

Evaluation of Assent Form for Children/Minors Used for Research in the Ministry of Health, Malaysia. May 2024

Presenter

Dr Charlotte Jane Joseph



MREC

Medical Research and Ethics Committee

9/12/2024







China

South Korea

Japan

India

Bhutan

Nepal

Myanmar (Burma)

Bangladesh

Laos

Thailand

Vietnam

Philippine

Sea

Brunei

Malaysia

Indonesia

Andaman & Nicobar Is. (India)

Singapore

Jawa

Timor-Leste

Papua New Guinea

Cocos Is.

Christmas

Mayotte (Fr.)

Jibouti

Arabian Sea

Bay of Bengal

Sri Lanka

Maldives

Andi

chelles

Mayotte (Fr.)

Taiwan

Guam (U.S.)

North

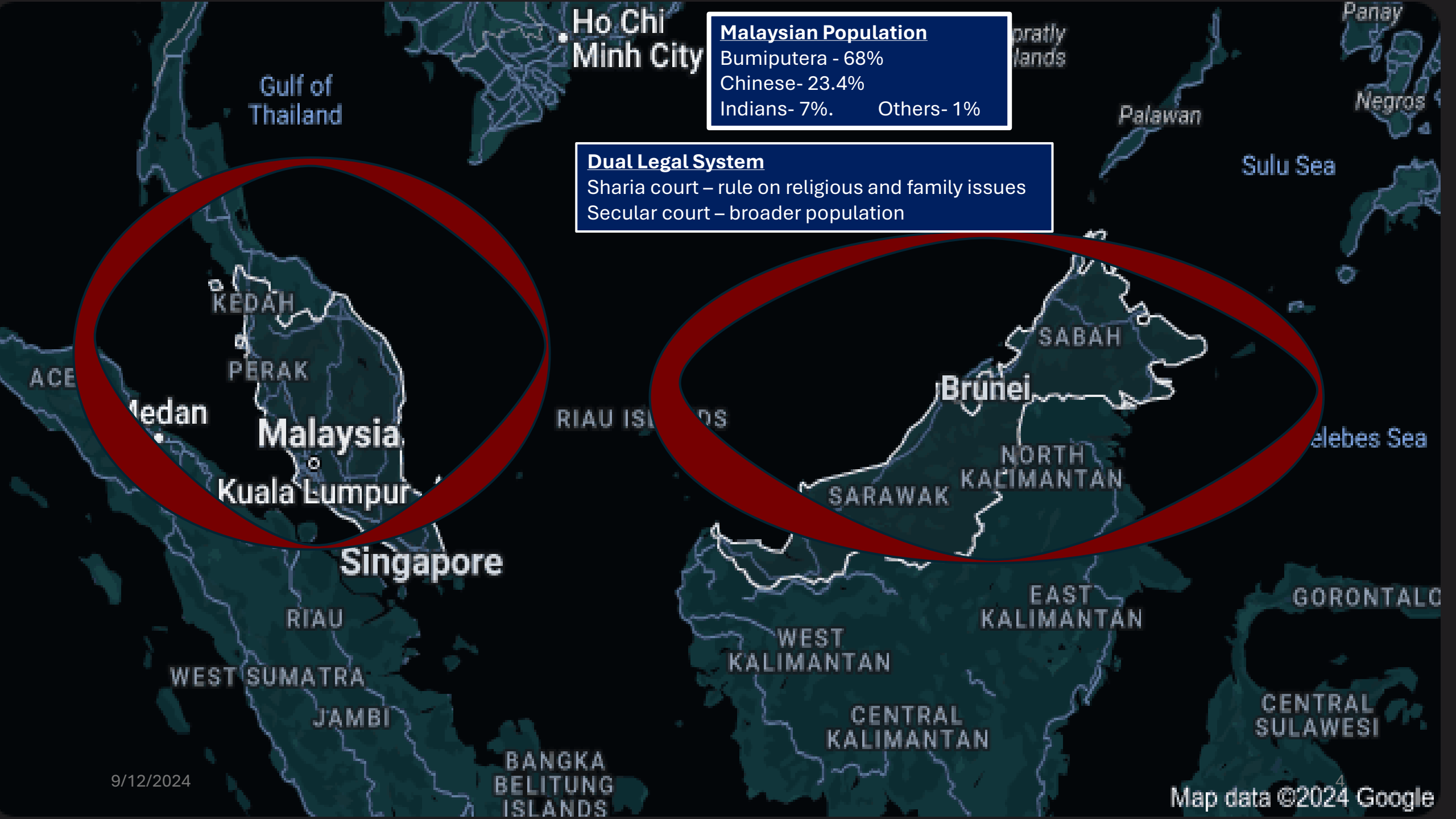
Island

Federat

of Mic

Papua New Guinea

Cor



Malaysian Population
 Bumiputera - 68%
 Chinese- 23.4%
 Indians- 7%. Others- 1%

Dual Legal System
 Sharia court – rule on religious and family issues
 Secular court – broader population



Presentation Outline



Introduction.



Team Introduction.



Background



Objective



Audit Measures
and Standards.



Stakeholders and
Involvement



Methodology



Results and
analysis.



Discussion and
recommendation.



Conclusion.

Meet The Team.



Dr. Lee Keng Yee.

Dr. Brian Carter

Dr. Stephanie Kurkora.

National Institute of Health, Malaysia.

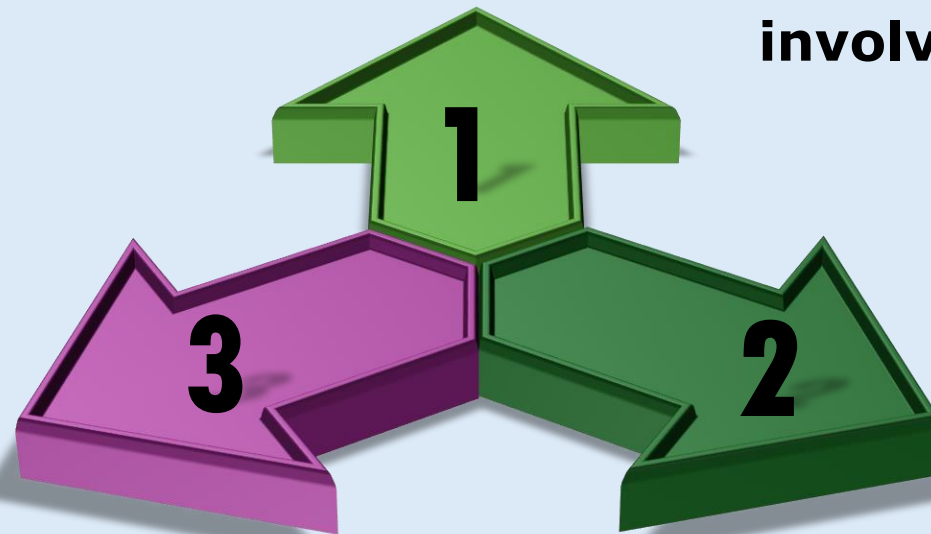
Background.

- The Medical Research and Ethics Committee (MREC) was established in 2002.
- Provides independent guidance on advice and decision on ethical issues of health research in the Ministry of Health (MOH).
- Continuous review of methods and materials to be used in obtaining and documenting consent of the human research subjects.
- Safe -guard the rights, safety and well - being of human research volunteers.



Agency & IRB/EC Responsibilities.

Determine whether children in the study are capable of providing assent and if so confirm adequate provisions are made for soliciting their assent.

