and at the conclusion of their site's pilot **(Appendix A)**. Between interviews, pilot sites received a weekly email with an exploration guide (**Appendix B**). Guides highlighted the Toolkit components for that week's exploration and key discussion questions. Three of the four sites elected to gather in a virtual meeting room, creating an audiovisual recording of their exploration and related conversation; one pilot site elected to respond to key discussion questions via questionnaire; to compensate for the austerity of data gleaned through questionnaires, two supplemental interviews were added to expand upon written responses. Recordings were transcribed and de-identified prior to analysis.

Analysis approach

Our qualitative analysis of pilot data was aimed to situate participants' accounts within their social and organizational contexts while attending to their own unique perspectives. Host scholars conducted reflexive thematic analysis to examine the meanings participants attributed to their experiences with the CHIRON Toolkit. Following Braun and Clarke's phases of reflexive thematic analysis, candidate themes were developed iteratively through repeated review and analytic discussion among host scholars.[28,29] Transcripts and other data were deidentified and coded within Delve, a cloud-based qualitative coding software platform; Delve platform AI integrations were not used within this analysis.[30]

As themes emerged and were refined, the host scholar team, in collaboration with external scholars, appreciated that the analysis would benefit from further refinement informed by contextual analysis.[31] Contextual analysis is a tool of implementation science, where various context layers are recognized as interacting, as barriers or facilitators, with the intervention and its implementation. Within implementation science, context analysis spans levels from micro to macro and extends across domains (e.g., geographical, sociocultural, socioeconomic). For the purposes of this project, we limited our application of contextual analysis to defining contextual layers which intersected with the parent themes that emerged from our reflexive thematic analysis.

Additionally, as we have described elsewhere, analysis was informed by insights generated through community experts' co-analysis of pilot data.[15] Tensions between the host scholars' analysis and community outputs were explicitly retained and incorporated into theme development rather than resolved by consensus. Finally, themes were reviewed and further refined with input from external scholars, again with attention to preserving both the host scholar's reflexive analytic interpretations and the distinct contributions of community co-analysis.

Results

Across the four pilot sites, we identified nine parent themes that cut across four contextual layers (Fig. 2). These contextual layers sought to describe conditions and environments surrounding observed responses to the Toolkit. At the micro level, CHIRON was itself a contextual layer: the Toolkit's design, the clarity of its wording, or complexity of topics could act as a barrier or facilitator to its own use. The

personal contextual layer includes participant-specific barriers or facilitators to using the Toolkit, such as personal preferences or past experiences. The institutional contextual level captures influences on pilot participants' use and perceptions of the CHIRON Toolkit specific to their own home institution or emanating from repository-enabled research culture or the norms of the broader research ecosystem. At the most macro level, societal context also influenced participants' use and receptivity to the CHIRON Toolkit. These larger forces were not tied to any particular individual, institution, or profession; societal context describes pervasive, often unspoken, assumptions about how the world works and what is possible; these assumptions influenced pilot participants' use and perception of the CHIRON Toolkit. Each of the nine parent themes are discussed in detail below, associated with quotes from participants who have been identified with a code.

The nine parent themes, although analytically distinct, are often interrelated (Table 2). For example, institutional-layer concerns about transparency also relate to the theme of US context, which captures the influence of shifts in US science policy and funding on the CHIRON toolkit pilot. The parent theme "not my job" which describes pilot participant pushback against the work of CHIRON relates closely to institutional contextual pressures against integrating personal and professional identities within the research enterprise.

Table 2
Parent theme overview

Theme name	Brief description
Transparency	Tension between ethical accountability to communities and the perceived risks of increased visibility, complicated by unclear data-handling practices within the Toolkit itself.
Context confusion	The boundary between primary research and repository-enabled research can be unclear; researchers often toggle between primary and secondary research tasks. Repositories themselves often function both as data collecting and data disseminating engines.
“Not my job”	The narrative evoked when participants often felt the topics raised by the CHIRON Toolkit, while important, were outside their roles/responsibilities.
Comfort versus Challenge	The CHIRON Toolkit and pilot environment both supported and challenged pilot participants’ principles, processes, and values.
Readability & Interpretation	The (lack of) readability of the Toolkit and (high) volume of reading associated with the documentation detracted from the mission of the Toolkit and impacted the pathways by which participants made sense of the Toolkit
US context	The CHIRON Toolkit was perceived as being US-centric by pilot participants. Notably, CHIRON pilots straddled significant shifts in US research policy and funding.
Personal & professional identities	CHIRON prompted pilot participants to reflect on their motivations, positionality, and community relationships; responses varied substantially.
Nudging versus instructing	This theme relates to the intervention itself: CHIRON was designed as to nudge rather than to instruct. This framing decision came in conflict with some pilot participants' expectations for a toolkit.
Thinking together > thinking alone	Collaborative use of CHIRON was often more generative than individual use, but this value came with caveats related to group dynamics and power.

Transparency

Transparency emerged as a central tension in participants’ responses to CHIRON. Community experts had identified transparency and, relatedly, accountability to communities as core values in the CHIRON Toolkit’s development. However, pilot participants often reacted cautiously to Toolkit features that requested or implied visibility of researcher intentions, positionality, or outputs. In some cases this reflected CHIRON-layer barriers such as lack of clarity about how the Toolkit handled user-entered information. This uncertainty about data handling reduced trust in the Toolkit before its substantive content had been fully engaged.

Within personal and institutional contexts, participants also described transparency as potentially personally and professionally risky. Within the personal context layer, some pilot participants expressed reluctance to store personal statements or to make themselves more visible as researchers (generally or as researchers with a community orientation more specifically), preferring anonymity and expressing

discomfort with public-facing communication. Participants highlighted a growing sense of professional risk associated with public disclosure.

