PARENTAL DECISION-MAKING THROUGH PSYCHOLOGICAL STANDPOINT: CHILDREN'S PARTICIPATION IN CLINICAL TRIAL

SITI MAISARAH MD ALI

MASTER OF ARTS (PSYCHOLOGY)
UNIVERSITI UTARA MALAYSIA
2026

Parental Decision-Making Through Psychological Standpoint: Children's Participation in Clinical Trial

BY
SITI MAISARAH MD ALI

Thesis Submitted to
College of Arts and Sciences,
Universiti Utara Malaysia,
in Fulfilment of the Requirement for the Master of Arts (Psychology)

Awang Had Salleh
Graduate School
of Arts And Sciences

Universiti Utara Malaysia

PERAKUAN KERJA TESIS / DISERTASI
(Certification of thesis / dissertation)

Kami, yang bertandatangan, memperakukan bahawa
(We, the undersigned, certify that)

SITI MAISARAH MD ALI

calon untuk Ijazah
(candidate for the degree of) MA (PSYCHOLOGY)

telah mengemukakan tesis / disertasi yang bertajuk:
(has presented his/her thesis / dissertation of the following title):

"PARENTAL DECISION-MAKING THROUGH PSYCHOLOGICAL STANDPOINT: CHILDREN'S PARTICIPATION IN CLINICAL TRIAL"

seperti yang tercatat di muka surat tajuk dan kulit tesis / disertasi.
(as it appears on the title page and front cover of the thesis / dissertation).

Bahawa tesis/disertasi tersebut boleh diterima dari segi bentuk serta kandungan dan meliputi bidang ilmu dengan memuaskan, sebagaimana yang ditunjukkan oleh calon dalam ujian lisan yang diadakan pada : **30 Jun 2025.**
That the said thesis/dissertation is acceptable in form and content and displays a satisfactory knowledge of the field of study as demonstrated by the candidate through an oral examination held on: ***30 June 2025.***

Pengerusi Viva: *(Chairman for VIVA)*	**Assoc. Prof. Dr. Abdul Razak Abd Manaf**	Tandatangan *(Signature)*
Pemeriksa Luar: *(External Examiner)*	**Prof. Dr. Norsuhaily Abu Bakar**	Tandatangan *(Signature)*
Pemeriksa Dalam: *(Internal Examiner)*	**Assoc. Prof. Dr. Mariny Abdul Ghani**	Tandatangan *(Signature)*
Nama Penyelia/Penyelia-penyelia: *(Name of Supervisor/Supervisors)*	**Assoc. Prof. Dr. Zarina Mat Saad**	Tandatangan *(Signature)*
Nama Penyelia/Penyelia-penyelia: *(Name of Supervisor/Supervisors)*	**Assoc. Prof. Dr. Nor Zalina Mohamad Yusof**	Tandatangan *(Signature)*

Tarikh:
(Date) ***30 June 2025***

Permission To Use

In presenting this thesis in fulfilment of the requirements for a Postgraduate degree from the Universiti Utara Malaysia (UUM), I agree that the library of this university may make it freely available for inspection. I further agree that permission for copying this thesis in any manner, in whole or in part, for scholarly purposes may be granted by my supervisor(s) or in their absence, by the Director of Postgraduate Studies Unit, College of Arts and Sciences where I did my thesis. It is understood that any copying or publication or use of this thesis or parts of it for financial gain shall not be allowed without my written permission. It is also understood that due recognition shall be given to me and to the UUM in any scholarly use which may be made of any material in my thesis.

Request for permission to copy or to make other use of materials in this thesis in whole or in part should be addressed to:

Dean (Awang Had Salleh Graduate School of Arts and Sciences)
UUM College of Arts and Sciences,
Universiti Utara Malaysia
06010 UUM Sintok

Abstract

Conducting clinical trials is essential for improving children's healthcare. However, parental involvement as a surrogate decision-maker remains a complex process influenced by cultural, social, and psychological factors. Furthermore, little is known about how parents navigate these challenges, particularly in regions of Malaysia, where the culture and religious beliefs strongly shape the health-related choices. Hence, this study aimed to explore in depth the processes, factors, and experiences that influence the parental decision-making on children's participation in clinical trials. Accordingly, a qualitative design was employed, involving semi-structured interviews with 14 parents whose children participated in the clinical trials at two government hospitals located in Northern Malaysia. In particular, thematic analyses were employed to analyse the data. The findings revealed that the parents underwent a process that began with the referral stage, followed by initial engagement, information sharing, weighing risks and benefits, and finally achieving the decision-making process. Three major themes shaped this process: trust, culture and religion, and socio-economic considerations. Specifically, trust in the clinical trial teams was central, and the clear and empathetic communication reinforced parental confidence. Meanwhile, cultural and religious beliefs, including Tawakkul, Redha, and Halal consideration, have provided moral guidance and psychological assurance. Moreover, socio-economic factors involving financial benefits and access to beyond routine medical healthcare have motivated participation. At the same time, parental experiences reflected a mixture of hope, reassurance, and gratitude. Parents valued opportunities for better healthcare and close monitoring. Notably, parents perceived themselves as surrogate decision-makers, supporters, and collaborators in the clinical trial process. In conclusion, while the benefits of participation may facilitate enrolment, parents' experiences highlight the crucial role of trust, cultural sensitivity, and supportive relationships in ensuring informed and ethical consent. Overall, this study revealed a new insight into parents' perspectives in Malaysia, suggesting that policymakers design culturally sensitive and parental-centred recruitment strategies to enhance future participation.

Keywords: Children's Clinical Trials, Parental Decision-making, Informed Consent, Trust and Communication

Abstrak

Pelaksanaan kajian klinikal adalah penting dalam meningkatkan penjagaan kesihatan kanak-kanak. Walau bagaimanapun, proses membuat keputusan ibu bapa sebagai wakil kepada anak mereka merupakan satu proses yang kompleks, dipengaruhi oleh faktor budaya, sosial, dan psikologi. Penyelidikan mengenai bagaimana ibu bapa mengharungi cabaran ini di Malaysia masih terhad, khususnya dalam konteks masyarakat yang kepercayaan budaya dan agamanya sangat mempengaruhi pilihan kesihatan. Justeru, kajian ini bertujuan untuk meneroka proses, faktor serta pengalaman ibu bapa dalam membuat keputusan berkaitan penyertaan anak mereka dalam kajian klinikal. Kajian kualitatif digunakan, melibatkan temu bual separa berstruktur dengan empat belas orang ibu bapa yang anak mereka sedang menyertai kajian klinikal di dua buah hospital kerajaan di utara Malaysia. Data dianalisis secara tematik. Hasil kajian menunjukkan bahawa proses ibu bapa membuat keputusan bermula dengan rujukan, diikuti dengan penglibatan awal, perkongsian maklumat, pertimbangan risiko dan manfaat, dan akhirnya membuat keputusan untuk memberi persetujuan. Tiga tema utama dikenal pasti melibatkan rasa percaya, budaya dan agama, serta pertimbangan sosio-ekonomi. Rasa percaya terhadap pasukan kajian klinikal adalah teras, ditambah komunikasi yang jelas dan empati memperkukuh lagi keyakinan ibu bapa. Nilai budaya dan agama, khususnya konsep Tawakkul, Redha, dan pematuhan Halal, telah memberi panduan moral serta jaminan psikologi. Faktor sosio-ekonomi, termasuk manfaat kewangan dan akses kepada rawatan kesihatan di luar rutin biasa, turut menggalakkan penyertaan tetapi tidak memadai tanpa kepercayaan dan keselarasan budaya. Pengalaman ibu bapa mencerminkan gabungan harapan, ketenangan, rasa syukur, dan bebanan emosi. Mereka menghargai peluang mendapatkan penjagaan kesihatan yang lebih baik dan pemantauan rapi, di samping melihat diri mereka sebagai wakil pembuat keputusan, penyokong emosi, dan rakan kerjasama dalam proses kajian klinikal. Kesimpulannya, walaupun manfaat kewangan dan perubatan boleh menggalakkan penyertaan, pengalaman ibu bapa telah menekankan kepentingan rasa percaya, sensitiviti budaya, dan hubungan yang baik dalam memastikan penyertaan yang beretika. Kajian ini memperlihatkan perspektif baharu tentang pandangan ibu bapa di Malaysia, serta mencadangkan agar pembuat dasar merangka strategi yang sensitif budaya dan berpusatkan ibu bapa bagi meningkatkan penyertaan dalam kajian klinikal kanak-kanak.

Kata Kunci: Pengambilan Keputusan oleh Ibu Bapa, Kajian Klinikal Kanak-kanak, Keizinan Termaklum, Kepercayaan dan Komunikasi

Acknowledgement

I would like to express my heartfelt gratitude to all those who have supported me throughout the journey of this thesis. First and foremost, I would like to thank my supervisors, Assoc. Prof. Dr Zarina Mat Saad and Assoc. Prof. Dr Nor Zalina Mohamad Yusof, for their invaluable guidance, encouragement, and expertise. Their insights and constructive feedback have been instrumental in shaping this research and enhancing my understanding of the subject matter.

I am also grateful to the participants of this study, the parents who shared their experiences and perspectives. Their willingness to engage in this research has provided essential insights that are crucial for understanding the complexities of parental decision-making in clinical trials. I would like to extend my appreciation to my colleagues and friends for their unwavering support and camaraderie. Their encouragement and discussions have motivated me to persevere through the challenges of this research.

Special thanks to the staff at Hospital Sultanah Bahiyah and Hospital Tuanku Fauziah for their assistance and cooperation during the data collection process. Their support made it possible to conduct this study effectively. Lastly, I would like to thank my husband and my children for their love, patience, and understanding. Their belief in me has been a constant source of strength, and I am forever grateful for their support throughout this academic journey.

This thesis is dedicated to all those who strive to improve the lives of children through research and innovation. Thank you.