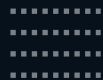
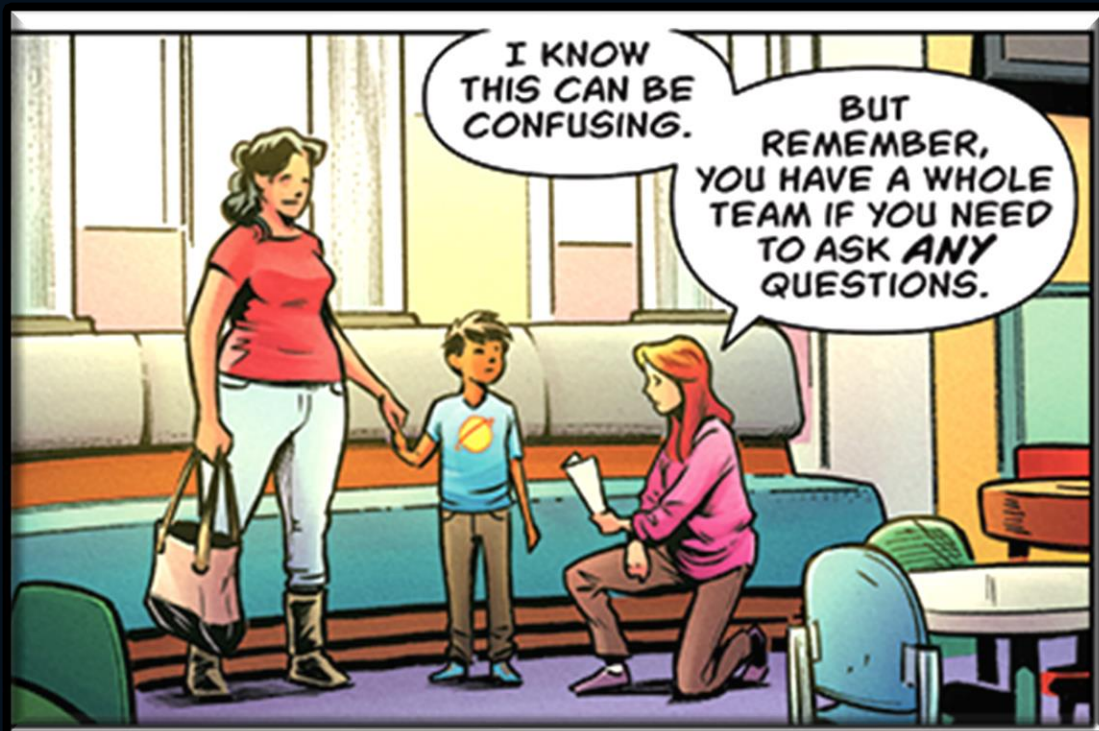


Review and approve research protocols involving minors.

Ensure adequate provisions are made for soliciting the permission of each child's parents or guardian.

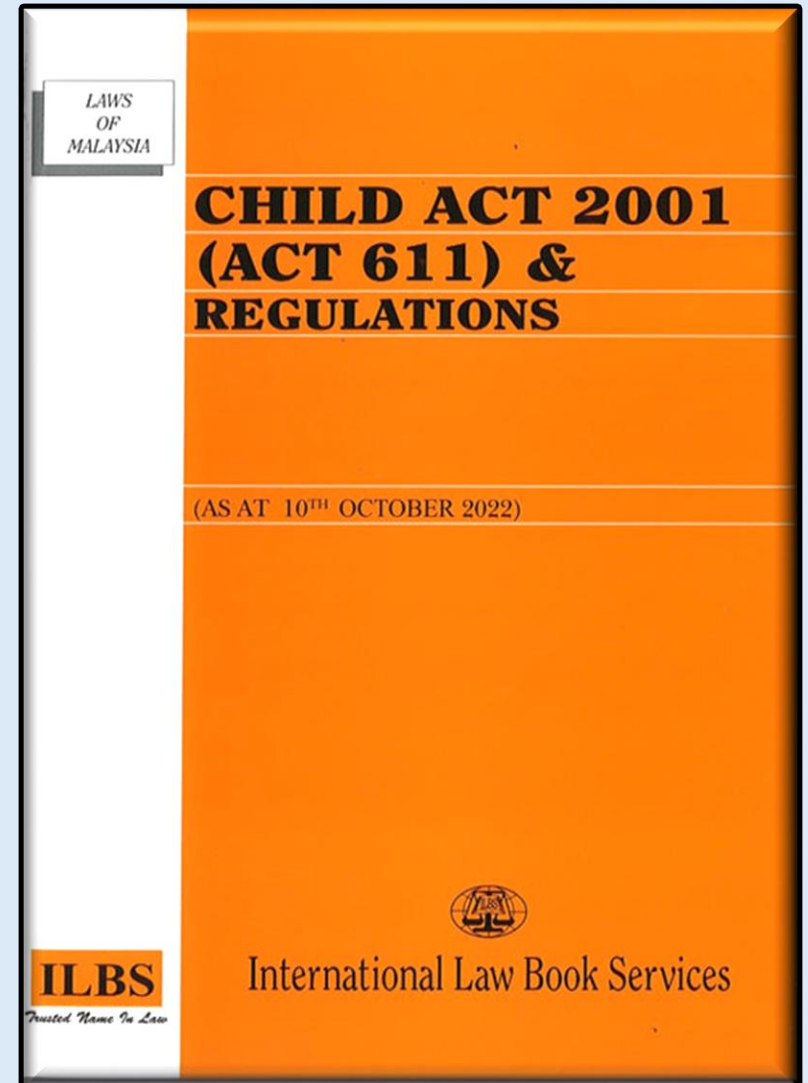


Ethics Relating to Children in Research.



Legal Framework in Malaysia

- Malaysian Child Act 2001 emphasizes the protection and rights of children.
- Healthcare decisions for minors are typically made by parents or guardians under Malaysian law.
- The Malaysian Medical Council (MMC) outlines ethical principles for involving minors in healthcare decisions



Parental Permission and Pediatric Assent



- ICH-GCP E6: Guideline for Good Clinical Practice
- ISO 14155 Parts 1 and 2

United States

- 45 CFR Part 46 – Protection of Human Subjects
- 21 CFR Part 50-Protection of Human Subjects
- 21 CFR Part 56- Institutional Review Boards

Europe

- Convention on Human Rights and Biomedicine (the Oviedo Convention)
- European Directive 2001/20/EC/ , Paediatric Regulation1901/2006
- Local Laws and Regulations

CIOMS Guideline 14

1

The research might not equally well be carried out with adults

2

The purpose of the research is to obtain knowledge relevant to health needs of children.

3

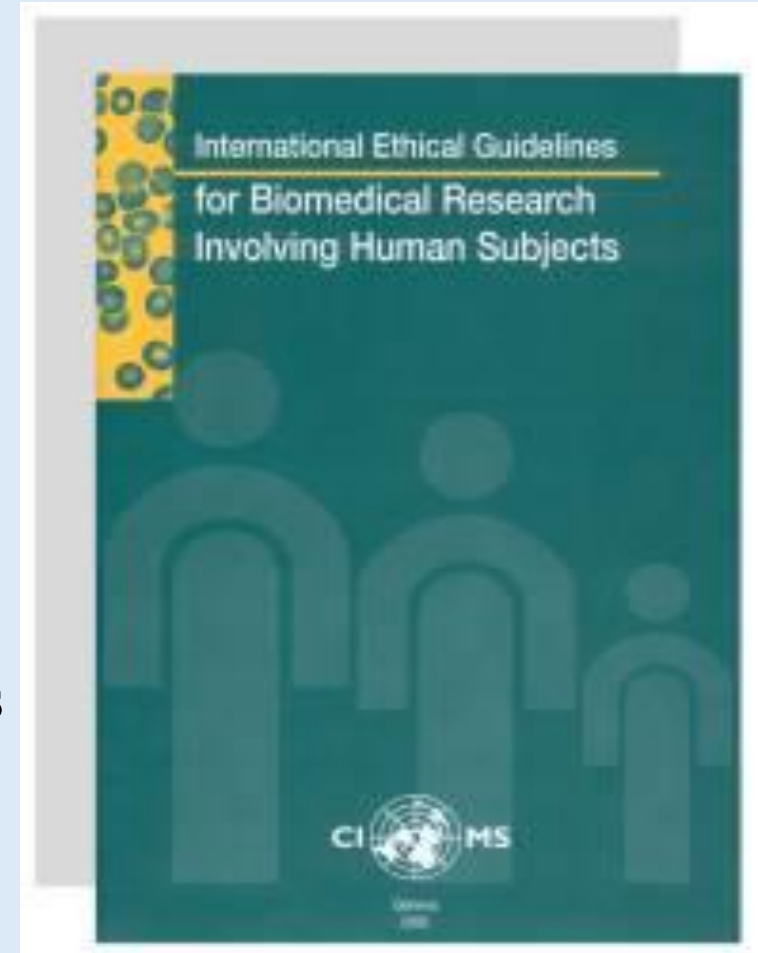
A parent or legal representative of each child has given permission (consent)

4

The agreement (assent) of each child has been **obtained to the extent of the child's capabilities**

5

A child's **refusal** to participate or continue in the research **will be respected.**



Assent

versus

Consent

Agreement with something, a request or to participate in an activity

Obtained from people who are not of legal age to give consent

Willingness to participate in a study

Not a legally binding permission

Giving permission to be involved in an activity

Obtained from adults (people above the legal age)


Legally entered agreement for a subject to participate in a study

Legally binding permission.