"I was in a conversation… about should researchers be making themselves visible in certain ways. [A]re you going the self-protection route and just trying to make sure you don't get yourself or your institution in trouble? I think that's a really hard thing to navigate. I think it's different for people in different positions of power already in their institutions." PSW5S

At the same time, transparency was not rejected outright: some participants explicitly linked it to community trust and to growing public interest in understanding who is doing research, why, and with what motivations.

"People are very interested in where the money's coming from, and understanding [research] motivations. Especially in this age of social media and conspiracies. People wanna know what's driving the [research] question." CCW3M

Transparency therefore functioned as a tension across contextual layers rather than a simple preference: participants recognized its ethical value while also associating it with individual vulnerability, institutional exposure, and the possibility of being targeted in a polarized public environment.

"Before [2025]… I think I would have been incredibly gung-ho about sort of a page of current researchers who are doing projects considering group level harms. Now… my strongest reaction is, oh god! That's… a list of people to be targeted." PSW5IB

Context confusion

The CHIRON Toolkit was designed for repository-enabled, or secondary, research. However, researchers, oversight committees, and repositories themselves often straddle both primary and secondary research contexts. Hence, and somewhat unsurprisingly, pilot participants frequently flowed between primary- and secondary-research frames when discussing the CHIRON Toolkit's relevance and utility. Some pilot participants viewed parts of CHIRON as more applicable to primary data collection. Others regarded the Toolkit's focus on repository-enabled research as too narrow to be useful within the broad context of research oversight.

"Because the Toolkit is focusing purely on biorepositories, it's so niche that if I threw in one of the [CHIRON] questions into the [IRB] application, I would imagine I'd get more confusion." UAW7C

Comments also suggested uneven familiarity with repository-enabled research across the pool of pilot participants. Some oversight professionals clearly struggled to differentiate primary and repository-enabled research, for example assuming repository data use should be tightly hypothesis-driven. Pilot participants who were themselves repository-researchers expressed concern that oversight offices do not know what to do and conversations about potential group harms often do not occur.

“[Repository researchers] fall into this weird grey area as secondary users of data where people don’t understand what we’re doing. We often find that the IRB office has no idea what to do with us… there aren’t even conversations of the potential group harms.” PSW5IB

Together, these responses suggested that context confusion was not simply a CHIRON usability issue. It also reflected the still-uncertain institutional location of repository-enabled research, especially where review structures remain oriented toward primary research and give limited attention to group-level harms in data reuse.

Not my job

Pilot participants frequently acknowledged that the issues raised by the CHIRON Toolkit were important while simultaneously positioning these topics as outside their role, expertise, or immediate responsibilities. This was especially visible among participants who were repository researchers, some of whom noted community engagement as something their projects had been encouraged to do but had not known how to operationalize. In these instances, CHIRON sometimes served as a bridge: participants described some tools as making engagement feel more approachable and less out of scope.

P1: *“We've gotten the request—or the recommendation— from [our project’s advisory board] to do community engagement, essentially. And we've always kind of been like, “Well, we don't really know how,” or “Is that in scope?” And, “What does that look like?”*

P2: *“We're statistical geneticists.” [general laughter]*

P1: *Yeah. So, I think [tool 8]... makes it a little bit more approachable to say, “Okay, well, this could look many different ways”... And so, yeah, I think it aligns with some things we would like to do [in our project] but have maybe felt out of scope or people don't really know where to start.”* PSW13

At the same time, several participants framed community-oriented practices as constrained by training, temperament, and workload. Within the institutional context layer, pilot participants noted that their training had not prepared them to communicate with communities.

“I kinda missed how to communicate with the participants [in my training]. …when you’re only sitting with data, you forget that there are people behind the data.” FGW1N

Others described entering computational work partly to avoid outward-facing communication. Institutional conditions reinforced these boundaries. Participants referred to the “overburdened researcher,” repeated that “I don’t have time” was a common refrain, and linked time use to funders, publishers, and institutions. Resistance to CHIRON was therefore not only about individual reluctance; it also reflected an institutional context in which community-centered reflection could be acknowledged as valuable while still being treated as somebody else’s work.

Pilot participants described persistent privileging of the research enterprise over community concerns. Participants referred to “methodological momentum” toward existing analytic plans and raised questions about what should happen when researchers and communities disagree. Some defended a view in which the researcher’s responsibility ends with presenting results in a neutral manner, even if those results may be received negatively by affected groups. In this sense, “not my job” was not merely a statement about task allocation. It was also a statement about where responsibility for anticipating and mitigating group harm was understood to reside, further highlighting the tensions at the institutional context layer.

Comfort versus challenge

Independent from role boundaries, participants’ engagement with CHIRON was shaped by whether the Toolkit and the piloting environment felt manageable, coherent, and safe enough to support deeper reflection. Several comments pointed to CHIRON contextual layer barriers that interfered with substantive engagement. Participants were unsure what the completed Toolkit would produce, questioned whether they would receive multiple disconnected outputs, and described difficulty tracking prior responses across screens. In these moments, CHIRON itself appeared to compete with the more reflective work the Toolkit was designed to prompt.

By contrast, when pilot groups had rapport and enough trust to speak candidly, the Toolkit appeared to function as a jumping-off point for more vulnerable and thoughtful discussion.