Siti Maisarah Md Ali

Table of Contents

List of Figures

List of Tables

List of Appendices

List of Abbreviations

COVID-19	Coronavirus disease 2019
CRC	Clinical Research Centre
CRM	Clinical Research Malaysia
DM	Diabetes mellitus
etc.	et cetera
FGD	Focus group discussion
HBM	Health Belief Model
HSB	Hospital Sultanah Bahiyah
HTF	Hospital Tuanku Fauziah
GCP	Good Clinical Practice
ICR	Institute of Clinical Research
ICTRP	International Clinical Trials Registry Platform
IIR	Investigator-Initiated Research
ISR	Industry-Sponsored Research
LAR	Legal Authorized Representative
MENA	The Middle East and North Africa
MOH	Ministry of Health Malaysia
MREC	Medical and Ethics Committee
NIH	National Institute of Health
NMRR	National Medical Research Register
SDM	Shared Decision-making
SOP	Standard Operation Procedure
WMA	World Medical Association
WHO	World Health Organisation

CHAPTER ONE

INTRODUCTION

1.1 Background of Study

Children's medical care has significantly improved due to the clinical trial conducted. However, the list of advances in children's health due to clinical trials is unfortunately short and limited to paediatric disorders, heavily clustering around cancer. This is largely attributed to the paucity of paediatric trials (De Abreu Lourenco, McCarthy, McMillan, Sullivan, & Gillam, 2021). Moreover, the children are reliant on others for resources and safety due to their physiological vulnerability and immaturity in terms of development. As a result, there is a need for further trials, particularly in places with high clinical demand. This can be achieved by strengthening paediatric clinical trials to provide information that enables children to benefit from new medical advancements, similarly to adults (Joseph, Craig, & Caldwell, 2015; Lagler, Hirschfeld, & Kindblom, 2021).

Nonetheless, the safety and efficacy information on medicines used in children is scarce. Correspondingly, some of the medicines used in children are ineffective or have unknown side effects (Gerson et al., 2023; Van der Zanden et al., 2021). Hence, more effective and relevant clinical trials in children are necessary to identify safe medicines to prevent delays in beneficial treatment. Currently, the clinical trial is the only method that can provide reliable evidence of therapies through systemically controlled testing of interventions on human subjects (Sundaram, Selvaganesan, Deo, & Karnib, 2022).

REFERENCES

Aarthun, A., Øymar, K. A., & Akerjordet, K. (2017). How health professionals facilitate parents' involvement in decision-making at the hospital: A parental perspective. *Journal of Child Health Care, 22*(1), 108–121. https://doi.org/10.1177/1367493517744279

Akhtar, S. (2024, October 15). The Ethics and Role of Resilience: A moral and spiritual perspective. https://www.fnd.irdiw.org/index.php/Faithanddiscovery/article/view/15

Almomani, B. A., Al-Azzam, S. I., & Al-Shatnawi, S. F. (2020). Knowledge and views of parents regarding ethical aspects of medical research among their children in Jordan. *Journal of Pharmaceutical Health Services Research, 11*(1), 49–54. https://doi.org/10.1111/jphs.12342

Alomar, A. Z. (2021). Confidence level, challenges, and obstacles faced by orthopedic residents in obtaining informed consent. *Journal of Orthopaedic Surgery and Research, 16*(1). https://doi.org/10.1186/s13018-021-02531-1

Aristizabal, P., Ma, A. K., Kumar, N. V., Perdomo, B. P., Thornburg, C. D., Martinez, M. E., & Nodora, J. (2021). Assessment of Factors Associated With Parental Perceptions of Voluntary Decisions About Child Participation in Leukemia Clinical Trials. *JAMA Network Open, 4*(5), e219038. https://doi.org/10.1001/jamanetworkopen.2021.9038

Asher, N., Raphael, A., Wolf, I., Pelles, S., & Geva, R. (2022). Oncologic patients' misconceptions may impede enrollment into clinical trials: a cross-sectional study. *BMC Medical Research Methodology, 22*(1). https://doi.org/10.1186/s12874-021-01478-5

Aurich, B., Vermeulen, E., Elie, V., Driessens, M. H. E., Kubiak, C., Bonifazi, D., & Jacqz-Aigrain, E. (2020). Informed consent for neonatal trials: practical points to consider and a check list. *BMJ Paediatrics Open*, *4*(1), e000847. https://doi.org/10.1136/bmjpo-2020-000847

Baquet, C. R., Commiskey, P., Mullins, C. D., & Mishra, S. I. (2006). Recruitment and participation in clinical trials: Socio-demographic, rural/urban, and health care access predictors. *Cancer Detection and Prevention*, *30*(1), 24–33. https://doi.org/10.1016/j.cdp.2005.12.001

Bodicoat, D. H., Routen, A. C., Willis, A., Ekezie, W., Gillies, C., Lawson, C., Yates, T., Zaccardi, F., Davies, M. J., & Khunti, K. (2021). Promoting inclusion in clinical trials—a rapid review of the literature and recommendations for action. *Trials*, *22*(1), 880. https://doi.org/10.1186/s13063-021-05849-7

Boland, L., Kryworuchko, J., Saarimaki, A., & Lawson, M. L. (2017). Parental decision making involvement and decisional conflict: a descriptive study. *BMC Pediatrics*, *17*(1). https://doi.org/10.1186/s12887-017-0899-4

Braun, V., & Clarke, V. (2022). Conceptual and design thinking for thematic analysis. *Qualitative Psychology*, *9*(1), 3–26. https://doi.org/10.1037/qup0000196

Brooks, S. P., & Bubela, T. (2020). Application of protection motivation theory to clinical trial enrolment for pediatric chronic conditions. *BMC Pediatrics*, *20*(1). https://doi.org/10.1186/s12887-020-2014-5

Bukstein, D. A., Guerra, D. G., Huwe, T., & Davis, R. A. (2020). A review of shared decision-making. *Annals of Allergy, Asthma & Immunology*, *125*(3), 273–279. https://doi.org/10.1016/j.anai.2020.06.030

Burckart, G. J., & Kim, C. (2020). The Revolution in Pediatric Drug Development and Drug Use: Therapeutic Orphans No More. *The Journal of Pediatric Pharmacology and Therapeutics*, *25*(7), 565–573. https://doi.org/10.5863/1551-6776-25.7.565

Burns, K. E. A., Prats, C. J., Maione, M., Lanceta, M., Zubrinich, C., Jeffs, L., & Smith, O. M. (2017). The experience of surrogate decision makers on being approached for consent for patient participation in research. a multicenter study. *Annals of the American Thoracic Society*, *14*(2), 238–245. https://doi.org/10.1513/annalsats.201606-425oc

Champion, V. L., & Skinner, C. S. (2008). *THE HEALTH BELIEF MODEL* (4th ed.). John Wiley & Sons, Inc.

Chan, H.-K., Soelar, S. A., Md Ali, S. M., Ahmad, F., & Abu Hassan, M. R. (2018). Trends in Vaccination Refusal in Children Under 2 Years of Age in Kedah, Malaysia: A 4-Year Review From 2013 to 2016. *Asia Pacific Journal of Public Health*, *30*(2), 137–146. https://doi.org/10.1177/1010539517751312

Chan, N. N., Ong, K. W., Siau, C. S., Lee, K. W., Peh, S. C., Yacob, S., Chia, Y. C., Seow, V. K., & Ooi, P. B. (2022). The lived experiences of a COVID-19 immunization programme: vaccine hesitancy and vaccine refusal. BMC Public Health, 22(1). https://doi.org/10.1186/s12889-022-12632-z

Chappuy, H. (2005). Parental consent in paediatric clinical research. *Archives of Disease in Childhood*, *91*(2), 112–116. https://doi.org/10.1136/adc.2005.076141

Charuel, E., Bernard, M., Vaillant Roussel, H., Cambon, B., Ménini, T., Lafarge, E., Dutheil, F., & Vorilhon, P. (2021). “I Can’t Go Far”: Perceptions and Experiences of Heart Failure Patients Regarding Physical Activity: A

Qualitative Study Using Semistructured Face-to-Face Interviews. *Health Education & Behavior*, 109019812110532. https://doi.org/10.1177/10901981211053247

Chatterjee, K., & Das, N., (2021). Informed consent in biomedical research: Scopes and challenges. *Indian Dermatology Online Journal*, *12*(4), 529. https://doi.org/10.4103/idoj.idoj_83_21

Clark, H., Coll-Seck, A. M., Banerjee, A., Peterson, S., Dalglish, S. L., Ameratunga, S., Balabanova, D., Bhan, M. K., Bhutta, Z. A., Borrazzo, J., Claeson, M., Doherty, T., El-Jardali, F., George, A. S., Gichaga, A., Gram, L., Hipgrave, D. B., Kwamie, A., Meng, Q., & Mercer, R. (2020). A future for the world's children? A WHO–UNICEF–Lancet Commission. *The Lancet*, *395*(10224), 605–658. https://doi.org/10.1016/s0140-6736(19)32540-1

ClinicalTrials.gov: Definition of a Clinical Trial. (2015). Clinical Research Resource HUB. https://hub.ucsf.edu/clinicaltrialsgov-definition-clinical-trial

Clinical Research Malaysia. (2022). Phase 1 Realisation Project Report (P1RP) (2016-2021) [Review of Phase 1 Realisation Project Report (P1RP) (2016-2021)]. In Clinical Research Malaysia (Ed.), www.clinicalresearch.my. Clinical Research Malaysia.

CodeBlue. (2022, March 21). Malaysian Clinical Research Highest In 2021 With 215 Studies [Review of Malaysian Clinical Research Highest In 2021 With 215 Studies]. CodeBlue (Health Is a Human Right).

Colom, M., & Rohloff, P. (2018). Cultural considerations for informed consent in paediatric research in low/middle-income countries: a scoping review. BMJ Paediatrics Open, 2(1), e000298. https://doi.org/10.1136/bmjpo-2018-000298

Comis, R. L., Miller, J. D., Colaizzi, D. D., & Kimmel, L. G. (2009). Doctor-Related factors involved in patient decisions to enroll onto cancer clinical trials. *Journal of Oncology Practice*, *5*(2), 50–56. https://doi.org/10.1200/jop.0922001

Corporate Info. (2019). National Institutes of Health. https://www.nih.gov.my/about-nih/corporate-info

Crane, S., & Broome, M. E. (2017). Understanding Ethical Issues of research participation From the perspective of participating children and Adolescents: A Systematic review. *Worldviews on Evidence-based Nursing, 14*(3), 200–209. https://doi.org/10.1111/wvn.12209

Crane, S., Croop, J. M., Lee, J., Walski, J., & Haase, J. (2021). Parents' Insights into Pediatric Oncology Phase I Clinical Trials: Experiences from Their Child's Participation. Seminars in Oncology Nursing, 37(3), 151162. https://doi.org/10.1016/j.soncn.2021.151162

CTG Labs - NCBI. (2023). Clinicaltrials.gov. Retrieved November 27, 2023, from https://clinicaltrials.gov/search?locStr=Malaysia&country=Malaysia&distance=50&cond=Diabetes%20Mellitus%20Type%202

