Intellectual Property Right Policy
(2022)

Kalyan Singh Super Specialty Cancer Institute
C.G. City, Sultanpur Road, Lucknow-226002

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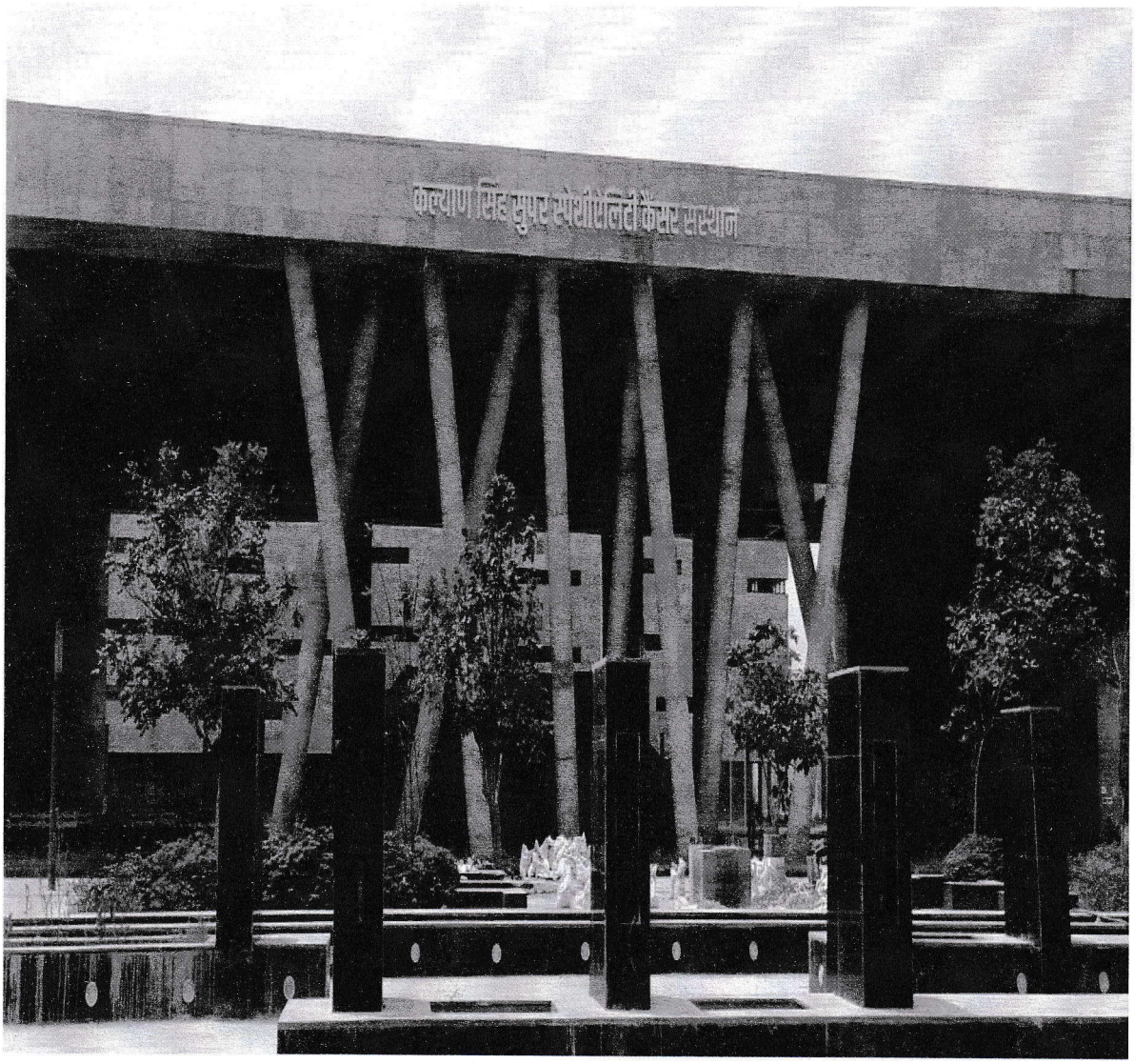
(2022)



Kalyan Singh Super Specialty Cancer Institute
C.G. City, Sultanpur Road, Lucknow-226002

कल्याण सिंह अतिविशिष्ट कैंसर संस्थान
Kalyan Singh Super Specialty Cancer Institute
(An Autonomous Institute of the Govt. of Uttar Pradesh)
C. G. City, Sultanpur Road, Lucknow-226002

Prof. R. K. Dhiman
MD, DM, FAMS, FACG, FRCP Edin.,
FRCP London, FAASLD
Director

FOREWORD

It gives me immense pleasure in releasing the Intellectual Property Right Policy 2022 of Kaylan Singh Super Specialty Cancer Institute. The KSSSCI is an autonomous Institute of the Government of U.P. It is envisioned as a state-of-the-art cancer treatment facility, and is slated to offer a complete range of clinical services for cancer patients, including end-of-life care, under one roof. It will also train doctors in various broad specialties and sub-specialties; and focuses on innovation and research aimed at providing cost-effective and value-based strategies for the diagnosis and management of cancer patients.

The institute is committed to encourage research & facilitate translational research with priority being accorded to in the field of Public health and cost effective treatment for the cancer patients.

As a part of this goal, the KSSSCI, seeks to protect the IPR of its innovators/inventors or researchers to prevent the unscrupulous use of these advances by vested interest. The KSSSCI, IPR policy is prepared on the basis of Indian Patent Act, 1970 and the IPR policy of AIIMS.

The Institute IP cell will help and encourage all KSSSCI faculty, students and researchers in their efforts to identify the innovative competent of their potential research and seek patent protection before publication, to commercially exploit all new knowledge generated with the institute support. The IP cell assisted by Intellectual Property Management Committee will take initiatives to provide technical, legal and other support needed for IP protection, technology transfer, licensing and commercialization issues etc.

For filing, technology transfer and commercialization of the Patents, the IP cell of the institute will facilitate to protect the inventor with its own mechanism following the IPR policy using third-party service provider through Government of India approved mechanisms viz. TIFAC (Technology Information Forecasting and Assessment Council)/CGPDTM (Controller General of Patents Designs and Trademarks).

