SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Minutes of the 13th Institutional Committee for Stem Cell Research (IC-SCR) meeting held on 29.11.2023 at 12:00 noon in the guest house committee room. The meeting was in a hybrid mode with the zoom link as below.

https://us02web.zoom.us/j/89342989221?pwd=cloyL3JNRWIWeklsVIJCc2xUNGhOUT09.

It was attended by the following members.

1. Dr. Chandishwar Nath, <i>Retd.</i> Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow	Chairman, Present physically
2. Prof. Pankaj Seth, Professor, National Brain Research centre, Manesar	Member, Present Virtually
3. Justice S.C Verma, Retd. High Court Judge Allahabad	Member, Could not attend
4. Judge Vijai Verma, Former District Judge & Chairman UpbhoktaForum, Lucknow	Member, Present Physically
5. Dr. Shalendra P Verma, Additional Prof. Dept. of Hematology, KGMU	Member, Present Physically
6. Dr. D.R. Sahoo, Professor & Head, Dept. of Sociology University of Lucknow	Member, Present Virtually
7. Prof. A. K. Srivastava, Retd. Prof. Department of Sociology, University of Lucknow	Member, Could not attend
8. Prof. Jonaki Sen, Sciectist, BSBE. IIT (K)	Member, Present Virtually
9. Dr. R. K. Chaturvedi, Seni, Prin. Scientist, Prof CSIR, Devel. Toxicology Lab., CSIR-IITR	Member, Present Physically
10. Dr. Satyendra Singh, Assistant Professor Cell/Stem Cell Lab. KGMU, Lucknow	Member. Present Virtually
11. Mr. V.P Sahi, Retd. Journalist & Advisor to Times of India, Lucknow	Member, Present Virtually
12. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member, Present physically
	aber Secretary, Present physically

A: General discussions and confirmation of Minutes:

The quorum of the meeting was complete with 11 members attending the meeting in the hybrid mode.

Approval of the minutes of the last meeting The Chairman presided over the discussion of the minutes of the 12th IC-SCR meeting held on 25.04.2023. All the members of IC-SCR approved the minutes of the meeting.

B. Review of New Proposals:

Agenda No. 1 IEC code: 2023-4-EMP-13

Type of submission: Project Extramural

Title of project: Restoration of adipogenic-osteogenic differentiation nexus in bone marrow mesenchymal stem

cells of aplastic anemia patients using epigenetic drugs

PI: Dr C P Chaturvedi Department: Clinical Hematology

Primary reviewer (Technical/SAE): Dr. Rajnish Chaturvedi

Primary reviewer (Legal): Judge Vijai Verma Primary reviewer PID and CF: Dr Shalini Mathur

Subject: Project for review

Scientific issues, ethical issues and PID, CF were discussed.

The committee has given the following suggestions to the PI:

1. The clarity about the situations/scenario and the objectives where the human bone marrow samples and/Or the commercial cell lines will be used, is lacking. It should be clarified.

- 2. Please mention or exemplify the drugs that will be used. Which kind of epigenetic pharmaceutical agents or any other alternative modality of epigenetic modification.
- 3. The PID and consent forms have several mistakes. This need to be prepared well in simple language with uniformity between English and Hindi Language
- 4. A copy of Human Ethics approval needs to be submitted.

Decision: Minor Modification.

PI was advised to submit above correction within 4 weeks, failing which the project will not be considered in next IC-SCR meeting for ethical approval.

Clarification was submitted by Dr Gyan Chand Dept. of Endocrine Surgery and clause 2.4 was amended accordingly in the CTA document.

C.Study Final/Annual/Progress reports /Close out Notification:

Agenda No. 1

IC-SCR Code: 2019-07-EMP-09

Type of submission: Project Extramural

Title of project: Role of human umbilical cord mesenchymal stromal cells (hucMSCs) derived exosomes in CNS drug delivery molecules for the modulation of chronic neuroinflammation, pain-related behavior and motor function in young injured brain.

PI: Dr Alok Kumar Department: Molecular Medicine

Subject: Annual Progress report and ICMR Approval.

The committee approved and accepted the progress report.

(Dr. Khaliqur Rahman)

Member Secretary, IC-SCR, SGPGI

(Dr . Chandishwar Nath) Chairman, IC-SCR, SGPGI

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SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Minutes of the 12th Institutional Committee for Stem Cell Research (IC-SCR) meeting held on 25.04.2023 at 02:00 PM. The venue of this meeting is e tumor board room, 2nd floor telemedicine building.