Cumberpatch, A. R., Weston, P. J., Harding, J. E., & Harris, D. L. (2019). Parents of babies who participated in an invasive clinical study report a positive experience: the Glucose in Well Babies (GLOW) study. Archives of Disease in Childhood Fetal & Neonatal, 105(1), 4–7. https://doi.org/10.1136/archdischild-2019-317417

De Abreu Lourenco, R., McCarthy, M. C., McMillan, L. J., Sullivan, M., & Gillam, L. (2021). Understanding decisions to participate in genomic medicine in children's cancer care: A comparison of what influences parents, health care

providers, and the general community. *Pediatric Blood & Cancer*, *68*(8). https://doi.org/10.1002/pbc.29101

De Castro, G., Kudaba, I., Wu, Y., Lopes, G., Kowalski, D. M., Turna, H. Z., Cho, B. C. (2022). Five-Year outcomes with pembrolizumab versus chemotherapy as First-Line therapy in patients with Non–Small-Cell lung cancer and programmed death ligand-1 tumor proportion score ≥ 1% in the KEYNOTE-042 study. Journal of Clinical Oncology, 41(11), 1986–1991. https://doi.org/10.1200/jco.21.02885

De Pretto-Lazarova, A., Brancati-Badarau, D. O., & Burri, C. (2020). Informed consent approaches for clinical trial participation of infants with minor parents in sub-Saharan Africa: A systematic review. *PLOS ONE*, *15*(8), e0237088. https://doi.org/10.1371/journal.pone.0237088

De Vries, M. C., Houtlosser, M., Wit, J. M., Engberts, D. P., Bresters, D., Kaspers, G. J. L., & Van Leeuwen, E. (2011). Ethical issues at the interface of clinical care and research practice in pediatric oncology: a narrative review of parents' and doctors' experiences. BMC Medical Ethics, 12(1). https://doi.org/10.1186/1472-6939-12-18

Definition of PARENT. (2019). Merriam-Webster.com. https://www.merriam-webster.com/dictionary/parent

Dellson, P., Nilsson, K., Jernström, H., & Carlsson, C. (2018). Patients' reasoning regarding the decision to participate in clinical cancer trials: an interview study. *Trials*, *19*(1). https://doi.org/10.1186/s13063-018-2916-9

Deml, M. J., Buhl, A., Huber, B. M., Burton-Jeangros, C., & Tarr, P. E. (2021). Trust, affect, and choice in parents' vaccination decision-making and health-care

provider selection in Switzerland. *Sociology of Health & Illness*, *44*(1), 41–58. https://doi.org/10.1111/1467-9566.13388

Díaz-Pérez, A., Quiroz, E. N., & Aparicio-Marenco, D. (2020). Moral structuring of children during the process of obtaining informed consent in clinical and research settings. *BMC Medical Ethics*, *21*(1). https://doi.org/10.1186/s12910-020-00540-z

Dimitri, P., Pignataro, V., Lupo, M., Bonifazi, D., Henke, M., Musazzi, U. M., Ernst, F., Minghetti, P., Redaelli, D. F., Antimisiaris, S. G., Migliaccio, G., Bonifazi, F., Marciani, L., Courtenay, A. J., Denora, N., & Lopedota, A. (2021). Medical Device Development for Children and Young People—Reviewing the Challenges and Opportunities. *Pharmaceutics*, *13*(12), 2178. https://doi.org/10.3390/pharmaceutics13122178

DOSM. (2023, July 31). *Department of Statistics Malaysia*. Www.dosm.gov.my. https://www.dosm.gov.my/portal-main/release-content/current-population-estimates-malaysia----2023. Accessed Dec 3, 2023.

Dougherty, T. (2020). Informed Consent, Disclosure, and Understanding. *Philosophy & Public Affairs*. https://doi.org/10.1111/papa.12164

Dr Noor Hisham: Cough syrup products linked to 66 child deaths in Gambia not registered in Malaysia. (2022, October 7). Malay Mail. https://www.malaymail.com/news/malaysia/2022/10/07/dr-noor-hisham-cough-syrup-products-linked-to-66-child-deaths-in-gambia-not-registered-in-malaysia/32245

Drury, N. E., Menzies, J. C., Taylor, C. J., Jones, T. J., & Lavis, A. C. (2021). Understanding parents' decision-making on participation in clinical trials in

children's heart surgery: a qualitative study. *BMJ Open*, *11*(2), e044896. https://doi.org/10.1136/bmjopen-2020-044896

Dubé, K., Hosey, L., Starr, K., Barr, L., Evans, D., Hoffman, E., Campbell, D. M., Simoni, J., Sugarman, J., Sauceda, J., Brown, B., Diepstra, K. L., Godfrey, C., Kuritzkes, D. R., Wohl, D. A., Gandhi, R., & Scully, E. (2020). Participant Perspectives in an HIV Cure-Related Trial Conducted Exclusively in Women in the United States: Results from AIDS Clinical Trials Group 5366. *AIDS Research and Human Retroviruses*, *36*(4), 268–282. https://doi.org/10.1089/aid.2019.0284

Earl, J. (2020). The Belmont Report and Innovative Practice. *Perspectives in Biology and Medicine*, *63*(2), 313–326. https://doi.org/10.1353/pbm.2020.0021

Edwards, K. M., & Kochhar, S. (2020). Ethics of Conducting Clinical Research in an Outbreak Setting. *Annual Review of Virology*, *7*(1), 475–494. https://doi.org/10.1146/annurev-virology-013120-013123

Eeckhout, D., Aelbrecht, K., & Van Der Straeten, C. (2022). Informed Consent: Research staff's perspectives and practical recommendations to improve research Staff-Participant communication. *Journal of Empirical Research on Human Research Ethics*, *18*(1–2), 3–12. https://doi.org/10.1177/15562646221146043

Elliott, M. W., Guttmann, K., Olszewski, A. E., Magnus, B. E., Li, S., Scott, Shah, A., Juul, S. E., Wu, Y. W., Ahmad, K. A., Bendel-Stenzel, E., Isaza, N., Lampland, A., Mathur, A. M., Rao, R., Riley, D. M., Russell, D. G., Salih, I., Torr, C. B., & Weitkamp, J.-H. (2021). Parental Enrollment Decision-Making for a Neonatal Clinical Trial. *The Journal of Pediatrics*, *239*, 143-149.e3. https://doi.org/10.1016/j.jpeds.2021.08.014

Ellithorpe, M. E., Aladé, F., Adams, R. B., & Nowak, G. J. (2022). Looking ahead: Caregivers' COVID-19 vaccination intention for children 5 years old and younger using the health belief model. *Vaccine*, *40*(10). https://doi.org/10.1016/j.vaccine.2022.01.052

Elwyn, G. (2020). Shared decision making: what is the work? *Patient Education and Counseling*, *104*(7). https://doi.org/10.1016/j.pec.2020.11.032

Fearn, P., Avenell, A., Mccann, S., Milne, A. C., & Maclennan, G. (2010). Factors influencing the participation of older people in clinical trials — data analysis from the MAVIS trial. The Journal of Nutrition, Health & Aging, 14(1), 51–56. https://doi.org/10.1007/s12603-010-0009-x

Fernandez, L. H. (2020). The right to withdraw from controlled human infection studies: Justifications and avoidance. *Bioethics*, *34*(8). https://doi.org/10.1111/bioe.12704

Fishman, M., Paquette, E. T., Gandhi, R., Pendergrast, T. R., Park, M., Flanagan, E., & Ross, L. F. (2020). Surrogate Decision Making for Children: Who Should Decide? The Journal of Pediatrics, 220, 221–226. https://doi.org/10.1016/j.jpeds.2019.10.023

Fogel, D. B. (2018). Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review. *Contemporary Clinical Trials Communications*, *11*, 156–164. https://doi.org/10.1016/j.conctc.2018.08.001

Folkman, S., & Lazarus, R. S. (1988). Coping as a mediator of emotion. Journal of Personality and Social Psychology, 54(3), 466–475. https://doi.org/10.1037/0022-3514.54.3.466

Forbes, M. (2021). Thematic analysis: A practical guide. *Evaluation Journal of Australasia*, *22*(2),1035719X2110582. https://doi.org/10.1177/1035719x211058251

Fountouki, A., Andrades Sanchez, M., & Theofanidis, D. (2020). Paternalism vs patient empowerment: nursing challenges from Spain and Greece. *International journal of Caring sciences*, *13*(3), 2288-2293.

Gayet-Ageron, A., Rudaz, S., & Perneger, T. (2020). Study design factors influencing patients' willingness to participate in clinical research: a randomised vignette-based study. *BMC Medical Research Methodology*, *20*(1). https://doi.org/10.1186/s12874-020-00979-z

Ge, P., Liu, S., Xu, S., Zhang, J., Lai, Y., Fu, R., Ke, X., Zhao, J., Bian, Y., & Wu, Y. (2022). The Influence of Parents on Medication Adherence of Their Children in China: A Cross-Sectional Online Investigation Based on Health Belief Model. *Frontiers in Public Health*, *10*. https://doi.org/10.3389/fpubh.2022.845032

Gerson, R., Malas, N., Feuer, V., Silver, G., Prasad, R., Mroczkowski, M., Pena-Nowak, M., Gaveras, G., Goepfert, E., Hartselle, S., Henderson, S., Jhonsa, A., Kelly, P., Mangini, L., Maxwell, B., Prager, L., Prasad, R., & DePena-Nowak, M. (2019). Best Practices for Evaluation and Treatment of Agitated Children and Adolescents (BETA) in the Emergency Department: Consensus Statement of the American Association for Emergency Psychiatry. *Western Journal of Emergency Medicine*, *20*(2), 409–418. https://doi.org/10.5811/westjem.2019.1.41344

Gill, D. (2003). Guidelines for informed consent in biomedical research involving paediatric populations as research participants. *European Journal of Pediatrics*, *162*(7-8), 455–458. https://doi.org/10.1007/s00431-003-1192-0

Glaser, J., Nouri, S., Fernandez, A., Sudore, R. L., Schillinger, D., Klein-Fedyshin, M., & Schenker, Y. (2020). Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: An Updated Systematic Review. *Medical Decision Making*, *40*(2), 0272989X1989634. https://doi.org/10.1177/0272989x19896348

Godskesen, T., Hansson, M., Nygren, P., Nordin, K., & Kihlbom, U. (2014). Hope for a cure and altruism are the main motives behind participation in phase 3 clinical cancer trials. *European Journal of Cancer Care*, *24*(1), 133–141. https://doi.org/10.1111/ecc.12184

Gonzalez-Argote, J. (2022). Effective communication and shared decision making: Theoretical approach from the doctor-patient relationship approach. Deleted Journal, 1, 12. https://doi.org/10.56294/mw202212

