SGT UNIVERSITY
SHREE GURU GOBIND SINGH TRICENTENARY UNIVERSITY
(UGC Approved)
Gurugram, Delhi-NCR
Budhera, Gurugram-Badli Road, Gurugram (Haryana) – 122505 Ph. : 0124-2278183, 2278184, 2278185

Details of Research / Statistical Databases / Health Informatics

SGTU Library online databases

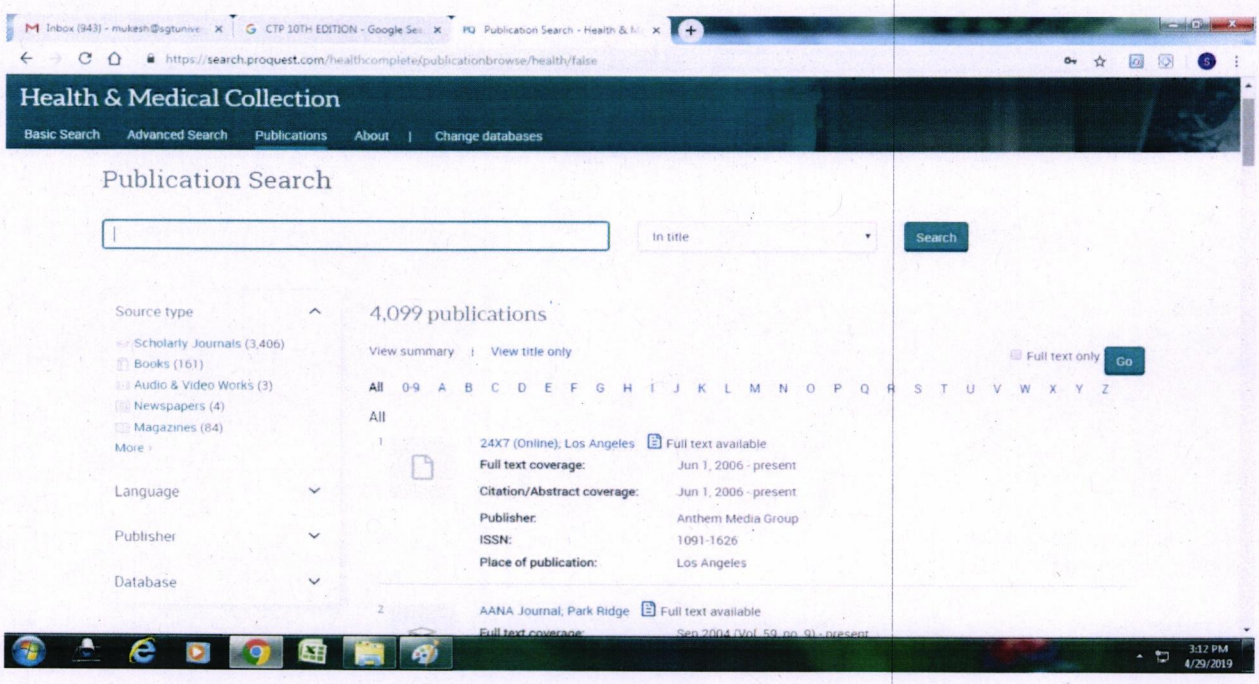
1. **ProQuest:** Health & Medical Collection- Online **e-Journals**

ProQuest Health and Medical Complete™ combine the clinical research titles available in ProQuest Medical Library™ with hundreds of additional consumer and health administration titles. ProQuest Health and Medical Complete provides in-depth coverage from over 1,500 publications with almost 4000+ available in full text and of these, over 900 include MEDLINE® indexing.

In addition, the database includes all charts, diagrams, graphs, tables, photos, and other graphical elements essential to medical research.

Subject coverage

- **Medicine & Health Sciences**
- **Dentistry**
- **Nursing**
- **Psychology**
- **Pharmacy**
- **Allied health Sciences**
- **Physiotherapy**
- **Ayurveda**
- **Biomedical Sciences**



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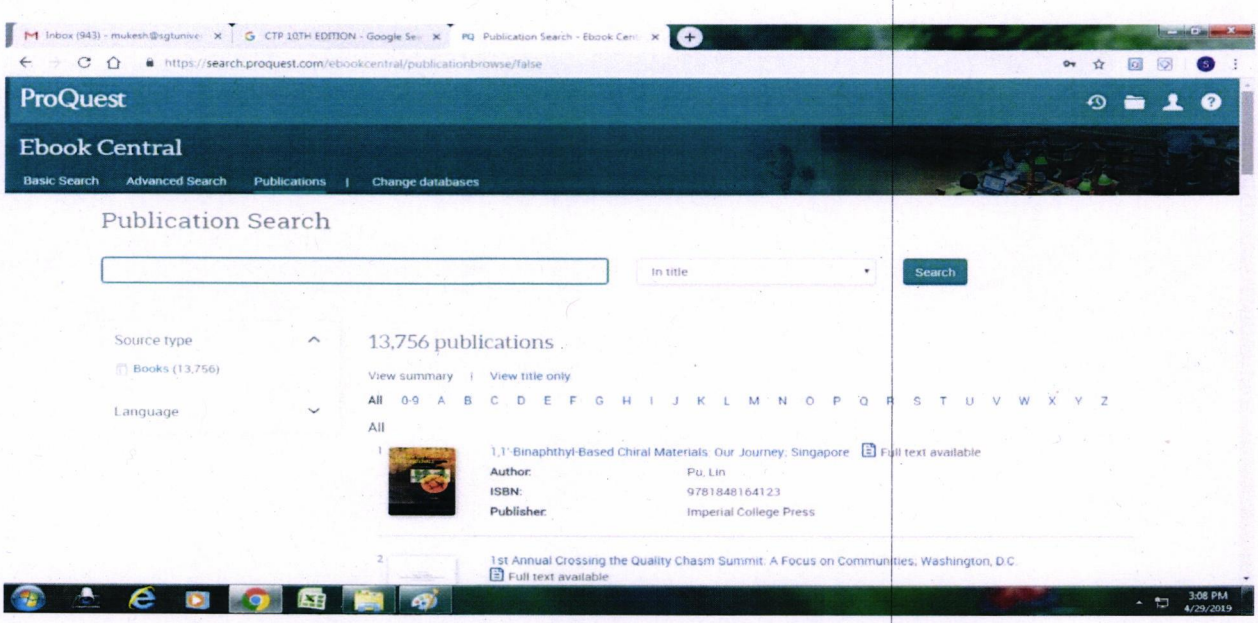
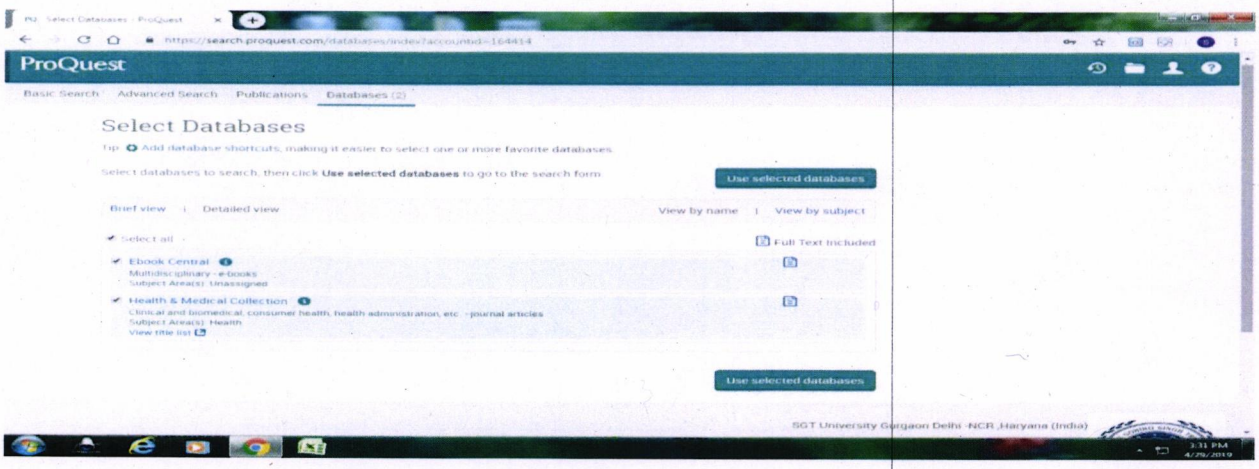
2. ProQuest: e-Book Central

e-book Central provides authoritative, full-text e-books in a wide range of subject areas along with powerful tools to find, use, and manage information.

Subject coverage

- Medical
- Dentistry
- Pharmacy
- Physiotherapy
- Nursing & allied health
- Physical sciences
- Psychology & social work
- Life sciences





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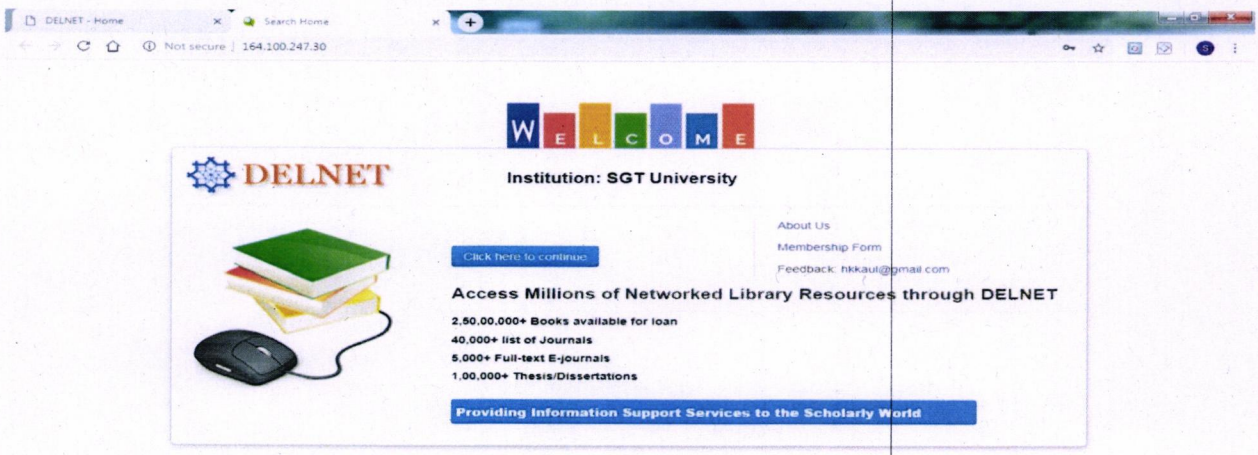
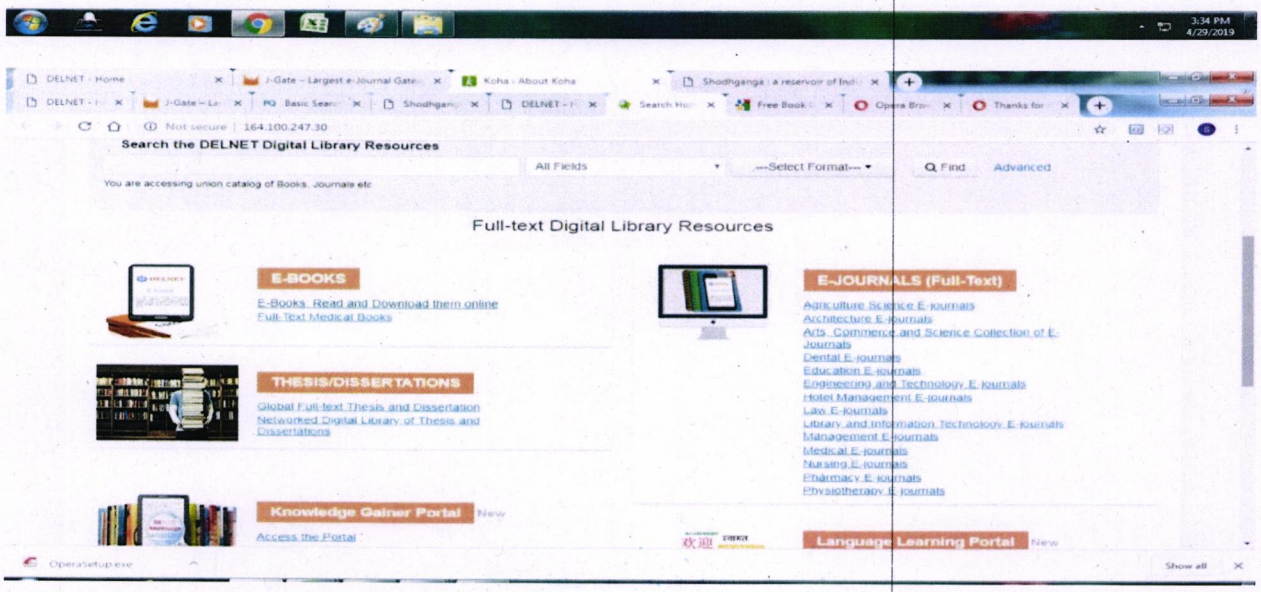
3. Delnet: Subject Coverage (E-Journals)

- Agriculture Science E-journals
- Architecture E-journals
- Arts, Commerce and Science Collection of E-Journals
- Dental E-journals
- Education E-journals
- Engineering and Technology E-journals
- Hotel Management E-journals
- Law E-journals
- Library and Information Technology E-journals
- Management E-journals
- Medical E-journals
- Nursing E-journals
- Pharmacy E-journals
- Physiotherapy E-journals





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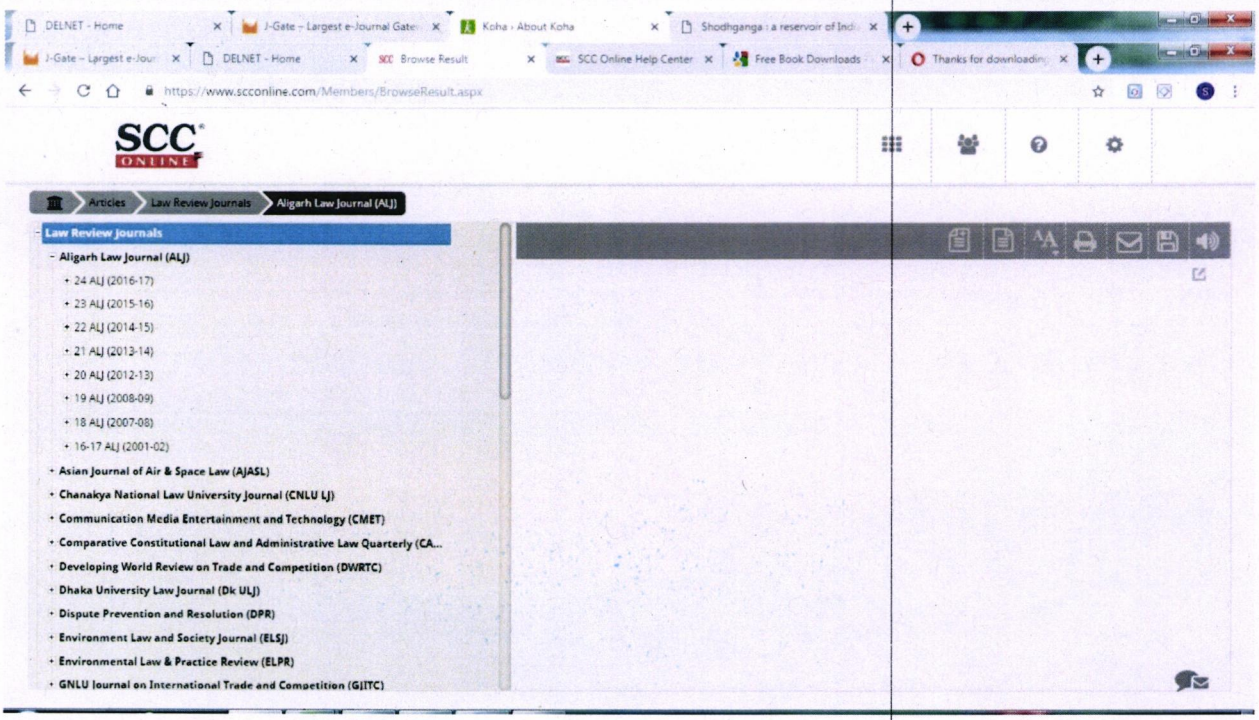
4. SCC Online:

Law database covers judgments of national and international courts, online e-journals, moot court resources, dictionaries, Law reports, Bare Acts, treaties and articles etc.



