MODEL INFORMED CONSENT

Informed consent is "consent given voluntarily by a competent individual who has received the necessary information, has adequately understood the information and after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement or intimidation".

Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research or not and protects the individual's freedom of choice and respect for the individual's autonomy. It also protects the subjects' rights.

Taking informed consent is a "process" and does not merely consist of a signature on the consent form. Informed consent is a communication process between the researcher and the participant and starts before the research is initiated and continues throughout the duration of the study. The investigator or his delegate must discuss all pertinent aspects of the study, answer any queries / doubts, request consent and then if freely given, documented. The ultimate responsibility is the investigator's.

Informed consent includes a verbal description and discussion of the details of the study including the process of randomization, the components of the study, and other details mentioned in the checklist below (from Schedule Y 2005) as well as a written *consent form* containing all relevant information in simple, non-technical language in the participant's vernacular and given to the participant to keep. Adequate time must be provided for the participant to decide on participation.

In case of illiterate participants, a witness is crucial and thumb impressions are allowed. All signatures should be dated and in case a date is forgotten on the day the consent is taken, it must be retaken on the next visit and dated, with a clear explanation documented in the source document. The investigator MUST NOT date the consent at any point in time; this must be done by the witness in the case of illiterate participants.

In the case of minors, proxy consent from a parent/responsible guardian is permitted and only the parent/responsible guardian may sign the informed consent form. However, it is mandatory that the minor provides assent (permission) to participate and, if possible, this should be recorded in a separate assent form. If the participant is incompetent to provide valid informed consent and it is deemed ethically justified to include this person in research, then the proxy consent of a responsible family member/legal guardian and a witness.

Checklist for study Subject's informed consent documents (from Schedule Y)

1.1 Essential Elements to be included in the information sheet:

1. Statement that the study involves research and explanation of the purpose of the research
2. Expected duration of the Subject's participation
3. Description of the procedures to be followed, including all invasive procedures and
4. Description of any reasonably foreseeable risks or discomforts to the Subject
5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.
6. Disclosure of specific appropriate alternative procedures or therapies available to the Subject.
7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records 8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
9. Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury
10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury
11. The anticipated prorated payment, if any, to the Subject for participating in the trial
12. Subject's responsibilities on participation in the trial
13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled
14. Any other pertinent information

1.2 Additional elements, which may be required

a. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the Investigator without the Subject's consent.
b. Additional costs to the Subject that may result from participation in the study.
c. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject. d. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

e. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable.

f. Approximate number of Subjects enrolled in the study.

2. Signature part of informed consent form for Subjects participating in a clinical trial.

Informed Consent form to participate in a clinical trial Study Title: Study Number: Subject's Initials: _____ Subject's Name (*if needed*): _____ Date of Birth / Age:_____

Please initial box (Subject)

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. []

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____ Date: _____/_____/_____ Signatory's Name: _____

Signature of the Investigator: _____ Date: _____/_____/_____

Study Investigator's Name: _____

Signature of the Witness (If needed): _____Date:_____/_____/_____

Name of the Witness (if needed): _____

MODEL CONSENT FORM

TITLE OF THE STUDY: ***A randomized trial comparing adjunctive Modafinil with placebo for clozapine related adverse effects in people with schizophrenia or schizoaffective disorder in remission.***

Study number:

You are being requested to participate in a study to see if a drug called Modafinil can help you with the side effects of increased sleepiness and increased saliva formation caused by Clozapine that has been prescribed to treat you. These are common side effects of Clozapine and many people given Clozapine suffer from these problems. There are other drugs that can help with these but we do not know of any that can help both at the same time. We hope to include about 70 people from this hospital in this study.

What does Modafinil do when taken along with Clozapine?

We have observed that when people who are sleepy in the daytime and sleeping long hours at night on Clozapine are given Modafinil, it keeps them awake and alert during the day. Modafinil has also helped reduce and even stop the increased salivation that had been a problem with Clozapine treatment. Modafinil also reduces appetite and many people lose some or all of the weight they had gained while taking Clozapine. However, we have only used this for a few people taking clozapine and we need to use it for more people to be sure it really helps

Does Modafinil have any side effects?