Gossman, W., Thornton, I., & Hipskind, J. E. (2023). *Informed consent*. National Library of Medicine; StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK430827/

Gowie, M., Wilson, D., Gregory, S., & Clark, L. L. (2020). Development of a core competency framework for clinical research staff. *Journal of Interprofessional Education & Practice*, *18*, 100301. https://doi.org/10.1016/j.xjep.2019.100301

Grant, S. C. (2021). Informed Consent—We Can and Should Do Better. *JAMA Network Open*, *4*(4), e2110848. https://doi.org/10.1001/jamanetworkopen.2021.10848

Greenberg, R. G., Gamel, B., Bloom, D., Bradley, J. S., Jafri, H. S., Hinton, D., Nambiar, S., Wheeler, C., Tiernan, R., Smith, P., Roberts, J., & Benjamin, D. K. (2018). Parents' perceived obstacles to pediatric clinical trial participation: Findings from the clinical trials transformation initiative. *Contemporary Clinical Trials Communications*, *9*, 33–39. https://doi.org/10.1016/j.conctc.2017.11.005

Gurmu, Y. (2022). Patient preferences in shared decision making during healthcare and associated factors among adult admitted patients at public hospitals of West Shoa Oromia, Ethiopia. *Patient Preference and Adherence, Volume* 16, 1781–1786. https://doi.org/10.2147/ppa.s376600

Habib, T., Richa, K., & Abou-Mrad, F. (2021). Challenges of the informed consent in some countries of the MENA region: A Literature Review. *Ethics, Medicine and Public Health*, *19*, 100706. https://doi.org/10.1016/j.jemep.2021.100706

Hariri, E., Al Hammoud, M., Donovan, E., Shah, K., & Kittleson, M. M. (2022). The Role of Informed Consent in Clinical and Research Settings. *Medical Clinics of North America*, *106*(4), 663–674. https://doi.org/10.1016/j.mcna.2022.01.008

Harmon-Jones, E., & Mills, J. (2019). An introduction to cognitive dissonance theory and an overview of current perspectives on the theory. In American Psychological Association eBooks (pp. 3–24). https://doi.org/10.1037/0000135-001

Hart, R. I., Cameron, D. A., Cowie, F. J., Harden, J., Heaney, N. B., Rankin, D., Jesudason, A. B., & Lawton, J. (2020). The challenges of making informed decisions about treatment and trial participation following a cancer diagnosis: a qualitative study involving adolescents and young adults with cancer and

their caregivers. *BMC Health Services Research*, *20*(1). https://doi.org/10.1186/s12913-019-4851-1

Harth, S. C., & Thong, Y. H. (1995). Parental perceptions and attitudes about informed consent in clinical research involving children. *Social Science & Medicine*, *41*(12), 1647–1651. https://doi.org/10.1016/0277-9536(95)00058-f

Hein, K., Knochel, K., Zaimovic, V., Reimann, D., Monz, A., Heitkamp, N., Borasio, G. D., & Führer, M. (2020). Identifying key elements for paediatric advance care planning with parents, healthcare providers and stakeholders: A qualitative study. Palliative Medicine, 34(3), 300–308. https://doi.org/10.1177/0269216319900317

Hennink, M., & Kaiser, B. N. (2022). Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Social Science & Medicine*, *292*, 114523. https://doi.org/10.1016/j.socscimed.2021.114523

Heo, D. H., Rodriguez, M. J., McNichol, M., & Moser, A. J. (2021). Does altruism affect participation in cancer research? A Systematic review. *Research Square (Research Square)*. https://doi.org/10.21203/rs.3.rs-1017250/v1

Heynemann, S., Lipworth, W., McLachlan, S., Philip, J., John, T., & Kerridge, I. (2023). When research becomes practice: the concept of the therapeutic misconception and challenges to consent in clinical trials. *Internal Medicine Journal*, *53*(2), 271–274. https://doi.org/10.1111/imj.16015

Hoberman, A., Shaikh, N., Bhatnagar, S., Haralam, M. A., Kearney, D. H., Colborn, D. K., Kienholz, M. L., Wang, L., Bunker, C. H., Keren, R., Carpenter, M. A., Greenfield, S. P., Pohl, H. G., Mathews, R., Moxey-Mims, M., & Chesney, R. W. (2013). Factors That Influence Parental Decisions to Participate in Clinical

Research. *JAMA Pediatrics*, *167*(6), 561. https://doi.org/10.1001/jamapediatrics.2013.1050

Hock, K. M., Dick, T. K., Loan, L. A., & Patrician, P. A. (2023). Does the standard medical procedure consent process meet the criteria required for informed consent? - A concept analysis. *Nursing Outlook*, 101916. https://doi.org/10.1016/j.outlook.2022.101916

Hoehn, K. S., Wernovsky, G., Rychik, J., Gaynor, J. W., Spray, T. L., Feudtner, C., & Nelson, R. M. (2005). What factors are important to parents making decisions about neonatal research? *Archives of Disease in Childhood - Fetal and Neonatal Edition*, *90*(3), F267-FF269. https://doi.org/10.1136/adc.2004.065078

Hong, P., Gorodzinsky, A. Y., Taylor, B. A., & Chorney, J. M. (2016). Parental decision making in pediatric otoplasty: The role of shared decision making in parental decisional conflict and decisional regret. *The Laryngoscope*, *126*, S5–S13. https://doi.org/10.1002/lary.26071

Hopper, A., & Crane, S. (2022). Evaluation of the burdens and benefits of participation in research by parents of children with life-limiting illnesses. *Nurse Researcher*, *30*(3).

Indonesia bans all syrup medicines after death of 99 children. (2022, October 20). *BBC News*. https://www.bbc.com/news/world-asia-63324653

Informed consent Definition & Meaning—Merriam-Webster. (n.d.). Retrieved May 29, 2023, from https://www.merriam-webster.com/dictionary/informed%20consent

International Clinical Trials Registry Platform (ICTRP). (2023). Www.who.int. https://www.who.int/clinical-trials-registry-platform

Janvier, A., Bourque, C. J., Dahan, S., Robson, K., & Barrington, K. J. (2019b). Integrating parents in neonatal and pediatric research. *Neonatology*, *115*(4), 283–291. https://doi.org/10.1159/000492502

Jawa, N. A., Boyd, J. G., Maslove, D. M., Scott, S. H., & Silver, S. A. (2023). Informed consent practices in clinical research: present and future. *Postgraduate Medical Journal*, *99*(1175), 1033–1042. https://doi.org/10.1093/postmj/qgad039

Jonas, D., Scanlon, C., & Bogetz, J. F. (2022). Parental Decision-Making for Children with Medical Complexity: An Integrated Literature review. Journal of Pain and Symptom Management, 63(1), e111–e123. https://doi.org/10.1016/j.jpainsymman.2021.07.029

Joseph, P. D., Craig, J. C., & Caldwell, P. H. Y. (2015). Clinical trials in children. *British Journal of Clinical Pharmacology*, *79*(3), 357–369. https://doi.org/10.1111/bcp.12305

Jungmann, S. M., Grebinyk, G., & Witthöft, M. (2023). Parents' views of psychological research with children: Barriers, benefits, personality, and psychopathology. PLoS ONE, 18(6), e0287339. https://doi.org/10.1371/journal.pone.0287339

Kallio H, Pietilä A, Johnson M, Kangasniemi M. Systematic methodological review: developing a framework for a qualitative semi-structured interview guide. Journal of Advanced Nursing [Internet]. 2016 May 25;72(12):2954–65. Available from: https://doi.org/10.1111/jan.13031

Kandi, V., & Vadakedath, S. (2022). Ethical Considerations in Clinical Research: A Comprehensive Review. *American Journal of Public Health Research*, *10*(2), 42–52. https://doi.org/10.12691/ajphr-10-2-2

Kilicarslan-Toruner, E., & Akgun-Citak, E. (2013). Information-seeking behaviours and decision-making process of parents of children with cancer. *European Journal of Oncology Nursing*, *17*(2), 176–183. https://doi.org/10.1016/j.ejon.2012.03.001

King, T. L., Tan, S. H., Tan, S. S. N., Lai, W. H., Bujang, M. A., & Voon, P. J. (2025). Malaysian patient perspectives on clinical trial participation: Willingness, knowledge, perceptions, confidence, and religious barriers. Scientific Reports. https://doi.org/10.1038/s41598-024-83626-7

KJ (n.d). *Malaysia can become world-class hub for clinical research*. The Star. Retrieved July 22, 2023, from https://www.thestar.com.my/news/nation/2022/09/06/kj-malaysia-can-become-world-class-hub-for-clinical-research

Kodish, E. (2003). Informed consent for pediatric research: Is it really possible? *The Journal of Pediatrics*, *142*(2), 89–90. https://doi.org/10.1067/mpd.2003.64

Kyrkoudis, T. (2020). Vaccination of the ethnic Greeks (Rums) against smallpox in the Ottoman Empire: Emmanuel Timonis and Jacobus Pylarinos as precursors of Edward Jenner. *Erciyes Medical Journal*. https://doi.org/10.14744/etd.2020.82856

Laffel, L. M., Kanapka, L. G., Beck, R. W., Bergamo, K., Clements, M. A., Criego, A., DeSalvo, D. J., Goland, R., Hood, K., Liljenquist, D., Messer, L. H., Monzavi, R., Mouse, T. J., Prahalad, P., Sherr, J., Simmons, J. H., Wadwa, R. P., Weinstock, R. S., Willi, S. M., & Miller, K. M. (2020). Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes. JAMA, 323(23), 2388. https://doi.org/10.1001/jama.2020.6940

Lagler, F. B., Hirschfeld, S., & Kindblom, J. M. (2020). Challenges in clinical trials for children and young people. *Archives of Disease in Childhood*, *106*(4), 321–325. https://doi.org/10.1136/archdischild-2019-318676

Langford, A. T. (2020). Health Communication and Decision Making about Vaccine Clinical Trials during a Pandemic. *Journal of Health Communication*, *25*(10), 780–789. https://doi.org/10.1080/10810730.2020.1864520

Lee, J. S., Ng, B. W., & Aziz, M. F. B. A. (2023). The ethics of informed consent for infants born to adolescents: A case study from Malaysia. Clinical Ethics, 19(1), 125–131. https://doi.org/10.1177/14777509231208366

Lester, J. N., Cho, Y., & Lochmiller, C. R. (2020). Learning to Do Qualitative Data Analysis: A Starting Point. *Human Resource Development Review*, *19*(1), 94–106. Sagepub. https://doi.org/10.1177/1534484320903890

