



INSTITUTE ETHICS COMMITTEE/ETHICS SUB-COMMITTEE
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI 110029
Room No 102, 1st Floor Old O.T. Block,
Tel No 4579 (Internal), 26594579 (Direct)

Ethics Committee
Chairman
 Prof. J.P. Wali, Former Prof
 Medicine, AIIMS

Members
 Prof. Rani Kumar, Dean
 (Academic), & Head,
 Anatomy, (Basic Scientist)

Prof. S. S. Siddhu
 Ex- Head, Dental Surgery,
 AIIMS (Clinician)

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 Principal, DPS School,
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 (Lay Person)

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 DDG, ICMR (Ethicist)

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 Sr. Advocate, Ex. SLC
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 Anaesthesiology (Clinician)

Dr. Rakesh Yadav, Sub-Dean
 (Academic) & Addl. Prof. of
 Cardiology (Clinician)

Member Secretary
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 Head, Hematology, AIIMS

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 Head, Hematology, AIIMS

Member-Secretary
 Dr. Rakesh Yadav
 Sub-Dean (Academic) and
 Additional Professor of
 Cardiology, AIIMS

November 08, 2012

Swetasmita Mishra
 Ph.D
 Deptt. Of Anatomy
 AIIMS, New Delhi

(Ref.No- IESC/T-329/31.08.2012)

Through Guide: Dr. Rima Dada

Sub: - Telomere status and DNA repair mechanisms in idiopathic male infertility

Dear Mrs Mishra,

The above mentioned protocol was discussed and reviewed in the Ethics Sub-Committee meeting held on 02.11.2012 at 3.00 PM in the Ethics Committee Room and subsequently in the Ethics Committee meeting held on 05.11.2012 at 1.45 PM in the Ethics Committee Room, AIIMS. The following comments of the Ethics Committee are brought to your notice.

Ref. No	Title of Study	Name/Department of Investigator	Original Objection	Remarks of Ethics Committee
RT-22/02.11.2012	Telomere status and DNA repair mechanisms in idiopathic male infertility (Ref.No.- IESC/T-329/31.08.2012)	Swetasmita Mishra Ph.D Deptt. Of Anatomy AIIMS, New Delhi Guide Dr. Rima Dada Additional Professor Deptt. Of Anatomy AIIMS, New Delhi	1. Submit through proper channels 2. In inclusion criteria for patients under the methodology section it should be mentioned that men suffering from infertility will be included. 3. Submit dated undertakings. 4. PICF should be for the subjects not for the son/daughter. Submit the corrected versions of Hindi & English PICF. 5. Clarify: a. How you will ensure that controls have normal karyotype. b. How you will plan to analyze the data to achieve the objective. 6. PIS for control should explicitly state that no benefit will accrue to	The protocol has been approved from ethical angle w.e.f. 05.11.12 for all prospective cases.



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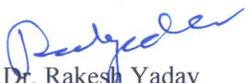
Dr. Manju Vatsa, Principal
College of Nursing, AIIMS

			<p>the participant.</p> <p>7. In PIS describe the setting for masturbation and attendant ill effect, if any?</p> <p>8. Clarify the need of controls and how you will recruit 150 healthy age matched controls.</p> <p>9. Describe the process of Age matching e.g. whether it would be precise or age group matched. Whether the matching would be concurrent or otherwise.</p> <p>10. PIS states one time involvement whereas in method section it says semen will be analyzed thrice at an interval of 3 weeks. Clarify the correct situation. Also it is not clear, if the testing scheduled is applicable only to the patient or also to the controls. Suitable changes may be included in the PIS.</p> <p>11. Describe the process of sample size calculation.</p> <p>12. Submit plan of analysis segment since it is missing.</p>	
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You are required to submit 6 monthly progress report to the Ethics Sub-Committee/ Ethics Committee.

With best regards,

Yours truly,


Dr. Rakesh Yadav
Member-Secretary
Ethics Sub-Committee



Dr. Renu Saxena
Member Secretary
Ethics Committee

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