P3: *“So, I have something to say that’s not gonna come out right, but I almost feel like* – P4: *It’s a safe space, and a safe recording.”* CCW5

Pilot sessions and interviews where participants had comfort (a stronger or longer history together as evidenced by shared “in jokes”, referencing shared experience) often appeared to be a context that supported the challenge of deeper or more contemplative conversation. Participants seemed more willing to engage difficult questions when the process of exploring felt supportive and when the tool’s structure did not itself become a distraction. While this appears at first glance to be an individual context layer indicator, institutional power structures, and societal contexts were also at play: within the pilot, participants directly and indirectly referenced professional positions, institutional roles, and societally-assigned power relationships (e.g., gender roles) as they navigated the the CHIRON Toolkit.

“I will say that, maybe it was something about the formatting of having the bolded and italicized big quotes, and then repeated again, about, ‘The project team strongly recommends this,’ or ‘against that’. I felt a little bit like, ‘Aah!’ [laughs] I think, especially because I was a little bit like, ‘Oh, gosh. I don’t think this is something that I really do, or my research group does.’ So, I was feeling a little bit – I don’t know if ‘defensive’ is quite the right word. And I feel like some of the way that things were being formatted and pulled out kind of contributed to that. But it is not about making all researchers feel comfortable, so…” PSW7S

Readability & Interpretation

At the CHIRON context level, the readability and volume of reading associated with the CHIRON Toolkit was a recurring barrier to use. Participants commented on unfamiliar vocabulary frequently across all Toolkit content types. Unfamiliar terms interrupted the flow of engagement and, for some participants, required real-time interpretation by peers or outside searching.

P5: *[reading from CHIRON Toolkit]* " 'With regard to social empowerment, people who are minoritized..'??

P6: *I don't think I've ever heard that terminology before.*

P5: *Me neither. I'm Googling it."* UAW4

One participant noted that English was not one of her several first languages and described repeatedly needing to look up words used in the toolkit. One pilot team enlisted a public AI chat bot to help simplify and explain Toolkit content. In practice, these comprehension problems affected not only the Toolkit's usability but also how participants made sense of CHIRON. This use of a "black box" AI agent with its own biases and perspectives was a source of consternation among community experts within their co-analysis process.

US context

Participants described CHIRON as strongly US-centered. This CHIRON-level contextual concern appeared in reactions to examples, terminology, and assumptions about racial and demographic categories spread across all elements of the Toolkit. For some, especially those working in international or multinational contexts, certain framings felt like *"a really American way of putting it"* (FGW3N) when addressing topics like race/ethnicity. Participants noted that discussions shaped by US datasets and US researchers could obscure how differently communities outside the United States describe themselves and how context-specific population descriptors can be.

"I think [the Toolkit] could still talk about the US census as an example, but if they want to be… have kind of an international focus, then maybe [CHIRON needs to be] getting examples from other countries." PSW7S

At the societal context level, participant conversation related to this theme increased in frequency and intensity following the change in US administration in January 2025, and subsequent shifts in science policy and funding. Participants shifted to speaking cautiously about terms related to diversity, equity, and community representation, sometimes explicitly noting that they were being recorded and that their institutions depended on US federal funds. Several comments conveyed fear, irony, or bitterness about what could still be said safely within institutional settings. CHIRON's content was not encountered in a neutral policy environment; during the pilot period, community-oriented language and practice became increasingly professionally and institutionally sensitive. It is important to note, however, that not all societal context layer comments referenced shifts in US political climate; some participants pointed more broadly to global capitalist structures as leaving not only communities but researchers behind.

"Because… you could have big companies that it's all about profit and not about the people and community and forget also the researcher as well." FGW20NA

Personal & professional identities

CHIRON asked participants to consider their motivations, positionality, and relationship to the communities implicated by their work, and responses to this invitation varied substantially. For some, these prompts were unfamiliar or conceptually difficult. For others, they opened productive reflection about what it means to study communities to which one does or does not belong. Some pilot participants appreciated the possibility of explicitly naming their limitations and treating a positionality statement as a form of accountability.

"I feel like there are many experiences and perspectives I very much lack. And I like the idea of a positionality statement, both in that it gives me the opportunity to be very clear about that and hopefully hold me accountable in terms of acknowledging that and doing the right things to partner with folks who can, hopefully, overcome those limitations." PSW12I

At the same time, participants also voiced discomfort with what they saw as blurring of personal and professional roles. Further, some pilot participants treated community membership as broad and diffuse, while others described a more particular connection to specific racial or ethnic communities and the impact of those connections on their approach to research.

*"I was getting data, and I thought I was, kind of, 'the great researcher' and did the most important thing. But when I moved back [to my community]… you gain the respect for the people behind [the data]. …So, that has changed for me. Only because I am***within**. *So, I don't know if you're not in it and you're not – are you able to see? To learn it? I don't know."* FGW20NB

Others held firm to the institutional norm of "scientific neutrality" and institutional traditions that insist on removing personal identity from research, suggesting that researchers should "just say our results" and avoid contextualization or interpretation, personal or otherwise.

"...once you start contextualizing [research], like, interpreting it into different contexts… it can… obviously, get a life of its own that you didn't intend to have, but just, that's why it's important to present the data, almost like in a raw fashion. 'We've studied this many people, and this is what we found' type of a thing. And not add too much context to it, because that's where you can go down where you're leading the discussion into a certain area." UAW5S

Thus, the tensions between personal and professional identities was not simply about individual willingness to self-disclose, as seen within the related theme of transparency; competing institutional pressures informed pilot participants' sense-making regarding identity, objectivity, and responsibility in big health data research.