Assent.

- 1 “Agreement by an individual not competent to give legally valid informed consent to participate in research”.
- 2 Child’s affirmative agreement to participate in research.
- 3 Assent form gives the child an opportunity to decide if they **want to take part** and to **decline** if they are not interested.
- 4 Written assent is using a physical document.
- 5 The IRB presumes that minors ages 7 and older should be given an opportunity to provide assent.

Components of an effective assent form.

- 
- 1** Clear, age-appropriate language.
 - 2** Explanation of the procedure or research
 - 3** Description of potential risks and benefits
 - 4** Assurance of voluntary participation
 - 5** Option to withdraw without consequences.

Age- specific Considerations.

Young Children (7–12 years):

Simplified language

Engaging visuals

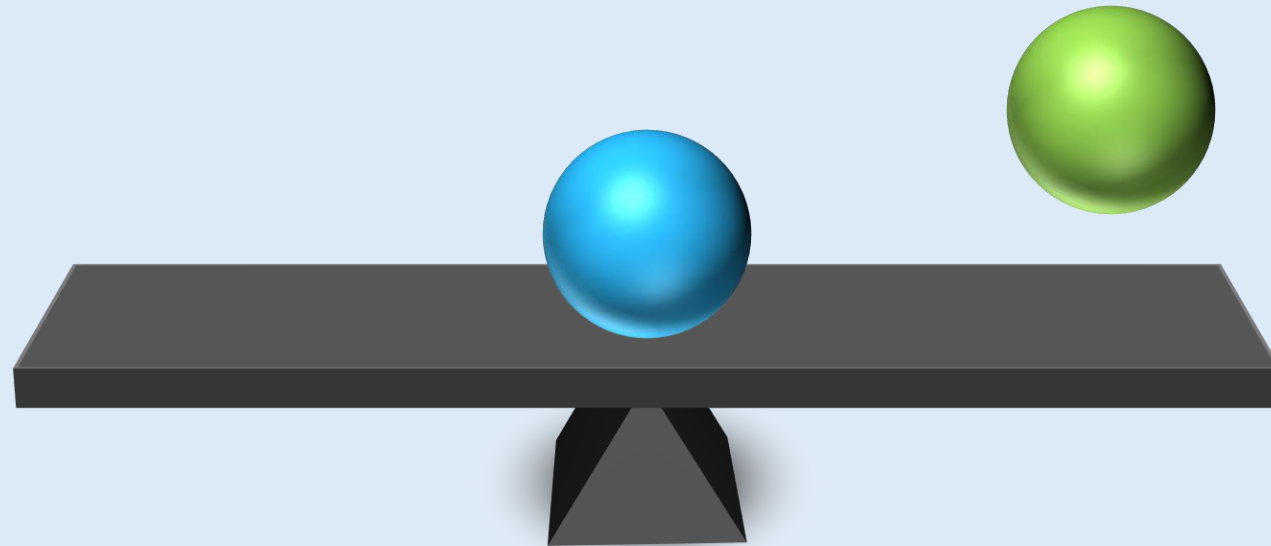
Short explanations.

Adolescents (13–17 years):

Detailed descriptions opportunities
for questions focus on autonomy.

Tailored discussions for
understanding varying cognitive and
emotional maturity.

Challenges



Simplicity

Completeness

Ensuring voluntary participation in hierarchical family structures

Current Assent Check-list.

2. Assent For Minors

2.1 Is language used in the assent form clear and age appropriate?

Complete 



2.2 Is there clear and brief information on the purpose of the study?

Complete 



2.3 Is there clear and brief information on the investigational product / device / process?

Complete 



2.4 Is there clear and brief information on the expected risk and discomfort?

Complete 



2.5 Is there clear statement that participation is voluntary?

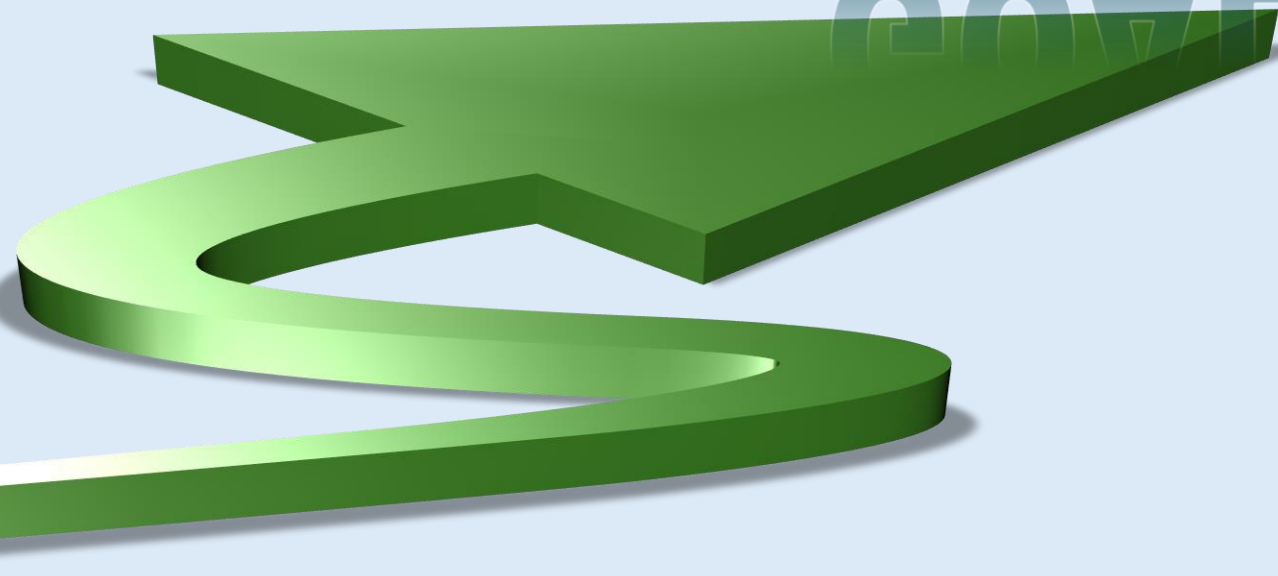
Complete 



Aim of the audit.

GOAL

- Percentage of assent documents fulfilling the MREC's requirement.
- The Flesch-Kincaid readability scores of the assent documents.



Objectives.


Primary Objective

Evaluate the assent forms submitted to MREC (Medical Research and Ethics Committee) on their concordance with the requirement.

Secondary Objective

To evaluate the Flesch-Kincaid readability scores of the assent documents submitted to MREC.

Audit Measures and Standards.



**World Health Organization (WHO)
Informed Assent Form Template for
Children/Minors.**



**Research Ethics Review Committee
(WHO ERC)**

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – [HTTP://WWW.WHO.INT/ETHICS/REVIEW-COMMITTEE](http://www.who.int/ethics/review-committee)

***Informed Assent Form Template for
Children/Minors***



Stakeholders and Involvement.



Audit discussed with secretariat MREC.



Audit approved & registered with Ministry of Health, Malaysia.

Me

Data

Da

Evalu

Mini

Asse

Part

Stud

Nam

spor

Subj

Desc

Purp

Brie

rese

Risk

rese

Ben

rese

Ens

Rec

Opti

Dis

Pro

Ass

Sign

Date

St

Re

F

F

G

S

C

A

Te

S

W

C

P

A

A

Assent form for pre-adolescent or young adult (12-16 years of age).

Part 1: Information Sheet

	YES	NO	NAD
Study title			
Name of Principle Investigator, Name of organization, name of sponsor, name of project and version.			
Introduction			
Purpose			
Choice of participants			
Participation is voluntary			
Information on the Trial Drug			
Procedures: What is going to happen to me?			
Risk: Is this bad or dangerous for me?			
Discomforts: Will it hurt?			
Benefits			
Reimbursement.			
Confidentiality			
Compensation			
Sharing the Findings			
Right to Refuse or Withdraw			
Who to contact?			