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5.J- Gate Online database

J-Gate, an electronic gateway to global e-journal literature; is the most efficient comprehensive platform to access research information from over 55 Million journal articles (with access to 10 Million Full Text articles) coming from 49,000+ journals covering multiple subject domains from all disciplines such as; Agriculture & biological Sciences, Arts & humanities, Basic Sciences, Biomedical Sciences, Social & Management Sciences.

The platform is fronted by simple, intuitive, and easy-to-use interface, and gives users complete control over search filters. J-Gate exponentially increases journal usage through its list of features and its ease of use.

- [x] Arts and Humanities
  - [ ] Architecture, Fine and Decorative Arts
  - [ ] Current Events & News
  - [x] Education & Careers
  - [x] Fashion & Entertainment
  - [x] General and Others
  - [x] History
  - [x] Human Rights, Women's Studies & Child Welfare
  - [x] Language & Linguistics
  - [x] Literature
  - [x] Performing Arts, Travel and Leisure
  - [x] Philosophy
  - [x] Religion
  - [x] Society and Culture
- [x] Business, Economy and Management
  - [x] Accounting and Auditing
  - [x] Actuarial Science, Insurance and Risk Management
  - [x] Banking and Investment
  - [x] Business Management
  - [x] E-Commerce
  - [x] Economics
  - [x] Finance
  - [x] General and Others
  - [x] International Business & Transnational Corporations

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- ☑ Marketing and Sales
- ☑ Material & Supply Chain Management
- ☑ Multimodal Transport & Logistics
- ☑ Operations Research
- ☑ Organisational Psychology
- ☑ Organizational change and Development
- ☑ Organiztional Communication, Business Writing
- ☑ Personnel Management & Training
- ☑ Projects and Consultancies
- ☑ Public Relations
- ☑ Quality Management
- ☑ Stocks and Shares
- ☑ Strategic Management & Business Policy
- ☑ Trade and Commerce

☑ Law

- ☑ Arbitration, Education & Training
- ☑ Banking Law
- ☑ Constitution and Judicial System
- ☑ Corporate laws
- ☑ Crime, Criminology and Law Enforcement
- ☑ Domicile and Immigration Laws
- ☑ Environmental Law & Policy
- ☑ Foreign Trade & Commercial Transactions
- ☑ General and Others
- ☑ Industrial Relations Law
- ☑ Insurance Law
- ☑ Intellectual Property
- ☑ Investment Laws
- ☑ Policies
- ☑ Regional and International Law
- ☑ Taxation Laws

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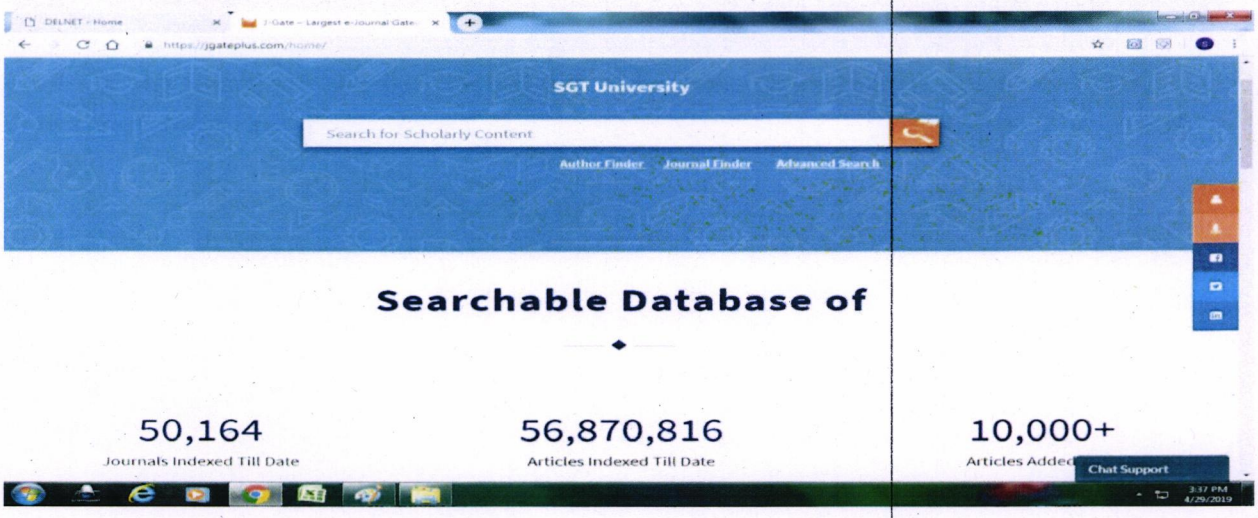
- Social Sciences

- Anthropology
- Archaeology
- Behavioural Science (Psychology)and Counselling
- Communities and Urban Planning
- Community Based Awareness and Relief Service
- Demographic Studies
- Developmental Issues & Socioeconomic Studies
- Disability Studies & Assistance
- Foreign Policy, Defence and Internal Secutiry
- Gender Studies
- General and Others
- Journalism, Mass Communication, Media & Publishing
- Museums & Heritage Organizations
- Political Science
- Public Policy & Administration
- Regional and International Studies
- Rehabilitation
- Sociology



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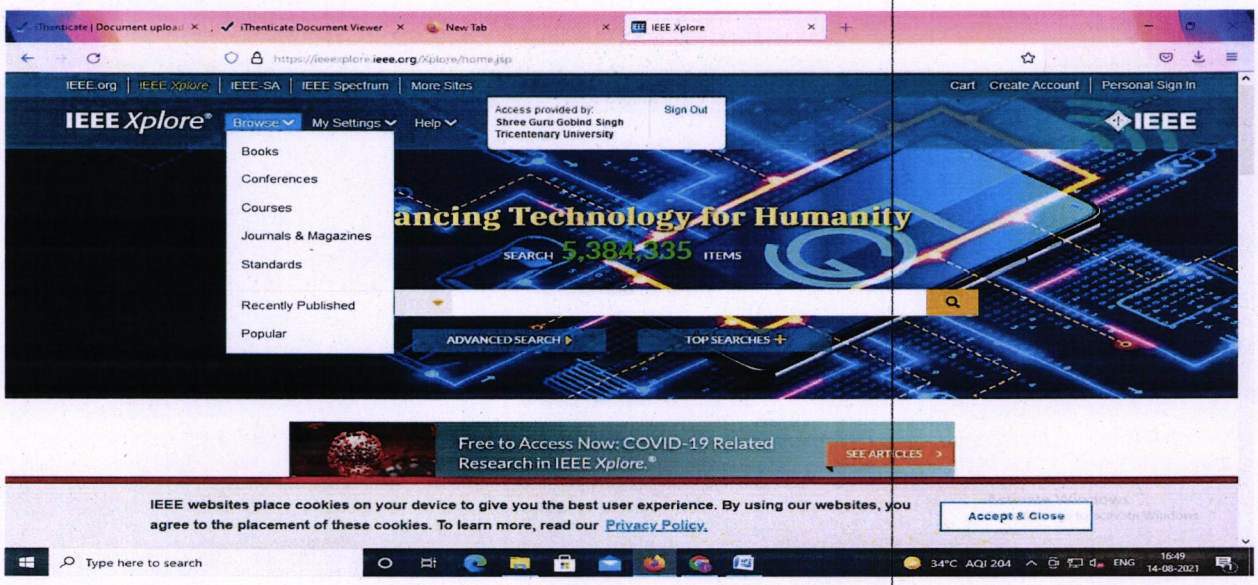
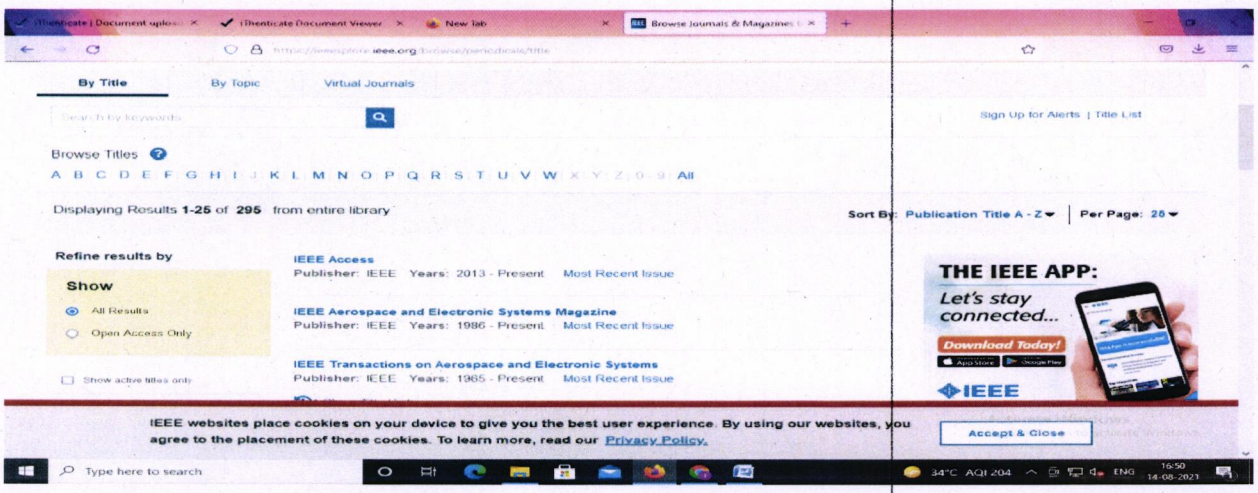
6-IEEE ASPP Online

IEEE Xplore, delivering full text access to the world's highest quality technical literature in engineering and technology.

The IEEE *Xplore* digital library is your gateway to trusted research—journals, conferences, standards, eBooks, and educational courses—with approximately 5 million documents to help you fuel imagination, build from previous research, and inspire new ideas.

IEEE *Xplore* opens a world of knowledge from many industries to enable you to improve or discover the next breakthrough. With powerful search tools to help you find only the most relevant research, IEEE *Xplore* delivers the information your company needs.





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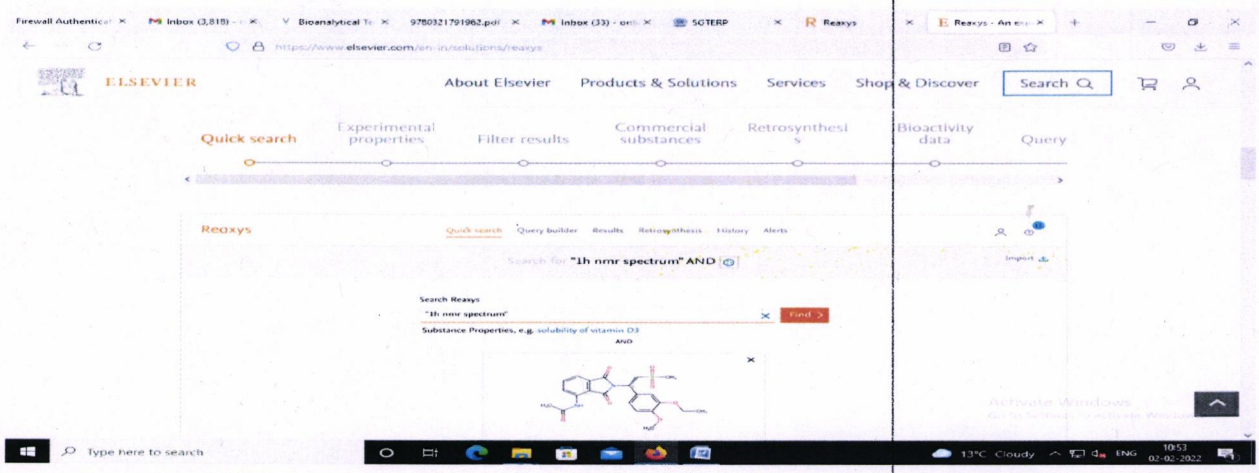
7. Reaxys Medicinal Chemistry Database:

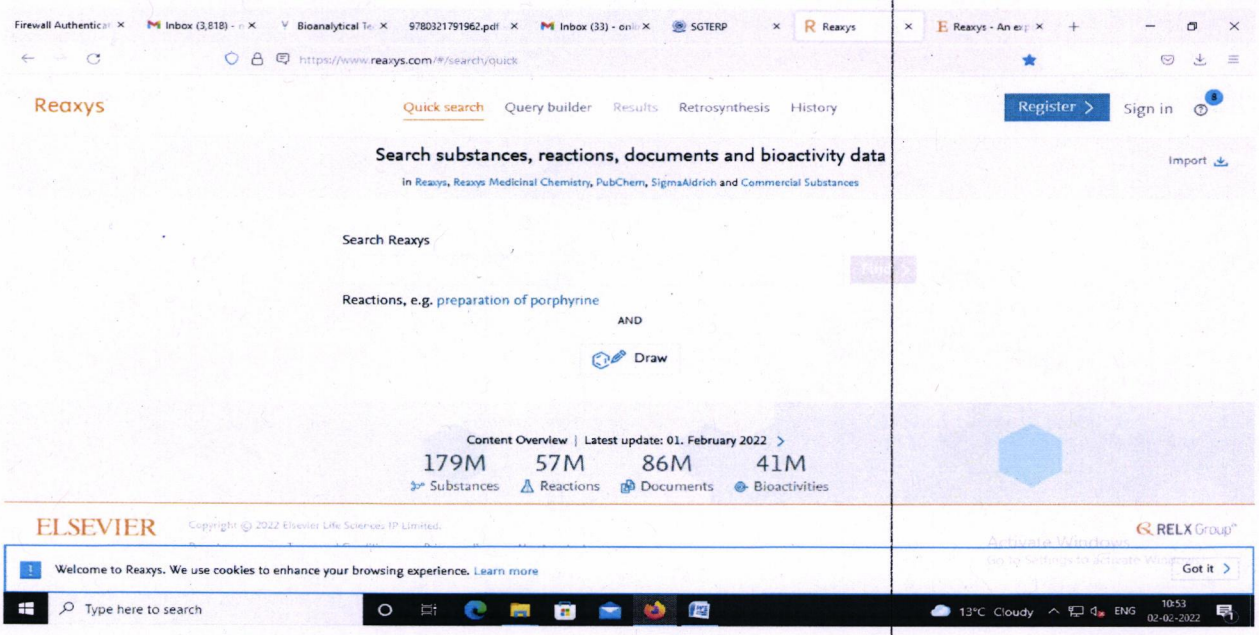
A chemical database that improves R&D productivity

Chemists in every field search for chemistry literature and bioactivity data with Reaxys. Query and filter for chemical substances and reactions with an intuitive interface. And discover more property types than with any other chemistry database.

