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Editorial

Informed Consent Template by Strategic Initiative for Developing Capacity in Ethical Review. A Good Alternate?

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Obtaining informed consent from (ICF) the participants of a clinical trial, bioavailability and bioequivalence studies, and investigator initiated research consists of two documents; participants' information sheet and informed consent form. Informed consent is also a mandate for epidemiological and observational studies. It ensure participants autonomy to enroll them in trials and also legally valid for their post trial access and compensation. As a dictum, it should be in English and vernacular language signed by study subjects or their legally accepted representative (LAR).[1] There are valid differences in opinion about amount of information that should be in given consent form. Participant information sheet in too much number of pages is often perceived tedious by the subjects and it is more complex when it comes to countries like India where there is diversity in language; Whereas it is an important for a sponsor and investigator to disclose all the elements, for an example, all the possible and rare adverse effects in the information to protect them from legal liability. Patient's ability to understand and thereby willing to participate in a study is challenged by amount of information and its simplicity. Too lengthy and complexity in understanding them is seen even in western scenario. In a study conducted by Hames B *et al.* in 2016 among Netherlands, Denmark and Norway population concluded that readability is not within acceptable range of the study subject's educational profile. This sort of assessment scale [Gunning's fog index] is neither developed nor adopted in our scenario.[2-3]

Utilizing the commonly made information sheet with back translation in vernacular language cannot be relied as simple and understandable by the all the participants and patients often tend to overlook essential elements in the information sheet. Study data comprehensiveness is one of the major tasks to be tackled to achieve patient's participants in our trial on their own.

In order to develop comprehensive information sheet and consent form, Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), an independent global network, supported by World health organization (WHO) for raising standards of ethics developed a model format containing all relevant materials of an informed consent. Highlights of SIDCER form is given in Table 1.

S No	SICDER ICF Template features
1	Precise and easy to adopt
2	Complies with all global regulatory requirements
3	Different colors[Gray, blue, orange code is denoted to fill the study related information (eg.orange for study methodology)
4	Template is short and self explanatory to naïve investigators as well
5	Covers basic and essential elements of informed consent form

Another alternatives are commonly made verbal conversation using audio visual aids to communicate details pertinent to the study can be given to the participants to visualize and/or hear leisurely before enrolling them into the study. Developing a common scale to assess understanding of study participants in our scenario is not an impossible take, but should be done as taskforce project before implementation.

However much is too much for documenting informed consent process should be tailor made. It should be specific, must carry all the essential and additional elements of informed consent process. Making additional measures to improve comprehensive ability and understanding of study participant is an additional task but inevitable to maintain ethical standards.[4-5]

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