Nudging versus instructing

The CHIRON Toolkit was designed using nudge theory and not as a didactic intervention. Some participants responded positively to this approach. They described CHIRON as prompting them to think about the community before the research, encouraging them to pause over demographic categories, and to reflect on the variables repository researchers had or had not chosen to include in analysis.

"[What] sticks with me is the tool… where you were looking at demographics and what's the best way to report on demographics. It's kind of made me pause. As I'm looking at new study submissions [to the IRB] and I'm seeing the demographic questions, I think back on that tool… And I find myself kind of looking up, is this a proper way to ask this question?" UAW12C

Others noted that the Toolkit's nudging tone was productive rather than belittling, even when it prompted uncomfortable self-reflection.

P7: *"Also just looking at how they describe if you are scoring lower, I like this language. This doesn't make you feel too bad about yourself…*

P8: *I think that that's something [CHIRON] consistently do well. Some of the tools, I feel a little overwhelmed with sort of the level of the questions potentially, but I never have felt any of the language has been belittling in any type of way.*

P7: *Yeah, I agree. I think it's been very productive. I think the times that I've felt bad, it's just been my own reflection on how I'm thinking through the questions. It's nothing that [the Toolkit is] saying or doing."* PSW12

However, at an individual level, some participants preferred more explicit direction. Participants often valued outputs that gave them a score, pointed them toward next steps, or resembled a standard operating procedure. In this sense, reflective prompting sometimes clashed with participants' expectations of what a toolkit should do. That said, institutional and societal layer pressures were evident within the data, pressing participants towards needing more closed end, right or wrong answers from the Toolkit not (or not only) as a matter of personal preference.

P9: "*...there could be some tips. Like, don't use the word Caucasian. Here's the root of the word. Use the preferred terms to use. To actually list out some tips of what is offensive 'cause that always changes, too.*

P10: *Absolutely. I was completely ignorant to the fact that Caucasian.. well… And actually, what was I reading just the other day? I was reading something – I don't remember what – and it was a recent thing, so I was just like, 'What?!?' Well it's one of those things not everybody's aware of, right?*

P11: *Yeah. …I was like, 'I'm pretty sure I've done all of these things.'*

P10: *Especially if you did it as a graduate student–maybe this was your first paper, 15, 20 years ago or whatever, is that gonna follow you forever?*

P9: *Well, there's too much memory now, right? … Any mistakes, they're tattoos."* CCW5

For some, CHIRON was most useful when it offered a concrete endpoint or recommendation; for others, its value lay in creating space for reflection. The tension between nudging and instructing therefore emerged as a core feature of how participants understood both the Toolkit's usefulness and its legitimacy.

Thinking together > thinking alone

Participants often described collaborative use of CHIRON as more generative than individual use. In one pilot site, participants explicitly stated that working through the Toolkit together produced more insight than going through it alone. Group discussion appeared to help participants interpret ambiguous prompts, connect questions to ongoing projects, and articulate concerns that might not have surfaced in solitary use.

P2: "*I really enjoyed going through this with you and just having an excuse to work with you.*

P13: *Same! I think I'm glad we did this as a collaborative thing... I got a lot out of it. I think it would have [been] less generative to try and go through it on your own. Which again, I think is a perfect use case for actually going through the tool itself, not just piloting it. You know?"* PSW15

At the same time, this apparent advantage came with caveats. Power differentials within groups and other interpersonal dynamics sometimes redirected discussion toward surface features, such as formatting or color choices, rather than the underlying ethical issues. For example, more than halfway through one site's pilot period, a key participant missed a meeting leaving the remaining pilot group to explore a tool on their own. Unlike in previous weeks, the site discussion focused on more "cosmetic" elements rather than the substance the tool presented: *"...I'm not sure the picture that's above it really tells me maybe what it's about right off the bat. It doesn't seem to be kind of connected to [this tool] in some ways. I don't know."* (UAW8S)

At the institutional context level, pilot participants expressed concern that, if made a requirement of data access or use, CHIRON Toolkit tasks could be delegated as low-status "grunt work", leaving insight gained from CHIRON in the hands of individuals with limited authority to shape research decisions. Thus, thinking together appeared promising, but not automatically transformative; the value of collaborative use depended on who was in the room, how power was distributed, and whether the group had enough influence to act on what emerged.

Cross-cutting observation from community co-analysis

Across themes, community co-analysis suggested that CHIRON sometimes produced meaningful but partial shifts in perspective.[15] Community experts highlighted moments in which participants appeared to encounter issues they had "never considered," experienced a "lightbulb moment," or began to refocus on the fact that there are people behind the data. At the same time, these shifts were understood as incomplete. As one co-analysis formulation put it, CHIRON sometimes created "a moment, and not a whole journey." Taken together, the findings suggest that the pilot did not simply reveal barriers to

uptake. It also showed that even partial engagement with CHIRON could prompt reflection, while leaving unresolved the question of how often reflection would translate into sustained changes in practice.

Discussion

The CHIRON Toolkit pilot generated nine parent themes that cut across four contextual layers, from the micro-level design of the Toolkit itself to the macro-level forces of societal context. These themes were neither linear nor neatly separable; they overlapped, interacted, and at times contradicted one another within and across pilot sites. Pilot participants who recognized the ethical importance of community engagement simultaneously positioned it as outside their role. Transparency was valued in principle yet feared in practice. The Toolkit was praised for prompting reflection while criticized for not providing definitive answers. This internal complexity is itself a finding: the governance of group harm in repository-enabled research does not lend itself to simple interventions, because the barriers to community-centered practice are not primarily informational: they are structural, cultural, and deeply embedded in the norms of the research enterprise.