I hope that the present IPR policy of KSSSCI will preserve the rights of innovators/inventors and researchers involved in innovative concepts. The policy will also motivate the faculty/scientists/researchers of KSSSCI to get Patent/IPR protection and facilitate technology transfer of their invention and help for commercialization of the product of design of patents to the industry for its wide application.

I want to thank to Dr. S. Srivastava and Dr. Sharad Singh for drafting the such a comprehensive IPR policy 2022, KSSSCI, for the use of various stake holders.

Dhiman

Dated: - 21/1/2023
Place: - LUCKNOW

(Prof. Radha Krishan Dhiman)
Director

Tel.: 0522-2982123 ✉ director.sscih@gmail.com

Kalyan Singh Super Specialty Cancer Institute
कल्याण सिंह सुपर स्पेशियलिटी कैंसर संस्थान
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(An Autonomous Institute of the Govt. of Uttar Pradesh)
(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

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डॉ शरद सिंह
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Acknowledgement

This gives us great pleasure and satisfaction that we have been able to draft the Intellectual Right Property (IPR) Policy 2022 of Kalyan Singh Super Specialty Cancer Institute to encourage innovative research and facilitate and protect the IPR of its innovators/inventors or researchers developed by them.

At the outset, I express gratitude and acknowledge the contribution of Prof. Radha Krishan Dhiman, the Director of the Institute for his valuable guidance in framing the IPR policy for this institute and creation for establishment of separate IP cell at this institute.

I gratefully acknowledge the contribution of Dr. S. Srivastava, Ex- Senior Research Officer/Scientist-IV, SGPGIMS, Lucknow for drafting a comprehensive IPR policy and drafting for establishment of a separate IP cell at this institute, which will be definitely helping the innovators/inventors for IP protection of their innovation.

It will be a very great opportunity for the Institute to have a separate Institute Patent Cell (IPC), which will provide technical, legal and other support needed for IP protection, technology transfer, licensing and commercialization issues.

I am also thankful to the Governing Body of the institute for accepting and approving the creation of separate IP cell and approval for the IPR policy KSSSCI 2022, which will definitely be helping the researcher/innovators for IP protection.

I wish to thank the Research Cell for their valuable contributions, without which this great achievement would not have been achieved.

Once again I am very thankful to the Director of KSSSCI for releasing this IPR policy on the occasion of 1st Institutional Research Committee meeting, so that this document will be available to all the stake holders.

I congratulate and wish all the success to the Intellectual Property Management Committee of the KSSSCI on the occasion of release of IPR policy 2022.

Dated: 21/1/2023
Place: Lucknow

(Dr. Sharad Singh)
Faculty In-charge (Research)

1. PREAMBLE

Kalyan Singh Super Specialty Cancer Institute (hereafter referred as 'KSSSCI') was established in 2016 through Society Bye-laws vide no. 3922, rule-7(2), registered by Go UP dated: 08.03.2016 as an Autonomous Institution of GoUP. It is envisioned as a state-of-the-art cancer treatment facility, and is slated to offer a complete range of clinical services for cancer patients, including end-of-life care, under one roof. It will also train doctors in various broad specialties and sub-specialties; and focus on innovation and research aimed at providing cost-effective and value-based strategies for the diagnosis and management of cancer patients.

The Institute is committed for teaching, training, research and patients care in the field of oncology and allied specialties. As per the Aims and Objectives of the Society Bye-laws of KSSSCI, the following three are the major Objectives:

a) The Institute shall create a centre for excellence for providing medical care, educational and research facilities of high order in the field of oncology and such other sub and super specialties, as may emerge in future in the field of oncology including continuing medical education.
b) To develop patterns of teaching in post-graduate medical education in oncology related specialties and super-specialties, so as to set a high standard of medical education.
c) To provide for training in para-medical and allied fields, particularly in relation to oncology.

In keeping with global research and developments activities in the field of oncology and allied specialties, KSSSCI is committed to high standard of research, development of technology and innovation in oncology and allied specialties. In order to encourage such innovations, derived from the research and development activities and subsequent to their translation into patient care & improvement to the quality of life for the patients & benefit of humanity, KSSSCI has to preserve the fundamental spirit of academic research in oncology and its allied specialties and will emerge as a pioneer institution in the country and will significantly contribute to improve the quality of life to the cancer patients and its early detection and reduce the cost of treatment.

Intellectual Property Rights (IPR) is an essential component of an Institution, to preserve the rights of the innovators/inventors involved in innovative concept.

The present policy aims to facilitate Intellectual property protection for a novel product/process/work or to keep it in public domain as is deemed fit. The policy will motivate the Faculty/Scientists and researchers of KSSSCI to get patent/IPR protection and facilitate technology transfer of their invention and help for the commercialization of the product of the design of the patent to the industry for its wide application.

2. OBJECTIVES

As per the following objectives, the documents described the IPR Policy (related administrative procedures) for its uniform implementation at this institute:

a) To enable KSSSCI to discharge its responsibility of stimulating and encouraging creative/innovative activities in the area of Oncology/allied Sciences and Technology in the widest sense possible.

b) To promote academic freedom and safeguard the intellectual property rights of all those, who are involved in the creation/invention of intellectual property at the Institute.
c) To provide an administrative set-up for ownership of the intellectual property created and owned by the institute.

d) To establish a mechanism for technology, transfer and proportionate share of revenue among valid stakeholders.

e) To establish a policy for guarding the interests of its employees in their role as authors/editors for ownership of copyright and royalty etc.

f) To promote fair use of traditional knowledge, while recognizing local traditional knowledge of stakeholders and benefit sharing etc.

g) To provide a suitable platform for the innovators/ inventors for their rights and procedures to be adopted for their application.

h) To safeguard the revenue sharing ratio between the innovators/ inventors & organizations and industry partners.

3. DEFINITIONS

Academic freedom: The freedom of the academic staff of the Institute to conduct their own academic/research activities including clinical care, teaching, training, basic & clinical applied research and its development. They should be free to choose their own research field, pursue self-initiated research and collaborate with others to achieve excellence and maintain high standards of research as per the aims and objective of the Institute.

Activity: Activities related to clinical care, teaching, training, research, consultancy, generation and dissemination of information carried out by a person or an Institution independently or collaboratively.