Lipstein, E. A., Brinkman, W. B., & Britto, M. T. (2011). What Is Known about Parents' Treatment Decisions? A Narrative Review of Pediatric Decision Making. *Medical Decision Making*, *32*(2), 246–258. https://doi.org/10.1177/0272989x11421528

Limbu, Y. B., Gautam, R. K., & Pham, L. (2022). The Health Belief Model Applied to COVID-19 Vaccine Hesitancy: A Systematic review. Vaccines, 10(6), 973. https://doi.org/10.3390/vaccines10060973

Lin, J. L., Lipstein, E. A., Wittenberg, E., Tay, D., Lundstrom, R., Lundstrom, G. L., Sediqzadah, S., & Wright, D. R. (2021). Intergenerational Decision making: The role of family relationships in medical decision making. MDM Policy & Practice, 6(2), 238146832110394. https://doi.org/10.1177/23814683211039468

Linden, H. M., Reisch, L. M., Hart, A., Harrington, M. A., Nakano, C., Jackson, J. C., & Elmore, J. G. (2007). Attitudes toward participation in breast cancer randomized clinical trials in the African American community. *Cancer Nursing*, *30*(4), 261–269. https://doi.org/10.1097/01.ncc.0000281732.02738.31

Lobe, B., & Morgan, D. L. (2020). Assessing the effectiveness of video-based interviewing: a systematic comparison of video-conferencing based dyadic interviews and focus groups. *International Journal of Social Research Methodology*, *24*(3), 1–13. https://doi.org/10.1080/13645579.2020.1785763

Lois A., M. (1974). The Health Belief Model: Origins and correlates in Psychological Theory* [Johns Hopkins University School of Medicine]. https://citeseerx.ist.psu.edudocument?repid=rep1&type=pdf&doi=9eafddac1bfa013658a6d7c0d03b3fecb08ff584

Luchtenberg, M., Maeckelberghe, E., Locock, L., Powell, L., & Verhagen, A. E. (2015). Young people's experiences of participation in clinical trials: reasons for taking part. *American Journal of Bioethics*, *15*(11), 3–13. https://doi.org/10.1080/15265161.2015.1088974

Luchtenberg, M. L., Maeckelberghe, E. L. M., Locock, L., & Verhagen, A. a. E. (2020). Understanding the child-doctor relationship in research participation: a qualitative study. *BMC Pediatrics*, *20*(1). https://doi.org/10.1186/s12887-020-02243-1

Madrigal, V. N., Hill, D. L., Shults, J., & Feudtner, C. (2022). Trust in Doctors, Anxiety and Depression, and Decision-Making Preferences among Parents of Children with Serious Illness. *Journal of Palliative Medicine*, *25*(3), 428–436. https://doi.org/10.1089/jpm.2021.0063

Malaysia Government (2006). LAWS OF MALAYSIA CHILD ACT 2001 [Review of LAWS OF MALAYSIA CHILD ACT 2001]. The Commissioner of Law Revision, Malaysia Under the Authority of The Revision of Laws Act 1968 In Collaboration with Percetakan Nasional Malaysia Bhd.

Mansuri, G., & Rao, V. (2013). Can participation be induced? Some evidence from developing countries1. Critical Review of International Social and Political Philosophy, 16(2), 284–304. https://doi.org/10.1080/13698230.2012.757918

Marraro, G. A., Cotroneo, R., & Spada, C. (2021). The Challenge of Conducting Research in the Neonatal and Pediatric Age and of Translating Results Into Clinical Practice*. *Critical Care Medicine*, *50*(1), 165–168. https://doi.org/10.1097/ccm.0000000000005192

Mathers, C. D. (2020). History of global burden of disease assessment at the World Health Organization. *Archives of Public Health*, *78*(1). https://doi.org/10.1186/s13690-020-00458-

Memon, R. (2023). Ethical Issues in randomised clinical trials for adolescents who self-harm: The limits of equipoise and evidence in the cultural context of Pakistan [PhD, UCL Department of Science and Technology]. https://discovery.ucl.ac.uk/id/eprint/10164878

Ministry of Health Malaysia, N. (2018). *Malaysian Guideline for Good Clinical Practice* (4th ed.). National Committee for Clinical Research (NCCR).

Mogensen, N., Ulrika Kreicbergs, Birgitte Klug Albertsen, Päivi Lähteenmäki, Heyman, M., & Arja Harila-Saari. (2023). Parental experiences of the informed consent process in randomized clinical trials—A Nordic study. *Pediatric Blood & Cancer*. https://doi.org/10.1002/pbc.30684

Morgan, C., Fetters, L., Adde, L., Badawi, N., Bancale, A., Boyd, R. N., Chorna, O., Cioni, G., Damiano, D. L., Darrah, J., De Vries, L. S., Dusing, S., Einspieler, C., Eliasson, A., Ferriero, D., Fehlings, D., Forssberg, H., Gordon, A. M., Greaves, S., . . . Novak, I. (2021). Early intervention for children aged 0 to 2 years with or at high risk of cerebral palsy. JAMA Pediatrics, 175(8), 846. https://doi.org/10.1001/jamapediatrics.2021.0878

Muscat, D. M., Shepherd, H. L., Nutbeam, D., Trevena, L., & McCaffery, K. J. (2020). Health Literacy and shared Decision-making: Exploring the relationship to enable meaningful patient engagement in healthcare. Journal of General Internal Medicine, 36(2), 521–524. https://doi.org/10.1007/s11606-020-05912-0

Nakada, H., Yoshida, S., & Muto, K. (2019). "Tell me what you suggest, and let's do that, doctor": Patient deliberation time during informal decision-making in clinical trials. *PLOS ONE, Volume 14, Issue 1*. https://doi.org/10.1371/journal.pone.0211338

Nathe, J. M., Oskoui, T. T., & Weiss, E. M. (2022). Parental Views of Facilitators and Barriers to research Participation: Systematic review. *Pediatrics*, *151*(1). https://doi.org/10.1542/peds.2022-058067

Ng, D.-L.-C., Gan, G.-G., Chai, C.-S., Anuar, N. A. B., Sindeh, W., Chua, W.-J., Said, A. B., & Tan, S.-B. (2022). The willingness of parents to vaccinate their children younger than 12 years against COVID-19: a cross-sectional study in Malaysia. *BMC Public Health*, *22*(1). https://doi.org/10.1186/s12889-022-13682-z

Ng, R. J., Choo, W. Y., Ng, C., & Hairi, N. N. (2024). Effect of Supplementary Private Health Insurance on Out-Of-Pocket Inpatient Medical Expenditure: Evidence

from Malaysia. *Health Policy and Planning*, *39*(3), 268–280. https://doi.org/10.1093/heapol/czae004

Ngan, O. M. Y., Yi, H., Bryant, L., Sahota, D. S., Chan, O. Y. M., & Ahmed, S. (2020). Parental expectations of raising a child with disability in decision-making for prenatal testing and termination of pregnancy: A mixed methods study. *Patient Education and Counseling*. https://doi.org/10.1016/j.pec.2020.05.010

Nielsen, Z. E., & Berthelsen, C. B. (2019). Cancer patients' perceptions of factors influencing their decisions on participation in clinical drug trials: A qualitative meta-synthesis. *Journal of Clinical Nursing*, *28*(13–14), 2443–2461. https://doi.org/10.1111/jocn.14785

Nielsen, Z. E., Eriksson, S., Harsløf, L. B. S., Petri, S., Helgesson, G., Mangset, M., & Godskesen, T. E. (2020). Are cancer patients better off if they participate in clinical trials? A mixed methods study. *BMC Cancer*, *20*(1). https://doi.org/10.1186/s12885-020-06916-z

Noble, L. M. (2020). Doctor-Patient communication and adherence to treatment. In *CRC Press eBooks* (pp. 51–82). https://doi.org/10.1201/9781003072348-5

Nyumba, T., Wilson, K., Derrick, C. J., & Mukherjee, N. (2018). The Use of Focus Group Discussion methodology: Insights from Two Decades of Application in Conservation. *Methods in Ecology and Evolution*, *9*(1), 20–32. Wiley.

Orsini, D., & Martini, M. (2022). Albert Bruce Sabin: The Man Who Made the Oral Polio Vaccine. *Emerging Infectious Diseases*, *28*(3). https://doi.org/10.3201/eid2803.204699

Ossin, D. A., Carter, E. C., Cartwright, R., Violette, P. D., Iyer, S., Klein, G. T., Senapati, S., Klaassen, Z., & Botros, S. M. (2022). Shared decision-making in urology and female pelvic floor medicine and reconstructive surgery. *Nature*

Reviews Urology, *19*(3), 161–170. https://doi.org/10.1038/s41585-021-00551-4

Ott, M. A., Crawley, F. P., Sáez-Llorens, X., Owusu-Agyei, S., Neubauer, D., Dubin,G.,Poplazarova, T., Begg, N., & Rosenthal, S. L. (2018). Ethical considerations for the participation of children of minor parents in clinical trials. Pediatric Drugs, 20(3), 215–222. https://doi.org/10.1007/s40272-017-0280-y

O' Sullivan, L., Feeney, L., Crowley, R. K., Sukumar, P., McAuliffe, E., & Doran, P. (2021). An evaluation of the process of informed consent: views from research participants and staff. *Trials, 22*(1). https://doi.org/10.1186/s13063-021-05493-1

Pant, S., Maya Annie Elias, Woolfall, K., Maria Moreno Morales, Bensitta Lincy, Jahan, I., Sumanasena, S. P., Ramji, S., Seetha Shankaran, & Sudhin Thayyil. (2021). Parental and professional perceptions of informed consent and participation in a time-critical neonatal trial: a mixed-methods study in India, Sri Lanka and Bangladesh. *BMJ Global Health*, *6*(5), e005757–e005757. https://doi.org/10.1136/bmjgh-2021-005757

Pargament, K., Feuille, M., & Burdzy, D. (2011). The brief RCOPE: Current psychometric status of a short measure of religious coping. Religions, 2(1), 51–76. https://doi.org/10.3390/rel2010051

Parker, K., Cottrell, E., Stork, L., & Lindemulder, S. (2021). Parental decision making regarding consent to randomization on Children's Oncology Group AALL0932. *Pediatric Blood & Cancer*. https://doi.org/10.1002/pbc.28907

Pietrzykowski, T., & Smilowska, K. (2021). The reality of informed consent: empirical studies on patient comprehension—systematic review. *Trials*, *22*(1). https://doi.org/10.1186/s13063-020-04969-w