Permeating all contextual layers and themes was a tension between two theoretical orientations toward change: transactional change and transformational change. Organizational change theory draws a foundational distinction between these modes.[17] Transactional change—also termed first-order change—operates within existing institutional and societal arrangements: it adjusts processes, refines criteria, and introduces incremental improvements without disturbing the underlying logic of the system.[32] Transformational change, i.e., second-order change, restructures the system itself, altering the assumptions, power relations, and values on which institutional practices rest.[32] At its core, organizational change theory recognizes that organizations are social systems composed of individuals, groups, cultures, and structures; change in such systems requires attention to human behavior, group dynamics, meaning, and context as much as to formal processes.[33] Models of organizational change further suggest that phases of change frequently overlap and that sustaining change requires ongoing reinforcement, which argues for adaptive, iterative approaches rather than rigid, linear interventions.[34]

The CHIRON Toolkit, grounded in nudge theory, was designed as a transactional intervention. Nudges work subtly to create incremental—and ideally sustainable—change by restructuring the decision environment rather than mandating specific behaviors.[21,22] CHIRON sought to orient researchers and oversight committees toward community interests and group harm within the existing architecture of repository-enabled research governance, not to dismantle or replace that architecture. However, as we finalized our analysis across host scholars' reflexive thematic analysis and community experts' co-analysis, what emerged was that this deliberately transactional approach was received simultaneously as *too much* by pilot participants and *not enough* by community experts. This asymmetry was not a failure of calibration; it reveals a structural fault line. Pilot participants, embedded in institutional roles and disciplinary training, experienced aspects of CHIRON as going too far. Community experts, whose value systems consistently prioritized communities first, felt that CHIRON did not push far enough. The

distance between these responses maps directly onto the distinction between transactional and transformational orientations toward change in the governance of big health data research.

Participants' responses were largely legible through the lens of transactional change. Their engagement was bounded by organizational expectations, professional norms, and practical constraints—conditions that organizational change theory identifies as powerful determinants of how individuals respond to interventions within institutional settings.[17] The theme of "not my job" captured a pervasive tendency to acknowledge the importance of community considerations while locating responsibility for them elsewhere—with community engagement specialists, IRBs, or data access committees—really anyone with a role different from their own. Transparency was treated cautiously: participants recognized its ethical value but associated it with professional vulnerability, particularly within the shifting US political context during the pilot period. The preference some participants expressed for scores, checklists, and standard operating procedures over open-ended reflection reflects a transactional expectation: that tools should produce actionable outputs within existing workflows rather than prompt fundamental reconsideration of those workflows. Much of what pilot participants sought from CHIRON aligned with first-order change: practical modifications that could be integrated without disrupting established institutional logics.[32] This is consistent with organizational change theory's observation that individuals within institutions tend to interpret interventions through existing cognitive frames, and that second-order change is resisted precisely because it requires altering those frames rather than working within them.[35]

Community experts occupied a fundamentally different position.[15] Their value systems, as expressed through co-analysis, consistently prioritized communities first, then individuals, then organizations, an inversion of the ordering implicit in most research governance frameworks. They identified moments of "unexpected growth" in participant responses and recognized when pilot participants were engaged in "rethinking things" or fretting over "unknown unknowns", but they also assessed these shifts as incomplete. The formulation that CHIRON created "a moment, and not a whole journey" captures the transformational aspiration of community experts alongside the recognition of its limits. Community experts frequently called out transactional engagement: instances where researchers engaged with community-oriented language or tools without fundamentally reorienting their relationship to the communities implicated by their work. In doing so, community experts articulated a transformational position that resonates with decolonial and Indigenous feminist scholarship.

Decolonial and Indigenous feminist thinkers argue that colonial and patriarchal structures, including the institutions that govern knowledge production, cannot be adequately reformed from within. María Lugones' concept of the colonial/modern gender system demonstrates how interlocking systems of domination are embedded in the very categories and logics through which institutions operate, rendering incremental reform insufficient because it leaves foundational structures intact.[36] Leanne Betasamosake Simpson's work on Indigenous resurgence centers refusal and world-building as alternatives to institutional accommodation, arguing that meaningful change requires the creation of

new relational practices outside the logics of extraction and control.[37] Linda Tuhiwai Smith's foundational critique of Western research methodologies exposes how the research enterprise itself has functioned as an instrument of colonization, and argues that decolonizing research requires not better procedures within existing systems but a restructuring of who defines research questions, who controls data, and who benefits from findings.[38] These theoretical traditions are explicitly skeptical of reform as a pathway to justice; they center transformation through relationality, community sovereignty, and the disruption of institutional logics that concentrate power. The community experts' co-analysis, while not framed in explicitly decolonial theoretical terms, enacted many of these commitments in practice: centering community voice, refusing to accept incremental accommodation as sufficient, and insisting that the research enterprise reorient its fundamental relationship to the communities it studies.

Creary's bounded justice framework offers an additional lens for understanding these dynamics.[16] Bounded justice theorizes how embodied outcomes of accumulated injustice and exclusion constrain justice receipt, even through intentional, well-researched programs. When basic social and physical infrastructures have been eroded by racism and historical exclusion, fairness and equity cannot fully exist. Applied to CHIRON, bounded justice explains why well-designed, community co-created tools encounter structural resistance. Transactional intervention operates within bounded space: it can surface considerations and prompt reflection, but cannot repair infrastructural erosion without applying transformational processes, principles, and practices, which limits the reach of justice-oriented reform. This framework provides structural account of the gap community experts identified between reflective moments CHIRON produced and transformational reorientation they called for.