Start with quick search and customize with query builder — the most powerful query engine in a chemistry database. Reaxys has the largest number of customization options and a transparent query process. You can easily follow your chosen path through to results.

Designed by chemists, Reaxys is more than a fast and flexible chemistry database. It's a cheminformatics solution that delivers chemistry facts the way chemists need them.





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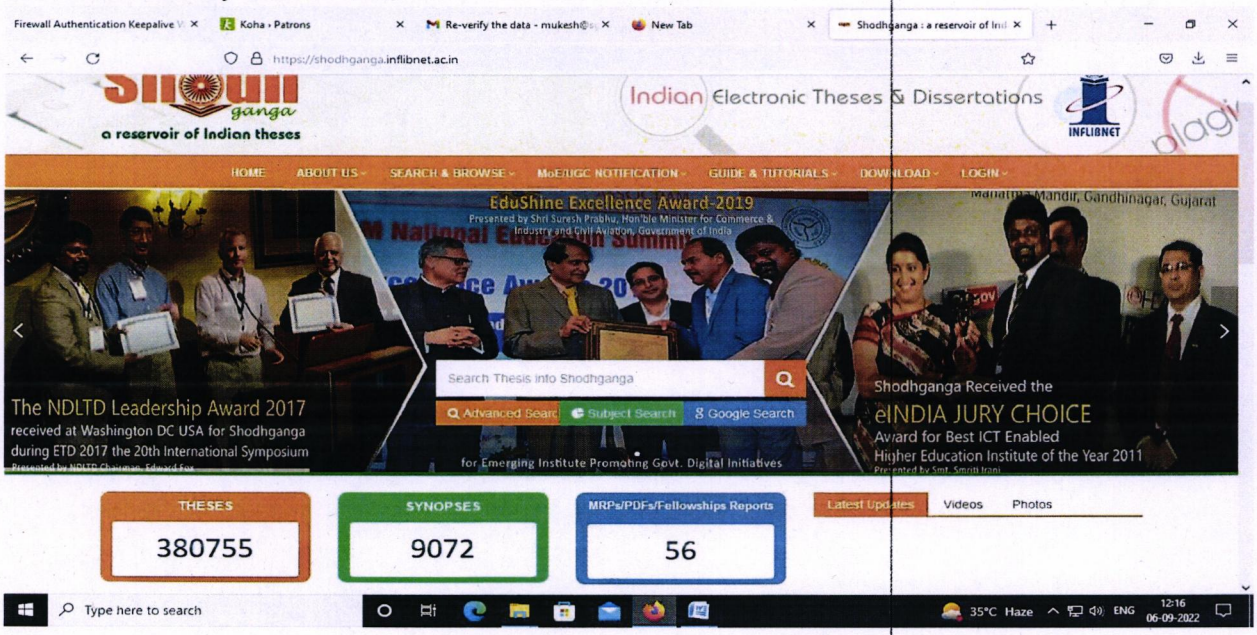
8.**Shodhganga**: a reservoir of Indian Theses

The Shodhganga@INFLIBNET Centre provides a platform for research students to deposit their Ph.D. theses and make it available to the entire scholarly community in open access. The repository has the ability to capture, index, and store, disseminate and preserve ETDs submitted by the researchers.
380000 theses and dissertations are available for researcher through the Shodhganga. Theses and dissertations are known to be the rich and unique source of information, often the only source of research work that does not find its way into various publication channels.
" Shodhganga stands for the reservoir of Indian intellectual output stored in a repository hosted and maintained by the INFLIBNET Centre.



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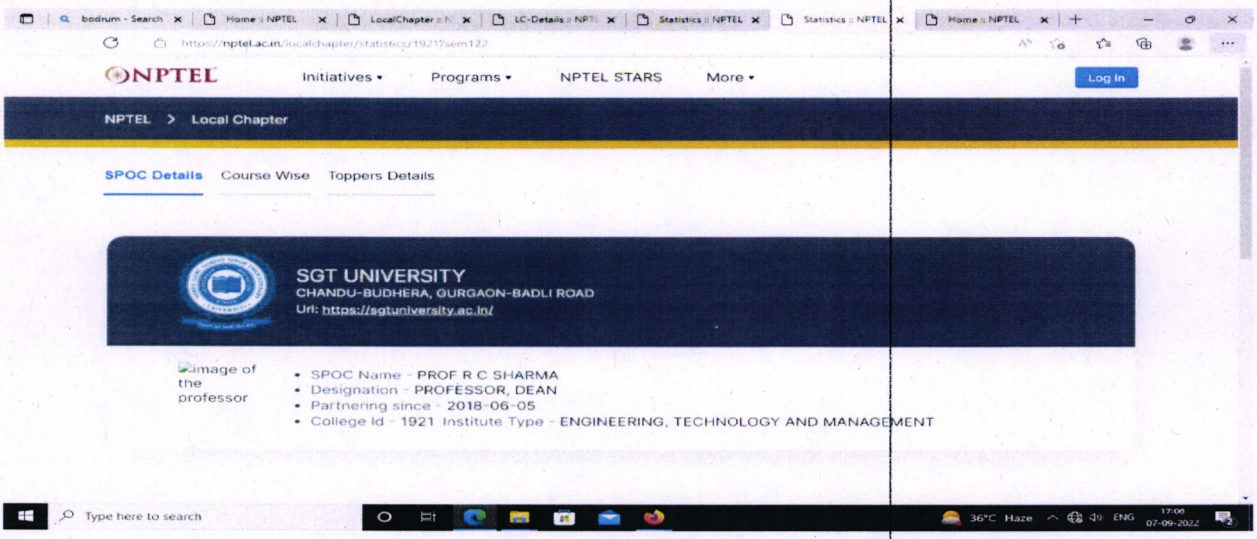
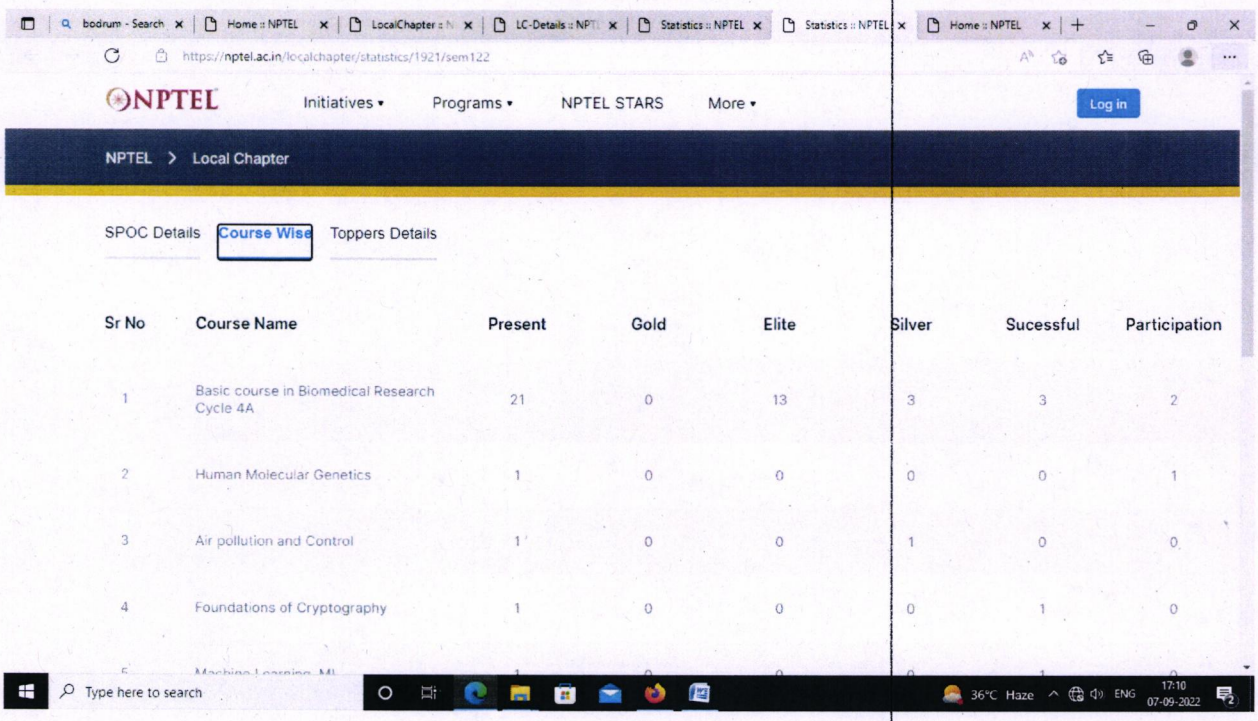
NPTEL has been offering self-study courses across engineering, humanities and science streams for more than a decade. These are available at: http://nptel.ac.in. From March 2014 NPTEL has been offering online certification for its courses, the highlight being the certification exam through which the student gets an opportunity to earn a certificate form the IITs!

These are available at: https://swayam.gov.in/NPTEL





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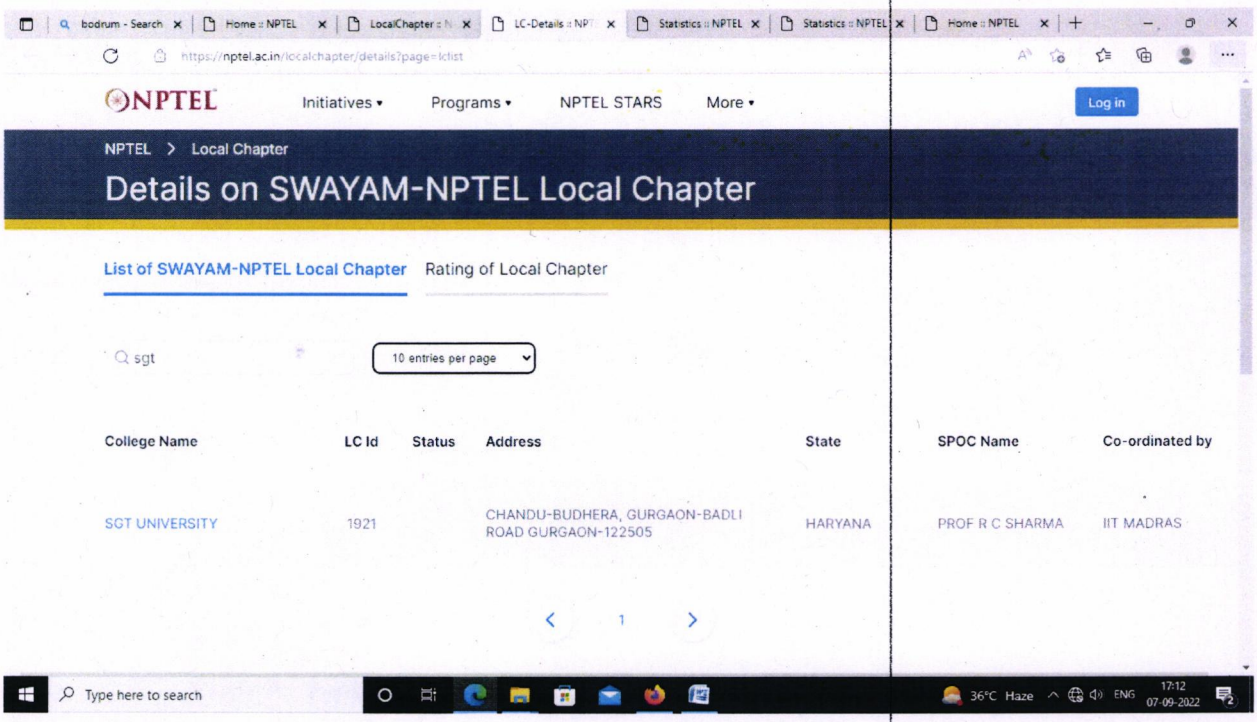
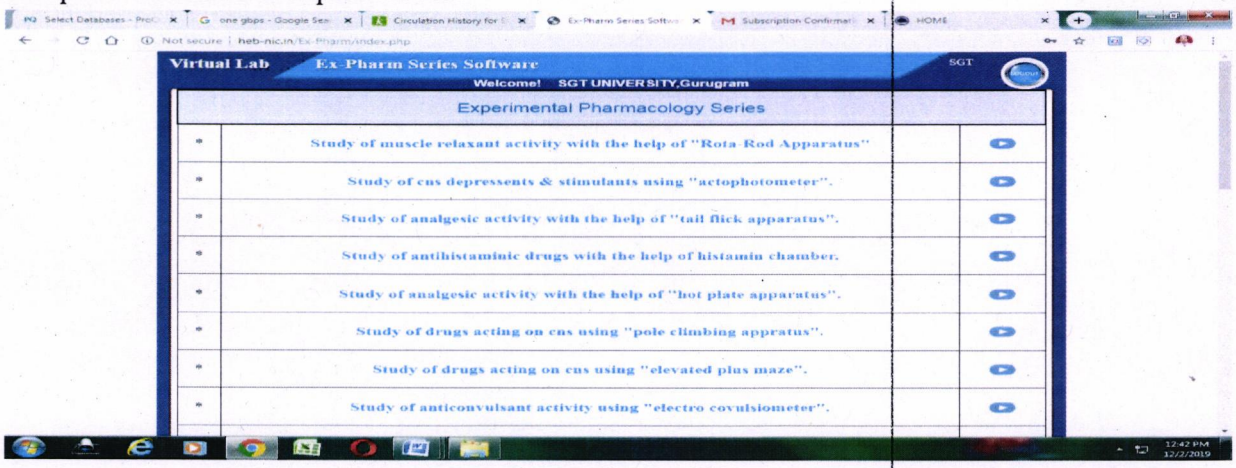


10. Experimental Pharmacology Series (Ex-Pharma Series)

This is a computer assisted learning package containing various programs which simulate animal experiments in Pharmacology. These programs can be used to demonstrate drug on different animals systems. The package is user friendly, highly interactive and full of animated sequences which make simulation appear realistic. The current version of Experimental Pharmacology Series (Ex-Pharm series) Software consists of various computer simulated experiments.