Associated Agreement: A document created with the mutual consent of involved parties defining the rights, roles and responsibilities of each of the parties, as per the following.

a) Memorandum of Understanding (MoU)
b) Memorandum of Association (MoA)
c) Research/Consultancy Agreement
d) Non-Disclosure Agreement (NDA)
e) Data Protection Agreement
f) Deed of Record, Research Contract
g) Grant Award Letter etc.
h) Conflict of Interest (COI)
i) Clinical Trial Agreement (CTA)

Biotechnology Inventions: Inventions/Innovation include the recombinant products such as vectors, nucleotide sequences, micro-organisms etc.

Collaborator: Collaborator refers to any Government, quasi-government, public enterprise, non-government organizers (NGO) or private entities/pharma industries, which are involved with the KSSSCI and its employees in the conduct of the research. The collaborator may or may not fund or part fund the study. The collaborator may be from national or international organization.

Faculty: Any person professionally qualified to carry out patient care, teaching, training /research and are employed at KSSSCI, as a whole time employee through a proper selection as prescribed in the Society Bye-laws of the Institute.

Intellectual property: Means any right to intangible property, including trade secret, trade mark, patent, design and plant variety as defined under the Copyright Act, 1957, the Patents Act, 1970, the Designs Act, 2000, the Semiconductor Integrated Circuits Layout-Design Act, 2000, and the Protection of Plant Varieties and Farmers' Rights Act, 2001; and their amendment time to time (reference- The Protection and Utilization of Public Funded Intellectual Property Bill).

Inventor(s): A person or a group of persons responsible for creating an intellectual property (IP).

Material Transfer Agreement (MTA): A Material Transfer Agreement is a contract that governs the transfer of tangible research materials between two organizations, when the recipient intends to use it for his or her own research purposes.

For exchange of human biological materials for biomedical research purposes, the Office Memorandum F. No. L.19015/53/97-IH (Pt.) dated: 19th November 1997, issued by Ministry of Health & F.W. Department of Health, Govt. of India, New Delhi and subsequent letter from the ICMR vide No. INDO/FRC/442/04/IHD dated: 31st March, 2004, F.No. INDO/FRC/442/2010-IHD dated: 24th January, 2020, have to be followed.

Non-Disclosure Agreement (NDA)/Confidentiality Agreement (CA): The agreement intends to protect proprietary or confidential information among the parties involved in executing the NDA/CA.

Patentee: Patentee is a person, who has been granted a patent by National/International organization, who is authorized to award.

Project staff: means a person employed temporarily by Investigator on a contract under a research project in a defined capacity as per the funding norms to support/carry out part of the research activity or any other activity at KSSSCI, for a defined period of time.

Revenue: means the amount derived from the technology transfer and commercialization of IP (if commercialized by the inventor or if commercialized by the Institute), net of taxes, expenses (which may be carried forward from year to year to offset gross revenue) incurred in the IP protection, IP fees (if any), maintenance and commercialization and includes, without limitation, proceeds from royalties, profit-sharing, lump sum payments and sale of rights as applicable.

Sponsor: Sponsor will refer to Government, quasi-government, non-government organization (NGO) or private entity, whether national or international, which funds the research/study/survey conducted at or by KSSSCI and its faculty.

Student: A person, who is registered or enrolled as a full-time bonafide student or exchange of student from other intuitions/universities for professional and research training (certified by both the institutions).

Supporting Research Staff: A person, employed by the Principal Investigator for full-time or part-time in a research project under defined capacity to support/carry out part of the research activity or other ancillary activities.

Traditional knowledge: The knowledge developed by the indigenous or local communities for the use of a natural resource with respect to traditional practice, food, medicine etc. over a period of time and has been passed from one generation to another traditionally.

Visitor: A person either from India or abroad visiting under a collaborative activity or associated work at KSSSCI, provided the collaborative study and the visitor has been approved by the competent authorities of the collaborative institutions.

Work Commissioned/Outsourced: work commissioned by KSSSCI to a consultant/author or group of consultants/authors either employed by KSSSCI or invited from outside KSSSCI with or without any consideration in cash or kind. Typical examples of KSSSCI commissioned works may be as are:

a. Design/Surgical Devices
b. Medical/Engineering/Bio Medical Engineering/Architectural Models
c. Computer Software
d. Reports based on surveys and analysis
e. Recombinant Projects (vectors, nucleotides sequences, micro–organisms, Recombinant DNA/RNA)
f. Video works.

Work for hire: the work (or a product) originated from KSSSCI and its meant for the specific purpose of KSSSCI and produced by -

a. An author/ a consultant during his/her employment at KSSSCI.
b. non-employee under contracted work by KSSSCI.

4. GENERAL PRINCIPLES

a. Researchers and Faculty should maintain a laboratory notebook/register/logbook while performing research that has the potential to be commercialized and should ensure that it is regularly signed and dated by a senior colleague, wherever applicable. This may be required to be produced as evidence in a court of law in case of any dispute arises.

b. Activities carried out jointly with other departments, institutions or agencies or under a sponsorship by an agency, should be initiated after the governing terms are agreed upon mutually and approved by the competent authorities as deemed fit.

c. IPRs which are barred / exempted under the governing laws of India shall not be taken / permitted for protection by the Institute. Inventors are requested to refer to the IP statutes and other related rules for further confirmation.

5. ADMINISTRATIVE MECHANISM

KSSSCI shall establish an **Institute Patent Cell,** which will be assisted by, through an Intellectual Property Management Committee **(IPMC),** duly constituted by the institute as per the provisions laid down by the Governing Body of the institute to facilitate the IPR Policy.

5.1 Institute Patent Cell (IPC): The IP Cell will take initiatives for the commercialization under the terms and conditions of the IPR policy and under the guidance of IPMC.

5.2 Intellectual Property Management Committee (IPMC)

Intellectual Property Management Committee (IPMC) will be the core administrative body, which will be responsible for evolving detailed procedures to facilitate implementation of the IPR policy of KSSSCI and carry out related responsibility on behalf of KSSSCI. This committee will have the following members:

S.N.	Designations	Positions	
1.	Chairperson	Dean, KSSSCI	Ex-officio
2.	Vice Chair person	Faculty In-charge (Research), KSSSCI	Ex-officio
3.	Member	Coordinator (Patent cell) KSSSCI	Ex-officio
4.	*Members (03 Nos.)	To be nominated by the Director, KSSSCI	
5.	Member	Representative from Finance & Accounts, KSSSCI	Ex-Officio
6.	Member	One Senior person from Administration, KSSSCI	Ex-officio
7.	Member Secretary	An employee of the institute to be nominated by the Director, KSSSCI (Preferably from Research Cell)	

***Members of the committee:** Would be appointed from amongst the active researchers/scientist in different areas to give a wide perspective and logical inputs to accelerate IPR related activities at KSSSCI in different areas. **One member should have legal background**.

