MINUTES OF THE MEETING OF THE STAKEHOLDERS HELD ON 17.07.2014 TO DELIBERATE THE DRAFT RULES PUBLISHED VIDE NOTIFICATION GSR 364 (E) DATED: 07.06.2013.

A meeting was held on 17.07.2014 under the Chairmanship of DGHS in the Committee Room, 4th Floor, A-wing, Nirman Bhawan, New Delhi for deliberation on the comments/suggestions received on the draft Rules published vide notification GSR 364 (E) dated: 07.06.2013 for audio/video recording of the informed consent process (ICF) in Clinical trials.

List of participants is annexed.

DCG (I) welcomed the members and stated that the issue of audio-visual (AV) recording of informed consent process is a very important matter. He stated that Ministry of Health and Family Welfare has published draft rules on 07.06.2013 which were made available to the public for comments. Many suggestions/ objections have been received which have already been forwarded to the members and the same would be deliberated today in details and balanced recommendations of the committee would be forwarded to the Ministry of Health and Family Welfare for finalization of the draft rules.

The Chairman stated that the Hon'ble Supreme Court vide it's order dated: 19.10.2013 had made AV recording for informed consent process mandatory for five Global Clinical Trials (GCTs) approved between 01.01.2013 to 30.08.2013. However, CDSCO with the approval of Ministry of Health and Family Welfare have made AV recording of informed consent process mandatory for all clinical trial. Consequent to this, concerns have been raised by the researchers/experts and other stake holders that such AV recording is very difficult to implement due to various issues like privacy and confidentiality of patients, logistic issues, resource required etc.

He, therefore, stated that the meeting is very important to deliberate the matter to make balanced recommendations, so that the rights, safety and well-being of the subject are protected and at the same time medical research is encouraged for benefit of the society. The Chairman expressed his preliminary view that AV recording of IC process should not be made mandatory in all cases of clinical trial in light of various representations received by him. However, he requested the members to express their views in this regard.

Dr. Sarojini N. (Sama), stated that earlier in clinical trials like HPV trials, informed consent process have not been followed as per the requirements. Therefore, AV recording has been proposed for the informed consent process. However, we have to

articulate it properly in the rule regarding AV recording for informed consent process maintaining Privacy and Confidentiality.

Shri S. Srinivasan, LOCOST, stated that lot of mixed comment on the draft rules have been received. Concerns have been raised about the requirements. He opined that AV recording of informed consent process should be made mandatory in cases of clinical trials of New chemical entities/ New Molecular entities (NCEs/NMEs).

Dr. Amar Jesani, opined that ethics is not only the domain of Doctors, but it is to be considered by all Stakeholders. He agreed to the opinion expressed by Srinivasan and opined that AV recording of informed consent process should be made mandatory in cases of clinical trial of NCEs/NMEs. He also stated that Hon'ble Supreme Court in its order dated: 19.10.2013 did not made AV recording of informed consent process recording mandatory for all clinical trials. The spirit of the order is that such AV recording should be done in cases of NCEs. However, AV recording of informed consent process have been made mandatory for all clinical trial through the administrative order in light of the order of the Hon'ble Supreme Court.

Dr. K. Satyanarayan, Chairman, Ethics Committee (EC) , RML Hospital, opined that AV recording of informed consent process should not be mandatory of all clinical trials. AV recording should be done in certain cases, where the respective EC feels that such recording is necessary for protection of rights of the subjects. Therefore, he opined that it should be left to ethics committee, who can decide depending on the nature of clinical trial, whether AV recording of informed consent process is required or not. Accordingly, Investigator should maintain AV recording wherever the respective ethics committee considered it necessary.

Dr. A.K. Das, JIPMER, opined that we have to do research for both new molecules as well as for new use of old molecules. Medical research is to be encouraged in the benefit of the society. No where in the world, AV recording of informed consent process is required in clinical trial. It does not mean that we will not have the requirement of AV recording of informed consent process. However, there has to be a balanced approach so that the rights of the patient are protected and at the same time,ethical clinical trial is conducted to investigate the new drug.Many writers have expressed their views that we are creating hurdles through requirement of AV recording of informed consent process. He opined that he is in favour of the AV recording, however, it should be in an appropriate manner. As it is a labour- intensive activity, it should not be a lengthy process of recording of whole informed consent process. The investigator can provide all essential information to the patients through videography and then the understanding by the patients and his signing in the Informed Consent Form can be AV recorded.