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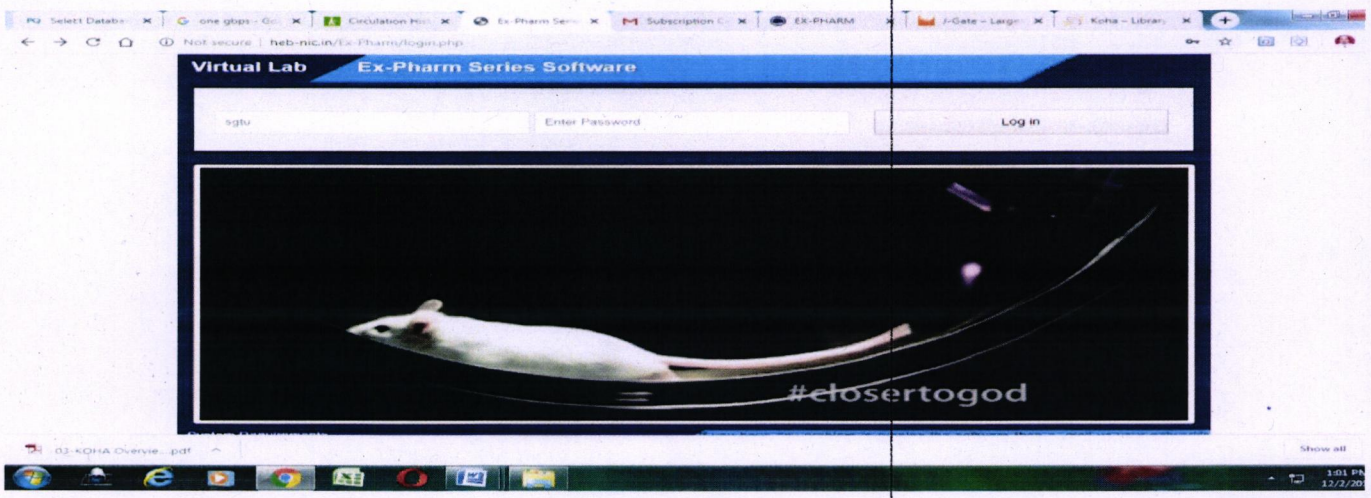

SCOPUS-Indexing Database-https://www.scopus.com/search/form.uri?display=basic#basic

Scopus uniquely combines a comprehensive, expertly curated abstract and citation database with enriched data and linked scholarly literature across a wide variety of disciplines.

Scopus quickly finds relevant and authoritative research, identifies experts and provides access to reliable data, metrics and analytical tools. Be confident in progressing research, teaching or research direction and priorities — all from one database and with one subscription.

Scopus delivers the broadest coverage of any interdisciplinary abstract and citation database. Covering 240 disciplines, researchers, instructors, librarians and students who rely on Scopus are confident that the odds of missing key publications are greatly reduced.

Learn how the interdisciplinary depth and breadth of Scopus can help drive your organization's research and knowledge forward.

Scopus can help your organization achieve a variety of goals, including:

- Improve efficiency and effectiveness of research and analytics workflows
- Identify research gaps for further exploration and discovery
- Bolster research performance, rank and reputation
- Support education and learning goals of instructors and students
- Optimize research funding and investments
- Protect the integrity of authors and the scholarly record and combat predatory publishing

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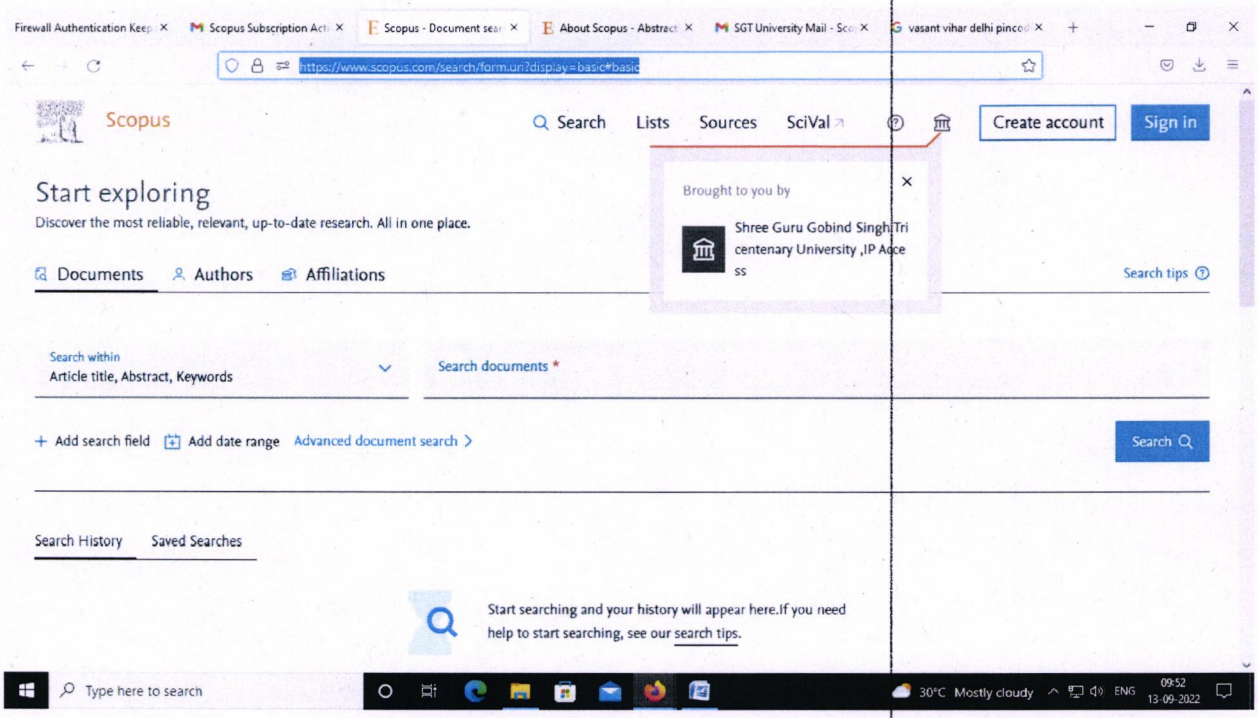

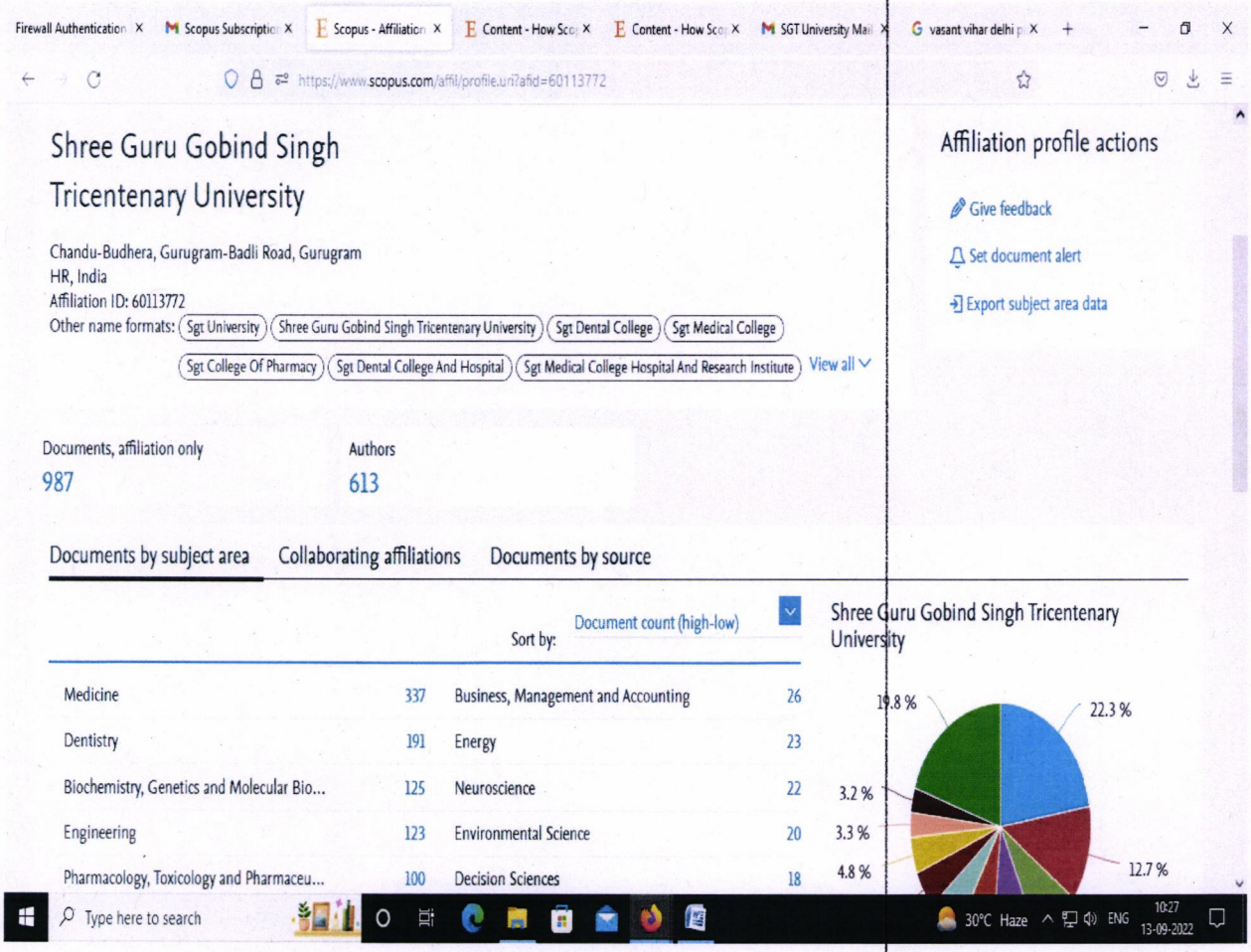

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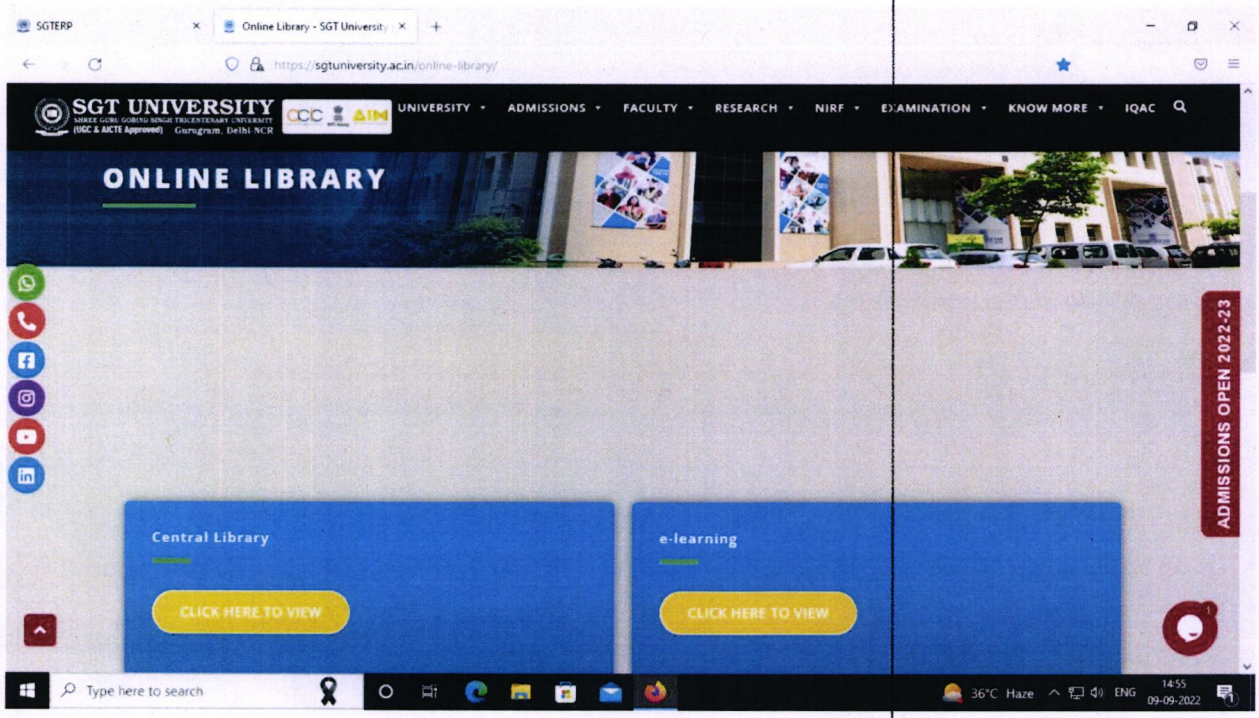

https://sgtuniversity.ac.in/online-library/

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Gurugram, Delhi-NCR
Budhera, Gurugram-Badli Road, Gurugram (Haryana) – 122505 Ph. : 0124-2278183, 2278184, 2278185

Details of Clinical Trials

FORM CT-02

(See rules 8, 9, 10 and 14)

GRANT OF REGISTRATION OF ETHICS COMMITTEE RELATING TO CLINICAL TRIAL OR BIOAVAILABILITY AND BIOEQUIVALNENCE STUDY

Registration No. ECR/1443/Inst/HR/2020

The Central Licencing Authority hereby registers and permits Institutional Ethics Committee , SGT Medical College Hospital Chandu, Budhera, Gurugram-Badli Road Gurugram Gurugram Gurugram Haryana - 122505 Contact No.: 01242278183,84 Fax No.: 01242278151 to perform duties of ethics committee as specified in the New Drugs and Clinical Trials Rules, 2019.