5.3. Function of Intellectual Property Management Committee (IPMC)

Intellectual Property Management Committee (IPMC) of the institute will be the core administrative body, which will be responsible for evolving detailed procedures to facilitate implementation of the IPR policy of KSSSCI. The role of IPMC would be as follows:

a) To create and finalize guidelines & procedures for implementation of the IPR policy at KSSSCI;

b) To create and finalize draft agreements to facilitate IP protection by KSSSCI. The Chairperson of the IPMC will be authorized signatory on behalf of KSSSCI, to sign all agreements/power of attorney/MOU and all documents related to IPR after due approval from the competent authority of the institute;

c) To facilitate filling of IPs by both the Institute appointed bodies as well as by individual Faculty/Staff using their projects and other funding; and formulate programs for educating Faculty/Scientists/Students/Supporting staff/Project staff/Visitors about IPR and other associated issues;

d) To decide on funding of any IPR application from Faculty/Scientists/Students/Project staff/ Supporting staff/Visitors of KSSSCI;

e) To redress any conflict, grievances regarding ownership of IP, processing of IP proposals, procedures adopted for implementation of IPR policy and interpretation of various clauses of IPR policy.

f) To deal with any relevant issues arising out of promotion as well as implementation of IPR policy.

g) Any other task assigned by the appropriate authority (Director & Governing body of the Institute) from time to time.

h) The Institute will formulize a SOP separately, as per the criteria mentioned in the Appendix – I for the faculty regarding the number of hours to be allotted for clinical care, teaching, training and research at this Institute.

i) The IPMC Committee will draft an SOP, which will be having all the above components/formats and modify it time to time as per the standard norms prescribed for the IPR.

5.4. Powers to Amend IPR Policy

KSSSCI, on the recommendation of IPMC, through its Governing Body (GB), will have the full powers to make changes to the IPR policy of the institute or bring out a new policy as an when, it will be required and also to keep its IPR policy updated in line with the National IPR policy. The changes or the new policy shall be applicable to all Faculty/Students/Project staff/Supporting staff/Visitors.

6. SCOPE OF ASSERTION OF RIGHTS

a. For purposes of this Policy, the governance terms will apply to all Intellectual Property (IP), potential IP and other technology or knowhow having commercial application.

b. It is advisable to disclose an invention directly to the Coordinator, Institute Patent Cell (IPC) and seek assistance before the details of the invention are included in any grant application or published or disclosed to an industrial party.

c. Any waiver of the Institute's rights shall only be effective in writing, signed by the Coordinator of the Institute Patent Cell (IPC) and duly approved by the Director, KSSSCI before its implementation.

d. Except as otherwise specified below in the policy, IP created by its employees in the course of their employment or study at KSSSCI, commissioned by KSSSCI or produced under the terms

of a research grant or contract between KSSSCI and an external third party shall solely belong to KSSSCI.

7. OWNERSHIP OF IPR

There could be a number of scenarios, when an IP is created. The policy will apply to them as categorized bellows:

A. CONDITION-1:

IP GENERATION BY INVENTORS AT KSSSCI WITH OR WITHOUT KSSSCI FUNDING AND IN THE ABSENCE OF ANY OTHER EXTERNAL SPONSOR

a. Faculty/Scientists/Students/Project Staff /Supporting Staff /Visitors of KSSSCI can be a part of the invention and IP creation depending on their contribution.

b. Where there is more than one inventor from KSSSCI, the Principal inventor (investigator)/corresponding inventor/author (co-investigator) must be a permanent staff of KSSSCI.

c. All Intellectual Property (IP) rights with respect to research carried out by Faculty/Scientists/Students/Project Staff/Supporting Staff /Visitors of KSSSCI with or without intramural support, shall vest in and will be the absolute property of the KSSSCI.

d. KSSSCI can protect and/or commercialize such IP with its own mechanism or using a third party service provider through Govt. of India approved mechanisms viz., TIFAC (Dept. of Science and Technology, New Delhi)/Controller General of Patents, Designs & Trade Marks (CGPDTM, Govt. of India)

e. Inventors of KSSSCI can also undertake protection and maintenance of IP in the name of KSSSCI after the approval of IPMC and subsequently by the competent authority of the Institute with their own resources for fast track filing in order to get priority. However, for all other official purposes, it would be considered as patent owned by KSSSCI.

f. Steps for commercialization, can also be initiated and effected by the KSSSCI inventors, if IPMC does not agree/does not support financially for technology transfer or if there is an urgency for any such technology transfer.
In the event of successful commercialization, the inventors shall share the Revenue as provided for hereunder the **Section 10** with KSSSCI. The expenses towards the protection/maintenance of the

IP and technology transfer shall be reimbursed by KSSSCI at the rate it would have protected and maintained the IP with its own mechanism or using a third party service provider through Govt. of India approved mechanisms.

g. In case of an unfavorable IPMC decision not to protect or maintain the IP, the inventors would have the liberty to treat the IP the way they mutually agree upon without any interference from KSSSCI. The KSSSCI will convey such decision to the inventor in writing.

B. CONDITION-2:

IP GENERATION BY INVENTORS AT KSSSCI WITH EXTERNAL SPONSOR

a. Where IP arises out of research funded by an external Sponsor viz., Government agency or other agency/Institution/Private company or Pharma industry but the work/research is conducted at KSSSCI, the IPR of inventions arising out of such research projects in the absence a written arrangement shall be owned by KSSSCI. KSSSCI will meet the entire cost of filing and protection of IPR in the same manner as provided under **Section 7A** and Revenue sharing as provided under **Section 10**.

b. If, however, there is a written Associated Agreement between the inventor, KSSSCI and the sponsor (Tripartite Agreement on duly Non-judicial stamp paper of Rs. 100) dealing with matters of ownership of Intellectual Property or between KSSSCI and the sponsor, ownership will be determined by the express terms of such Associated Agreement and if the Associated Agreement is silent in this regard then it will be decided by the conditions under which funding of the research work is being granted.