Polfuss, M., Mooney-Doyle, K., Keller, M. C., Gralton, K. S., Giambra, B. K., & Vance, A. (2023). Developing a Family Resource: Considerations for family member research participation. *Journal of Family Nursing*, *29*(2), 202–222. https://doi.org/10.1177/10748407231157433

Price, K. N., Lyons, A. B., Hamzavi, I. H., Hsiao, J. L., & Shi, V. Y. (2020). Facilitating clinical trials participation of low socioeconomic status patients. *Dermatology*, *237*(5), 843–846. https://doi.org/10.1159/000511889

Quay, T. a. W., Frimer, L., Janssen, P. A., & Lamers, Y. (2017). Barriers and facilitators to recruitment of South Asians to health research: a scoping review. BMJ Open, 7(5), e014889. https://doi.org/10.1136/bmjopen-2016-014889

Rauscher, E. A., Hesse, C., & Campbell-Salome, G. (2020). Applying family communication patterns to patient-provider communication: examining perceptions of patient involvement, satisfaction, and medical adherence. *Journal of Health Communication*, *25*(2), 180–189. https://doi.org/10.1080/10810730.2020.1728596

Resnicow, K., Catley, D., Goggin, K., Hawley, S., & Williams, G. C. (2021). Shared Decision Making in Health Care: Theoretical Perspectives for Why It Works and For Whom. *Medical Decision Making*, *42*(6), 0272989X2110580. https://doi.org/10.1177/0272989x211058068

Richards, J., Rankin, J., Juszczak, E., Dorling, J., McGuire, W., & Embleton, N. D. (2020). Parental experiences of being approached to join multiple neonatal clinical trials: qualitative study (PARENT). *Archives of Disease in Childhood*

- *Fetal and Neonatal Edition*, *106*(1), 84–87. https://doi.org/10.1136/archdischild-2020-319031

Rosenstock, I. M. (1974). The health belief model and Preventive health behavior. Health Education Monographs, 2(4), 354–386. https://doi.org/10.1177/109019817400200405

Roth, M., Unger, J. M., O'Mara, A., Lewis, M. A., Budd, T., Johnson, R. H., Pollock, B. H., Blanke, C. D., & Freyer, D. R. (2020). Enrollment of adolescents and young adults onto SWOG cancer research network clinical trials: A comparative analysis by treatment site and era. *Cancer Medicine*, *9*(6), 2146–2152. https://doi.org/10.1002/cam4.2891

Rothmier, J. D., Lasley, M. V., & Shapiro, G. G. (2003). Factors influencing parental consent in pediatric clinical research. *Pediatrics*, *111*(5), 1037–1041. https://doi.org/10.1542/peds.111.5.1037

Rouzic, M. L., & Claudot, F. (2020). Characteristics of parental decision-making for children with advanced cancer who are offered enrollment in early-phase clinical trials: A systematic review. *Pediatric Hematology and Oncology*, *37*(6), 500–529. https://doi.org/10.1080/08880018.2020.1759738

Rumetta, J., Abdul-Hadi, H., & Lee, Y.-K. (2019). A qualitative study on parents' reasons and recommendations for childhood vaccination refusal in Malaysia. *Journal of Infection and Public Health*, *13*(2). https://doi.org/10.1016/j.jiph.2019.07.027

Sany, S. B. T., Behzhad, F., Ferns, G., & Peyman, N. (2020). Communication skills training for doctors improves health literacy and medical outcomes among patients with hypertension: a randomized controlled trial. *BMC Health Services Research*, *20*(1). https://doi.org/10.1186/s12913-020-4901-8

Sawicka-Gutaj, N., Gruszczyński, D., Guzik, P., Mostowska, A., & Walkowiak, J. (2022). Publication ethics of human studies in the light of the Declaration of Helsinki – a mini-review. *Journal of Medical Science*, *91*(2), e700–e700. https://doi.org/10.20883/medical.e700

Sawyer, K., & Rosenberg, A. R. (2020). How Should Adolescent Health Decision-Making Authority Be Shared? *AMA Journal of Ethics*, *22*(5), E372–E379. https://doi.org/10.1001/amajethics.2020.372

Schunk, J., Jacobsen, K., Stephens, D., Watson, A., Olsen, C., Casper, T. C., Glaser, N., & Kuppermann, N. (2021). Enroller experience and parental familiarity of disease influence participation in a pediatric trial. *˜the œWestern Journal of Emergency Medicine/Western Journal of Emergency Medicine*, *22*(5), 1176–1182. https://doi.org/10.5811/westjem.2021.4.54647

Schwarz, K., Parasuraman, S., Singh, S., Horowitz, J. D., Dawson, D. K., & Frenneaux, M. P. (2021). The unspoken benefit of participation in a clinical trial. *Clinical Medicine*, *21*(6), e645–e647. https://doi.org/10.7861/clinmed.2021-0292

Shen, A. K., Browne, S., Srivastava, T., Michel, J. J., Tan, A. S. L., & Kornides, M. L. (2022). Factors Influencing Parental and Individual COVID-19 Vaccine Decision Making in a Pediatric Network. *Vaccines*, *10*(8), 1277. https://doi.org/10.3390/vaccines10081277

Sheridan, R., Martin-Kerry, J., Hudson, J., Parker, A., Bower, P., & Knapp, P. (2020). Why do patients take part in research? An overview of systematic reviews of psychosocial barriers and facilitators. *Trials*, *21*(1). https://doi.org/10.1186/s13063-020-4197-3

Sherratt, F. C., Beasant, L., Crawley, E. M., Hall, N. J., & Young, B. (2020). Enhancing communication, informed consent and recruitment in a paediatric urgent care surgical trial: a qualitative study. *BMC Pediatrics*, *20*(1). https://doi.org/10.1186/s12887-020-02040-w

Shilling, V., & Young, B. (2009). How do parents experience being asked to enter a child in a randomised controlled trial? BMC Medical Ethics, 10(1). https://doi.org/10.1186/1472-6939-10-1

Sisk, B. A., Kang, T. I., & Mack, J. W. (2019). The evolution of regret: decision-making for parents of children with cancer. *Supportive Care in Cancer*, *28*(3), 1215–1222. https://doi.org/10.1007/s00520-019-04933-8

Snethen, J. A., Broome, M. E., Knafl, K., Deatrick, J. A., & Angst, D. B. (2006). Family patterns of decision-making in pediatric clinical trials. *Research in Nursing & Health*, *29*(3), 223–232. https://doi.org/10.1002/nur.20130

Stevenson, D. (2020). The Polio Pioneer: Dr. Jonas Salk and the Polio Vaccine by Linda Elovitz Marshall. *Bulletin of the Center for Children's Books*, *73*(11), 485–485. https://doi.org/10.1353/bcc.2020.0479

Stoll, M. (2020). *Unintended Effects of Conflict of Interest Disclosure: a Psychological Perspective* (Doctoral dissertation, Johannes Gutenberg-Universität Mainz).

Sundaram, V., Selvaganesan, P., Deo, S., & Karnib, M. (2022). The importance of randomization in clinical research. *Indian Journal of Thoracic and Cardiovascular Surgery*, *38*(5), 562–565. https://doi.org/10.1007/s12055-022-01401-7

Svensson, K., Ramírez, O. F., Peres, F., Barnett, M., & Claudio, L. (2012). Socioeconomic determinants associated with willingness to participate in

medical research among a diverse population. *Contemporary Clinical Trials*, *33*(6), 1197–1205. https://doi.org/10.1016/j.cct.2012.07.014

Tai, S. J., Nielson, E. M., Lennard-Jones, M., Ajantaival, R. J., Winzer, R., Richards, W. A., Reinholdt, F., Richards, B. D., Gasser, P., & Malievskaia, E. (2021). Development and Evaluation of a Therapist Training Program for Psilocybin Therapy for Treatment-Resistant Depression in Clinical Research. *Frontiers in Psychiatry*, *12*. https://doi.org/10.3389/fpsyt.2021.586682

Tait, A. R., Voepel-Lewis, T., & Levine, R. (2015). Using digital multimedia to improve parents' and children's understanding of clinical trials. Archives of Disease in Childhood, 100(6), 589–593. https://doi.org/10.1136/archdischild-2014-308021

Tan, C., Lau, S. C. D., Latiff, Z. A., Lee, C. C., Teh, K. H., & Sidik, S. M. (2021). Information needs of Malaysian parents of children with cancer: A qualitative study. Asia-Pacific Journal of Oncology Nursing, 9(3), 143–152. https://doi.org/10.1016/j.apjon.2021.11.001

Thomas, C., Mulnick, S., Krucien, N., & Marsh, K. (2022). How do study design features and participant characteristics influence willingness to participate in clinical trials? Results from a choice experiment. *BMC Medical Research Methodology*, *22*(1). https://doi.org/10.1186/s12874-022-01803-6

Thompson, M., & Thompson, C. (2020). Commentary: Do we need new parenting programmes for different cultural groups or should we adapt those that already exist: a commentary on Ward et al. (2019). *Journal of Child Psychology and Psychiatry and Allied Disciplines*, *61*(4), 513–517. https://doi.org/10.1111/jcpp.13172

To, S., Yang, L., Lau, C. D., Wong, C. V., & Su, X. (2021). Associations of Parental Variables and Youth's Career Decision-Making Self-Efficacy: A Meta-Analysis. *Journal of Child and Family Studies*, *31*(2), 530–544. https://doi.org/10.1007/s10826-021-02125-9

Tsang, V. W. L., West, L., Woods, C., Koh, C. J., McCune, S., Mullin, T., Smith, S. R., Gaillard, S., Claverol, J., Nafria, B., Preston, J., Dicks, P., & Thompson, C. (2019). Role of patients and parents in pediatric drug development. Therapeutic Innovation & Regulatory Science, 53(5), 601–608. https://doi.org/10.1177/2168479018820875

Turbitt, E., Klein, W. M. P., Rogers, K., D'Amanda, C. S., & Biesecker, B. B. (2020). Parental decision making about clinical trial enrollment: A survey of parents of children with Fragile X syndrome. *Health Psychology*, *39*(12), 1070–1077. https://doi.org/10.1037/hea0001038

Unger, J. M., Hershman, D. L., Till, C., Minasian, L. M., Osarogiagbon, R. U., Fleury, M. E., & Vaidya, R. (2020). "When Offered to Participate": A Systematic Review and Meta-Analysis of Patient Agreement to participate in cancer clinical trials. *Journal of the National Cancer Institute*, *113*(3), 244–257. https://doi.org/10.1093/jnci/djaa155