2. The ethics committee shall observe the conditions of registration specified in Chapter III of the New Drugs and Clinical Trials Rules, 2019 and the Drugs and Cosmetics Act, 1940.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
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Date: 2020.08.21 12:51:03 +05'30'

Place : New Delhi

Date : 20-AUG-2020

Central Licencing Authority
Stamp

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

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Budhera, Gurugram

File No. EC/20/000268

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

सत्यमेव जयते

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 20-Aug-2020

To

The Chairman
Institutional Ethics Committee
SGT Medical College Hospital
Chandu, Budhera, Gurugram-Badli Road Gurugram
Gurugram Gurugram Haryana - 122505 India

Subject: Ethics Committee Registration No. ECR/1443/Inst/HR/2020 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2020/9188 dated 23-Jul-2020 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/1443/Inst/HR/2020. The said registration is subject to the conditions as mentioned below:

Yours faithfully

VENUGOPAL GIRDHARILAL SOMANI

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Date: 2020.08.21 12:50:34 +05'30'

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid for a period of five years from the date of its issue, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-

(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;

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(v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,

(i) one lay person;
(ii) one woman member;
(iii) one legal expert;
(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

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19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee,bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

Registrar
SGT University
Budhera, Gurugram

File No. EC/20/000268

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 20-Aug-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. Nudrat Jahan	BA (MA - Psychology)	Social Scientist
2	Ms. Shraddha Oberoi	LLB (Master of Laws (LL.M.))	Legal Expert
3	Ms. Yogita Jain	LLB (Master of Laws (LL.M.))	Legal Expert
4	Dr. Mohindar Pal Sawhney	MBBS (MD - Dermatology , Venereology & Leprosy)	Clinician
5	Dr. Kapil Hazarika	MBBS (MD - Pharmacology and Therapeutics)	Basic Medical Scientist
6	Dr. Nimarpreet Kaur	MBBS (MD/MS – Physiology)	Basic Medical Scientist
7	Dr. Sanjiv Kumar Bansal	MBBS (MD/MS- Biochemistry)	Basic Medical Scientist
8	Dr. Akanksha Yadav	BSc (MSc)	Scientific Member
9	Ms. Savitri Yadav	BA (Not Applicable)	Lay Person
10	Dr. Pradeep Garg	MBBS (Surgeon)	Chair Person
11	Dr. Bindoo Yadav	MBBS (Women Representative)	Clinician
12	Dr. Debasish Chattopadhya	MBBS (MIcrobiologist)	Member Secretary

VENUGOPAL GIRDHARILA L SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Registrar
SGT University
Budhera, Gurugram

मालेगाव महानगरपालिका,मालेगाव

(०२५५४) २३१८०५, २३४३४२, (Ex.२१६) फॅक्स २३०८१४
Email ID-mlghealth@gmail.com
आरोग्य अधिकारी कार्यालय

जा.क्रं.मनपा/आ.का.कोरोना/३९१/२०२० दिनांक:- २२/०६/२०२०

To
Prof. Shobha Broor,
Professor and Head, Microbiology
SGT Medical College, Hospital & Research Institute, Haryana.

Sub: Participation in the seroprevalence study for covid 19 antibodies in Malegaon antibodies in malegaon Community, Maharashtra

Dear professor Broor,

We are aware of the current need for seroprevalence of the covid 19 antibodies in the community in order to measure the the degree of prevalence of the disease and to be able to also plan for and manage the disease spread in the community. We are privileged to be co-investigators in the study to conduct sero-surveillance of covid 19 antibodies in the community of malegaon, where we are currently working. We will willingly work towards the study and participate in the process. We also look forward to analysing the data and give permission for publication of the study data in a peer reviewed journal for the betterment of understanding the disease and advancing the science in this fight against the current pandemic.

We are aware that dr. Mukesh Sharma will be the principal investigator.

Thank you

1. Dr. Govind Chuadhary - (M.B.B.S., MDPSM) EPIDEMOLOGIST,HFWTC, Nasik
2. Dr. Shriram Gosavi - (MDPSM) ASSOCIATEPROFESSOR,SBHGMC, Dhule
3. Dr. Hitesh Mahale - (MD Medicine) Medical Officer, GH Malegaon
4. Dr. Sapna Thakre - (BAMS) MOH,Malegaon Municipal Corporation-
5. Dr. Alka Bhavsar - (MBBS) Medical officer, MMC

.Deepak Kasar
(Commisioner)
Malegaon Municipal Corporation

Registrar
SGT University
Budhera, Gurugram

MALEGAON MUNICIPAL CORPORATION
OFFICE OF THE MUNICIPAL COMMISSIONER

Phone : 91 2554 231900, Fax : 912554230894
Email : mlgmmc@gmail.com
Visit us : www.malegaoncorporation.com

MMC O. No. 196/2020

22nd June 2020

To,
Prof. Shobha Broor,
Professor and Head, Microbiology
SGT Medical College,
Hospital & Research Institute, Haryana.

Subject : Willingness for seroprevalence study of Covid 19 antibodies in Malegaon antibodies in Malegaon Community, Maharashtra.

Dear Professor Broor,

I am aware of the current need for seroprevalence of the Covid 19 antibodies in the community in order to measure the degree of prevalence of the disease and to be able to plan for and manage the disease spread. I am privileged to participate in the study of the antibodies. Under my guidance, I, Deepak Kasar, as the Municipal Commissioner of Malegaon, will provide all necessary assistance required by the Malegaon Municipal Corporation, with prior permission of State Government of Maharashtra. We will willingly work towards the study. We look forward to analyzing the data and give permission for the publication of the study data in the peer reviewed journal for the betterment of understanding the disease and advancing the science in the fight against the pandemic.

I am aware that Dr. Mukesh Sharma will be the principal investigator.

Thanking you.

(Deepak Kasar)
Municipal Commissioner
Malegaon Municipal Corporation.

Registrar
SGT University
Budhera, Gurugram

IGIB
INSTITUTE OF GENOMICS & INTEGRATIVE BIOLOGY
Genomics Knowledge Partner

सी.एस.आई.आर.–जीनोमिकी और समवेत जीवविज्ञान संस्थान
(वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्, भारत सरकार)
CSIR-Institute of Genomics & Integrative Biology
(Council of Scientific & Industrial Research, Govt. of India)

डॉ. अनुराग अग्रवाल,
एम.बी.बी.एस, डिप्लोमेट अमेरिकन बोर्ड ऑफ इंटरनल मेडीसिन,
पीएचडी, एफ.एन.ए., एफ.ए.एस.सी., एफ.सी.सी.पी., ए.टी.एस.एफ
निदेशक

Dr. Anurag Agrawal,
MBBS, Diplomate American Board of Internal Medicine,
PhD, FNA, FASc, FCCP, ATSF
Director

20 May 2020

Dear Ajay

On behalf of the surveillance verticals of CSIR, the expert taskforce at PSA office, and the empowered committee for vaccines and other R&D, I acknowledge iSPIRT's help in conducting seroprevalence studies for Covid-19 in India. To that end, I confirm that the first batch of 10K Rapid Antibody tests have been received and deployed for seroprevalence studies in Mumbai, as confirmed by Dr Sudeep Gupta, Director ACTREC. We look forward to receiving the remaining 20K tests as per your commitment, and these too shall be deployed towards conducting important seroprevalence studies for Covid-19 in India.

Sincerely,

Anurag Agrawal

Registrar
SGT University
Budhera, Gurugram

North Campus, Mall Road, Delhi-110007 • Tel. : 91-011-27662407/7578, Fax : 91-011-27667471 • E-mail : a.agrawal@igib.res.in
South Campus, Mathura Road, New Delhi-110025 • Tel. : 91-011-29879102/03, Fax : 91-011-29879111 • Website : http://www.igib.res.in

TELEGRAM : SCINDRECH
दूरभाष/ TEL : 26962819, 26567373
: 26565694, 26562133
: 26565687, 26562144
: 26562134, 26562122 (EPBAX)
फैक्स/FAX : 26960629, 26529745
: 26516078
Website : http://www.dsir.gov.in

सत्यमेव जयते

भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
वैज्ञानिक और औद्योगिक अनुसंधान विभाग
टेक्नोलॉजी भवन
नया महरौली मार्ग, नई दिल्ली – 110016
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
Department of Scientific and Industrial Research
Technology Bhavan
New Mehrauli Road, New Delhi-110 016

No. TU/V/RG-CDE (1)/2016 **Dated: 16-03-2018**

To,
The Director
CSIR-Institute of Genomics & Integrative Biology
Mall Road, Near Jubilee Hill,
New Delhi – 110 007

Subject: Renewal of Registration of Public Funded Research Institutions or a University or an Indian Institute of Technology or Indian Institute of Science, Bangalore or a Regional Engg. College, other than a Hospital*, for purposes of availing Customs Duty exemption in terms of Notfn. No. 51/96-Customs dt. 23.07.1996, Notfn. No. 47/2017-Integrated Tax (Rate) dt. 14.11.2017 and Notfn. No. 45/2017- Central Tax (Rate) dt. 14.11.2017, Notfn. No. 45/2017- Union Territory Tax (Rate) dt. 14.11.2017, as amended from time to time.

With Reference: Your letter dated 15th March, 2018 on the above subject, this is the certificate of registration.

CERTIFICATE OF REGISTRATION

This is to certify that, **CSIR-Institute of Genomics & Integrative Biology, New Delhi** is registered with the Department of Scientific and Industrial Research (DSIR) for purposes of availing Customs Duty exemptions in terms of Notfn. No. 51/96- Customs dt. 23.07.1996, Notfn. No. 28/2003- Customs dt. 01.03.2003, Notfn. No. 43/2017- Customs dt. 30.06.2017 & Notfn. No. 47/2017- Integrated Tax (Rate) dt. 14.11.2017, Notfn. No. 10/2018-Integrated Tax (Rate) dt. 25.01.2018 and Notfn. No. 45/2017- Central Tax (Rate) dt. 14.11.2017, Notfn. No. 45/2017- Union Territory Tax (Rate) dt. 14.11.2017 & Notfn. No. 9/2018- Central Tax (Rate) dt. 25.01.2018, Notfn. No. 9/2018- Union Territory Tax (Rate) dt. 25.01.2018, as amended from time to time for research purposes only. This Registration is subject to terms and conditions mentioned overleaf.

This is issued in-lieu of DSIR letter no. TU/V/RG-CDE (1)/2016 dated 26th August, 2016 which is cancelled.

This Registration is valid upto **31.08.2021.**

Please acknowledge the receipt.

Yours faithfully,

Kamini Mishra
(K. Mishra)
Scientist - 'F' / Director

Registrar
SGT University
Budhera, Gurugram

Certificate of registration is not valid for activities falling within the definition of "hospital" as per notification no. 51/96 – Customs dated 23-07-1996 issued by the Department of Revenue. The institutions are cautioned to go through the notification before availing duty exemptions under this notification.

Terms and conditions for registration of public funded research institutions, etc., other than a hospital for the purposes of availing Customs Duty exemption in terms of Notfn. No. 51/96-Customs dt. 23.07.1996, Notfn. No. 47/2017-Integrated Tax (Rate) dt. 14.11.2017 and Notfn. No. 45/2017- Central Tax (Rate) dt. 14.11.2017, Notfn. No. 45/2017- Union Territory Tax (Rate) dt. 14.11.2017, as amended from time to time.

01. The institution should acknowledge receipt of the registration letter by stating that they will abide by the terms and conditions of registration.

02. The registration would be valid for the period specified in the registration letter**. Request for renewal of registration shall be made in the prescribed proforma, at least 3 months before the expiry of the valid registration. Applications received late may not be considered.

*** However, certificate of registration is not valid for activities falling within the definition of 'hospital' as per notification no. 51/96-Customs dated 23.07.1996 issued by the Department of Revenue. The institutions are cautioned to go through the notification before availing duty exemptions under this notification.*

03. Brief summary of the R&D activities, status of on-going projects and achievements of the institution shall be submitted to the DSIR at the end of 5(five) years, in case of institution where validity of registration is 10(ten) years. This should include details related to papers published, patents obtained and processes developed, new products introduced, awards & prizes received and copy of the latest Annual Report.

04. The institution should have a broad based research advisory committee (RAC), which should meet at regular intervals for approving, guiding and monitoring the ongoing and future research projects.

05. The institution should have separate budget for research. The institution should utilise the duty exemption facility as per the above-mentioned notification, for research purposes only. Non-research requirement such as the one for service activities, teaching, training, patient care, etc. should not be procured availing the facility.

06 DSIR will not be responsible for any misuse of the duty exemption facility using this certificate. The onus that duty exemption has been availed for research purpose only lies with the institution

07. The institutions should introduce a chapter in its Annual Report dealing with the research & development work. This could contain the on-going research projects, achievements during the year, publications, patents if any, etc. The R&D income & expenditure should be separately shown in an annexure/schedule in the statement of accounts in the Annual Report.

08. The registration will entitle the institutions to avail custom duty exemption on purchase of equipment, instruments, spares thereof, consumables etc. used for research & development subject to relevant Government policies in force from time to time. Such exemption will have to be separately applied for in the prescribed formats. The institutions should also abide by the terms & conditions of the customs notifications issued/amended from time to time.

09. In case of disposal/sale of R&D equipment, clearance from customs authorities will also be required in view of the applicable notification under which the equipment was imported in India.

10. The institution should submit details of the imports at the time of renewal in the proforma issued by DSIR.

11. Any violation of the terms & conditions mentioned above and/or provisions of taxation in force will make the institution liable to de-registration.

12. The institution will also conform to such other conditions for registration stipulated in the Guidelines, as may be specifically provided in the registration letter and notices placed on department official website (http://www.dsir.gov.in) from time to time.

—*—*—*—

Registrar
SGT University
Budhera, Gurugram

सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पद्म श्री
एम.डी., डी.एम., एफआरसीपी (ग्लै.), एफआरसीपी (ई.), एफएसी.सी.,
एफएचए, एफएएमएस, एफएनएएसस्सी, 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

D.O.No. VIR/4/2020/ECD-I (Vol.I)
Dated: 17th April 2020

Addl.Chief Secretaery/Secretary/Principal Secretary Health (All States)

Sub: Protocol for using 'Rapid antibody test' in Hot area – epidemiological studies and surveillance

I am writing to you with reference to the rapid antibody test kits for COVID-19 testing. It is understood that many States intend to use these kits in affected areas.

2. The National Task Force at ICMR has carefully reviewed the data evolving from various countries on use of such kits. Based on available evidence, the testing strategy for COVID-19 has been revised further. The revised document is enclosed for your reference.

3. It is critical to understand the following key facts while using the rapid antibody tests:

- Gold standard frontline test for COVID-19 diagnosis is real time PCR based molecular test, which is aimed at early virus detection.
- The rapid antibody test cannot replace the frontline test.
- The rapid Antibody test is a supplementary tool to assess the prevalence of the diseases within a specific area / perimeter.
- The rapid antibody test will only be of utility after a minimum of 7 days of onset of symptoms.
- Data about these rapid tests is emerging and understanding of their utility for diagnosis is still evolving.
- The rapid tests are useful for epidemiological studies and surveillance purposes.
- THE TEST HAS TO BE DONE UNDER STRICT MEDICAL SUPERVISION.

4. The enclosed ICMR advisory is for Hot spots. In case your state does not have a Hot spot, these tests may be used for:-

a) Any hotspot which may emerge in future
OR
b) As a surveillance tool for epidemiological purposes in such areas where cases have not emerged so far.