C. CONDITION-3:

IP GENERATION UNDER COLLABORATIVE RESEARCH

a. All intellectual property jointly created, authored, discovered or invented during the course of collaborative research undertaken jointly by Institute with Collaborating entities (Collaborator), shall be jointly owned (proportion would be mutually decided between KSSSCI and respective collaborator based on the quantum of intellectual input). The cost sharing for IPR protection and maintenance, shall be as per the terms & conditions mentioned in the collaborative research agreement executed by the parties before initiating the work & duly approved by the competent authorities of both the collaborative originations.

b. In case the Collaborating Institutions are not forthcoming to bear fully the cost of filing and maintenance, if considered expedient by the Institute, the Institute will share the cost equitably with the Collaborating Institutions. Where the Collaborating Institutions are not forthcoming for filing joint IPR application, the Institute at its discretion may file the application with absolute ownership and Institute will meet the entire cost of filing and protection of IPR in the same manner as provided under **Section 7 A** and Revenue sharing as provided under **Section 10**.

D. CONDITION-4:

IP GENERATION UNDER RESEARCH PROJECTS THAT FORM A PART OF THE DEGREE PROGRAMMES AT ALL LEVELS

a. Research projects that form a part of the degree programs at postgraduate level viz., MD/MS,DM/M.ch & Ph.D. or any other recognized degree course of the institute, are usually initiated and proposed by members of teaching Faculty and will often be connected in some way to the concerned specialties on-going research interests. In such cases, Students work on a specific project or join a team to investigate one particular aspect of a much larger research programs, thereby drawing on the considerable expertise, reputation and infrastructure of the supervising Guide and substantial use of KSSSCI resources. The IP thus created is part of the whole IP portfolio developed by the research team and is considered to be based on advice of and/or otherwise based on confidential, proprietary or valuable information that already belongs to the Research Guide (Supervisor) or his/her team. KSSSCI seeks to avoid a position, where a small gap in its IP portfolio precludes successful commercialization.

b. The student shall be the co-inventor of the IP, if they have contributed significantly to the development of the research project and have worked for a significant period of time on the project from which the IP is created. The ownership of the IP (except copyright as provided under the **Section 10**) shall lie with KSSSCI and will be managed in the same manner as provided under **Section 7 A** and Revenue sharing as provided under **Section 10**.

c. The ownership rights of KSSSCI will be subject to the terms & conditions of organizations which have awarded fellowships or scholarships to the students and KSSSCI shall enter into necessary Associated Agreement in this regard.

d. The Research Guide/Supervisor, shall ensure that Students has completed the work and signed a confidentiality and intellectual property agreement before commencing work on the project.

e. This policy covers only to the bonafide students enrolled with the institute, while working at KSSSCI and after they leave.

f. The project staff, which is employed in a research project other than those enrolled for a Ph.D ,DM/M.ch, MD/MS or any other recognized degree course at KSSSCI will not have any IP right as they would be working on contract basis without any innovative contribution for IP creation.

E. CONDITION-5:

IP GENERATION AT THE TIME OF SUPERANNUATION/LEAVING THE INSTITUTE

a. Any Faculty/Scientist/Researcher employed by the institute, if approaching superannuation, he/she will not be allowed to submit the IPR application within 03 years from the date of superannuation.

b. Any Principal Investigator approaching superannuation should not submit IPR application, if the remaining service period of the Principal Investigator is shorter than the duration of the project.

F. CONDITION-6:

To investigate the matter of violation/infringement of any intellectual property rights related to KSSSCI, the matter will be referred before the IPMC and the committee will submit its recommendation to the Director for the resolution of such violation/infringement.

8. TECHNOLOGY TRANSFER

a. Whether the invention or technology or know-how developed by Faculty at KSSSCI has been formally protected by patent(s) or not, KSSSCI, shall have the right to monetize or commercialize them through transfer of technology.

b. Whether the invention or technology or know-how has been formally protected by patent(s) or not, the IPR cell and IPMC of KSSSCI or the KSSSCI inventors/Faculty can jointly or severally identify potential licensee(s) or transferee(s) for the same subject to the Revenue sharing mechanism as provided under **Section 10**.

c. In case of presence of an Industrial Partner, which has sponsored the activity, the industry will have the first right to commercially utilize the technology know-how emanating from the collaboration activity only, if it has been pre-specified in the agreement between KSSSCI and industry partner before hand.

d. The licensing/sub-licensing for commercialization would be on the terms and conditions through tripartite agreement on duly non -judicial stamp paper of Rs. 100, duly executed by the Parties (Inventors, KSSSCI and the Industrial Partner) which may involve technology transfer fee and/or royalty payment or any other form of benefit sharing.

e. In the event of the above Industry not undertaking the commercialization process within a period of two years from the first date of license or transfer of the technology, KSSSCI reserves the right to transfer the said know-how to a Third Party for its commercialization and its use.

f. In the presence of any non-commercial collaborating research organizations which has contributed to the development of technology know-how, then KSSSCI shall have the sole right on the Revenue from such commercialization unless agreed otherwise before the commencement of the project as provided for under **Section 10**.

9. RESPONSIBILITY OF THE INVENTOR AND THE IPC

a. While the process of obtaining IPR, protection is ongoing, sending abstracts, research articles to public domain, presenting work in public interfaces like conferences, symposiums, seminars, workshops & newspapers are strictly prohibited. However, after filing IPR either in provisional or in full, innovators would be able to bring their innovation to public domain, subject to the approval from the competent authority of the Institute.

b. Inventors and the IP Cell shall enter into Non-Disclosure Agreement (NDA)/ Confidentiality Agreement before sharing proprietary or confidential information with any third party apart from inventors.

c. Inventors and the IP Cell shall enter into Material transfer agreement with any third party apart from inventors to govern the transfer of tangible research materials. MTAs should define the rights, obligations and restrictions for both the provider and recipient with respect to the materials and any derivatives and any confidential information exchanged with the material, publication of recipient research results, permitted use of the material and other associated legal issues that the provider and recipient may wish to specify in the transaction.

d. Inventors should make Data protection agreement as part of Collaborative research agreement to primarily deal with the obligations to protect "Sensitive Personal Data or Information" (SPDI) and compensation for negligence in implementing and maintaining reasonable security practices and procedures in relation to SPDI.

e. Inventors and or the IP Cell shall allow third party use of the technology, know-how or IP only after due execution of Tech-Transfer or License Agreement respectively duly approved by the competent authority of the Institute.

f. Innovations and practices associated with use and application of traditional knowledge and biological resources, shall abide by the provisions of the Biological Diversity Act, 2002.

