# Informing clinical data sharing standards

### Work Stream / Subgroup:

Regulatory & Ethics Work Stream
Clinical Data Sharing & Consent Subgroup

**Date** (Day/Month)**:** April 4, 2025
**Time** (EDT)**:** 9:00 AM - 10:30 AM
**Session chair**(s): Yann Joly & Juliann Savatt
**Session chair(s) will be present:** Yann Joly
**Link to slides:** presentation

**Aim of meeting:**

- To share findings on an analysis of existing institutional policies on clinical genomic data sharing
- To seek the viewpoints of the GA4GH community around institutional policies and to brainstorm a set of standards that can inform clinical data sharing practices.

**Session description:**

In the context of clinical practice, sharing patient-level genetic information is crucial to advancing the quality of care, as it can inform variant classification, define phenotype spectrum and improve treatment efficacy. While clinical institutions have established policies around the sharing of data, uncertainty remains as to when institutions can share data without explicit consent and with whom. This session brings the GA4GH community together to 1.) discuss findings from a review of institutional policies, 2.) assess the view points of the community on these policies, and 3.) brainstorm the development of a set of standards that inform institutional practices.

**Agenda:**

| | Agenda item | Presented by | Time |
|---|---|---|---|
| 1.0 | **Welcome** | Yann Joly | 5 mins |
| 1.1 | Overview of the Clinical Data Sharing Group | Yann Joly | 10 mins |

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| 2.0 | **Survey update: Institutional practices on clinical genetic data sharing** | Ariel Xue & Aaron Ju | 20 mins |
| | • Aim<br>• Brief Methodology<br>• Research question<br>• Findings | | |
| 3.0 | **Brainstorming session** | Yann Joly | 40 mins |
| | • What do you find interesting as to these findings? Do they represent the global context for clinical data sharing well?<br>• Are there other contexts that should or could be drawn out?<br>• What challenges do you envision with some of the approaches identified?<br>• What strategies could we use to go forward?<br>• How can REWS contribute to the improvement of standards in the field? | | |
| 4.0 | **Next steps** | Yann Joly | 5 mins |

**Resources and links:**

- Brief findings report

**Meeting minutes:**

Attendees

1. Brittany Chao
2. Danielle Azzariti
3. Edmund Su
4. Emma Tudini
5. Jessica Seegobin
6. Diya Uberoi
7. Leigh Carmody
8. Lindia Xiang
9. Maria Luisa

18. Grace Pendlebury
19. Jules Savatt
20. Kayla Socarras
21. Mauno Vihinen
22. Mette Peters
23. Zhaoping Ju
24. Ray Krasinski
25. Abby Rud
26. Heather Baseshore

36. Roberto Amato
37. Nicky Mulde
38. Vaso Rahimzadeh
39. Jaime Delgado
40. Benjamin Haibe-Kains
41. Cameron MacPherson
42. Paul Esselaar

Alessandro
10. Chloe Mignion
11. Nicholas Owen
12. Ma’n Zawati
13. Nephi Walton
14. Dulaw spaldine
15. Raja Kathirvel
16. Heidi Rehm
17. Vame Wirk
27. Yann Joly
28. Holly LaDuca
29. Mercury S
30. Joe Flores-Toro
31. Jordan Lerner Ellis
32. Jules Savatt
33. Kayla Socarras
34. Mauno Vihinen
35. Mette Peters
43. Donrich Thaldar
44. Mallony Feeberg
45. Angela Page
46. Kahlil Lawless
47. Gemma Brown
48. Ariel Xue
49. Zhaoping Ju
50. Ray Krasinski

## Meeting Introduction:

The meeting began with opening remarks from **YJ**, who welcomed participants and reiterated the scope of the clinical data sharing study. He emphasized that the group’s current focus is on clinical-to-clinical data sharing—specifically within the context of patient care, not research. Jules (**JS**) introduced the preliminary survey conducted last year, explaining its goals and limitations due to the low response rate. Given the limitations, Ariel (**AX**) and Zhaoping (**ZJ**) presented findings from a new analysis that examined 33 institutional policies from clinical genetic institutions around the world. The study focused on the circumstances under which clinical genetic data can be shared without explicit consent and the types of data involved. **ZJ** provided detailed results on consent practices, security measures, data types, and opt-out provisions. A link to the presentation can be found here. A copy of the report is also included here.

## Discussion Points:

Following the presentation, participants raised key points related to consent terminology, data specificity, and the inconsistency across policies. **CM** recommended that requiring post-facto patient notification could increase transparency and bring institutional practices closer in line with data protection laws. **HR** noted the absence of phenotypic and variant-level data sharing (e.g., ClinVar submissions) in the analysis and suggested these should be explicitly examined. Participants agreed that current policies lack granularity and transparency, and that this hampers consistent clinical practice and policy development.

Several attendees advocated for the development of a model or exemplar policy to help guide institutions. **MZ** emphasized the importance of understanding how policies are implemented in practice, suggesting case studies or narrative reviews to capture real-world practices and barriers.

Other participants raised the idea of better categorizing types of consent and defining a gradation scale to differentiate between dynamic consent, explicit consent with or without notification, and implicit consent.

Several legal and jurisdictional challenges were highlighted, including differences in policy enforcement between academic and commercial institutions, and between regions such as North America, Europe, and Africa. Examples included France's proposed dynamic consent registry and the European Health Data Space regulation.

## Next Steps Discussion:

**YJ** turned the conversation to planning the next phase of work. There was broad agreement on the need to move toward guidance development. Participants proposed developing a tool or template to summarize and standardize institutional policy language and practices.
Key proposals included:

- Creating a model lab requisition form that reflects best practices in clinical genetic data sharing.
- Drafting a rationale document for each data-sharing practice to support implementation and legal review.
- Incorporating patient advocacy stories to build support for clinical sharing under appropriate circumstances.
- Re-analyzing policies to better include categories such as phenotypic data, variant evidence, and co-occurrence information.
- Partnering with the Clinical Genomic Laboratory community to form a task force for iterative feedback and development of the model policy.
- Exploring use cases like clinical trial matching as practical, high-value examples of data sharing for patient benefit.

## Key Takeaways:

- There is a need for a harmonized, best-practice template to guide clinical genomic data sharing across institutions.
- Variability in consent language, data types, and opt-out provisions highlights the importance of clearer standards.
- Greater involvement from patient communities and stakeholders will be essential to develop ethically robust and practically useful guidance.
- Case studies or narratives could be used to explore how policies are applied in practice.

- Legal frameworks vary widely, but shared challenges around consent, identifiability, and privacy create opportunities for consensus.

## Next Steps:

### Policy & Practice Tool Development:

- Begin drafting a model clinical data sharing policy or requisition form.
- Develop a companion rationale document explaining the ethical and legal justifications for each data-sharing category.
- Identify gaps in the existing policy data set and re-analyze to include categories such as phenotypic data and ClinVar submissions.

### Stakeholder Engagement:

- Form a task force with members from the Clinical Genomic Laboratory Community for feedback and collaboration.
- Include patient stories and advocate perspectives in the next phase of the work.

### Outreach & Expansion:

- Explore potential partnerships for case studies of clinical practice implementation.
- Assess opportunities to align this work with clinical trial matching initiatives and broader health system innovations.

### Follow-Up:

- the next group meeting will be in 3–4 months to review progress on the template tool and to discuss expanded findings from the re-analysis and case studies.