# Length of a consent process- lessons from a field research on use of helmets by motorized two-wheeler drivers

**Parallel Session 25.**
**Surveillance and Epidemiological Research**
**3rd National Bioethics Conference**
**All India Institute for Medical Sciences, New Delhi**
**Nov 20, 2010**

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An informed consent is indicative of a research participant's intention to engage with the researcher after being informed of the purpose of research.

Origins: The Holocaust
Nuremberg Trials
Nuremberg Codes
Declaration of Geneva
Declaration of Helsinki

Over the last 60 years the requirements for obtaining informed consent have become more rigorous and standardized .

But more is the information provided
-more is the risk of provoking anxiety and confusion.

Principles of Informed Consent:

The process of modifications is constant but the basic principles remain as follows:

- There should be no unnecessary risk to the participants;
- Unnecessary, aimless and studies without benefit should be avoided;
- Scientifically unsound studies must be avoided;
- Poor planning should be avoided.

But above all,
The well being of the subject takes precedence over other interests.

**Do No Harm**

The process of taking consent:

- Assess decision making capacity or competence;
- Disclose relevant information about the proposed research;
- Ensure that the subject understands the information;
- Ensure that the subject is positioned to make voluntary decision;
- Authorize a decision by the subject and sign a consent form.

**Do No Harm**

- ‘If research subject consents without reading and understanding the IC is their consent inadequate?’

- ‘ Should all possible information concerning a study be put into the informed consent form or are there some limits to disclosure?’

A researcher informing the potential subject and seeking their consent is actually seeking favours from participants.

The balance of power:

- The process of obtaining consent - a tacit deal.
- Motive for the exercise - to obtain consent not refusal.
- The subject’s power to accept or refuse - keeps shifting.
- The researcher too is doing the study for the benefit of the society.
- Researchers – disillusioned and disinterested in further research.

The problems of administering a lengthy consent form were experienced collecting data for our study entitled-

“*Policy study of helmet legislation in Kerala and its implications.*”

The cross sectional survey conducted was one of the components of the whole study and was done to find the factors related to helmet wearing status and the risk perception.

The study used an interview schedule among the motorized two-wheeler drivers selected randomly from 31 public parking lots in Thiruvananthapuram City.

However, the researcher was seen as an added nuisance in the parking lot by most drivers.

Their ability to decline participation is absolute and there is very little scope for exploitation in this context.

In all 300 participants were approached of whom 256 participants agreed to respond leading to a response rate of 85.3%.

One of the major reasons for refusal was perceived to be the length of the consenting process.

In the 10 minute interview, the consent process took up about 60-180 seconds.

Most of the people approached were in a hurry thus allowing very less time to complete the interview process.

Many people did not have time to listen to the whole informed consent.

A few among those who had initially shown keen interest backed out with suspicion when the informed consent was read out.

The length of the consent form also made many apprehensive of the length of interview.

Thus we find that the length of the consent form has been a major deterrent towards participation.

More information provided seems to have given scope for more refusals.

It may be contextual to the place and people among whom this study was conducted.

Too much of information (hyper information) is construed to have some hidden agenda and arouses suspicion.

Another problem faced during the study is the reluctance on the part of participants to give signed consent.

The IRBs though have remained steadfast to the belief that consent form must be standardized irrespective of the inherent risk or absence of it for study participants

A uniform requirement is forced upon the researcher regardless of the type of study being planned, what interventions  are or how the data shall be processed and applied.

Usually there is no regard to reasonable exceptions

A shorter informed consent form would have gone a long way towards improving the response rate.

IC should present just enough information to a volunteer allowing them to intelligently decide whether or not to participate as a research subject.

It should ideally describe the overall experience and research activity and they should be made aware that the whole purpose is for public good.

The call is for more flexibility in the length of the consent form.

A shorter form giving only bare essential details and not expecting a signed consent would facilitate research and reduce bias in terms of possible differentials in dropout rates.

Graded consent forms that take into account the level of risk of violation of autonomy would serve to solve such problems and this would not in any way compromise the other principles of ethical research.