10. REVENUE SHARING

The revenue arising out of licensing of IPR/Technology/Know-how/royalty/or any other form of benefit sharing in favor of KSSSCI would be allocated in the ratio as given below.

- Institute Share - 30%
- Inventor's share - 70%

For the above purpose, Revenue is defined as all financial benefits in connection with a single project or venture in excess of the direct commercialization costs incurred, including but not limited to costs of securing legal protection and third party intellectual property rights, the enforcement and commercial exploitation of the IP. Such costs will be reclaimed prior to any distribution taking place. In the event that two or more pieces of IP are combined in a single project or venture, then an agreement defining the distribution of Cumulative Net Financial Benefit to the contributing parties must be concluded before the start of the commercialization process. Where more than one inventor contributes to the creation of IP, the inventor share of the Revenue will be divided in the ratio of 50% to the principal inventor/investigator and the remaining 50% among other inventors/investigators, unless there is a signed written agreement to the contrary. In case there is any co-principal investigator/inventor, the share will be 40% to the principal inventor corresponding to the IPMC, 30% to the co-principal investigator/inventor and the remaining 30% for other co-investigators.

11. COPYRIGHT ON SCHOLARLY MATERIALS

a. As a tradition to encourage literary inputs of researchers of KSSSCI, their Scholarly Materials will be exempted from the assertion of rights of KSSSCI ownership including the contributions towards books, book chapters, articles, conference papers and presentations, theses and dissertation works, electronic media creations etc. except such work, which is Commissioned/Outsourced or it is a work for hire.

b. Copyright would be exempted from revenue sharing and 100% of the royalty will be for the author(s) or originator(s) of the scholarly material(s). However, the royalty received towards such activities must be reported to the IP Cell of the institute for information and Finance & Accounts Department for tax calculation if applicable. In the event of joint authorship, the revenue sharing must be decided among the authors before the start of the work, even if the co-author is a student/project staff.

c. KSSSCI shall retain a free, non-exclusive, perpetual, irrevocable license to use, copy and modify such works for teaching, training & research purposes and will respect the moral rights of originator in such material, where asserted. The originator of Scholarly Materials will ensure that where they have been produced in collaboration with non KSSSCI entities, the collaborators will also grant license to KSSSCI in the same way.

12. APPOINTING THIRD PARTY AS SERVICE PROVIDER FOR IPR AND TECHNOLOGY MANAGEMENT

Any third party which would be engaged as a third party service provider for IPR and technology transfer management will not be assigned any IPR but will be governed by specific terms of license fees structure and Specific Power of Attorney.

13. IPR PROTECTION FOR COUNTRIES OTHER THAN INDIA

a. The decision to file **Patent Cooperation Treaty (PCT)** and filing patent in other countries would be reviewed and decided by the IPMC from time to time based on the scope of invention.

b. If the IPMC decide that the invention has a merit for international patent, then the cost may be borne by the institute.

c. Inventors of KSSSCI can also undertake protection and maintenance of IP in the name of KSSSCI after the approval of IPMC with their own resources for fast track filing in order to get priority. However, for all other official purposes, it would be considered as patent owned by KSSSCI. The expenses towards the protection/maintenance of the IP shall be reimbursed by KSSSCI at the rate it would have protected and maintained the IP with its own mechanism or using a third party service provider through the Govt. of India approved mechanisms.

d. In case of an unfavorable IPC decision not to file or protect or maintain the IP in any country; the inventors have the liberty to treat the IP the way they mutually agree upon without any interference from KSSSCI.

14. INFRINGEMENTS, DAMAGES, LIABILITY AND INDEMNITY

a. As a matter of policy, KSSSCI shall, in any contract between the licensee and KSSSCI, seek indemnity from any legal proceedings including but not limited to validation issues, manufacturing defects, production problems, design guarantee and up-gradation obligation etc.

b. KSSSCI shall also ensure that KSSSCI personnel have an indemnity cover built into the agreements with licensee(s) while transferring technology, know-how or IP.

c. KSSSCI shall retain the right to engage in or desist from becoming a party in any litigation concerning IP and license infringements.

15. CONFLICT OF INTEREST

The inventor(s) are required to disclose any conflict of interest or potential conflict of interest. If the inventor(s) and/or their immediate family have a stake in a licensee-company, then they are required to disclose the stake they and /or their immediate family have in the company and license or an assignment of rights for a patent to the licensee/company in such circumstances, shall be subject to the approval of the IP Cell with the proper scrutiny by the IPMC.

16. DISPUTE RESOLUTION

a. In case of any disputes between IPC and the Inventor(s) of KSSSCI, regarding the implementation of the IPR policy and Technology management which shall include the apportionment of the cost and the expenses payable by each of them, the inventor(s) may appeal to the Director of KSSSCI. The Director's decision in this regard would be final and binding on both.

b. Disputes arising from Collaborative research or from externally sponsored research out of or relation to the construction, meaning, scope, operation or effect of IP ownership and exploitation shall be governed by the terms and conditions as described in the Associated Agreement between the parties.

c. Provided, in the absence of any written Associated Agreement between the parties and if the parties there to agree, Director, KSSSCI shall refer the dispute to an independent expert who shall conciliate and pass an award that shall be final and binding on all the relevant parties.

d. Any disputes arising out of this policy between parties, sections, Individuals, Institutions etc. will be settled through to mutual discussions and consensus, failing which the disputed issues will be settled as per the Arbitration and Conciliation Act, 1996. The Director KSSSCI, shall appoint the arbitrator and the seat of conciliation shall be Lucknow and the proceedings shall be conducted in English Language.

e. It is important for researchers to enter into any such associated agreement should strive to incorporate the above stated Dispute Resolution Mechanism, therein unless the sponsor is governed by any other prescribed mode of Alternative Dispute Resolution Mechanism provided it should be within the prescribed mechanism as per the appropriate laws in India.

17. JURISDICTION

As a policy, all agreements to be signed by KSSSCI, will have the jurisdiction of the Courts in Lucknow and shall be governed by appropriate laws in India.

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APPENDIX-I

PREAMBLE:

To achieve excellence in providing medical care, educational and research in the field of Oncology and its other sub specialties, there has to be a definite number of hours (% time) allocated to three components viz., clinical care, teaching & training, research at this Institute for each faculty member.