5. Before starting the rapid test, it should be registered on covid19cc.nic.in/ICMR and data related to the test should be reported on the same.

With best regards

Yours sincerely

Balram Bhargava

(Balram Bhargava)

Enclosed: As above

CC: Chief Secretary/Administrators

IGIB
INSTITUTE OF GENOMICS & INTEGRATIVE BIOLOGY
Genomics Knowledge Partner

सी.एस.आई.आर.–जीनोमिकी और समवेत जीवविज्ञान संस्थान
(वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्, भारत सरकार)
CSIR-Institute of Genomics & Integrative Biology
(Council of Scientific & Industrial Research, Govt. of India)

डॉ. अनुराग अग्रवाल,
एम.बी.बी.एस, डिप्लोमेट अमेरिकन बोर्ड ऑफ इंटरनल मेडीसिन,
पीएचडी, एफ.एन.ए., एफ.ए.एस.सी., एफ.सी.सी.पी., ए.टी.एस.एफ
निदेशक

Dr. Anurag Agrawal,
MBBS, Diplomate American Board of Internal Medicine,
PhD, FNA, FASc, FCCP, ATSF
Director

May 6, 2020

To,
iSPIRT FOUNDATION
No.231-236, 2nd Floor, Raheja Arcade,
Koramangala
Bangalore, Karnataka 560095

Thank you for your offer of pro-bono help for helping fight the COVID19 crisis. You have offered to donate 30,000 Rapid Antibody Test kits for enabling us to conduct Seroprevalence studies. These tests will help us to better understand the COVID disease spread, develop better policy formulations, and eventually help the health and economy of the population.

I head the vertical for molecular and digital surveillance for CSIR COVID19 efforts, and also co-lead the same for the expert advisory group to the office of the Principal Scientific Advisor to PM. The work is approved by empowered committee for COVID19 related research, of the Govt of India, chaired by Dr Vinod Paul and Dr Vijayraghavan. I am therefore deeply engaged with seroprevalence efforts.

We therefore gladly accept your kind offer to procure these kits towards this effort, and donate them as technical assistance for such studies to be executed by a consortium of researchers. CSIR-IGIB will be happy to accept and distribute to other members of the consortium for such efforts

We are grateful for iSPIRT's help in this hour of national crisis.

Warm regards,

Anurag Agrawal

cc: Dr Shekhar Mande, DG, CSIR, Delhi

Registrar
SGT University
Budhera, Gurugram

North Campus, Mall Road, Delhi-110007 • Tel. : 91-011-27662407/7578, Fax : 91-011-27667471 • E-mail : a.agrawal@igib.res.in
South Campus, Mathura Road, New Delhi-110025 • Tel. : 91-011-29879102/03, Fax : 91-011-29879111 • Website : http://www.igib.res.in

DEPARTMENT OF PULMONARY MEDICINE

FACULTY OF MEDICINE & HEALTH SCIENCES

SGT MEDICAL COLLEGE, HOSPITAL & RESEARCH INSTITUTE

BUDHERA, GURUGRAM-122505, HARYANA

Project Title	Protective effect of re-vaccination with BCG against COVID-19 in healthcare workers – A Pilot Study
Project Number	
Name& Address of Principal Investigator	Dr. DPS Sudan Professor & HOD Department Of pulmonary Medicine Contact number- 7042495699 hod.tbchest@sgtuniversity.org
Name & Address of Co- Investigator	Dr. Sachet dawar Designation: Assistant Professor Department of Pulmonary Medicine Faculty of Medicine & Health Sciences S G T Medical College, Hospital and Research institute Contact No.-9654756755 Email- sachetdawar@gmail.com

Signature

Registrar
SGT University
Budhera, Gurugram

FACULTY OF MEDICINE & HEALTH SCIENCES

SGT MEDICAL COLLEGE , HOSPITAL & RESEARCH INSTITUTE

BUDHERA, GURGAON -122505, HARYANA

DEPARTMENT OF PULMONARY MEDICINE

The project titled "The protective effect of re-vaccination with BCG against COVID-19 in health care workers – A Pilot Study" has been discussed in the Departmental Research Committee and has been cleared.

Registrar
SGT University
Budhera, Gurugram

STATEMENT OF COMPLIANCE

The study will be carried out in accordance with Good Clinical Practice (GCP) as required by the following:

- New Drug and Clinical Trial Rules, 2019 (NDCTR 2019)

All key personnel (all individuals responsible for the design and conduct of this study) have completed Human Subjects Protection Training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements (NDCTR 2019) and ICMR and ICH guidelines.

Name of Investigator:

Signed:_____Date: _____

Name
Title

Registrar
SGT University
Budhera, Gurugram

TABLE OF CONTENTS

Registrar
SGT University
Budhera, Gurugram

SUMMARY

Study Title: Protective effect of re-vaccination with BCG against COVID-19 in healthcare workers – A Pilot Study

Type of study: Randomized controlled Trial

Objective: The objective of the trial is to assess the protective and prophylactic effect of re-vaccination with BCG in healthcare workers who shall be going for COVID-19 ward duty.

Patient Population: Initially, 400 healthcare workers (200 in each group) shall be enrolled after fulfilment of inclusion / exclusion criteria of the study protocol. Since this is a pilot study, additional patients will be recruited later for detailed analysis.

Number of Sites: One

Study Duration: 6 months (5 months of enrollment and 1 month of follow-up)

Description of Intervention:

1. Freeze dried BCG vaccine reconstituted with 1ml of Sodium Chloride administered in a dose of 0.1 mg in 0.1 ml volume intra-dermally.
2. Estimation of CD4+T cell counts and CD8+ T cell counts of test group before the administration of BCG and after 6 weeks.

Registrar
SGT University
Budhera, Gurugram

TABLE 1: STUDY CALENDER

Procedure	Baseline[$]	1 week prior to COVID duty[%]	On the 7th day of Quarantine post COVID-duty	End of study[@] (after 6 weeks)
Informed consent	X			
Inclusion and Exclusion criteria	X			
Demographics	X			
Medical history	X			
Pregnancy test , (if applicable)	X			
Physical Examination[#]	X	X	X	X
Vital signs[#]	X	X	X	X
BCG Scar mark evaluation	X			
Enrollment in the applicable study group	X			
Assessment of CD4+ T cell counts & CD8+ T cell counts	X			X
Study medication administration		X		
Development of new symptoms			X	X
Nasal or oropharyngeal swab*			X	

$ Baseline data would be recorded according to the duty roster of the healthcare workers i.e 1 week prior to the COVID-19 isolation ward duty or as suitable to the Investigator.
% May overlap with Baseline visit.
# Activities to be performed at every visit.
@ End of study (after 6 weeks from the day of BCG administration).
*Will be performed on Day-7 of quarantine post COVID-19 isolation ward duty. If any other investigation performed, will be documented.

Registrar
SGT University
Budhera, Gurugram

1. BACKGROUND INFORMATION AND RATIONALE

In 1948, a BCG Vaccine Laboratory was established at King Institute, Guindy, Madras (Chennai), Tamil Nadu that made India self sufficient for BCG production and vaccination[1]. Bacille Calmetter –Guerin (BCG) vaccine is recommended to be administered at birth according to Indian Academy Of Paediatrics (IAP) (2014 Guidelines) and National Immunization Programme (NIP) for prevention of tuberculosis in children[2]. The aim of BCG vaccination is to induce a benign, artificial primary infection which will stimulate an acquired resistance to possible subsequent infection with virulent tubercle bacilli.Till date, BCG is the most widely used vaccine worldwide and has been administered to approximately more than four billion individuals with astonishing safety records[3,4].. The WHO has recommended the "Danish 1331" strain for the production of BCG vaccine.

In addition to its specific action against tuberculosis, the BCG vaccine has beneficial immune-modulator effect on the immune system that protect against a wide range of other infections and are used routinely to treat bladder cancer andvarious skin disorders[5,6].

Immunological experimental model shave confirmed that α/β T cell receptor expressed by $CD4^+$ and $CD8^+$ T cells and MHC I and II are necessary for control of mycobacterial infections [7,8]. Studies have provided evidence that protective T cell mediated immunity is generated by BCG. Studies indicate that $CD4^+$ T cells are essential to reduce bacterial burden in the lung and spleen, while $CD8^+$ T cells control bacterial burden only in the spleen. These results implicate that $CD4^+$ T cells are the main effector cells generated by BCG in the lung, and also highlight the importance of $CD8^+$ T cells in preventing dissemination [9–12], potentially making them the main effector cells responsible for preventing miliary TB and TB meningitis.

BCG vaccination followed by *Mycobacterium tuberculosis(M.tb)* challenge confirms that in the absence of $CD4^+$ T cells, $CD8^+$-specific T cells are able to reduce *M.tb* bacterial burden in the lung at later stages postinfection, supporting the importance of $CD8^+$ T cells during the late phases of the disease [9,13]. These results signify that BCG can stimulate protective $CD4^+$ and $CD8^+$ T cells.

In the recent times , the world has been struck by an unfortunate pandemic caused by severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) which is a single stranded positive-sense RNA virus that has wreaked havoc globally since its inception in December 2019. The BCG vaccine has shown to reduce the severity of infections by other viruses with similar structure as that of SARS CoV2 virus in controlled trials. For example, the BCG vaccine reduced yellow fever vaccine viraemia by 71% (95% CI 6–91) in volunteers in the Netherlands [14] and it markedly reduced the severity of mengovirus (encephalomyocarditis virus) infection in two studies in mice[15,16].

There are several immunomodulators being launched by leading pharmaceuticals during the COVID-19 pandemic fighting the race against time.Cadila Pharmaceuticals has produced Sepsivac which is an immunotherapy treatment which is a Mycobacterium w (heat killed)

suspension already approved for severe sepsis. Council of Scientific & Industrial Research (CSIR) is currently testing "Sepsivac" against COVID-19 as a repurposed vaccine and is presently in Phase-2 trials which are being conducted in All India Institute Of Medical Sciences (AIIMS) New Delhi , Bhopal and Post graduate institute of medical education and research (PGIMER) Chandigarh.

This has led to the suggestion that vaccination/ re-vaccination with BCG (as BCG vaccination is routinely done in high endemic areas) might have a role in protecting health-care workers and other vulnerable individuals against severe coronavirus disease 2019 (COVID-19).

1.1 Similar Trials In Progress

Randomised controlled trials are already ongoing in the Netherlands and Australia to assess whether BCG-Danish strain reduces the incidence and severity of COVID-19 in health-care workers[17].

Indian Council Of Medical Research (ICMR) has launched a trial which will focus on the vaccine's potential in reducing the chance of Covid-19 death among those who are above age 60. The study will cover 1,450 elderly people in six red and orange zones. Results could be seen as early as March 2021.

Hence, we intend to study the effect of re-vaccination with BCG vaccine in all healthcare workers who will be indirect contact of laboratory confirmed COVID-19 cases including doctors, nursing staff , paramedical staff and sanitization workers in the SGT Hospital which is a Haryana government designated partial COVID hospital.

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2. TRIAL OBJECTIVES AND END POINTS

2.1 Study Objectives

Primary Objective

To assess the protective and prophylactic effect of re-vaccination with BCG vaccine in health care workers who shall be going for COVID-19 isolation ward duty.

Secondary Objective

The secondary objectives of the study are:

1. To study the rate of COVID-19 infection in healthcare workers in direct contact with laboratory confirmed COVID-19 patients re-vaccinated with BCG vaccine versus controls.
2. To assess the severity of COVID-19 in healthcare workers re-vaccinated with BCG vaccine versus controls.
3. To study the change in CD4+ T cell counts and CD8+T cell counts in health care workers before and after BCG vaccination.

3. TRIAL DESIGN AND TIMELINES

3.1 Design

The study would be randomized , non-blinded ,two arm study.

3.2 Study Duration and timelines

6 months duration which includes 5 months of enrollment and 1 month of follow-up.

SGT Hospital is a Haryana government designated partial COVID hospital with total COVID bed strength of 180 beds. A team of healthcare workers including 4 doctors, 12 nursing staff, 2 lab technicians , 4 sanitations workers are deployed every week. Till now, no team of healthcare workers have repeated the duty.

Written and informed consent shall be obtained from the participants involved in the study. The study will include all healthcare workers including doctors, nursing staff, para-medical staff,sweepers and sanitisation workers.

The study would be randomized , non-blinded ,two arm study and shall be conducted over a period of 6 months in which enrolment of the participants would be done for 5 months from the time of approval of the study and 1 month of follow-up.

Health care workers who would be going for COVID-19 ward duties during the period of study shall be randomly distributed in 2 groups i.e the control group and the test group. Prior to enrolment in the study , clinical screening of the healthcare worker would be done and the scar mark of previous BCG vaccine would be checked which is administered to every individual at birth as per National Immunization schedule, and the healthcare workers would be randomly distributed in the study groups. Baseline CD4+ T – cell count & CD8+ T-cell

count would be recorded for the test group and after that, BCG vaccine would be administered 1 week prior to COVID-19 ward duty as per standard protocol.

Method of Administration

BCG vaccine would be administered in a dose of 0.1mg in 0.1 ml volume which shall be injected intradermally using a "Tuberculin" syringe (Omega microstat syringe fitted with a 1cm steel 26 gauge intradermal needle) just above the insertion of deltoid muscle on the left upper arm.

All health care workers receiving vaccine would be informed about the complications associated with vaccination such as ulceration at the site of vaccination ,suppurative lymphadenitis , local abcess formation etc.

Outcome parameters would be :- rate of infection of COVID-19 in healthcare workers re-vaccinated with BCG as compared to controls, change in the CD4+ T- cell count and CD8+T-cell count – before vaccination and after 6 weeks.

There shall be 4 encounters with the participants as described below with the purpose of encounters :-

Encounter-1	Encounter-2	Encounter-3	Encounter-4
Clinical screening of the healthcare worker Enrollment in the applicable group Scar mark of previous BCG vaccination Estimation of baseline CD4+ T cell counts and CD8+ T cell counts.	Administration of BCG vaccine 1 week prior to COVID-19 isolation ward duty. Physical signs and vitals of the healthcare workers would be recorded.	All healthcare workers would be quarantined for a period of 1 week after the COVID-19 isolation ward duty and their nose and oropharyngeal swab would be sent for RT-PCR on Day-7 of their quarantine. All healthcare workers would be investigated about development of any new symptoms. Physical signs and vitals of the healthcare workers would be recorded.	Follow-up at 6 weeks for repeat estimation of CD4+ T cell counts and CD8+ T cell counts. All healthcare workers would be investigated about development of any new symptoms. Physical signs and vitals of the healthcare workers would be recorded.