Part 2: Certificate of Assent

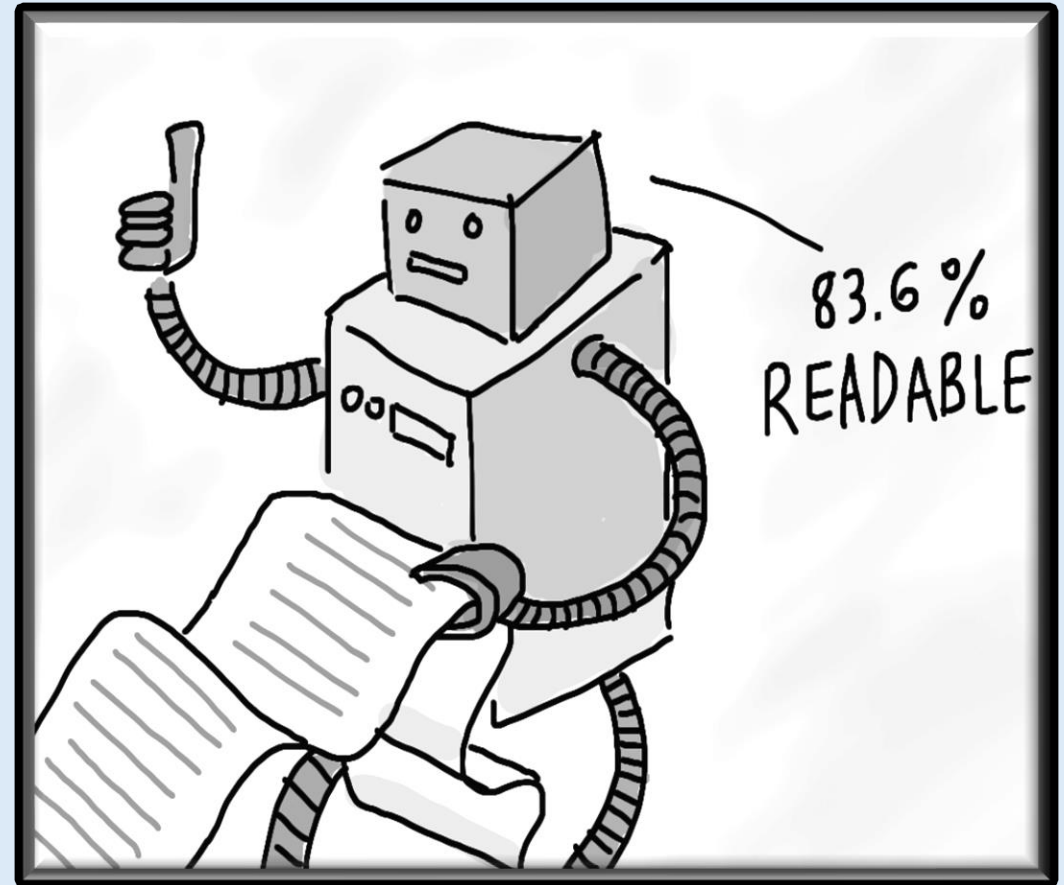
	YES	NO	NAD
Introduction			
Agreement to take part in research			
Disagreement to take part in research			
Name of the child printed			
Signature of the child			
If illiterate			
Statement that of witness that accurate reading of assent form to the child and the consent is given freely.			
Thumb print of participant			
Name of witness			
Signature of witness			
Date			
Statement that the researcher has witnessed the accurate reading			
Name of researcher			
Signature of researcher			
Date			
Statement by researcher or person taking consent that child understands			
Name of researcher/ person taking the assent			
Signature of researcher/ person taking the assent			
Date			



obtained from 150
assent forms that were
obtained between December

Readability Test.

- 1** The tests measure “**how easy it is to understand a text**”.
- 2** They can help ensure that content is **understandable by the target audience**.
- 3** The score roughly estimates the **level of education** someone would need in order to read a passage of text easily.
- 4** For the general public, the text should reflect a readability about 8th grade.



Solnyshkina, Marina & Zamaletdinov, Radif & Gorodetskaya, L.A. & Gabitov, A.I.. (2017). Evaluating Text Complexity and Flesch-Kincaid Grade Level. Journal of Social Studies Education Research. 8. 238-248.

Readability Test.

Flesch Kincaid Reading Ease and Grade Level

Score	Grade	Average Words per sentence	Score
90-100	5	8	123
80-90	6	11	131
70-80	7	14	139
60-70	8-9	17	147
50-60	10-12	21	155
30-50	College	25	167
0-30	College Grad	29	192

Gunning Fog Index

Fog Index	Reading Level By Grade
6	Sixth grade
7	Seventh grade
8	Eight grade
9	High School Freshman
10	High School Sophomore
11	High School Junior
12	High School Senior

Readability Test.

Simple Measure of Gobbledygook™ (SMOG) Index.

Word Count (for longer materials)	Grade Level
0-2	4
3-6	5
7-12	6
13-20	7
21-30	8
31-42	9
43-56	10

Coleman Liau

Index Score	Grade
≤ 6	6 th grade
7	7 th grade
8	8 th grade
9	High school freshman
10	High school sophomore
11	High school junior
12	High school senior
13	College freshman
14	College sophomore