Global practice:
The global practice in various reputed academic Institutions, is to hire according to different tracks where different faculty members spend different % of time in these activities. This is made explicit at the time of hiring. The broad guidelines are as follows.

SR. No.	TRACK	CLINICAL CARE AND CLINICAL TEACHING %	TEACHING & TRANING %	RESEARCH % EXTRAMURAL/COLABORATIVE
1	CLINICAL TRACK	90	10	-
2	CLINICAL- EDUCATOR TRACK	20	70	10
3	CLINICAL- SCIENTIST TRACK	20	10	70
4	INVESTIGATOR TRACK	-	10-20	80-90

Proposal for KSSSCI
Since the KSSSCI, is under the preview of National Medical Commission (NMC) of India, in terms of qualifications and experience of teachers in medical Institutions of this country, hence, the above global practices may be difficult to implement at the time of hiring. The following criteria may be adopted for percentage of work distribution of the faculty between clinical care, teaching& training and research.

SR. NO.	TRACK	CLINICAL SERVICES/PATIENT CARE %	TEACHING AND TRANING %	RESEARCH ACTIVITIES %
1	CLINICAL TRACK (MD)	70	15	15
2	CLINICAL RESEARCH TRACK (MD PhD)	40	20	40
3	BASIC RESEARCH TRACK (PhD)	-	10	90

APPENDIX-II

F.No.L.19015/53/97-IH(Pt.) GOVERNMENT OF INDIA

Ministry of Health &F.W.

Department of Health

Nirman Bhawan

New Delhi, the 19th November, 1997

OFFICE MEMORANDUM

Subject: **Guidelines for Exchange of Human Biological Material for Biomedical Research Purposes.**

1. The Ministry of Health & F.W. issued an office Memorandum No.L.20025/90-90-F. dated 27th Feb., 1992 which permitted the restricted transfer of biological material abroad under certain circumstances for research/diagnostic purposes. The O.M. also indicated that the Director-General. ICMR would be the nodal point to clear all such proposals.

2. The need for revised/expanded guidelines has been felt over the past two years. Accordingly, the Ministry of Health & F.W. have taken necessary steps in this regard.

3. The revised guidelines in respect of HUMAN BIOLOGICAL MATERIAL, in supersession of this Ministry's Office Memorandum No.L.20025/90/90-F, dated 27th Feb., 1992 are prescribed as under:

I. DEFINITION

Human Material with potential for use in biomedical research' :

Organs and parts of organs; Cells and tissue; Sub-cellular structures and cell products: Blood; Gametes (sperm and Ova); Embryos and Fetal Tissue; Wastes (urine, fasces, sweat, hair, epithelial scales, nail clippings, placenta etc.); Cell lines from human tissues;

The sources of these materials could be from patients following diagnostic or therapeutic procedures, autopsy specimens, donations of organs or tissue from living or dead persons, fetal tissue, body wastes or abandoned tissue. Human material could also be held in tissue banks and used for research.

II. TRANSFER

i. Guidelines for considering requests for transfer of biological material abroad for research/diagnostic purposes and requests for transfer of biological material from abroad to Indian Institutions for research purposes:

ii. Exchange of material for diagnostic or therapeutic purposes for individual cases may be done without restriction, if this exchange is considered necessary by the doctor(s) in charge of the patient. No permission needs to be sought from any authority for this purpose

iii. Exchange of material from and to recognized laboratories such as WHO Collaborating Centers or WHO Centers may be allowed as part of their routine activities relating to quality control, quality assurance, comparison with reference material etc., without having to seek permission from any authority.

iv. Where exchange of material is envisaged as part of a collaborative research project, the project proposal as a whole must be routed through the appropriate authorities (details under III below) for evaluation and clearance. The exchange of human

materials should be an integral part of a collaborative project, which should have been approved by the Institutional Review and Ethics committees, and not be a separate activity.

i. The availability of facilities within India for carrying out certain investigation need not prevent collaboration with scientists in other countries for the same investigations, including transfer of human material, if required.

ii. On the issue of technology transfer/training of Indian scientists abroad/training of foreign scientists and students in India, and visits by the foreign collaborators to their Indian partner's laboratories to work with Indian material, there should be no restrictions on the visits of scientists to the laboratories concerned. However, any field work to be undertaken in the community and other sensitive issues would have to be regulated according to the rules of the Government.

iii. In order to protect the rights of the Indian study subjects as well as Indian scientists/organizations, Memoranda of Understanding and/or Agreements on Material Transfer should be entered into between the collaborating partners (Indian and Foreign). These should, according to the requirements of case under consideration, include items pertaining to identification of the collaborating or sending/receiving parties, background, the material to be transferred and its quantities, purpose of transfer, the research to be carried out using the material, confidentiality, intellectual property rights, filling of patents, arrangements for future commercial exploitation, reporting, publication rights, indemnification, termination of agreement, assignation or transfer of agreement/rights; safety norms to be observed, shipping arrangements. Qualified user information, and any other matter that may be relevant to the particular exchange of material.

III. MECHANISM

i. Mechanism for processing requests for transfer of biological material abroad for research / diagnostic purposes.

ii. Agencies and Departments such as ICMR, CSIR, ICAR, DBT, and DST could make use of these guidelines and take decisions accordingly on the requests from their respective institutions.

iii. The Directorate-General of Health Services/Ministry of Health & F.W. could utilize the guidelines and take decisions on the requests from the DGHS/Health & F.W Ministry administered institutions, as also on referrals, if any, from any other government/agency/department not covered under (i) above.

iv. Autonomous Institutions and Institutions of National Stature such as PGIMER, Chandigarh; AIIMS, New Delhi; Shree Chitra Tirunal Institute of Medical Sciences & Technology, Thiruvananthapuram; and Sanjay Gandhi Post-Graduate Institute of Medical Sciences, Lucknow, and similar institutions of national stature, could be empowered to take decisions on their in-house proposals for foreign collaboration, by following the guidelines.

v. Private institutions engaging in collaboration directly with foreign institutions should send their requests to ICMR. If, however, they are also collaborating with an Indian institution as part of the collaborative programs with a foreign institution (for example, between a private institution and CSIR lab. Collaborating with a foreign institution)., then the appropriate central agency (CSIR in the example cited) may decide on the request according to all relevant guidelines.

vi. Biomedical research project proposals for foreign collaboration from Medical Colleges, Universities and Institutions under the UGC may be routed through ICMR.

vii. State health authorities may take the decision in respect of institutions under their administrative control.

viii. All foreign collaborative Projects in biomedical research (after scrutiny and decision by the respective agencies/Departments as described above from (i) to (vi) are to be placed before the Health Ministry Screening Committee (HMSC) for final endorsement. This would mean that all institutions, agencies and

departments would have to send their proposals to the ICMR for obtaining such endorsement by the HMSC, as ICMR is the Secretariat for the HMSC at present.

ix. It is essential for information to be available in a central location. This could be the secretariat of the HMSC, i.e. the ICMR Headquarters.