Dr. Santanu Tripathi opined that the proposed rules on AV recording is in addition to the requirement of written informed consent. It is going to be an evidence for informed consent. If written informed consent process is done properly than there may not be requirement of AV recording of informed consent process in all cases. It is not going to benefit all. Principal Investigator, Sponsor may be benefited from such AV recording.

He, therefore, opined that AV recording of informed consent process should not be made universal, it may be done in cases of clinical trials of NCEs/NMEs. However, what is to be recorded is also very important. Since, such AV recording is an evidence, only signing of Informed Consent Form by the patient should be AV recorded. Thus, he was in favour of AV recording of informed consent process in appropriate manner as above.

Dr. Nandini K. Kumar, agreed that AV recording of informed consent process should not be applicable for all the patients. Prof. Ranjit Roy Choudhury Committee has recommended AV recording only for vulnerable population. She also opined that in such activity Ethics Committee should play major role as opined by Dr. K. Satyanarayan. She stated that if it is made mandatory for all AV recording for whole informed consent process in clinical trial, the clinical trial in rural areas will go away. Therefore, we should work out to find that only understanding and signing of Informed Consent Form by the patients is AV recorded and not the whole informed consent process.

Dr. Rajni Kaul, ICMR, expressed her views that AV recording of informed consent process should be done in regulated clinical trials only and not in all clinical research.

Dr. S. Aneja, LHMC opined that such AV recording should be done only in case of illiterate and some vulnerable population. It should not be made mandatory for all patients in clinical trial.

Dr. Ritika Bajaj, ISCR opined that there are many practical challenges in such AV recording. There are situation when a patients likes to be in part of clinical trial, however, he/she does not like to be AV recorded. There should be some provisions for such patients to be enrolled in clinical trial. She also raised concern about validation of such AV recording, as Sponsor/CRO shall not have access to such recording. If it is not validated, later on it may create problem about recognizing the image and audio. Therefore, she opined that AV recording may be done in case of vulnerable population like mentally challenged patients, children etc.

Dr. Chirag Trivedi, OPPI, opined that such AV recording is good, but it should not be made mandatory for all clinical trial and also for not all patients in a particular clinical trial. There are many practical challenges in making such AV recording.

Dr. Anirban Roy Chowdhury, ISCR, opined that AV recording of informed consent process is not practiced anywhere in the world. In case of AV recording there may be violation on one aspect i.e. privacy and confidentiality of the subject.

For informed consent, the subject has to be given time, sometime not only in hours but may be in days or month. Therefore, AV recording in whole informed consent process has practical difficulties. Focus should be given for good governance to ensure that written informed consent process is done properly to protect rights of the subjects. AV recording should not be made mandatory for all cases. It may be done in cases where supplemental evidence on informed consent is considered necessary.

Dr. Shruti Grover, Rajiv Gandhi Cancer Institute and Research Centre, opined that there is possibility that in AV recording of informed consent process, the Privacy and Confidentiality of the subjects may be compromised. Due to AV recording many patients who are willing to participate for clinical trial may go out of the trial. Only few patients may agree for AV recording.

Dr. Mira Shiva, mentioned that many companies are already doing AV recording of informed consent process even before it was made mandatory. She gave example of a company and stated that the company feels that it will protect the Investigators and the Sponsor and it is not going to benefit the patients as such. However, Dr. Shiva opined that she does not agree that AV recording will only protect the Investigator and Sponsor. Earlier informed consent in clinical trial was a major problem. Therefore, written informed consent process should be strengthen and AV recording should be made mandatory for clinical trials of NCEs/NMEs. She also mentioned that for some patients, AV recording may be a problem. However, majority of patients may agree for such AV recording. She stated that whole process of informed consent process should be strengthen so that the clinical trials being conducted in the country are rationale. Dr. Shiva also pointed out that in some cases like in HIV, HCV trials the patients may not like to be AV recorded, in such cases only audio recording may be considered.

Dr. Sudha Prasad stated that consideration should be given so that such AV recording is not made mandatory for institutional Clinical Trials for academic purpose.

The Chairman while summarizing the opinions stated that most of the members are of the opinion that AV recording should not be done in all cases of clinical trial. The consensus view is that such AV recording should be made mandatory in some cases only. However, Chairman desired that the special cases where AV recording should be made mandatory to be decided based on further deliberation and discussion with DG, ICMR and others.

Thereafter, the Chairman requested Dr. B.D. Athani, Special DG (MS) to Chair the meeting as he had to attend some other meeting. After taking stock of the situation, Dr.

B.D. Athani started proceeding to discuss the suggestion/comments received on the draft rules.