It is important to recognize that the CHIRON project itself arises as a reaction to societal and institutional cultures that are, in practice, anti-community. The research enterprise, its funding structures, its reward systems, its governance traditions, concentrates power in institutions and, despite the pace of change in research methods, research governance remains remarkably resistant to structural change.[4,39,40] This resistance is not incidental; it reflects and reinforces existing distributions of power, including control over data access, intellectual property, and the distribution of research benefits. Individual pilot participants' resistance to CHIRON should not be read as individual failings or a lack of concern for communities. Rather, it reflects the force of institutional socialization: researchers are trained within, and constrained by, systems whose values are imposed on institutions and by institutions on individuals. The "overburdened researcher" narrative, the appeal to scientific neutrality, and the discomfort with positionality all emerged within this bounded structural context. That some participants nevertheless described CHIRON as prompting them to think about communities before research, or to pause over demographic categories they had previously taken for granted, suggests that even transactional engagement can open space for reflection even if it does not, on its own, produce transformation.

The societal context layer was amplified by the political environment during the pilot period. The CHIRON pilots straddled a significant shift in US research policy and funding beginning in early 2025, and participant discourse shifted noticeably in response. Language related to diversity, equity, and

community representation became professionally sensitive in ways that it had not been at the start of the pilot. Some participants described transparency features that they would have enthusiastically endorsed months earlier as potential sources of institutional or personal targeting. This political dimension is not external to the transactional–transformational tension; it intensifies it. When the societal environment actively penalizes community-oriented language and practice, transactional caution becomes more entrenched, and the distance to transformation grows. At the same time, pilot participants pointed to broader structural forces, such as global capitalist logics that subordinate both communities and researchers to institutional profit, suggesting that the political moment, while acute, reflects longer-standing dynamics that decolonial theorists have long identified as endemic to colonial modernity.[41]

The theme of nudging versus instructing captures the transactional–transformational tension at the level of intervention design. CHIRON was deliberately constructed as a choice architecture: it sought to nudge researchers and oversight committees toward pro-community decision-making rather than prescribing specific behaviors. Some participants responded positively to this approach, describing it as productive and non-belittling, even when it prompted uncomfortable self-reflection. Others wanted more directive guidance: concrete tips, explicit lists of preferred terminology, clear right-and-wrong answers. These preferences were not purely individual; institutional and societal pressures pushed participants toward wanting closed-ended outputs that could be implemented without ambiguity or professional risk. This suggests that the design tension between nudging and instructing is not merely a question of user experience. It reflects a deeper question about what kind of change a toolkit can and should attempt to produce within systems that reward compliance over reflection. Within the CHIRON project, we have intentionally maintained our focus on nudging rather than instruction with the release of an updated version of the CHIRON Toolkit: the CHIRON Discussion Kit centers dialogue as a vehicle for advancing community-centering within repository-enabled research practice.[42]

The finding that collaborative use of the CHIRON Toolkit was more generative than individual use offers a partial bridge between transactional and transformational orientations. Group discussion helped participants interpret ambiguous prompts, connect Toolkit content to ongoing projects, and surface concerns that might not have emerged in solitary use. When pilot groups had sufficient trust and rapport, the Toolkit functioned as a catalyst for more vulnerable and substantive conversation. However, this value was contingent on group composition and power dynamics. Participants raised concerns that, if institutionalized, CHIRON Toolkit tasks could be delegated as low-status work to individuals without decision-making authority, effectively decoupling the reflective process from the capacity to act on its outcomes. Delegation without authority is an example of how transactional implementation can neutralize even well-designed intervention. The promise of collaborative engagement therefore depends not only on whether people think together but on who is in the room, how power is distributed, and whether those present have the institutional standing to translate reflection into practice.

Critically, our findings suggest that both transactional and transformational change are needed to ensure all people benefit from repository research. Transactional tools like CHIRON serve a necessary function:

they create entry points for reflection, surface considerations that researchers and oversight committees might otherwise overlook, and build incremental capacity for community-centered thinking within existing institutional arrangements. The pilot demonstrated that even within the constraints of transactional change, CHIRON could prompt meaningful reconsideration of how researchers relate to the communities represented in their data. But transactional change alone is insufficient. Creary's bounded justice framework offers a way to theorize this insufficiency: when the social and physical infrastructures that underlie equity have been shaped by racism, colonialism, and exclusion, interventions that operate within those infrastructures inherit their constraints.[16] The reflective shifts that CHIRON prompted among pilot participants occurred within governance systems whose foundational logics were not designed to center community interests, and whose institutional arrangements continue to distribute power away from the communities most affected by repository-enabled research. Bounded justice suggests that the limits pilot participants encountered—the inability to act on reflection, the delegation of community-centered work to those without authority, the retreat to scientific neutrality under political pressure—are not merely implementation challenges. They are expressions of the bounded societal conditions under which justice-oriented tools must operate.

Without complementary structural changes in oversight committee mandates, funder requirements, the professional development of researchers and ethics professionals, and in the redistribution of decision-making authority toward communities, the reflective shifts that tools like CHIRON produce risk remaining isolated moments rather than sustained reorientations. Interventions that rely on individual researcher behavior change will encounter structural limits if the institutional environment does not support community-centered practice. The value of collaborative engagement suggests that governance tools for repository research should be designed for group use and embedded within existing team structures, with attention to who participates and at what level of authority. And the distance between pilot participant and community expert perspectives underscores the need for governance frameworks that do not merely consult communities but share power with them—a fundamentally transformational aspiration that transactional tools can support but cannot achieve alone.