IV. EXCHANGE OF BIOLOGICAL MATERIAL FOR COMMERCIAL PURPOSES

Guidelines for Exchange of Biological material for commercial purposes:

The ICMR has been advised to set up a Committee consisting of experts from relevant fields for deciding each proposal on a case-by-case basis and to furnish their views to the Government for consideration. The Committee, in addition to biological material, will also consider proposals involving transfer of medicinal plants and biological molecules developed in the laboratories, after seeking inputs from the relevant experts, if such transfer is for commercial purposes and a proposal in this regard is received from the Foreign Investment Promotion Board (FIPB). A minimum of three months' time would be required to process the FIPB proposals.

Sd/-

(Ashok Mehta)
Under Secretary to the
Govt. of India

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री
एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएएस, एफएएससी, एफ.एन.ए., डी.एस.सी.
सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक, आई सी एम आर

Prof. (Dr.) Balram Bhargava, Padma Shri
MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNASc, FASc, FNA, DSc
Secretary to the Government of India
Department of Health Research
Ministry of Health & Family Welfare &
Director-General, ICMR

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare
Government of India
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029

F.No.INDO/FRC/442/2010-IHD
Dated: 24th January, 2020

Dear All,

I wish to bring an important issue related to international collaborative research projects undertaken by scientists to your notice.

All applications for research projects involving foreign assistance and/or collaboration in biomedical/ health research are necessarily required to be submitted by the Indian Investigators to Indian Council of Medical Research (ICMR), Hqrs. through HMSC portal for approval of Government of India through Health Ministry's Screening Committee (HMSC). It is a High Level Committee constituted by the GoI to screen & consider such proposals relating to the health research and are sought to be carried out with the foreign assistance and / or collaboration.

There are certain other regulatory requirements as listed out on ICMR website under "Guidelines for International Collaboration/ Research Projects in Health Research; MoU & HMSC Procedure" which are to be followed by the Indian Researchers as a part of documents to be submitted along with their project for HMSC's consideration such as Institutional Ethics Committee (IEC) clearance(s) from all centres/study sites involved in the study; approval of Drugs Controller General of India (DCGI); registration with Clinical Trial Registry of India (CTRI), wherever required.

Additional FCRA clearance is must for all Private Institutes/ NGOs/ Agencies receiving foreign funds. These should be empanelled with NITI Ayog and they should submit certain other documents also.

Any transfer of biological material has to be an integral part of a collaborative research project and a duly filled in Material Transfer Agreement (MTA) needs to be submitted. The guidelines of the Ministry of Health & Family Welfare for exchange of human biological material F.No.L.19015/53/97-1H (Pt.) dated 19/11/1997 are to be followed (available on ICMR wet site).

For projects involving foreign assistance/ collaboration, all Directors/ HODs/ Scientists must ensure that PIs should obtain HMSC approval, before initiation of the study. Otherwise, it will be taken as a serious lapse on their part.

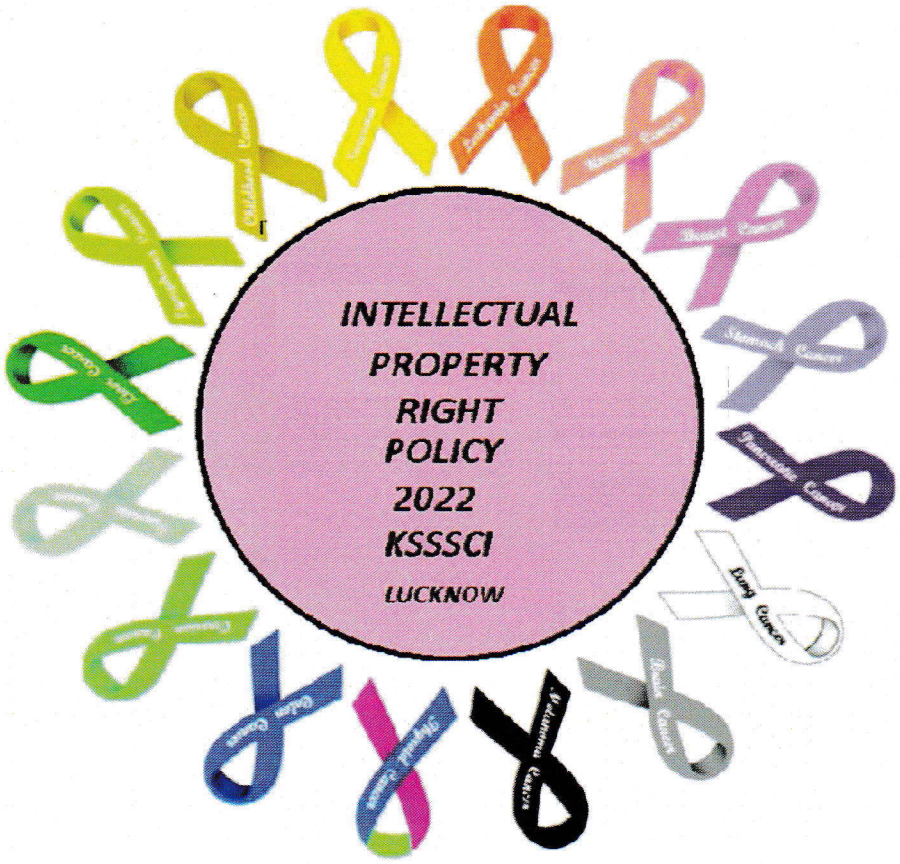
Best regards,

Yours sincerely,

Balram Bhargava

(Balram Bhargava)

To
All Directors of ICMR Institutes/Centres
All HODs
ICMR website



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