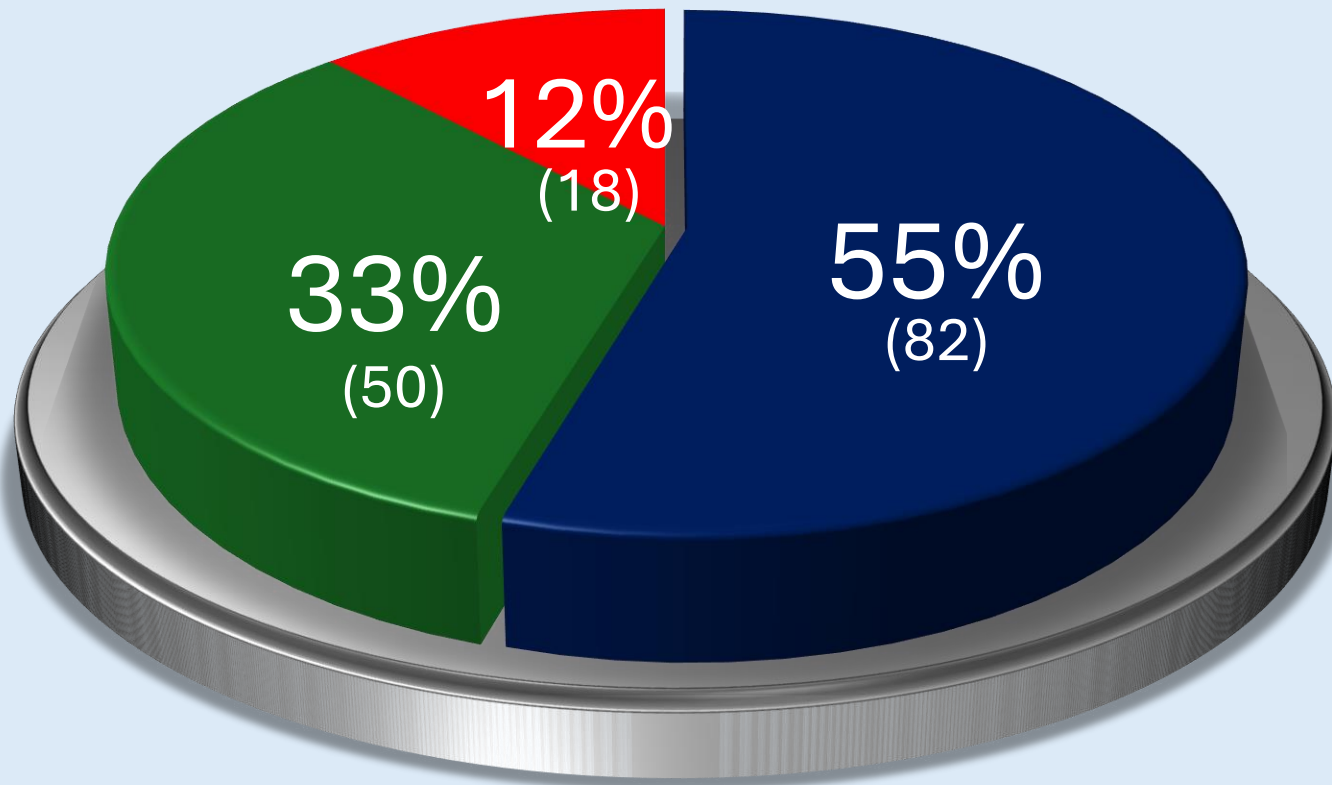
RESULTS

Name _____

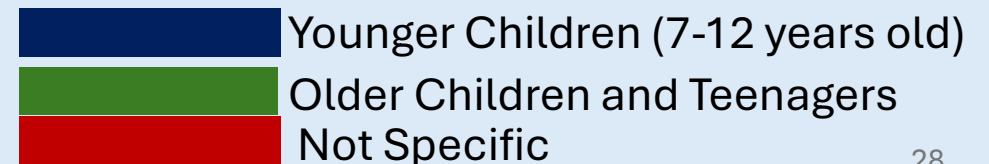
Signature _____

Date _____

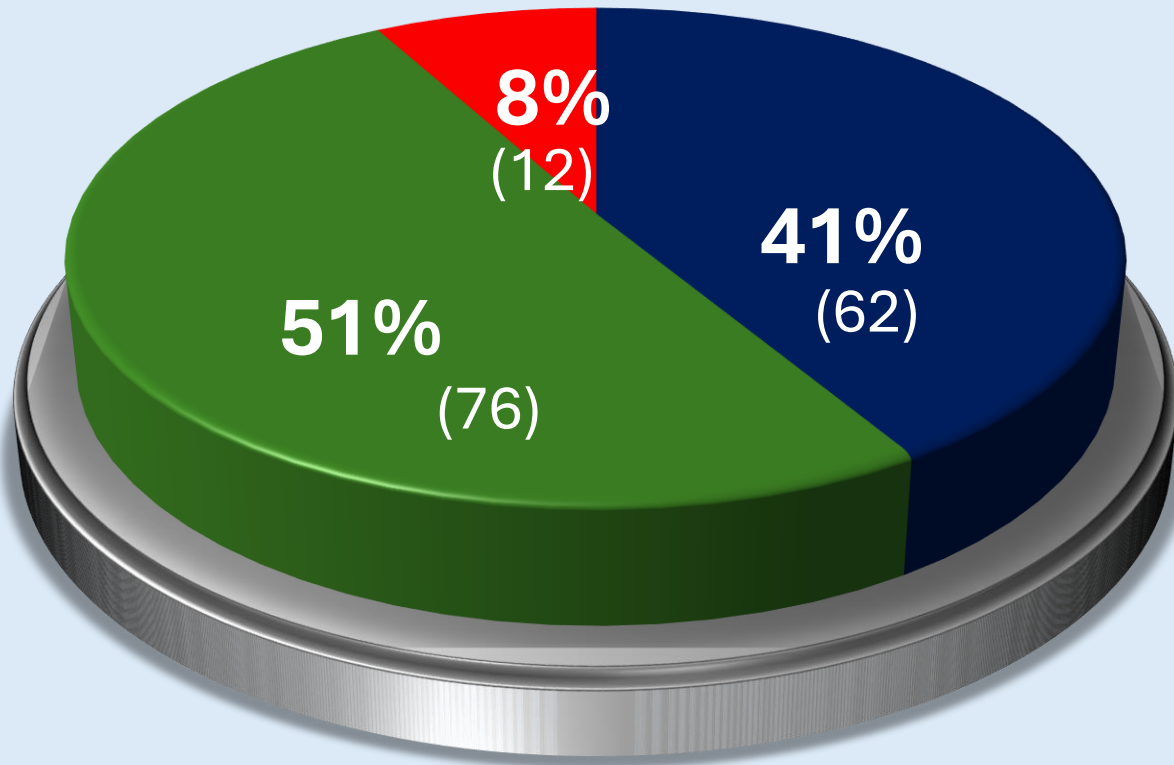
Age Groups for Information Sheet and Assent.



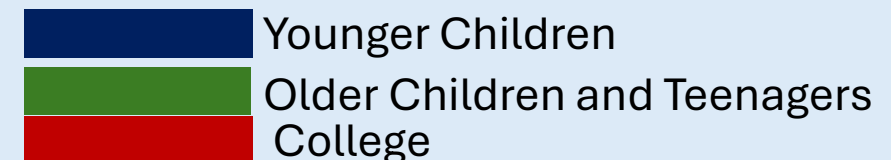
- **More than half of the assent forms were for younger children.**
- About 1/3 of the assent forms were for older children and teenagers.
- A small proportion had no specific age group.



Flesch Kincaid Reading Ease for all age groups.



- **Most of the assent forms had a reading ease for older children and teenagers.**
- There was a small percentage, whereby the reading was meant for college students.



Flesch Kincaid Reading Ease

Younger Children

Older Children

Others



53%

Younger
Children

43%

Older
Children

4%

College
Students



22%

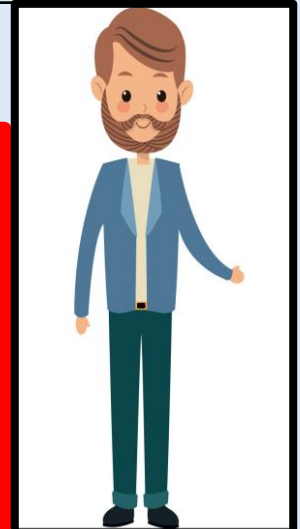
Younger
Children

64%

Older
Children

14%

College



39%

Younger
Children

50%

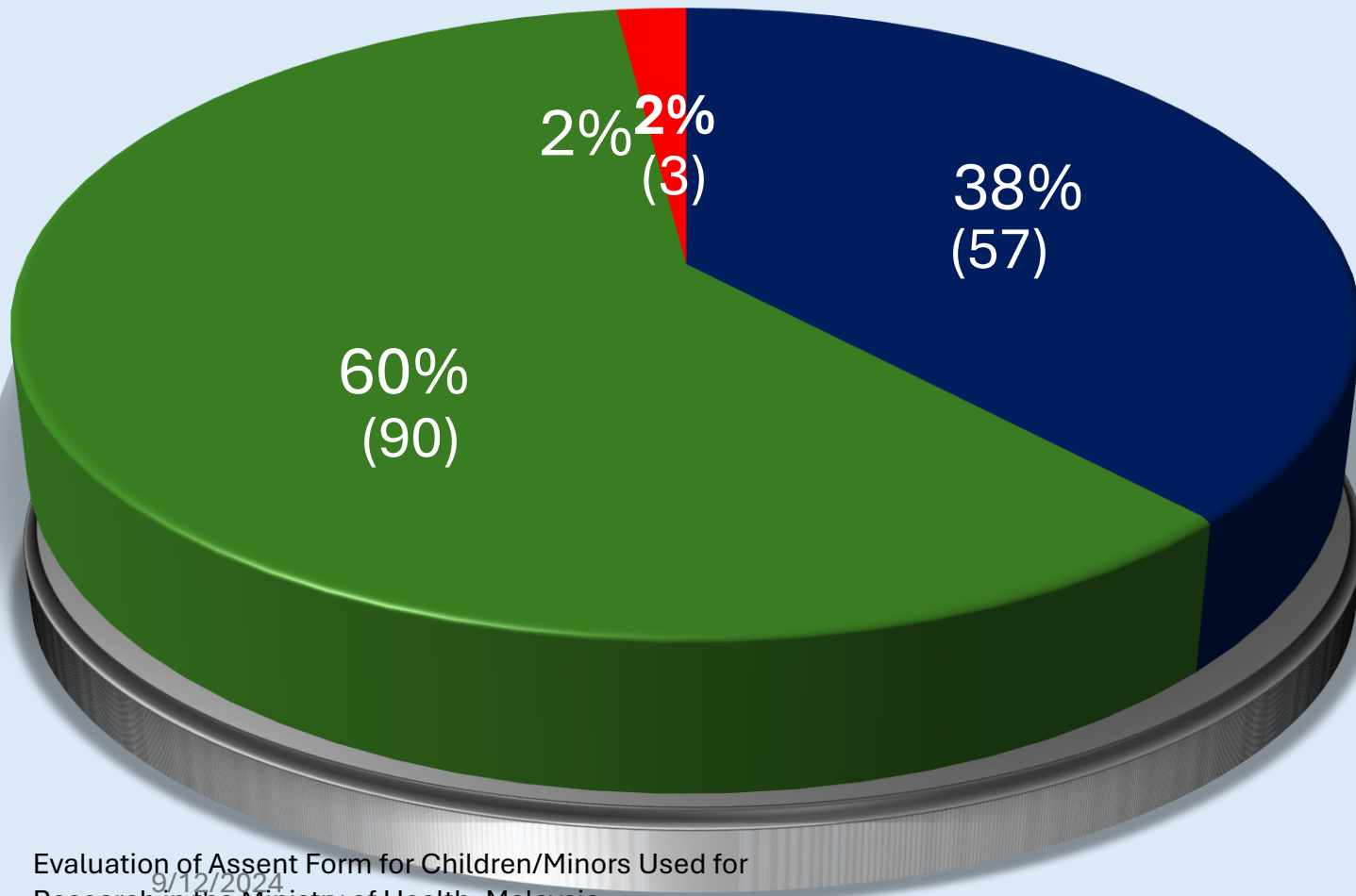
Older
Children

11%

College

Gunning Fog Score.