Present:

	1 Oboate	
	1. Dr. Chandishwar Nath, Retd. Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow	Chairman
	2. Prof. Pankaj Seth, Professor, National Brain Research centre, Manesar	Member
,	3. Justice S.C Verma, Retd. High Court Judge Allahabad	Member
4	4. Judge Vijai Verma, Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
	5. Dr. Shalendra P Verma, Additional Prof. Dept. of Hematology, KGMU	Member
(6. Dr. D.R. Sahoo, Professor & Head, Dept. of Sociology University of Lucknow	Member
,	7. Prof. A. K. Srivastava, Retd. Prof. Department of Sociology, University of Lucknow	Member
- 3	8. Prof. Jonaki Sen, Sciectist, BSBE. IIT (K)	Member
9	9. Dr. R. K. Chaturvedi, Seni, Prin. Scientist, Prof CSIR, Devel. Toxicology Lab., CSIR-IITR	Member
	10. Dr. Satyendra Singh, Assistant Professor Cell/Stem Cell Lab. KGMU, Lucknow	Member
ľ	11. Mr. V.P Sahi, Retd. Journalist & Advisor to Times of India, Lucknow	Member
	12. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
	13. Dr. Khaliqur Rahman, Associate Prof., Dept. of Hematology, SGPGIMS, Lucknow.	Member Secretary

A: General discussions and confirmation of Minutes:

The quorum of the meeting was complete with 13 members attending the meeting.

Approval of the minutes of the last meeting The Chairman presided over the discussion of the minutes of the 11th IC-SCR meeting held on 28.03.2022. All the members of IC-SCR approved the minutes of the meeting.

Lt Col Varun Bajpai VSM Executive Registrar

SGPGIMS, Lucknow

B. Review of New Proposals:

Agenda No. 1

IEC code: 2023-3-DT-12

Type of submission: Project Drug Trial

Title of project: A prospective, randomized, assessor-blind, active controlled, multi-center study to demonstrate the safety and efficacy of VELGRAFT, an allogenic cell-based wound dressing, in comparison to standard moist wound dressing in management of chronic diabetic foot ulcers that have attained granulation tissue.

PI: Dr Gyan Chand Department: Endocrine Surgery

Primary reviewer (Technical/SAE): Dr. Rajnish Chaturvedi

Primary reviewer (Legal): Judge Vijai Verma

Primary reviewer PID and CF: Prof. A. K. Srivastava

Subject: Project for review

Scientific issues, ethical issues and PID, CF were discussed.

The committee has given the following suggestions to the Pl:

1. There is an objection pertaining to Cl. 2.4 of the CTA. In case Dr.Gyan Chand retires or is unwilling to continue with the Study then he can't be compelled to continue with the study. Based on this objection and comment, the cl. 2.4 should suitability be amended.

2. The PID is too long. It should be briefed with information pertaining to this particular study only. Try

to minimize it in not more than 3 pages.

3. It was also brought to notice that there were certain suggestions given by the IEC during its meeting related to this project and corrections were needed by the PI. The PI is instructed to kindly submit a copy of the answer submitted to the IEC in this regard along with pertinent modification in the study documents

Decision: Minor Modification.

PI was advised to submit above correction within 4 weeks, failing which the project will not be considered in next IC-SCR meeting for ethical approval.

Clarification was submitted by Dr Gyan Chand Dept. of Endocrine Surgery and clause 2.4 was amended accordingly in the CTA document.

C. Reporting decisions of Member Secretary/3 Member Committee/Expedite Review Committee: Agenda No. 2 IEC code: 2023-01-EMP-EXP-5

Type of submission: Project Extramural

Title of project: "Development of human iPSCs derived 3D lung organoid as a model for Idiopathic pulmonary fibrosis (IPF) disease: A potential preclinical platform for screening of anti-fibrosis drug and novel biomarker discovery"

PI: Dr Vinod Verma

Primary reviewer (Technical/SAE): Dr. Satyendra Singh

Primary reviewer (Legal): Justice S.C Verma Primary reviewer PID and CF: Dr. D.R. Sahoo

Subject: Project for review

Department: Clinical Hematology

Committee has noted and Approved.

Agenda No. 3

Type of submission: Project Extramural

Title of project: Repurposing of α-Lipoic Acid for Breast cancer; Effect on Autophagy and Energy

IEC code: 2023-2-EMP-EXP-5

Metabolism of Breast Cancer Stem Cells

PI: Dr Vinod Verma Department: Clinical Hematology

Primary reviewer (Technical/SAE): Prof. Jonaki Sen Primary reviewer (Legal): Judge Vijai Verma Primary reviewer PID and CF: Prof. A. K. Srivastava

Subject: Project for review

Committee has noted and Approved.

Agenda No. 2 IEC code: 2022-2-EMP-11

Type of submission: Project Extramural

Title of project: Studies on Novel 2 D Nanomateria Mediated Expansion of Stem Cell Derived

Pancreatic β -cell For the Treatment of Diabetes.

PI: Dr Vinod Verma Department: Clinical Hematology

Primary reviewer (Technical/SAE): Dr. Satyendra Singh

Primary reviewer (Legal): Justice S.C Verma Primary reviewer PID and CF: Dr. D.R. Sahoo

Subject: Project for review

Committee has noted and Approved.

Agenda No. 3 IEC code: 2022-3-EMP-11

Type of submission: Project Extramural

Title of project: Probing the dynamic balance of histone H2AUb1 regulatory axis in hypertrophic

cardiomyopathy and early heart development.