Van der Zanden, T. M., Mooij, M. G., Vet, N. J., Neubert, A., Rascher, W., Lagler, F. B., Male, C., Grytli, H., Halvorsen, T., Hoog, M., & Wildt, S. N. (2021). Benefit-Risk Assessment of Off-Label Drug Use in Children: The Bravo Framework. *Clinical Pharmacology & Therapeutics*, *110*(4), 952–965. https://doi.org/10.1002/cpt.2336

Varadan, S. (2020). Article 5: The Role of Parents in the Proxy Informed Consent Process in Medical Research involving Children. *International Journal of*

Children's Rights, *28*(3), 521–546. https://doi.org/10.1163/15718182-02803009

Varma, S., Jenkins, T., & Wendler, D. (2008). How do Children and Parents Make Decisions About Pediatric Clinical Research? Journal of Pediatric Hematology/Oncology, 30(11), 823–828. https://doi.org/10.1097/mph.0b013e318180bc0d

Vedasto, O., Morris, B., & Furia, F. F. (2021). Shared decision-making between health care providers and patients at a tertiary hospital diabetic Clinic in Tanzania. *BMC Health Services Research*, *21*(1). https://doi.org/10.1186/s12913-020-06041-4

Weaver, M. S., October, T. W., Feudtner, C., & Hinds, P. S. (2020). "Good-Parent Beliefs": research, concept, and clinical practice. *Pediatrics*, *145*(6). https://doi.org/10.1542/peds.2019-4018

Webmaster. (2023). *Vision, Mission & Function | Clinical Research Centre*. https://www.crc.gov.my/vision-mission-function/

Weindling, P. (2022). Painful and sometimes deadly experiments which Nazi doctors carried out on children. *Acta Paediatrica*, *111*(9). https://doi.org/10.1111/apa.16310

Weiss, E. M., Olszewski, A. E., Guttmann, K. F., Magnus, B. E., Li, S., Shah, A. R., Juul, S. E., Wu, Y. W., Ahmad, K. A., Bendel-Stenzel, E., Isaza, N. A., Lampland, A. L., Mathur, A. M., Rao, R., Riley, D., Russell, D. G., Salih, Z. N. I., Torr, C. B., Weitkamp, J.-H., & Anani, U. E. (2021). Parental Factors Associated With the Decision to Participate in a Neonatal Clinical Trial. *JAMA Network Open*, *4*(1), e2032106. https://doi.org/10.1001/jamanetworkopen.2020.32106

Williams, D. (2010). *Surviving and Thriving: How Transition Psychology May Apply to Mass Traumas and Changes*. 523–567. https://doi.org/10.1007/978-1-4419-0748-6_27

Wilman, E., Megone, C., Oliver, S., Duley, L., Gyte, G. M., & Wright, J. (2015). The ethical issues regarding consent to clinical trials with pre-term or sick neonates: a systematic review (framework synthesis) of the empirical research. *Trials*, *16*(1). https://doi.org/10.1186/s13063-015-0957-x

Winkfield, K. M., Phillips, J. K., Joffe, S., Halpern, M. T., Wollins, D. S., & Moy, B. (2018). Addressing financial barriers to patient participation in clinical trials: ASCO Policy Statement. *Journal of Clinical Oncology*, *36*(33), 3331–3339. https://doi.org/10.1200/jco.18.01132

World Health Organization. (2024, December). Number of clinical trial registrations by location, disease, phase of development, age and sex of trial participants (1999-2024). Global Observatory on Health Research and Development. https://www.who.int/observatories/global-observatory-on-health-research-and-development/monitoring/number-of-trial-registrations-by-year-location-disease-and-phase-of-developmen

Yap, J. B. H., Botabara, E. A., Abdul Kadir, S. N. A., Ibrahim, A., & Rahman, A. A. (2017). Cultural influences on health and healthcare in Malaysia. International Journal of Health Planning and Management, 36(5), 1314–1330. https://doi.org/10.1002/hpm.3256

Zainun, W. N. A., Nasir, N., Ghazali, N. I. I., & Ying, T. K. (2018). Assessment of Public Knowledge and Perception towards Childhood Vaccination in Perlis, Malaysia. *EDITORIAL BOARD*, 104.

Zhong, Y., Zhou, L., Li, L., Zhang, T., & Zhang, X. (2021). Updated Analysis of Pediatric Clinical Trials Registered in ClinicalTrials.gov, 2008-2019. *Research Square (Research Square)*. https://doi.org/10.21203/rs.3.rs-137592/v1

Appendix A

Interview Protocol

Demographic Data Collection

1. Name:
2. Age:
3. Race:
4. Occupation:
5. Education Level:
6. Monthly Income:
7. Marital Status:

Skop Temubual	Kunci Soalan
Pemahaman tentang kajian klinikal	• Apa yang Encik/Puan tahu tentang kajian klinikal *Prob:* *- kajian ubat baru/penyakit baru* *- tujuan kajian klinikal dijalankan* *- jenis –jenis kajian klinikal yang anda tahu*
Sumber maklumat tentang kajian klinikal tersebut	• Bagaimana Encik/Puan mendapat maklumat tentang kajian klinikal? *Prob:* *-petugas kesihatan – doctor/misi* *-ahli keluarga* *-kawan-kawan* *-media sosial* *-media elektronik* *-media cetak* • Apakah maklumat yang diperolehi oleh Encik/Puan? • Apakah maklumat yang belum diperolehi dan pada pendapat Encik/Puan maklumat tersebut penting untuk diketahui?

Faktor yang menpengaruhi keputusan membenarkan anak menyertai kajian klinikal	• Mengapa Encik/Puan memberi kebenaran untuk anak terlibat dalam kajian klinikal ini? • Atau apakah sebab yang membuatkan encik/puan membenarkan anak terlibat di dalam kajian klinikal? *Prob:* *-manfaat yang ditawarkan* *- nasihat/pendapat daripada doctor yang merawat* *-keyakinan terhadap tahap keselamatan kajian/risiko rendah kepada anak* *-risiko rendah untuk kegagalan kajian* *-kajian dengan proses dan prosedur yang tersusun dan mudah dijalani.*
Pengalaman dialami/didapatkan semasa terlibat dengan kajian klinikal – anak sebagai "subject/participants"	• Bagaimana pemahaman Encik/Puan tentang kajian klinikal yg anak encik ikuti/jalani? • Bagaimana pengalaman Encik/Puan semasa anak terlibat dalam kajian tersebut? • Bagaimanakah perasaan encik/puan apabila anak terlibat di dalam kajian klinikal? *Prob:* *- tujuan* *-kelebihan/kebaikan/benefit* *-randomisation* *- risiko/implikasi hasil daripada kajian* *- berhenti daripada kajian lepas suatu tempoh dalam kajian*
Pandangan/cadangan terhadap kajian klinikal yang telah dijalankan	• Apakah pandangan Encik/Puan terhadap kajian klinikal yang anak anda jalani? Prob: - *Perasaan melihat anak menjalani kajian klinikal tersebut – lega/bimbang/risau/tiada rasa apa* - *Pengetahuan- perlu ditambah/ cukup penerangan* - *Penyesalan sebab?* - Penyelidik/doctor/study coordinator-membantu/masalah • Adakah apa-apa cadangan daripada pihak Encik/Puan untuk menambah baik pengurusan kajian klinikal di pihak penyelidik?

Appendix B

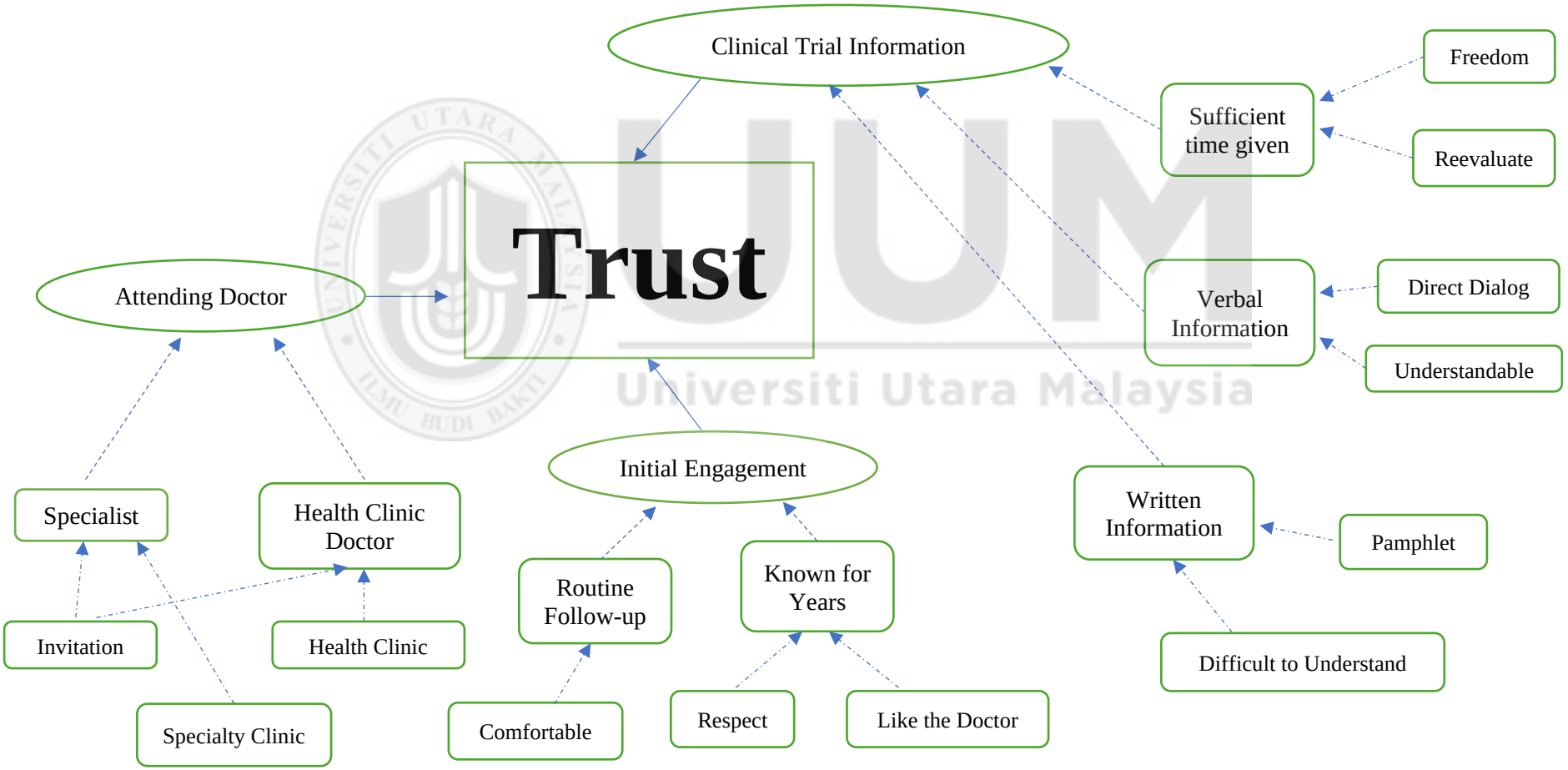
A 15-Point Checklist of Criteria for Good Thematic Analysis Process (Braun and Clarke, 2006)

