

Review of patient information leaflets and consent forms used in genetic research studies at a cancer hospital in Pakistan

Natasha Anwar, Mariam Hassan, Saima Faisal.
Shaukat Khanum Memorial Cancer Hospital & Research
Centre, Lahore.

Outline

- Background to study
- Assessment criteria
- Results
- Recommendations

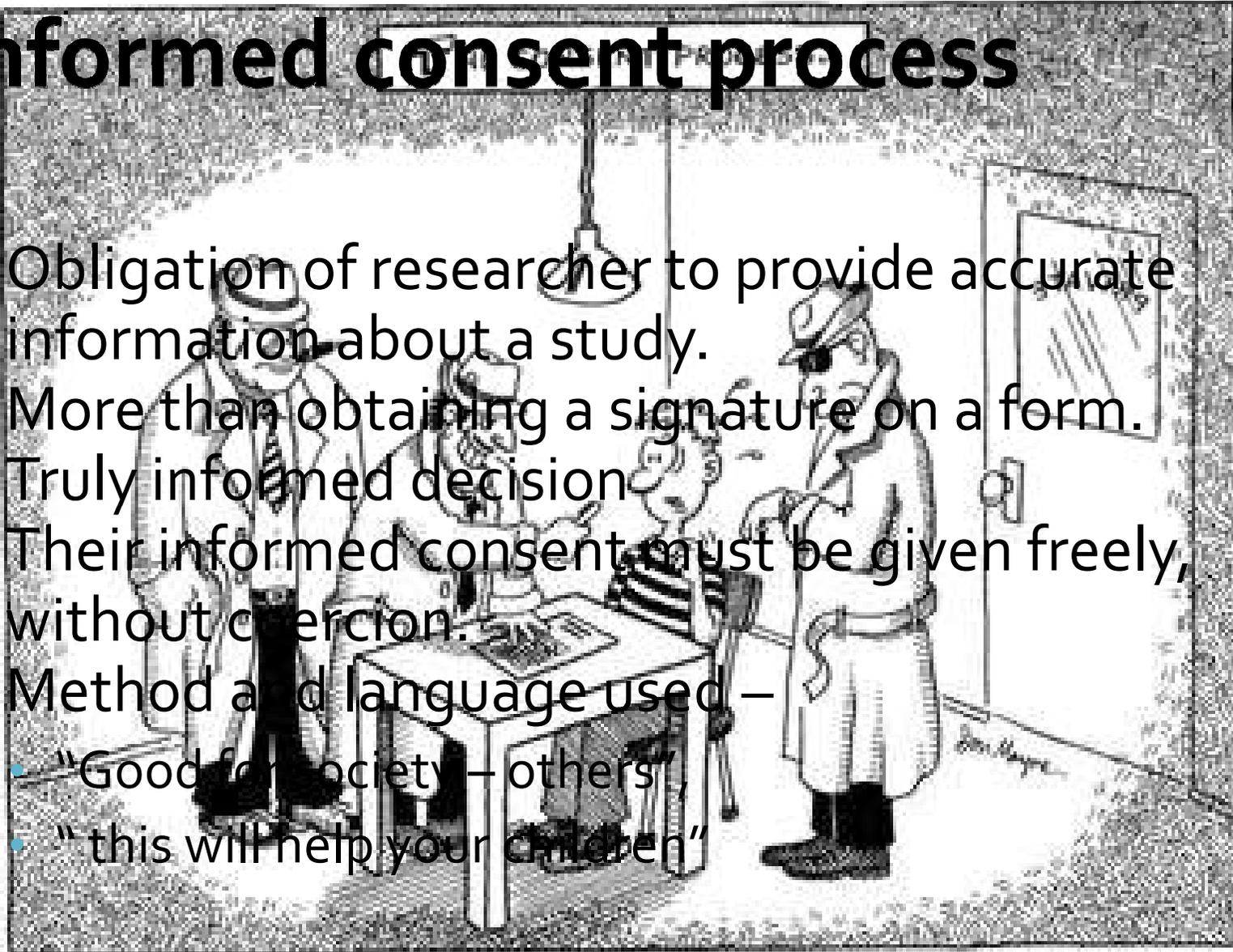
Shaukat Khanum Memorial Cancer Hospital & Research (SKMCH & RC)

- Only tertiary cancer care facility in Pakistan.
- Register approximately 3000 patients every year.
- Almost 70% of these patients are treated free of cost.
- Genetic research studies initiated in 2002.
- Post graduate diploma in Biomedical Ethics 2007 and 2009.