PI: Dr Anshika Srivastava

Primary reviewer (Technical/SAE): Prof. Jonaki Sen Primary reviewer (Legal): Judge Vijai Verma

Primary reviewer PID and CF: Prof. A. K. Srivastava

Subject: Project for review

Committee has noted and Approved.

(Dr. Khaliqur Rahman)

Member Secretary, IC-SCR, SGPGI

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Department: Medical Genetics

(Dr . Chandishwar Nath) Chairman, IC-SCR, SGPGI

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

Minutes of the 11th Institutional Committee for Stem Cell Research (IC-SCR) meeting held on 28th March 2022 at 03:00 PM. The venue of this meeting is e tumor board room, 2nd floor telemedicine building.

Present:

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1. Dr. Chandishwar Nath, Retd. Chief Scientist, Division of Toxicology, CSIR-CDRI, Lucknow	Chairman
2. Prof. Pankaj Seth, Professor, National Brain Research centre, Manesar	Member
3. Justice S.C Verma, Retd. High Court Judge Allahabad	Member
4. Judge Vijai Verma, Former District Judge & Chairman Upbhokta Forum, Lucknow	Member
5. Dr. Shalendra P Verma, Additional Prof. Dept. of Hematology, KGMU	Member
6. Dr. D.R. Sahoo, Professor & Head, Dept. of Sociology University of Lucknow	Member
7. Prof. A. K. Srivastava, Retd. Prof. Department of Sociology, University of Lucknow	Member
8. Prof. Jonaki Sen, Sciectist, BSBE. IIT (K)	Member
9. Dr. R. K. Chaturvedi, Seni, Prin. Scientist, Prof CSIR, Devel. Toxicology Lab., CSIR-IITR	Member
10. Dr. Satyendra Singh, Assistant Professor Cell/Stem Cell Lab. KGMU, Lucknow	Member
11. Mr. V.P Sahi, Retd. Journalist & Advisor to Times of India, Lucknow	Member
12. Ms. Shalini Mathur, Secretary, Suraksha NGO, Lucknow	Member
13. Dr. Khaliqur Rahman, Associate Prof., Dept. of Hematology, SGPGIMS, Lucknow.	Member Secretary

A: General discussions and confirmation of Minutes:

The quorum of the meeting was complete with 13 members attending the meeting.

Approval of the minutes of the last meeting The Chairman presided over the discussion of the minutes of the 10th IC-SCR meeting held on 06.11.2020. All the members of IC-SCR approved the minutes of the meeting.

Agenda No. 1 IEC code: 2022-1-IMP-11

Type of submission: Project Intramural

Title of project: Generation of iPSC-derived HLA negative Hematopoietic Stem Cells: A step towards

treatment of Aplastic Anemia

PI: Dr Vinod Verma Department: Clinical Hematology

Primary reviewer (Technical/SAE): Dr. Rajnish Chaturvedi

Primary reviewer (Legal): Judge Vijai Verma

Primary reviewer PID and CF: Prof. A. K. Srivastava

Subject: Project for review

Scientific issues, ethical issues and PID, CF were discussed.

Decision of the committee: APPROVED

The study is approved in its presented form. The approval is valid until one year or duration of the project, whichever is later from the date of sanction. You may make a written request for renewal /extension of the validity, along with the submission of annual status report.

Agenda No. 2 IEC code: 2022-2-EMP-11

Type of submission: Project Extramural

Title of project: Studies on Novel 2 D Nanomateria Mediated Expansion of Stem Cell Derived

Pancreatic β-cell For the Treatment of Diabetes.

PI: Dr Vinod Verma

Department: Clinical Hematology

Primary reviewer (Technical/SAE): Dr. Satyendra Singh

Primary reviewer (Legal): Justice S.C Verma Primary reviewer PID and CF: Dr. D.R. Sahoo

Subject: Project for review

Scientific issues, ethical issues and PID, CF were discussed.

Decision of the committee: APPROVED

The study is approved in its presented form. The approval is valid until one year or duration of the project, whichever is later from the date of sanction. You may make a written request for renewal /extension of the validity, along with the submission of annual status report.

Agenda No. 3

IEC code: 2022-3-EMP-11

Type of submission: Project Extramural

Title of project: Probing the dynamic balance of histone H2AUb1 regulatory axis in hypertrophic

cardiomyopathy and early heart development.

PI: Dr Anshika Srivastava

Department: Medical Genetics

Primary reviewer (Technical/SAE): Prof. Jonaki Sen

Primary reviewer (Legal): Judge Vijai Verma

Primary reviewer PID and CF: Prof. A. K. Srivastava

Subject: Project for review

Scientific issues, ethical issues and PID, CF were discussed.

Decision of the committee: APPROVED

The study is approved in its presented form. The approval is valid until one year or duration of the project, whichever is later from the date of sanction. You may make a written request for renewal /extension of the validity, along with the submission of annual status report.

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(Dr. Khaliqur Rahman) Member Secretary, IC-SCR, SGPGI (Dr . Chandishwar Nath) Chairman, IC-SCR, SGPGI