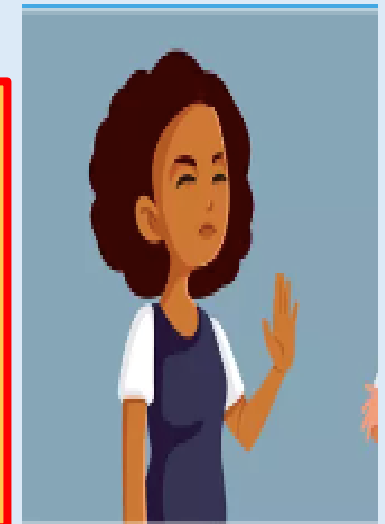
Gunning Fog For All Age Groups



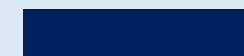
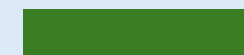

Gunning Fog for younger children



51%

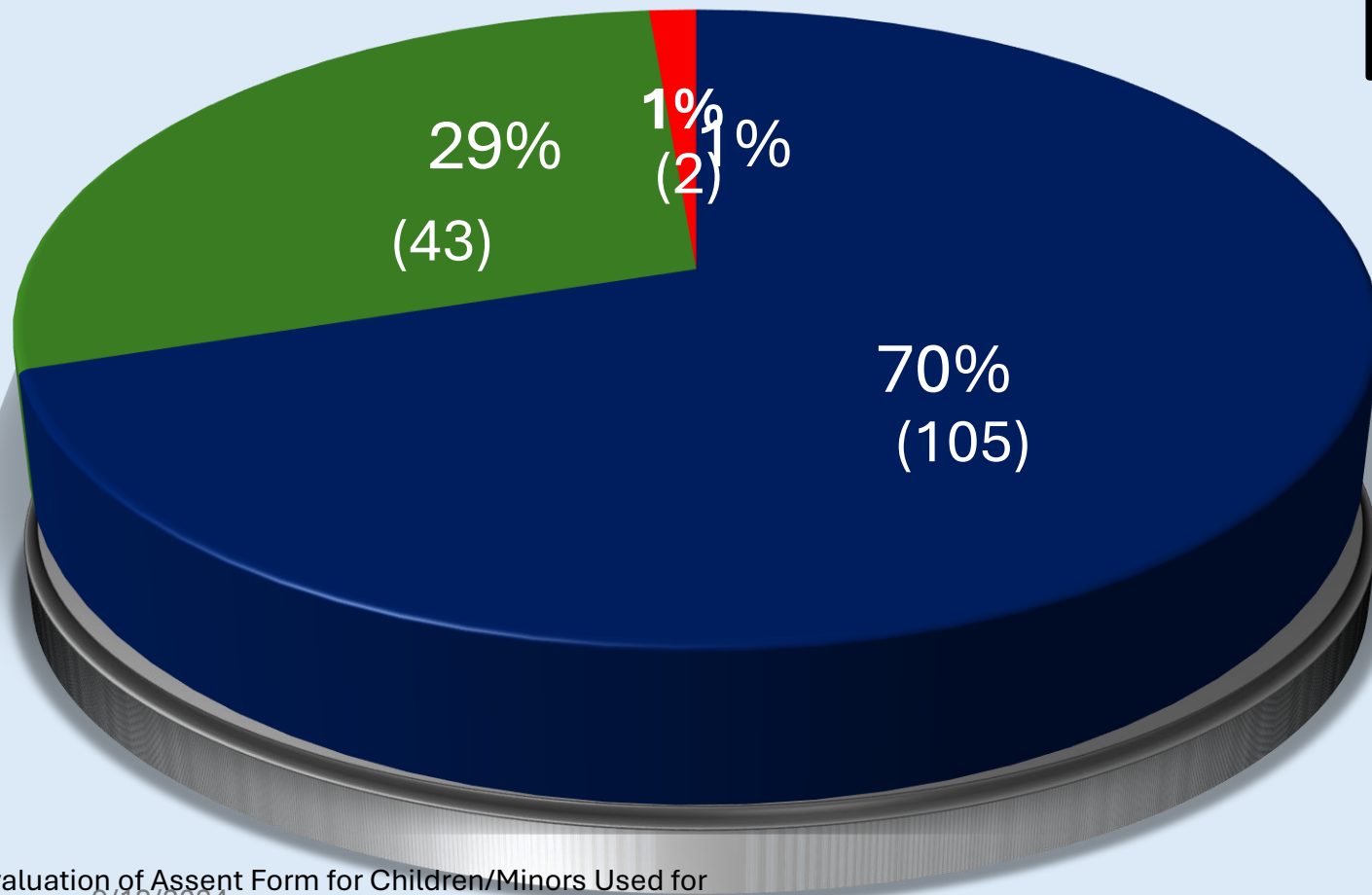


49%

-  Younger Children
-  Older Children and Teenagers
-  College

SMOG Index

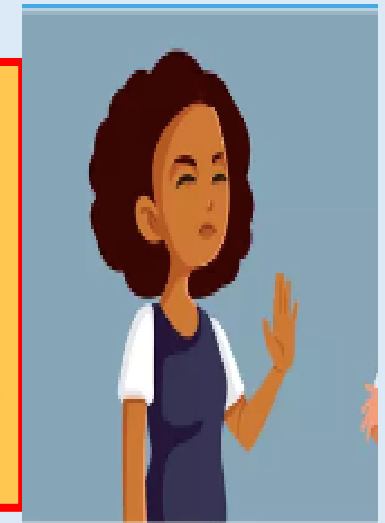
SMOG Index For All Age Groups




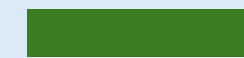

SMOG Index for younger children



62%

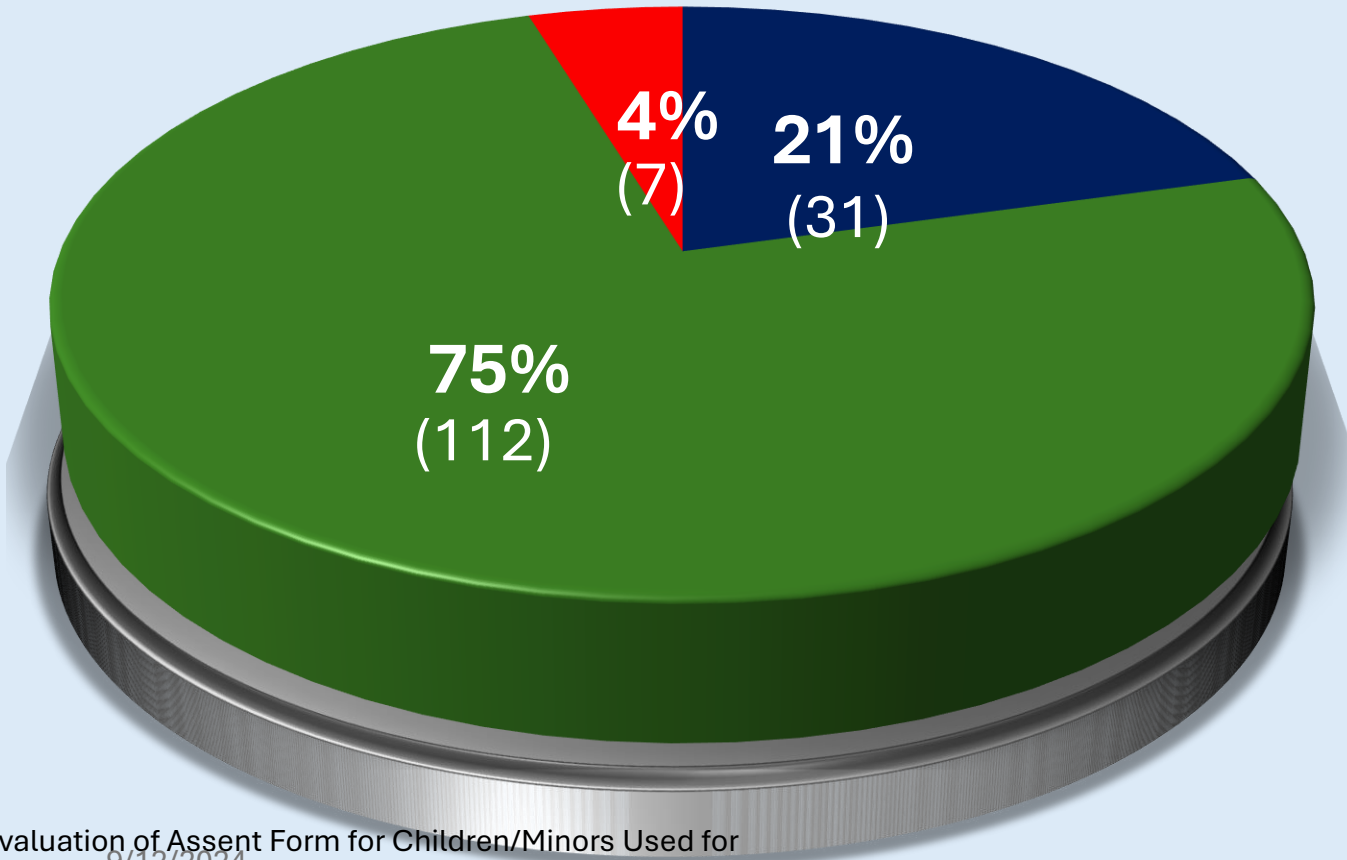


38%

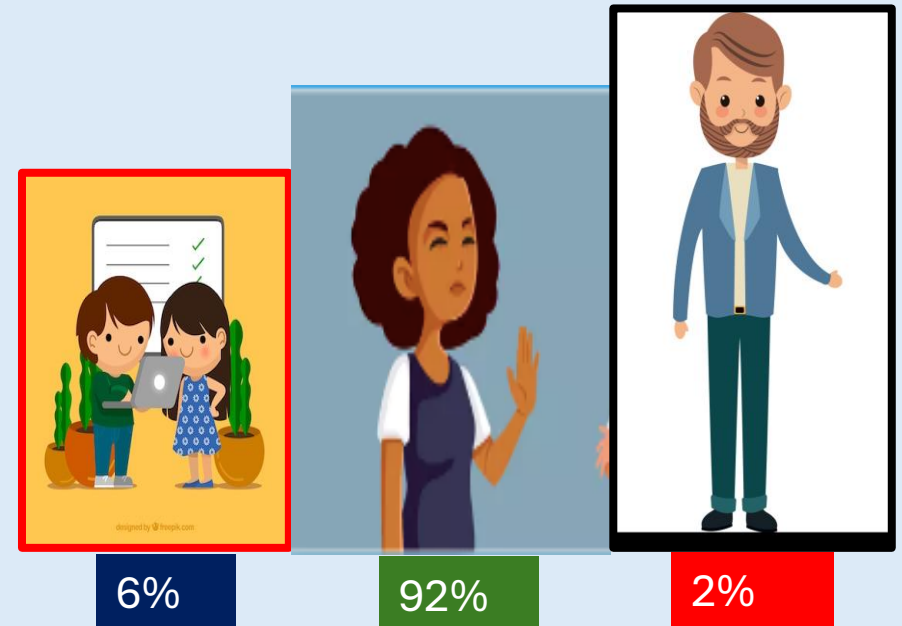
-  Younger Children
-  Older Children and Teenagers
-  College

Coleman Liau

Coleman Liau For All Age Groups.

