

## **Annexure C**

### **CENTRAL UNIVERSITY OF TAMIL NADU, THIRUVARUR PATIENT'S INFORMATION SHEET**

1. Brief aim and methods of the research:
2. Expected duration of the subject participation:
3. The benefits that might reasonably be expected from the outcome of research to the subject or to others:
4. Any risk to the subject associated with the study:
5. Maintenance of confidentiality of records:
6. Provision of free treatment for research related injury:
7. Compensation for disability or death resulting from such injury:
8. Freedom of individual to participate and withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled:

### **Risk/Benefit Assessment**

**Risk:** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in the daily life or during the performance of routine physical or psychological examination or tests.

**Check appropriate risk category:**

1. \_\_\_\_\_ The research involves no more than minimal risk to subject.
2. \_\_\_\_\_ The research involves more than minimal risk to subjects.

➤ The risk(s) represents a minor increase over minimal risk,

OR

➤ The risk(s) represents more than a minor increase over minimal risk.

**Benefit:** A research benefit is considered to be something of a health related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research related inconveniences.

**Check appropriate benefit category(ies):**

1. \_\_\_\_\_ no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participants' disorder or condition.
2. \_\_\_\_\_ no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge to further society's understanding or the disorder or condition under study; or
3. \_\_\_\_\_ the research involves the prospect of direct benefit to individual participants