For the estimation of CD4+ T Cell Count and CD8+ T cell count , blood samples would be

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analyzed by a commercial laboratory in the SGT campus , as they will bring the FACs scanner to our laboratory for the purpose of this study. Participants will be followed up after 1 month. All the participants who will be re-vaccinated with BCG Vaccine are healthy individuals. Hence, no clinical performa has been included.

4. SELECTION AND WITHDRAWAL OF PATIENTS

4.1 Number of Participants

Total 400 healthcare workers would be randomized in the study with 200 participants in each group. A detailed study would be conducted later with increased and adequate sample size.

4.2 Inclusion Criteria

1. Adult patients more than 18 years of age,
2. Health care workers including doctors, nursing staff, para – medical staff and sanitation workers who shall be going for the COVID-19 isolation ward duty.
3. Female healthcare workers who are currently using reliable methods of contraception (barrier methods and intrauterine contraceptive device), with a negative urine pregnancy test during screening and agree to informed compliance of contraceptive method until at least 3 months post-revaccination with BCG.
4. The participants must be able and willing to comply with the study protocol, available and willing to complete all the study assessments and must have signed an Informed Consent Form.

4.3 Exclusion Criteria

1. Pregnant and / or lactating female healthcare workers.
2. A family history of congenital or hereditary immunodeficiency.
3. History of dialysis, silicosis, solid organ transplantation such as renal or cardiac transplants, and disorders of the heart, or nervous system, or other metabolic inflammatory conditions, psychiatric, occupational problems that make it unlikely that the patients will comply with the protocol as determined by the investigator.
4. History of administration of any immunoglobulins, any immunotherapy (antineoplastic chemotherapy, radiation therapy, immunosuppressants to induce tolerance to transplants, and corticosteroids use) and/or any blood products within the 3 months preceding study..
5. Presence of any severe systemic/autoimmune disorders as determined by medical history and/or physical examination at the time of screening, which in the judgment of the Investigator would compromise the patient's health or is likely to result in nonconformance to the protocol or a patient's ability to give written informed consent.

4.4 Withdrawal Criteria and Premature Termination

The enrolled patient will be withdrawn or prematurely terminated from the study in the following conditions:

1. Participant withdraws consent.
2. Any intolerable adverse event

5. Investigational Product

The investigational product is a vial freeze dried BCG vaccine which shall be reconstituted with 1ml of sterile 0.9% w/v Sodium Chloride solution at the time of administration.

5.1 Injection Related Adverse Events

All health care workers receiving vaccine would be informed about the complications associated with vaccination such as ulceration at the site of vaccination ,suppurative lymphadenitis , local abcess formation etc. which resolves by 2-3 weeks. The participant would be assured of the harmless nature of the lesion. Appropriate therapy would be given till the adequate resolution of the lesion, in case it fails to resolve spontaneously.

6. PRECAUTIONS

6.1 Precautions and Warnings

BCG vaccine is not recommended to be administer via Intravenous, subcutaneous, intramuscular injection.

7. ASSESSMENT

The chronological order and frequency of all required assessments are summarized in the study calendar (refer Table 1).

7.1 Detailed Description of the Assessments

7.1.1 Baseline

The nature of the study will be explained to the patient and /or his/her legal representative (s) and a signed and dated written informed consent form will be obtained before any study related procedures are performed on the patient.

These procedures will be performed prior to first dose of study medication (Treatment day 1) to determine the preliminary eligibility of the patient for the study. The following data need to be recorded in the case report form (CRF):

1. Date of signed informed consent form
2. Serum or urine pregnancy test performed for women of childbearing potential
3. Demographics: patient's gender, date of birth and ethnic group
4. Medical history and current medical status: Pertinent patient history such as medical condition predisposing patient to fungal infection (e.g. underlying disease) and existing base line

conditions

5. Vital signs (including body temperature, blood pressure and pulse rate)
6. Physical examination
7. Laboratory evaluation (estimation of CD4+T cell counts, CD8+T cell counts and nasal or oropharyngeal swab) as per investigator's discretion, if available.
8. If the patient complies with inclusion and exclusion criteria, a randomization number will be assigned and this will be recorded in CRF.
9. All concomitant medications taken within two weeks prior to first dose of study medication will be recorded in the CRF.
10. Clinical assessment

Documentation of COVID-19 by clinical signs and symptoms as per hospital practice.

7.1.2 Assessment at the End of Therapy

The following data should be recorded in the CRF in case of patient completed the study

1. Physical examination & Vital signs
2. Development of any symptoms suggestive of COVID-19 infection.
3. Severity of infection of COVID-19
4. Estimation of CD4+T cell count and CD8+T cell counts after 6 weeks.

Any laboratory investigation shall be documented if performed.

7.2 Efficacy Assessment

Efficacy will be determined by the prevention in development of COVID-19 infection and increase in the CD4+ T cell counts and CD8+T cell counts.

7.3 Safety Assessment

Safety will be assessed from prevention of development of COVID-19 infection as compared to control group and change in the CD4+ T cell counts and CD8+T cell counts after revaccination as compared with the baseline CD4+ T cell counts and CD8+ T cell counts.

7.4 Laboratory Examination

For the estimation of CD4+ T Cell Count and CD8+ T cell count , blood samples would be analyzed by a commercial laboratory in the SGT campus , as they will bring the FACs scanner to our laboratory for the purpose of this study.

7.5 Additional Measurements

Any clinically significant laboratory data measured in the study should be recorded in the "Unscheduled Laboratory" section in the CRF. The worsening of the underlying disease has to be recorded in the "Adverse Event"section in the CRF.

8. ADVERSE EVENT REPORTING

8.1 Adverse Events

Adverse Event: ICHE6 defines an AE as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product regardless of its causal relationship to the study treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of medicinal (investigational) product. The occurrence of an AE may come to the attention of study personnel during study visits and interviews of a study recipient presenting for medicalcare, or upon review by a study monitor.

All AEs including local and systemic reactions not meeting the criteria for "serious adverse events" should be captured on the appropriate CRF. Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product and time of resolution/ stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Any medical condition that is present at the time that the patient is screened should be considered as baseline and not reported as an AE. However,if it deteriorates at any time during the study, it should be recorded as an AE.

All AEs must be graded for severity and relationship to study product.

Severity of Event: The clinician using a protocol defined grading system will assess all AEs. For events not included in the protocol defined grading system, then the following guidelines will be used to quantify intensity.

- Mild: events require minimal or no treatment and do not interfere with the patient's daily activities.
- Moderate: events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- Severe: events interrupt a patient's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually incapacitating.
- Lifethreatening: any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e. it does not include a reaction that had it occurred in a more severe form, might have caused death.

Changes in the severity of an AE should be documented to allow an assessment of the duration of the event at each level of intensity to be performed. Adverse events characterized as intermittent require documentation of onset and duration of each episode.

Relationship to Study Products: The clinician's assessment of an AE's relationship to test article (vaccine or study drug) is part of the documentation process, but it is not a factor in determining what is or is not reported in the study. If there is any doubt as to whether a clinical observation is an AE, the event should be reported. All AEs must have their relationship to study product assessed using the terms: associated or not associated. In a clinical trial, the study product must always be suspect. To help assess, the following guidelines are used.

- Associated–The event is temporally related to the administration of the study product and no other etiology explains the event.
- NotAssociated–The event is temporally independent of study product and/ or the event appears to be explained by another etiology.

8.2 Serious Adverse Events

Serious Adverse Event (SAE): An SAE is defined as an AE that meets one of the following conditions:

- Death during the period of protocol defined surveillance
- Life- threatening event (defined as a subject at immediate risk of death at the time of the event)
- An event requiring in patient hospitalization or prolongation of existing hospitalization during the period of protocol defined surveillance
- Results in congenital anomaly or birth defect
- Results in a persistent or significant disability/ incapacity
- Any other important medical event that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse experience when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

All SAEs will be:

- Recorded on the appropriate SAE CRF
- Followed through to resolution by a study clinician
- Reviewed and evaluated by a study clinician

8.3 Detection, Reporting and Responsibilities

8.3.1 Serious Adverse Events

Any AE considered serious by the Investigator or which meets the aforementioned criteria must be documented on a Serious Adverse Event Form. The investigator should ensure that information reported immediately by telephone or other means and

information entered in the case report form are accurate and consistent. In accordance with ICH GCP, the investigator is obliged to notify the IEC of any unexpected serious adverse reactions. This will be followed by a written report that gives additional information (using SAE report form) including a description of the adverse event, onset, date and type, duration, severity, cause-effect relationship with the drug, outcome, measures taken (symptomatic treatment, discontinuation of treatment) and all other relevant clinical and laboratory data. For all SAEs, the Investigator is obligated to pursue and provide information as requested by CRO, in addition to that on the CRF. Any SAE or death must be reported immediately independent of the circumstances or suspected cause if It occurs or come to the attention of the investigator at any time during the study through o ut the last follow up visit required by the protocol.

All AEs (including laboratory abnormalities) will be recorded in the Case Report Form. After the trial has been completed or terminated, all recorded adverse events will be listed, evaluated and discussed in the final report.

9. STASTISTICS

All the data will be analyzed using SAS software version 9.4 or higher. Quantitative data will be expressed as mean and standard deviation whereas, categorical data will be expressed as number and percentage. Descriptive analysis (Tabulations, graphs & charts, proportions, percentage etc.) will be performed to obtain the baseline parameters. All the quantitative variables will be analyzed using paired T test or one way ANOVA. P value of <0.05 will be considered as significant.

10. STUDY MEDICATION SUPPLY, HANDLING AND STORAGE

10.1 Supply of Investigational Product

The investigational product (BCG Vaccine) would be supplied by the SGT Hospital.

10.2 Packaging

Presentation: BCG Freeze dried vaccine packaged along with 1ml suspension of 0.9% w/v Sodium Chloride

10.3 Storage and Stability

The investigational product (BCG Vaccine) should be stored in a secure area according to institutional and Good Clinical Practice guidelines. It is the Investigator's responsibility to ensure that authorized and trained personnel dispense the investigational product.

The product is when stored at 2-8^{0}C (4^{0}C).
The IP should be stored at the temperature between +2^{0}C to +8^{0}C in a refrigerator, care

should be taken to avoid freezing.

10.4 Drug Accountability

BCG vaccine administration will be recorded in the participant's medical record and the CRF.

11. PUBLICATION POLICY

Following completion of the study, the Principal Investigator is expected to publish the results of this research in a scientific journal. The clinical trial will be registered in Clinical Trial Registry of India and/ or clinical trial.gov (sponsored by the National Library of Medicine).

12. ETHICAL CONSIDERATIONS

12.1 Ethical Standards

The Investigator will ensure that this study is conducted in conformity with the principles set forth in ICMR's Ethical Guideline for Biomedical Research on Human Subject, International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18,1979) and codified in 45CFR Part46 of Federal Regulations 25691 (1997) and/ or the ICHE6; R2.

12.2 Ethics Committee Approval

Each participating institution/ hospital must get approval of this protocol and the associated informed consent documents and recruitment material from an appropriate Independent Ethics Committee or Institutional Ethics Committee (IEC). Any amendments to the protocol or consent materials must also be approved before they are placed in to use.

12.3 Informed Consent Process

Informed consent is required for all subjects participating in a clinical study. In obtaining and documenting informed consent, the Investigator should comply with applicable regulatory requirements and should adhere to ICMR's Ethical Guidelines for Biomedical Research Involving Human Subjects (2002), and/ or ICH-GCP. Prior to the beginning of the trial, the investigator should have the IEC's written approval/ favorable opinion of the written informed consent form(s), and any other written information to be provided to the subjects.

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continuing through out the individual's study participation.

Extensive discussion of risks and possible benefits of this therapy will be provided to the subjects and their families. Consent forms describing in detail the study interventions/ products, study procedures, and risks are given to the subject and written documentation of informed consent is required prior to starting intervention/ administering study product. Consent forms must be in a local language or a language, which volunteers can easily understand. Consent form must be IEC- approved and the subject will be asked to read and review the document. Upon reviewing the document, the Investigator will explain the research study to the subject and answer any questions that may arise. The subjects will sign the informed consent document prior to any procedures being done specifically for the study. The subjects should have the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. The subjects may withdraw consent at any time through out the course of the trial. A copy of the informed consent document will be given to the subjects for their records. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study. Signature of the subjects will be obtained in the respective consent form prior to the start of any procedure. In case of illiterate patient, thumb impression of prospective subject and signature of impartial witness will be taken. The illiterate subject should be informed about the trial to the extent compatible with the subject's understanding. To achieve uniformity, right hand thumb impression will be taken for female subject and left hand thumb impression will be taken for male subject.

12.4 Subject Confidentiality

Subject confidentiality is strictly held in trust by the participating investigators, their staff and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to the clinical information relating to participating subjects. The study protocol, documentation, data, and all other information generated will be held in strict confidence.

The study monitor or other authorized representatives of the EC may inspect all documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) and pharmacy records for the subjects in this study. The clinical study site will permit access to such records.

13. QUALITY CONTROL AND QUALITY ASSURANCE

The trial site involved in the study is required to have a plan in place for assuring the quality of the research being conducted.

The trial site should have standard operating procedures (SOPs) for quality management, which describes:

- How data will be evaluated for compliance with the protocol and for accuracy in relation to source documents.
- The documents to be reviewed (eg,CRFs, clinic notes, product accountability), who is responsible, and the frequency for reviews should be identified, either in a formal

quality management plan or in site SOPs.

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SUBJECT INFORMATION SHEET

- STUDY TITLE: "To study the protective effect of re-vaccination with BCG against COVID-19 in health care workers"
- INVESTIGATOR: Dr. DPS Sudan
  Professor & Head
  Department Of Pulmonary Medicine

- INTRODUCTION:- You are being invited to take part in this study. Before you decide it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

- PURPOSE OF RESEARCH: The purpose of this research is to study the protective effect of re-vaccination with BCG in healthcare workers against COVID-19.

- TYPE OF RESEARCH INTERVENTION : This study involves you if you are a doctor/ nursing staff/ paramedical staff/ sanitation worker involved in the care of COVID-19 patients.

- PARTICIPANT SELECTION: You are a part of this study as you are a health care worker doctor/ nursing staff/ paramedical staff/ sanitation worker involved in the care of COVID-19 patients.

- VOLUNTARY PARTICIPATION: It is upto you to decide whether or not to take part, taking part in the study is entirely voluntary. If you do decide to take part you will be

given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any timeand without giving a reason. This will not affect the standard of care you receive.