The Committee was informed that all the comments/suggestions received on the draft rules and the draft guidelines were circulated to the members in advance. The members were requested to give recommendations on these comments. The Committee after detailed discussion recommended following for the draft rules.

1. The AV recording should be made mandatory only in cases of clinical trials of NCEs/NMEs (New chemical entity/New Molecular entity).There were also views that the AV recording should be done in vulnerable population in such trials.
2. In AV recording, Privacy and Confidentiality of the subject should be maintained in the similar manner as it is maintained in case of written informed consent process.
3. In case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording should be done.
4. In a particular trial AV recording of informed consent process should be done for all patients.
5. Whole informed consent process which include providing information on essential elements as per Appendix-V of Schedule Y of the Drugs and Cosmetics Rules and understanding and signing of informed consent form by the patients/his or her LAR/witness should be AV recorded.
6. Suitable AV camera should be used to ensure good quality of AV recording so that the image and the sound is recognizable.
7. After AV recording of Informed consent process in a particular subject, the documentation should be made by the investigator or his/her study team member specifying that AV recording has been done and preserved adhering to the principle of confidentiality.A copy of the documentation should be handed over to the patient or his/her attendant.
8. AV recording should be stored properly for at least five years from the termination/completion of the study.

The Committee also recommended that the guidelines should also be finalized as per the above recommendations. On the issue of making videographer as a part of the study team, to ensure privacy and confidentiality of the trial subject, the committee recommended that one of the member of study team of investigator should be involved in such audio video recording.

Meeting ends with vote of thanks to the chair.

Annexure

List of participants:

1. Dr. Jagdish Prasad, DGHS, Ministry of Health & Family Welfare
2. Dr.B.D.Athani, Special DG (MS) Dte.GHS, Ministry of Health & Family Welfare
3. Dr. Sudha Prasad, Prof. & HOD Obstetrics & gynaeocology , Maulana Azad Medical College (MAMC) New Delhi.
4. Dr. K. Satyanarayan, The Chairman, Ethics Committee C/o. Medical Superintendent, RML Hospital, New Delhi.
5. Dr. Rajni Kaul, Scientist 'F', Division of BMS Co-Ordinator, ICMR, New Delhi.
6. Dr. Mira Shiva, Director, Initiative for Health Equity & Society, New Delhi.
7. Dr. Sarojini N.,Sama-Resource Group for Women and Health (Sama) 2nd Floor, B-45, Shivalik Main, Malviya Nagar, New Delhi – 1100017
8. Dr. Amar Jesani, Indian Journal of Medical Ethics, Mumbai
9. Shri S. Srinivasan, LOCOST, Baroda
10. Dr. Santanu Tripathi, Calcutta School of Tropical Medicine, Kolkata.
11. Chirag Trivedi, Organisation of Pharmaceutical Producers of India, Peninsula Chambers, ground floor, Ganpatrao kadam Marg, Lower Parel, Mumbai-400013
12. Ritika Bajaj, Indian Society for Clinical Research, C/o Pfizer centre, 5 Patel Estate, S.V. Road, Jogeshwari (West) Mumbai – 400102.
13. Anirban Roychowdhury, Indian Society for Clinical Research, C/o Pfizer centre, 5 Patel Estate, S.V. Road, Jogeshwari (West) Mumbai – 400102
14. Dr. Ashok Kumar Das, Director-Professor of Medicine & Medical Superintendent, JIPMER, Puduchery
15. Dr. B.L. Sherwal, Director-Professor,Dept. of Microbiology, LHMC &Associted Hospitals, New Delhi.
16. Prof. S. Aneja, Head, dept. of Pediatrics, Lady Harding Medical College.
17. Prof. Rohit Saxena,Dr. R.P.Centre, AIIMS, New Delhi.
18. Dr. Shruti Grover, For Dr. D.C. Doval, Chief of Medical Oncology, Rajiv Gandhi Cancer Centre, New Delhi.
19. Dr. Nandini K. Kumar, Former DDG SG (ICMR), Adjunct Prof. Kasturba College Manipal, Vice President, FERCI.

From CDSCO:

20. Dr. G.N.Singh, DCG(I), CDSCO, New Delhi
21. Dr. V.G. Somani, JDC(I), CDSCO, New Delhi
22. Shri. A.K.Pradhan, DDC(I), CDSCO, New Delhi
23. Shri.R. Chandrashekar, DDC(I), CDSCO, New Delhi
24. Mrs. Annam Visala, DDC(I), CDSCO, New Delhi