Informed consent process

- Obligation of researcher to provide accurate information about a study.
- More than obtaining a signature on a form.
- Truly informed decision
- Their informed consent must be given freely, without coercion.
- Method and language used –
 - “Good for society – others”
 - “this will help your children”



Genetic Studies at SKMCH & RC

- Studies numbered 1-4
- Recruited participants with ovarian, colorectal, and breast cancer , one study enrolled healthy donors.
- Requirement of extra tissue (biopsy) sample and/or blood sample
- Involved screening samples for genetic alterations.
- No impact on clinical management.
- IRB approved studies.

Assessment Criteria

- Reviewed both the English and Urdu information leaflets and forms to determine:
 - i) appropriate content recommended by the Office of Human Subjects Research (OHSR), National Institute of Health, US and
 - ii) clarity calculated using Microsoft Office Word readability statistics.
 - Level of Urdu was assessed by a) comparison with Punjab Text Book Board's General Science book for high school students b) clarity calculated based on sentence length and syllables.

i) OHSR Outline for consent forms

- **Statement that study involves research (1)**
- **Purpose and duration of research participation (2)**
- **Study procedures (1)**
- **Risks: description +likelihood +prevention strategy (3)**
- **Description of benefits +statement of monetary compensation(2)**
- **Alternatives procedures or treatments**
- **Confidentiality and record access (2)**
- **Compensation +contact information in the event of injury (2)**

OHSR Criteria Continued

- Contact info of research representative + patient rights representative (2)
- Voluntariness of participation + freedom to discontinue (2)
- Cost of participation (1)
- Information about new findings during course of study (1)
- Approx. total no. of subjects (1)
- PI's financial or other conflict of interest (1)
- Reading ease: formatting/use of headings, length of sentences, words with more than two syllables*, continuous run-on text (1)

ii) The Flesch Reading Ease Readability Formula

- The specific mathematical formula is:

$$RE = 206.835 - (1.015 \times ASL) - (84.6 \times ASW)$$

RE = Readability Ease

ASL = Average Sentence Length (i.e., the number of words divided by the number of sentences)

ASW = Average number of syllables per word (i.e., the number of syllables divided by the number of words)

- The higher the number, the easier the text is to read:-
 - Scores between **90.0 and 100.0** are considered easily understandable by an average **5th grader**.
 - Scores between **60.0 and 70.0** are considered easily understood by **8th and 9th graders**.
 - Scores between **0.0 and 30.0** are considered easily understood by **college graduates**.

Readability of English Forms

Study	Source of Form	No. of words	Flesch Reading Ease	OHSR Criteria Score (22)
1	UK Collaborator	1109	50.8	15
2	SKM Researcher	1098	60.8	9
3	SKM Researcher	788	63.3	9
4	UK Collaborator	992	43	14

Urdu Consent Forms



جزل سائنس

- Review for language (comparison with Punjab Text Book Board's General Science book for Level 9-10).
- We used three chapters for their relevance to a medical context:-
 - 'Human Health' انسانی صحت
 - 'Diseases, causes and prevention' (اور بچاؤ) (بیماریاں) and
 - 'Biochemistry and Biotechnology' بائیوٹیکنالوجی . بائیو کیمسٹری اور

Readability of Urdu Forms

Study	Words	Syllables	Sentences	Flesch Reading Ease	OHSR Criteria Score (22)
3	950	1256	45	74.13	9
4	1250	2000	62	51.02	14

Summary of review of Urdu forms

- More medical terminology present
- Readability for study 2 was lower than study 1
- Direct translation of English text often uses words not used in everyday language.
- Terms such as cancer (سرطان), genes (جينز), genetic mutations (جينياتي تبديلياں), stomach (معدہ), virus (واءرس) were common, other more complicated terms such as tissue (ٽشو) pathology sample (بايوپسي) biopsy (بيٺهاالوجي), hereditary cancer (سرطان موروثي) were not.

Summary of findings

- The content of the forms compared poorly with OHSR criteria and they were not easy to read.
- There were no pictures/diagrams.
- The Urdu forms contained terms more complex than terms found in a high school level general science book.
- High school level English and Urdu may not be appropriate for our patient population, majority of who have not attended high school.

Recommendations

- Training of researchers.
- Use an assessment tool to evaluate consent forms prior to IRB submission.
- Direct translations should not be used as they add to the complexity of text.
- Need to determine comprehension level of research participants – is high school level English/Urdu a good benchmark for our population?

Acknowledgements

- Mariam Hassan and Saima Faisal – Clinical Research Officers
- Dr M. Awais – Associate Professor, Dept of Computer Science, Lahore School Management Sciences.
- NBC Secretariat – Neha & Divya

Dil Ka Darwaja Khol Ke aana...
Par Wapis jaa Kar Bhul naa jaana



 PUNJAB HERITAGE & TOURISM PROMOTION BOARD