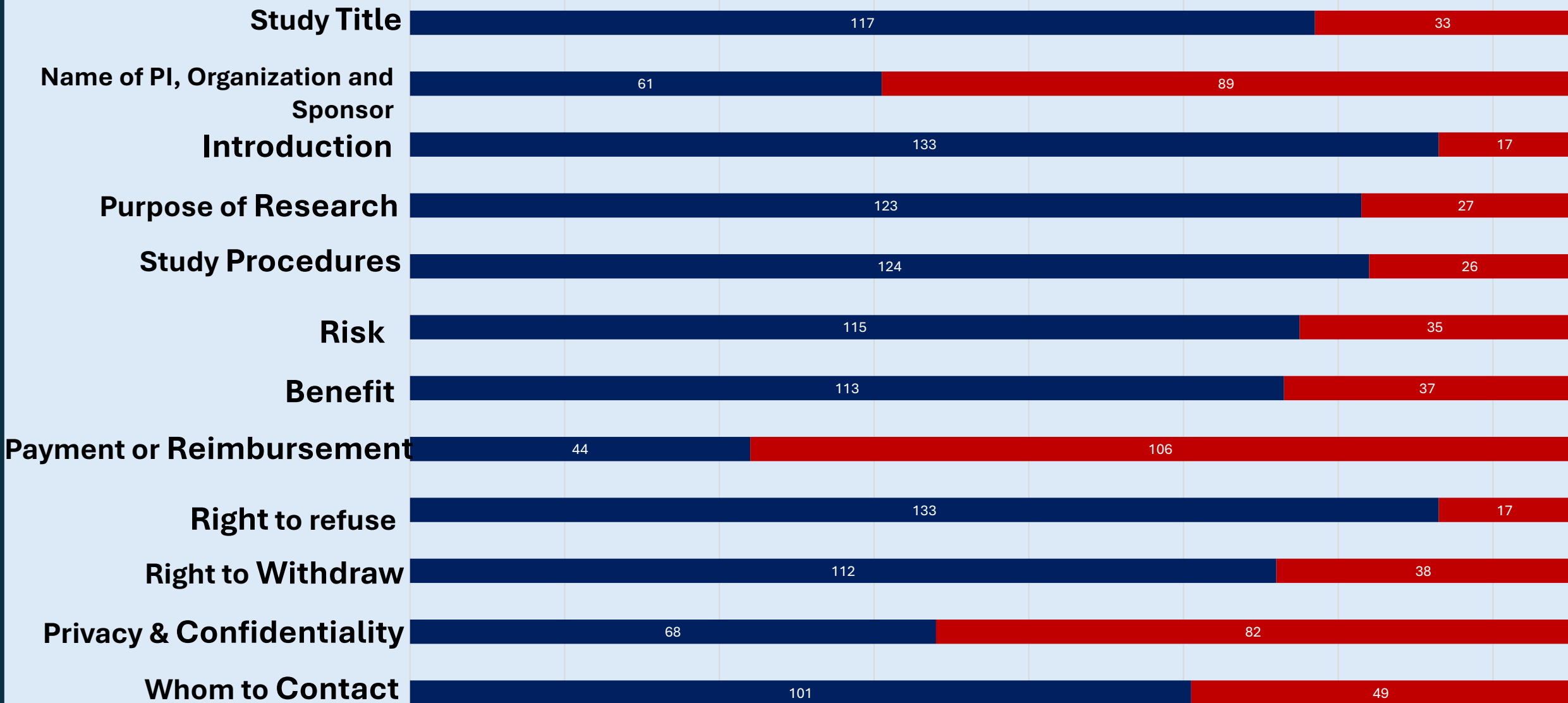


Coleman Liau for younger children

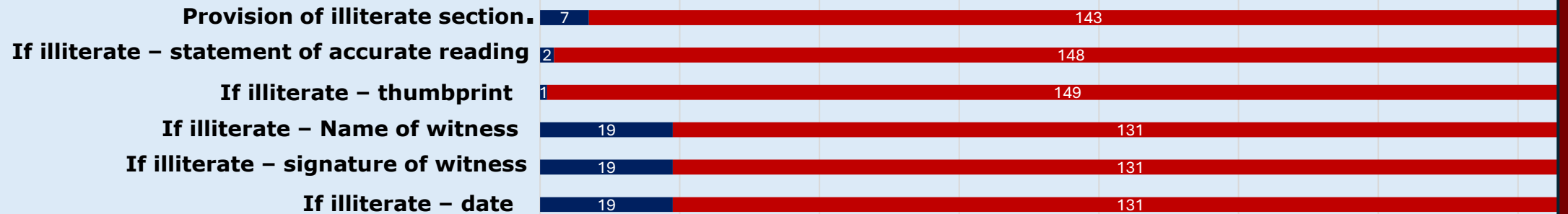
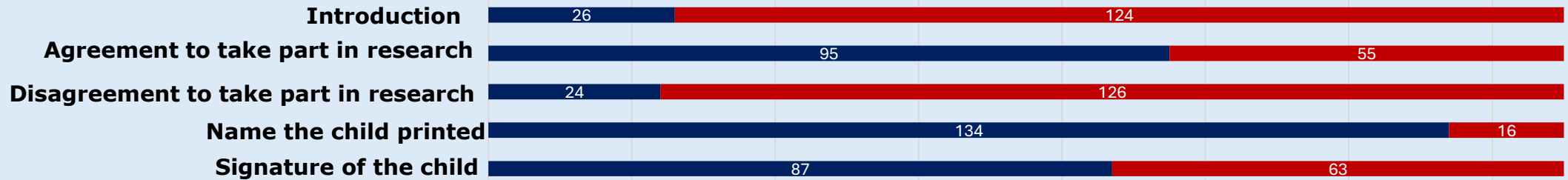


- Younger Children
- Older Children and Teenagers
- College

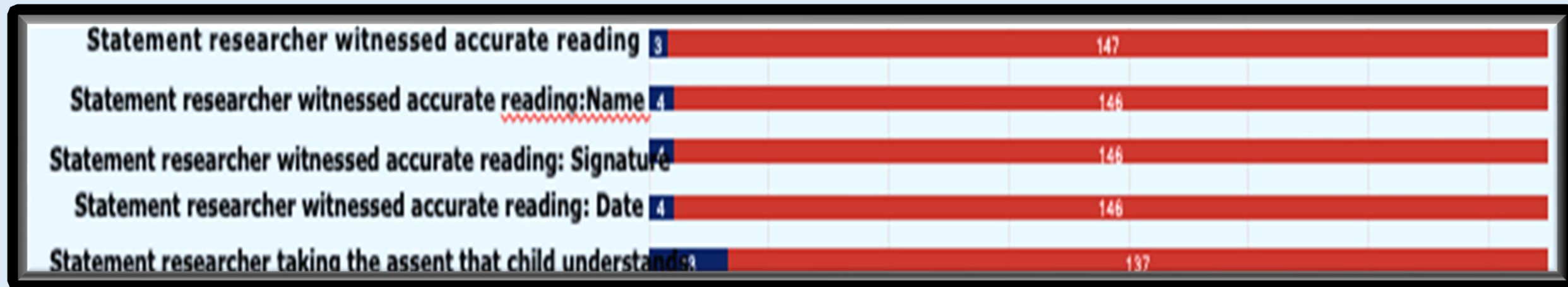
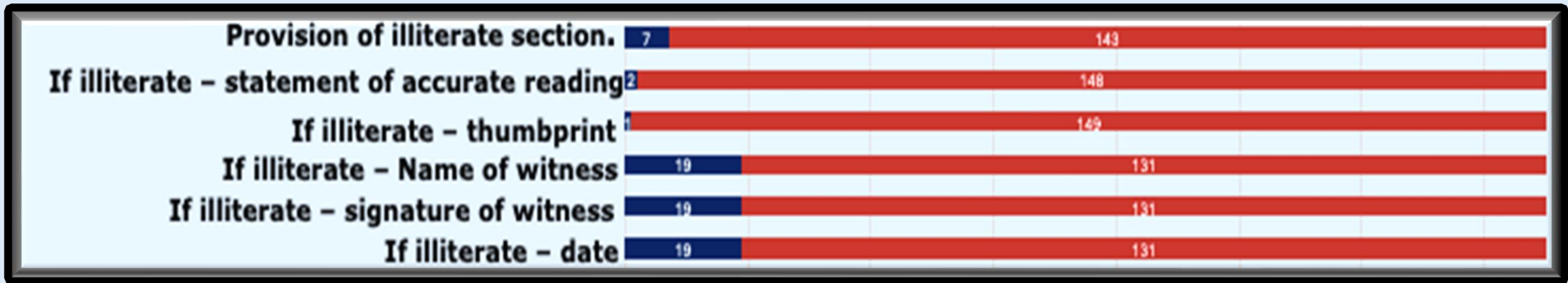
Completeness of Information in PIS.



Completeness of Certificate of Assent Form



Completeness of Assent Form



A group of business professionals in an office setting. A woman in a grey blazer is pointing at a tablet held by another person. A man in a dark suit and tie is also looking at the tablet. There are coffee cups and a smartphone visible on the table. The word "DISCUSSION" is overlaid in large white letters.

DISCUSSION

Discussion.

1. Most of the requirements met with a score of 80% or higher. However, there still lacks information in some of the assent forms. This issue should be addressed when ethics committee assess information sheet for children.
2. Generally, the language used in the information sheets may not be appropriate for the age group it is intended for. This could potentially impact the effectiveness of both the information sheet and the assent form in research.
3. This may be because the ethics committee members review the information sheets, which can be subjective. Therefore, it is important to pay more attention to ensure that the language used in the information sheets is appropriate for the intended age group.



Limitations.



This study is not able to demonstrate the appropriateness of the information sheet according to the local standards as we compared it to the international standards in this study.

Conclusion.

The assent information sheets and assent forms should be improved to ensure completeness. It is important to pay more attention to the language used in the documents to make sure it is age-appropriate.

Further studies may be conducted in the future to determine whether the consent documents have been improved in terms of their language appropriateness and the completeness of the information provided.

Recommendation.



- Ethics committee to use separate checklist for children when assessing assent documents.
- To provide template of assent documents to researchers as a guide so that they do not miss out information or use language that is inappropriate to age.

References.