Limitations

This study has several limitations. The pilot included four sites and eleven participants, a sample that enabled depth of qualitative engagement but limits the transferability of findings across the diversity of repository research contexts. Pilot sites were selected through purposive and convenience sampling and, despite variation in institutional role and organizational structure, may not represent the range of governance arrangements, disciplinary cultures, or geographic contexts in which repository-enabled research occurs. The pilot was conducted primarily within Anglophone research settings and, despite the inclusion of an international site, the Toolkit's US-centric framing was a recurring concern among participants, suggesting that findings may not generalize well to non-US contexts without substantial adaptation.

The pilot period coincided with significant shifts in US science policy and funding, which visibly affected participant discourse and may have amplified certain themes, particularly around transparency, US context, and professional risk, relative to what might emerge in a different political environment. We elected to retain rather than control for this influence, treating it as part of the societal context in which governance interventions must operate, but we acknowledge that the political moment shaped what pilot participants felt able to say and do. Additionally, the integration of community co-analysis introduced productive tensions but also methodological complexity; the co-analysis process was itself a novel approach, and its outputs do not map neatly onto conventional analytic frameworks. Finally, the pilot evaluated Toolkit engagement rather than downstream changes in research practice. Whether the reflective shifts observed during the pilot translate into sustained behavioral or institutional change remains an open empirical question.

Conclusions

The CHIRON Toolkit pilot demonstrates that a community co-designed, nudge-theory-informed governance intervention can prompt meaningful reflection among repository researchers and oversight professionals, even within institutional cultures that have historically externalized community interests. At the same time, the pilot exposes a fundamental tension between transactional change—incremental improvements within existing governance structures—and transformational change—the structural reorientation of research governance toward community-centered values. This tension is not a limitation of the Toolkit; it is a feature of the landscape in which any such intervention must operate. The widespread adoption of genetic ancestry estimation in genomics illustrates the risk plainly: a tool embraced as scientifically rigorous (and socially progressive) has, in practice, often functioned as a more acceptable heuristic for the same genetic differences once proxied by racial typologies, substituting technical sophistication for the deeper structural reckoning the field requires. If adoption and deployment become the primary measures of success for community engagement interventions like CHIRON—integration into research workflows, standard deployment within repositories—there is a real concern that transactional gains could similarly pre-empt the transformational changes they were meant to advance, allowing institutions to satisfy governance expectations without redistributing power. Both modes of change remain essential. Transactional tools like CHIRON create necessary entry points; transformational commitments—to power sharing, to community sovereignty over data and findings, to the restructuring of who defines and benefits from research—define the horizon toward which those entry points must lead. CHIRON produced moments of recognition, discomfort, and reconsideration. Whether those moments accumulate into durable change will depend on whether institutions, funders, and the research community create the structural conditions to sustain them.

Abbreviations

AIANNHPI: American Indian, Alaska Native, Native Hawaiian, Pacific Islander

CHIRON: Community Health Interests for Researchers & Oversight Networks

DAC: Data Access Committee

HSRP: Human Subjects Research Professionals

IRB: Institutional Review Board

LGBTQIA2S+: Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual, Two-Spirit

US: United States of America

WIRB: Western Institutional Review Board, now rebranded as WCG IRB

Declarations

Ethics approval and consent to participate

The pilot protocol was reviewed and approved by a commercial IRB, the Western Institutional Review Board, Inc. (WIRB approval #20170371), now known as WCG™. This work was conducted in accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing Interests

The authors declare no competing interests.

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Author Contribution

M.J.D., C.M., A.N.R., and J.-H.Y. contributed to conceptualization of this project. M.J.D., S.K., O.K., and C.M. curated data. M.J.D., S.K., O.K., C.M., A.N.R., M.T., J.-H.Y., and M.S.C. performed formal analysis. M.J.D. and J.-H.Y. acquired funding. M.J.D., S.K., O.K., A.N.R., M.T., J.-H.Y., and M.S.C. conducted investigation. M.J.D., S.K., C.M., and J.-H.Y. developed the methodology. M.J.D., S.K., and C.M. managed project administration. M.J.D., O.K., and C.M. provided resources. M.J.D. supervised the study. M.J.D., S.K., O.K., M.T., and M.S.C. performed validation. M.J.D. and S.K. developed visualizations. M.J.D. and

M.S.C. wrote the original draft. All authors reviewed and edited the manuscript and approved the final version.

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Data Availability

The dataset supporting the conclusions of this article is available via direct request to the corresponding author.

Clinical trial statement

This is not a clinical trial. There is no applicable clinical trial number.