Modafinil has been used by many people all over the world to help reduce excessive sleep due to a variety of problems, including that caused by medicines. The majority of people have not had any side effects. Some people on Modafinil have experienced some side effects such as headache, feeling anxious, feeling like vomiting, loose motion and stomach discomfort, but these were usually mild and temporary. Modafinil does not cause addiction or any problems when it is stopped suddenly. It may cause mild increases in blood pressure but these are usually not serious. It is not known to cause any problems to the heart. Rarely, it can cause a worsening of the psychiatric problem but this has been observed only at doses higher than what we plan to use in this study.

If you take part what will you have to do?

If you agree to participate in this study, you will be given either one table of Modafinil to be taken every morning, or an identical looking tablet that does not contain Modafinil, for a total period of 9 weeks. Using thus dummy tablet will help us be sure that any improvement in your sleepiness or increased saliva formation is actually due to Modafinil and not due to chance (coincidence) or normal fluctuations in your condition. Neither you nor your doctor will have any choice in whether you will get Modafinil or the dummy tablet as this will be decided by a computer program; this is like tossing a coin and you have an equal chance of getting either tablet. Also, neither you nor your doctor will know which tablet you are taking till the study is over. All other treatments that you are already on will be continued and your regular treatment will not be changed during this study. You will be expected to come for a review to the hospital 2 weeks after starting the tablet and again after 4 more weeks and finally after a further 4 weeks. Before starting the study and at each visit you will be asked questions about your sleep,

saliva formation, activities, how you feel and about any side effects. Your weight and blood pressure will also be recorded at each visit. No additional procedures or blood tests will be conducted routinely for this study.
If at any time you experience any problems, you will be expected to report this to the doctor. You will also be contacted by telephone at least once in between the monthly visits by the doctors in this study who will ask you about any side effects you are experiencing.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way. In addition, if you experience any serious side effects or your condition worsens, the study tablets will be stopped and you may be given additional treatment.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will you have to pay for the study tablets?

Both Modafinil and dummy tablets will be given free for a total period of 9 weeks. We will also reimburse you and one person accompanying you the money that you spent on travel to come for review (please keep your bus or train tickets) for the visits that you make for this study.
Any other treatment that you usually take will continue but the usual arrangements that you have with the hospital will decide how much you pay for this.

What happens after the study is over?

You may or may not benefit from the study drug that you are given. Once the study is over, if the tablet you were given is Modafinil and if it has helped you and you wish to continue, then your doctor may prescribe it for you. If you were given the dummy tablet and Modafinil has helped the people who took it, then your doctor will give you the choice of taking Modafinil. However, this will not be part of the study and you may have to pay for it.

Will your personal details be kept confidential?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.
If you have any further questions, please ask Dr.XXX, Dr. XXX or Dr. XXX (tel: 0471 228XXX/ 228XXX/ 228XX) or email: xxx@sctimst.ac.in

Name of the PI:/Address and Contact Details
Signature of the PI:

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of the SCTIMST-IEC. The phone number is: and the email id is iec.mem.sec@sctimst.ac.in

Participant's name: Date of Birth / Age (in years): I_____ _____, son/daughter of _____ (Please tick boxes) •

Declare that I have read the above information provide to me regarding the study: ***A randomized trial comparing adjunctive Modafinil with placebo for clozapine related adverse effects in people with schizophrenia or schizoaffective disorder in remission*** and have clarified any doubts that I had. [ ]

- I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]
- I also understand that neither I, nor my doctors, will have any choice or knowledge of whether I will get Modafinil or the identical looking dummy tablet [ ]
- I also understand that during the 9 weeks of the study, the Modafinil or dummy tablet will be provided free, but after this, if Modafinil is prescribed, I may have to pay for it [ ]
- I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]
- I understand that my identity will not be revealed in any information released to third parties or published [ ]
- I voluntarily agree to take part in this study [ ]
- I received a copy of this signed consent form [ ]

Name:
Signature:
Date:
Name of witness:
Relation to participant:
Date:
Signature:

(Person Obtaining Consent) I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

_____

Name and Signature of Person Obtaining Consent

(For Principal Investigator)

Witness:

(Note: This format is adapted from Vellore Medical College, IRB-SOP)