1. Shuster, E. Fifty Years Later: The Significance of the Nuremberg Code. *New England Medical Journal* 1997; 337:1436-1440. DOI:10.1056/NEJM199711133372006
2. U.S Department of Health and Human Services. Federal Policy for the Protection of Human Subjects. Code of Federal Regulations. Additional Protections for Children Involved as Subjects in Research of the Common Rule (Protection of Human Subjects, 45 CFR 46(2)).
3. WMA. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 2008. http://www.wma.net/en/30publications/10_policies/b3/index.html
4. American Academy of Paediatrics Committee on Bioethics, Aviva L. Katz, Robert C. Macauley, Mark R. Mercurio, Margaret R. Moon, Alexander L. Okun, Douglas J. Opel, Mindy B. Statter; Informed Consent in Decision-Making in Pediatric Practice. *Pediatrics* August 2016; 138(2): e20161484.10.1542/ped.2016-1484
5. International Ethical Guidelines for Health-related Research Involving Humans. Prepared by the Council of International Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). Geneva 2016 <https://doi.org/10.56759/rgxl7405>

References.



6. Unguru Y. Pediatric decision making: Informed consent, parental permission, and child assent. In: Diekema D., Mercurio M., Adam M., editors. *Clinical Ethics in Paediatrics. A Case-Based Testbook*. Cambridge University Press; Cambridge, UK:2011.pp.1-6
7. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. Research involving children: report and recommendations of the National Commission for Human Subjects of Biomedical and Behavioral Research. *Federal Register*. 1978; 43(9): 2084-2114
8. Alan R.Tait, Terri Voepel-Lewis, Shoba Malviya; Do They Understand? (Part 1): Parental Consent for Children Participating in Clinical Anesthesia and Surgery Research. *Anaesthesiology* 2003; 98:603-608 doi: <https://doi.org/10.1097/00000542-200303000-00005>
9. Alan R.Tait, Terri Voepel-Lewis, Shoba Malviya; Do They Understand? (Part 2): Parental Consent for Children Participating in Clinical Anesthesia and Surgery Research. *Anaesthesiology* 2003; 98:603-608 doi: <https://doi.org/10.1097/00000542-200303000-00006>
10. Vreeman R, Nyandiko W, Meslin E. *Journal of Empirical Research on Human Research Ethics*, pp3-16. Jan 2009 DOI: 10.1525/jer.2009.4.1.3
11. Research Ethics Committee World Health Organization. Informed Assent Form Template for Children/Minors <https://cdn.who.int/docs/documents/ethics>

Q and A