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Figures

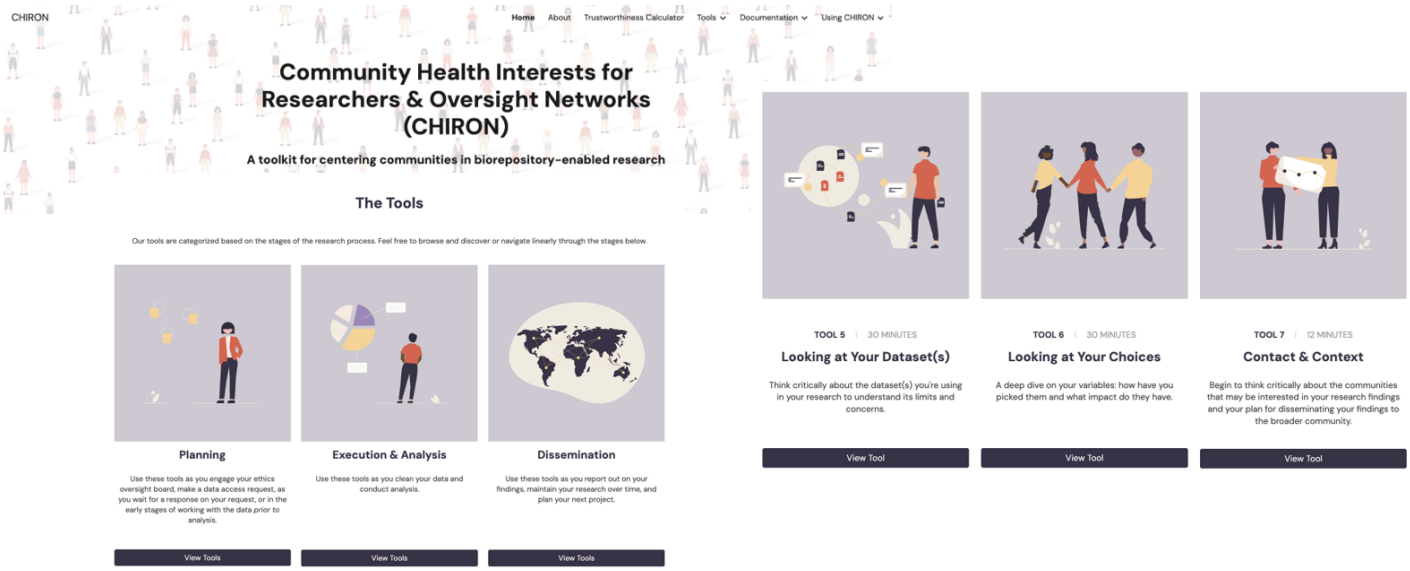

Figure 1

Screenshots from the CHIRON Toolkit

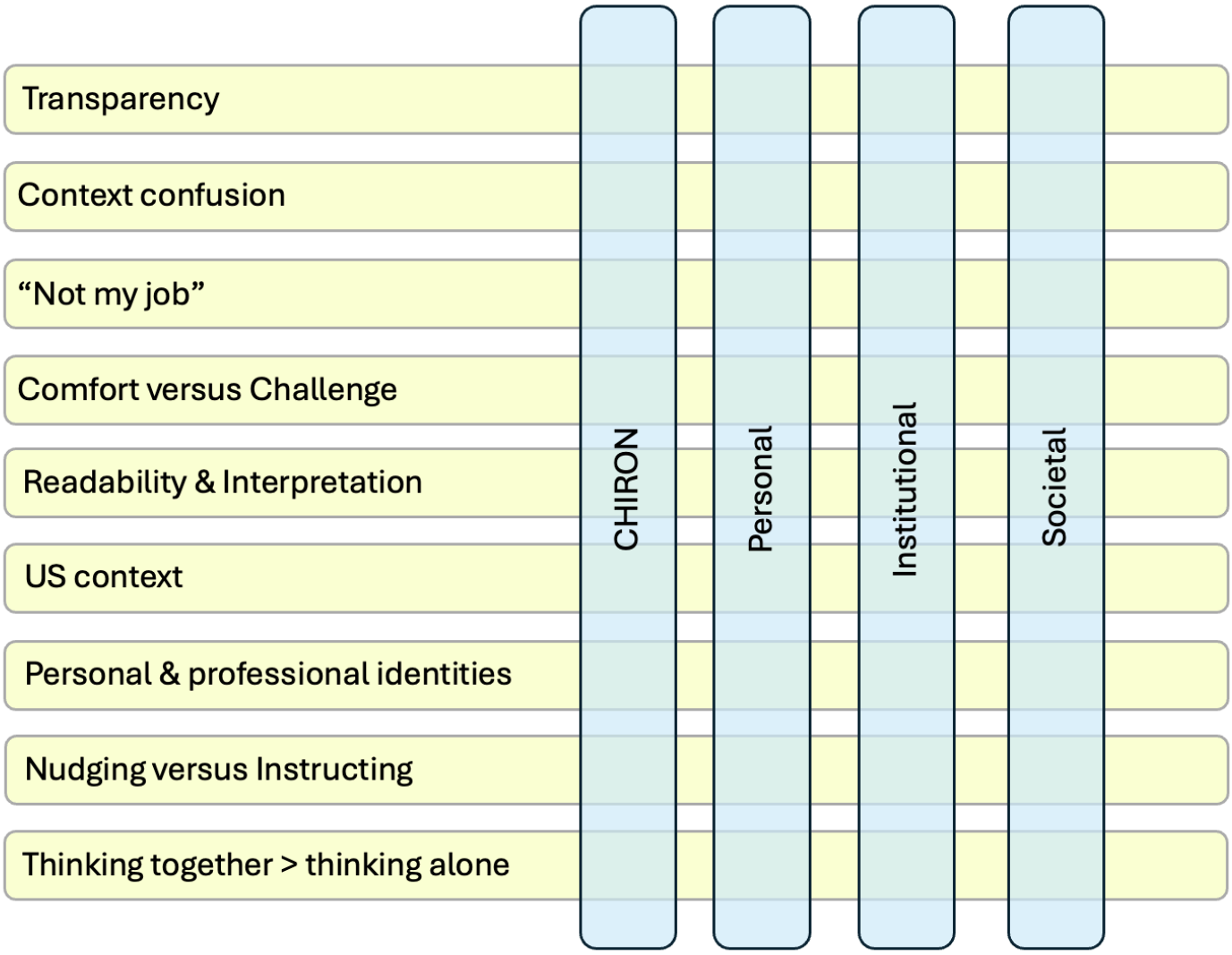

Figure 2

Parent themes (yellow) and cross-cutting contextual layers (blue)

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