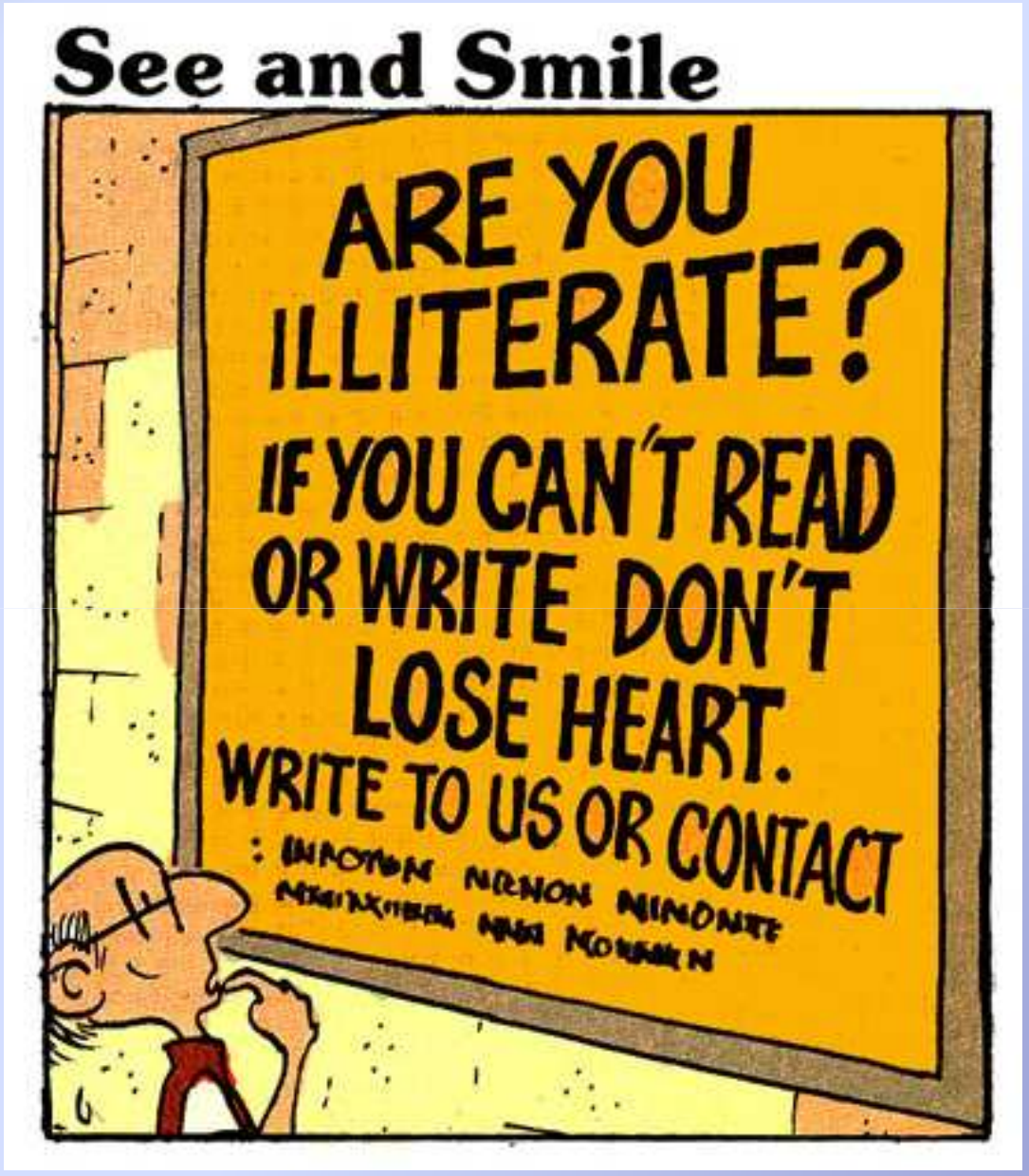
It is more relevant to emphasize the importance of norms such as intelligibility, relevance, accuracy and honesty rather than demanding extended disclosure in the consent form.

Informed consent cannot and should not aim to be fully specific and fully explicit.

The aim should rather be to simplify the consent forms.

The length of consent forms and their legalistic format may be intimidating to the subjects.

- Is a lengthy and standardized consent form the only way of assuring autonomy?
- Why cannot we have graded consent forms?
- Is it always necessary to take signatures for consent?
- Is it not but ethical to safeguard the interests of the researchers too?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# Thank You