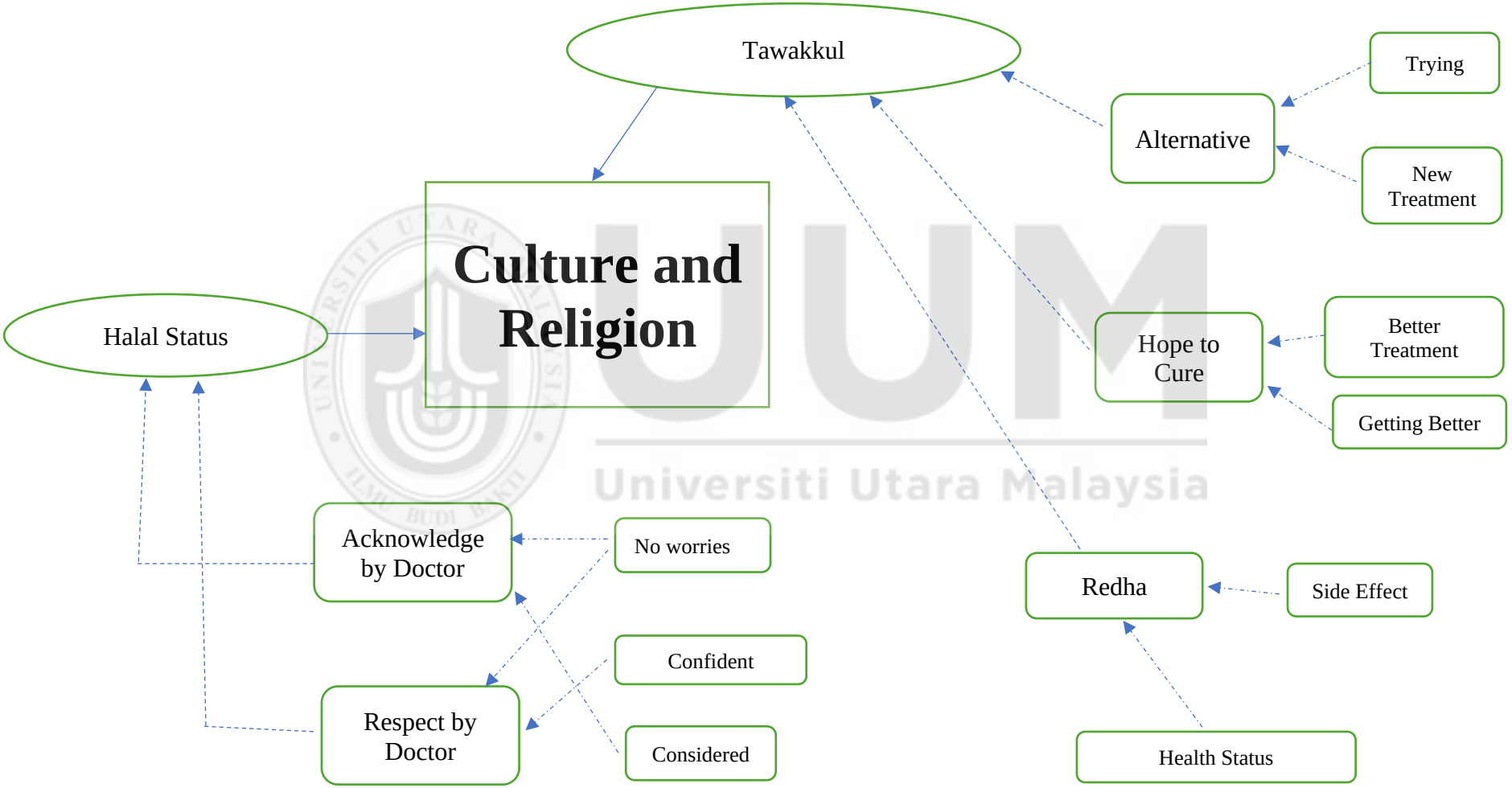
Stage	Criteria	Application to Current Study
Transcription	1. Data transcribed accurately and checked with recordings.	All interviews were transcribed verbatim and cross-checked with the audio for accuracy.
Coding	2. Each data item received equal attention during coding.	All transcripts were read several times and coded equally without bias.
	3. Themes developed from full data, not just vivid examples.	Themes were based on patterns across all 14 participants, ensuring completeness.
	4. All relevant data extracts for each theme were gathered.	Supporting quotes were organized under each theme.
	5. Themes reviewed against each other and the full data set.	Themes were refined through continuous comparison with original transcripts.
	6. Themes are coherent, consistent, and distinct.	Final themes are clear, internally consistent, and separate from one another.
Analysis	7. Data were interpreted, not just described.	Analysis explored meanings behind parental decisions using psychological insight.
	8. Data and analysis match - extracts support the claims.	Participant quotes directly support each analytical point in Chapter Four.
	9. Analysis tells a clear and convincing story.	Findings explain the decision-making journey from referral to consent, including the roles and experiences within the journey.
	10. Balance between narrative and participant quotes.	Each theme combines explanation with selected meaningful quotations.

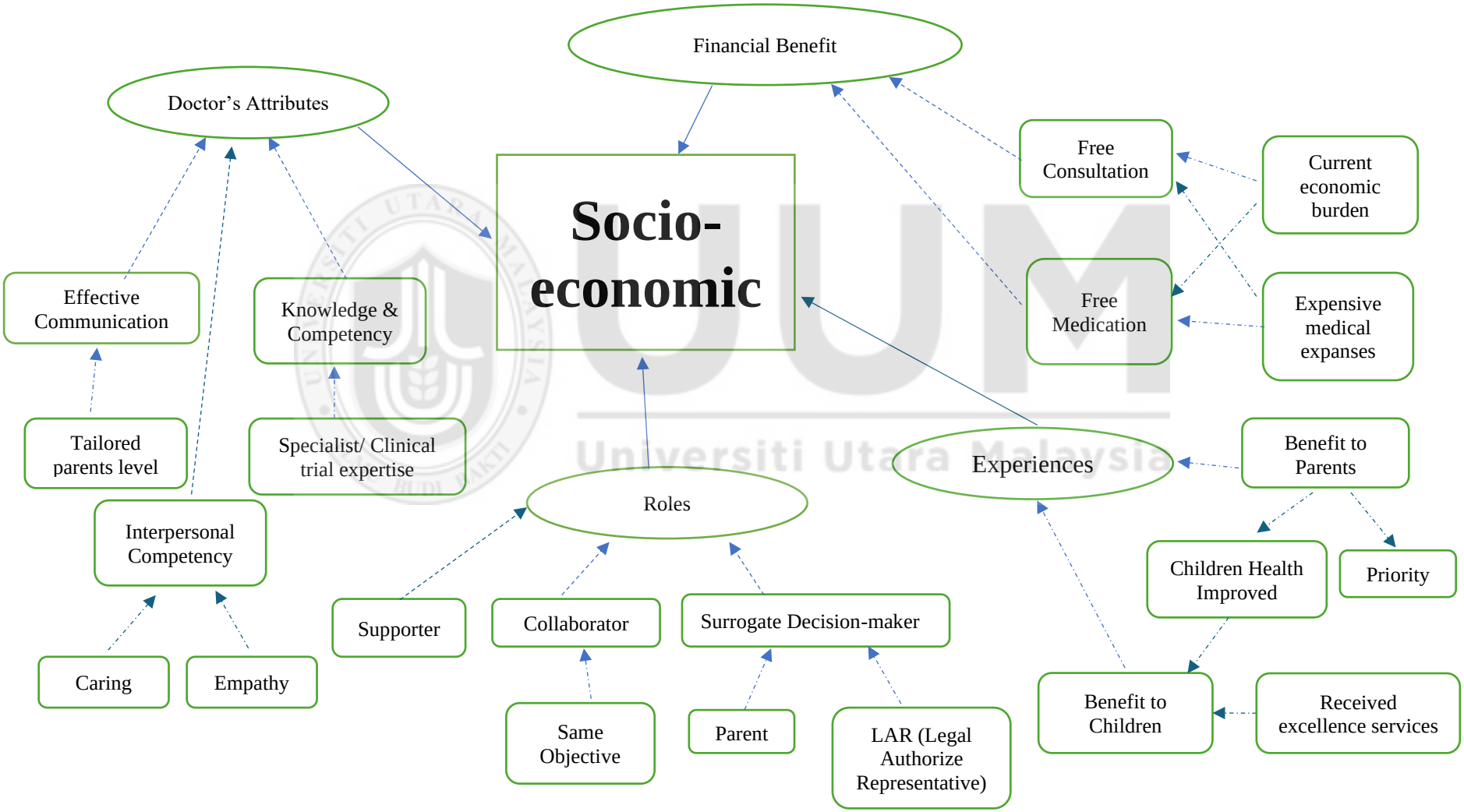
Overall	11. Analysis shows a clear, systematic process.	Thematic analysis followed Braun and Clarke's approach.
Written Report	12. Language fits the study's qualitative approach.	Writing reflects an interpretive and constructive perspective throughout.
	13. Researcher acknowledged own role in the process.	Reflexivity maintained to manage bias in the data analysis.
	14. Report shows both process and results clearly.	Thematic development is shown with supporting quotes and explanation.
	15. Analysis is concise, logical, and interesting.	Final report presents a clear, engaging and meaningful account of findings.

Appendix C

Thematic Analysis (Themes, Subthemes and Codes)






Financial Benefit
Doctor's Attributes
Socio-economic
Free Consultation
Current economic burden
Free Medication
Expensive medical expanses
Effective Communication
Knowledge & Competency
Tailored parents level
Specialist/ Clinical trial expertise
Interpersonal Competency
Caring
Empathy
Roles
Supporter
Collaborator
Surrogate Decision-maker
Same Objective
Parent
LAR (Legal Authorize Representative)
Experiences
Benefit to Parents
Children Health Improved
Priority
Benefit to Children
Received excellence services