Improving Regulatory Compliance in Research Informed Consent and Assent Taking for Minors in KKH

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1. Introduction

Informed Consent
A fundamental ethical and legal requirement in research.

Assent
A child's affirmative agreement to participate in research.

In human subject research involving minors, there are additional informed consent and assent requirements to protect their rights.

However, **many non-compliances (NCs) in informed consent for minors were observed** from audits conducted under KKH Research Quality Audit Framework since Year 2019. These non-compliances may put the minors' rights at risk, and serious non-compliances may trigger regulatory inspections and result in legal implications.

2. Aim

To **improve** regulatory compliance in informed consent and assent taking for minors

by **reducing** the average number of non-compliance per consent.

3. Methodology

Baseline Data Collection

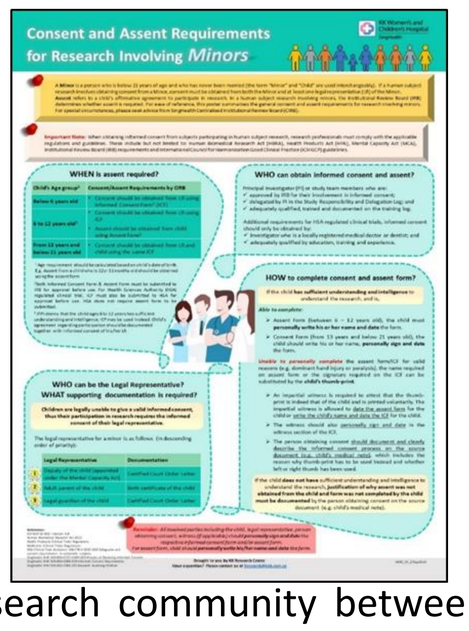
- A list of informed consent NCs was tabulated based on Human Biomedical Research Act, Health Products Act, SingHealth Policies and Procedures, and International Council for Harmonisation-Good Clinical Practice guidelines. These were used to quantify the informed consent NCs.
- NC data were collected from informed consent and assent forms from five studies that were reviewed during the audits conducted between Sep and Oct 2019.

Root Causes Analysis

- Research stakeholders were surveyed on their awareness and difficulties to comply with informed consent and assent requirements.
- The root causes identified and selected were **'Lack of consent training materials'** and **'Difficult to comprehend the lengthy and wordy guidelines and policy documents'**.

Solutions Development and Implementation

- **Consent Training Slides Templates** and **Poster** summarizing informed consent and assent requirements were developed to address the selected root causes.



- These were first shared with KKH research community between Nov and Dec 2019 through various platforms including KKH Infopedia, staff notice boards, mass emails, KKH Clinical Research Coordinator (CRC) Network events etc.

Post-intervention Data Collection

- NC data were collected from informed consent and assent forms from eight studies taken for minors between Jan to Dec 2020, after the intervention.

4. Result

	BEFORE	AFTER
Total no. of non-compliance	211	19
Total no. of consent forms	570	248
Average no. of non-compliance per consent	**0.3701**	**0.0766**
95% Confidence Interval	0.3 to 0.4	0.05 to 0.1
P-Value (Poisson Statistical Test)	**P < 0.001**	

≈ 80% reduction

Non-compliance rate AFTER the intervention is **significantly lower** than BEFORE the intervention.

5. Sustainability Strategies

Increase Accessibility	• **The training slides and poster were uploaded to KKH CRC Network intranet page.**
Continuous Awareness & Easy Retrieval	• **A brand new KKH CRC Network email signature was created with the hyperlink of CRC Network Intranet page embedded in it.**
Sharing with New Research Professionals	• **The availability of the materials will be shared with new research professionals, and relevant training courses can be conducted using the materials.**
Sharing with Study Team during Audits	• **The materials will be shared with researchers and the study team by KKRC Research Quality Officer during the regular audit activities.**

6. Conclusion

The interventions have resulted in **significant increased compliance (improvement)** in research informed consent and assent taking for minors, with **close to 80% reduction in average number of non-compliance per consent**.

To ensure sustainability, these materials will continued to be shared with KKH research community through various platforms.