- PROCEDURE: This is an analytical study including healthcare workers doctors/ nursing staff/ paramedical staff/ sanitation workers who are involved in the care of COVID-19 patients.. You shall be enrolled in this study if you are yet to go for COVID ward duty, , your clinical screening would be done and the scar mark of previous BCG vaccination would be checked assuming that you have been vaccinated with BCG at birth as per National Immunization Schedule, then you would be randomly distributed in the study arms. If you have been enrolled in the control group, then you shall not be re-vaccinated with BCG. If you belong to the test groupyour baseline CD4+ T cell counts and CD8+ T cell counts shall be estimated prior to BCG administration. You shall be revaccinated with BCG 1 week prior to the COVID ward duty. There shall be repeat estimation of your CD4+ T cell counts and CD8+ T cell counts at 6 weeks . You shall be followed up for the duration of 1 month. There have been ICMR recommendation dated March 20, 2020 about the prophylaxis with hydroxy-chloroquine for asymptomatic healthcare workers involved in the care of either suspected or laboratory confirmed COVID-19 patients. This study endorses free will of the participant if he/she wants to take the prophylaxis or not.

- DURATION: The study will be conducted over a period of 6 months.

- SIDE EFFECTS: There are few minimal side effects associated with administration of BCG vaccine like local injection site swelling, pain, abscess formation, ulceration. However, in case the need arises and these minor side effects do not resolve spontaneously, adequate supportive treatment would be provided by the hospital and free of cost.

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- DISADVANTAGES AND RISKS: There are no possible disadvantages and risks associated with the study.

- BENEFITS OF PARTICIPATION: Thestudy is considered helpful to provide better knowledge about the prevention of disease which has become a global health emergency. With the help of this study we would be able to provide an economical solution for the prevention of disease when the world economy is spending billions of dollars for the development of vaccine. The study is conducted for advancement of knowledge and keeping in view the public interest at large.

- REIMBURSEMENTS: There is no cost or time involved in conducting this study, as this study is based on re-vaccination with BCG if you are a part of test group.
    - CONFIDENTIALITY: Informed consent shall be obtained and you will be kept fully appraised of all the consequences. All the information that you provide during the study will be kept confidential.

    - SHARING THE RESULTS: The knowledge that we get from doing this study will be shared with you. We can publish these results and present it in the conferences, so that people can benefit from this research. Confidential information will not be shared.

    - RIGHT TO REFUSE OR WITHDRAW:You can refuse to take part in this study or withdraw your participation in study anytime you want.

    - RISK OF DISCOVERY OF BIOLOGICALLY SENSITIVE INFORMATION:There is no risk of disclosing biologically sensitive information in this study.

    - PUBLICATION, IF ANY, INCLUDING PHOTOGRAPHS AND PEDIGREE CHARTS:There can be display of results . pedigree charts of research , without disclosing your personal identity.

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- PAYMENT FOR RESEARCH-RELATED INJURIES:There is minimal risk factor of study related injuries. If it happens, Institution will provide the compensation and free treatment for the same.

- ALTERNATIVES TO PARTICIPATION: You reserve the right to opt out at any point of time during the course of the study without prejudice of your right to undergo further treatment at SGT Hospital & Research institute.

- RESPONSIBILITY OF INVESTIGATORS: The study will be conducted according to standard ICMR guidelines.

- CONTACTS: Please contact Dr.DPS Sudan as Principal Investigator at 7042495699 and email hod.tbchest@sgtuniversity.orgfor all research related matters and any further information required for study concerned.
  Thank You for taking part in the study !

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SGT University
Budhera, Gurugram

Dr. DPS Sudan
HOD & Professor
Department of Pulmonary Medicine
SGT Medical College,
Hospital & Research Institute
SGT University
Gurugram, Haryana

सूचनापत्र

अध्ययनशीर्षक:स्वास्थ्य- कर्मी में कोविड-19 के खिलाफ बी.सी.जी के साथ पुन: टीकाकरण के सुरक्षात्मक प्रभाव का अध्ययन

पर्यवेक्षक: डॉ डी.पी.एस सुदन
एचओडी और प्रोफेसर
श्वासरोगविभाग

परिचय: - आपको एक खोज में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले यह समझना आपके लिए महत्वपूर्ण है कि अध्ययन शोध क्यों किया जा रहा है और इस में क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय लें और यदि आप चाहें तो दोस्तों, रिश्तेदारों और अपने इलाज चिकित्सक / परिवार के डॉक्टर से चर्चा करें। जो भी चीज स्पष्ट नहीं है वह आप हमसे पूछ सकते हैं या यदि आप अधिक जानकारी चाहते हैं। यह तय करने के लिए समय लें कि आप भाग लेना चाहते हैं या नहीं।

- **खोज का उद्देश्य**: इस शोध का उद्देश्य कोविड-19 के खिलाफ स्वास्थ्य कर्मी में बी.सी.जी के साथ पुन: टीकाकरण के सुरक्षात्मक प्रभाव का अध्ययन करना है|

- **खोज का प्रकार**: यह अध्ययन आपको शामिल करता है यदि आप एक डॉक्टर / नर्सिंगस्टाफ / पैरामेडिकल स्टाफ / स्वच्छता कर्मचारी हैं जो कोविड-19 रोगियों की देखभाल में शामिल हैं।

- **प्रतिभागी चयन**: आप इस अध्ययन का एक हिस्सा हैं क्योंकि आप कोविड-19 रोगियों की देखभाल में शामिल एक स्वास्थ्य देखभाल कार्यकर्ता डॉक्टर / नर्सिंग स्टाफ / पैरामेडिकल स्टाफ / स्वच्छता कार्यकर्ता हैं।

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• **<u>स्वैच्छिक भागीदारी</u>:** यह तय करना आप पर निर्भर है कि भाग लेना है या नहीं, अनुसंधान में भाग लेना पूरी तरह से स्वैच्छिक है। यदि आप भाग लेने का निर्णय लेते हैं तो आप को यह जानकारी पत्र दिया जाएगा और सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का फैसला करते हैं तो आप किसी भी समय बिना किसी कारण के वापस लेने के लिए स्वतंत्र हैं। यह आपके द्वारा प्राप्त देखभाल के मानक को प्रभावित नहीं करेगा।

<u>प्रक्रिया</u> : यह एक विश्लेषणात्मक अध्ययन है, जिसमें स्वास्थ्य-कर्मी डॉक्टर / नर्सिंग स्टाफ / पैरामेडिकल स्टाफ़ / सैनिटेशन वर्कर शामिल हैं, जो कोविड-19 रोगियों की देखभाल में शामिल हैं .. यदि आपको कोविड वार्ड ड्यूटी के लिए अभी तक जाना है, तो आप को इस अध्ययन में शामिल किया जाएगा, आपकी नैदानिक जांच की जाएगी और पिछले बीसीजी टीकाकरण के निशान को यह मानते हुए जाँचा जाएगा कि आपको राष्ट्रीय टीकाकरण अनुसूची के अनुसार जन्म के समय बीसीजी के साथ टीका लगाया गया है, उसके बाद आपको अध्ययन में बेतर तीब ढंग से वितरित किया जाएगा। यदि आपको नियंत्रण समूह में नामांकित किया गया है, तो आपको बीसीजी के साथ पुन: टीकाकरण नहीं किया जाएगा। यदि आप परीक्षण समूह से संबंधित हैं तो आपका आधार रेखा CD4 + T सेल काउंट और CD8 + T सेल काउंट का अनुमान लगाया जाएगा। आपको कोविड वार्ड ड्यूटी से 1 सप्ताह पहले बी.सी.जी से पुन: टीकाकरण किया जाएगा। आपके CD4 + T सेल काउंट्स और CD8 + T सेल काउंट्स का 6 सप्ताह में दोहराव अनुमान होगा। आपको 1 महीने के अंतराल की अवधि के लिए पालन किया जाएगा। संदिग्ध या प्रयोगशाला की पुष्टि की गई कोविड-19 रोगियों की देखभाल में शामिल स्पर्शोन्मुख स्वास्थ्य सेवा श्रमिकों के लिए हाइड्रोक्सी-क्लोरोक्वीन के साथ प्रोफिलैक्सिस के बारे में 20 मार्च, 2020 को आई . .सी.एम.आर की दिशानिर्देश जारी
की गई है।यह अध्ययन प्रतिभागी की स्वतंत्र इच्छा का समर्थन करता है कि वह प्रोफिलैक्सिस लेना चाहता है या नहीं।

•**<u>अवधि:</u>** अध्ययन 6 महीने की अवधि में आयोजित किया जाएगा।

•**<u>साइड-इफेक्ट्स</u>**: स्थानीय इंजेक्शनसाइटसूजन, दर्द, फोड़ा गठन, अल्सर जैसी बी.सी.जी वैक्सीन के प्रशासन से जुड़े कुछ न्यूनतम दुष्प्रभाव हैं। हालाँकि, यदि कोई समस्या उत्पन्न होती है और ये मामूली

दुष्प्रभाव अनायास नहीं सुलझते हैं, तो अस्पताल द्वारा पर्याप्त सहायक उपचार और मुफ्त उपलब्ध कराया जाएगा।

• **विवाद और जोखिम:** खोज से जुड़े कोई भी संभावित नुकसान और जोखिम नहीं हैं।

भागीदारी का लाभ: अध्ययन को बीमारी की रोक थाम के बारे में बेहतर ज्ञान प्रदान करने के लिए सहायक माना जाता है जो वैश्विक स्वास्थ्य आपातकाल बन गया है। इस अध्ययन की मदद से हम बीमारी की रोक थाम के लिए एक किफायती समाधान प्रदान करने में सक्षम होंगे जब विश्व अर्थव्यवस्था टीका के विकास के लिए अरबों डॉलर खर्च कर रही है। अनुसंधान ज्ञान की प्रगति और बड़े पैमाने पर जनता के हित को ध्यान में रखते हुए आयोजित किया गया है।

भागीदारी के लिए विकल्प: आप एस.जी.टी. अस्पताल और अनुसंधान संस्थान में आगे के उपचार से गुजरने के अपने अधिकार के पूर्वाग्रह के बिना अध्ययन के दौरान किसी भी समय बाहर निकलने का अधिकार सुरक्षित रखते हैं।

प्रतिपूर्ति: इस अध्ययन के संचालन में कोई लागत या समय शामिल नहीं है।

परिणाम साझा करना: इस शोध को करने से हमें जो ज्ञान मिलता है वह आपके साथ साझा किया जाएगा | हम इन परिणामों को प्रकाशित कर सकते हैं और इसे सम्मेलनों में प्रस्तुत कर सकते हैं, ताकि लोग इस शोध से लाभ उठा सकें। गोपनीय जानकारी साझा नहीं की जाएगी।

इनकार करने या निकालने काअधिकार:
आपइसअध्ययनमेंभागलेनेसेइनकारकरसकतेहैयाकिसीभीसमयअध्ययनमेंअपनीभागीदारीकोरोकसकतेहै।

जैविकरूपसेसंवेदनशीलजानकारीकीखोजकाजोखिम:
इसअध्ययनमेंजैविकरूपसेसंवेदनशीलजानकारीकाखुलासाकरनेकाकोईखतरानहींहै।

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प्रकाशन,वंशावलीचार्टसहितप्रकाशन, यदिकोईहो,
तोपरिणामप्रदर्शितहोसकतेहैंआपकीव्यक्तिगतपहचानकाखुलासाकिएबिनाशोधकेवंशावलीचार्ट।

अनुसंधानसेसंबंधितचोटोंकेलिएभुगतान:
अनुसंधानसेसंबंधितचोटोंकान्यूनतमजोखिमकारकहै।यदिऐसाहोताहै,
तोसंस्थानइसकेलिएकॉपेन्सेशनऔरमुफ्तउपचारप्रदानकरेगा।

जांचकर्ताओंकीजिम्मेदारी: अध्ययनICMRदिशानिर्देशोंकेअनुसारआयोजितकियाजाएगा।

गोपनीयता:आपकीसूचितसहमतिप्राप्तकीजाएगीऔरआपकोसभीपरिणामोंकापूरीतरहसेमूल्यांकनकियाजाएगा।अध्ययनकेदौरानप्रदानकीजानेवालीसारीजानकारीगोपनीयरखीजाएगी।

संपर्क:यदिकिसीभीसमयअध्ययनअवधिकेदौरानआपकोलगताहैकिआपकोपर्याप्तरूपसेसूचितनहींकियागयाहै, तोकृपयासंपर्ककरनेमेंसंकोचनकरें।

संपर्क:कृपया7042495699 परप्रिंसिपलइनवेस्टिगेटरकेरूपमेंडॉ।डी.पी.एससुदानसेसंपर्ककरेंऔरसंबंधितशोधमामलोंकेलिए hod.tbchest@sgtuniversityपरईमेलकरेंऔरसंबंधितअध्ययनकेलिएआवश्यककोईऔरजानकारीप्राप्तकरें।

डॉडी.पी.एससुदान
एचओडी और प्रोफेसर
श्वासरोगविभाग
एस.जी.टी.मेडिकलकॉलेज,एस.जी.टी.मेडिकलकॉलेज,
अस्पतालऔरअनुसंधानसंस्थान
एस.जी.टी. विश्वविद्यालय
गुरुग्राम, हरियाणागुरुग्राम, हरियाणा

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CONSENT FORM

I have read and understood the foregoing information. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected. I understand that the principal investigator and others working on their 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. However, I understand that my identity will not be revealed in any information released to third parties or in publication. 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.

Name of Participant_____

Signature of Participant _____

Date _____

Witness

Signature

Name: _____ Address: _____

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.Participant's blood sample would be withdrawn for the estimation of CD4+ T cell count and CD 8+ T cell count.

2.Participant would be re-vaccinated with BCG vaccine.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF will be provided to the participant.

Name of Researcher/person taking the consent- Dr.

Signature of Researcher /Person taking the consent_____

Date _____

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सहमति पत्र

मैंने पूर्वगामी जानकारी को पढ़ और समझ लिया है। मुझे इसके बारे में प्रश्न पूछने का अवसर मिला है और मैंने जो भी प्रश्न पूछे हैं, उनका उत्तर दिया गया है जिससे मैं संतुष्ट हूँ । मैं समझता/समझती हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं बिना किसी कारण के और बिना किसी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए, किसी भी समय वापस लेने के लिए स्वतंत्र हूं। मैं समझता/समझती हूं कि मुख्य जांचकर्ता और उनकी तरफ से काम करने वाले अन्य लोगों, नैतिकता समिति और नियामक प्राधिकरणों को वर्तमान अध्ययन के संबंध में और मेरे संबंध में किए जा सकने वाले किसी और शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड देखने की अनुमति की आवश्यकता नहीं होगी। , भले ही मैं परीक्षण वापिस ले लूँ । हालांकि, मैं समझता/समझती हूं कि मेरी पहचान तीसरे पक्ष या प्रकाशन में जारी की गई किसी भी जानकारी में प्रकट नहीं होगी। मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्य के लिए है।

प्रतिभागी का नाम_____

प्रतिभागी का हस्ताक्षर_____

तारीख _____

गवाह_____

हस्ताक्षर_____

नाम पता: _____

शोधकर्ता / सहमति लेने वाले व्यक्ति का वक्तव्य

मैंने संभावित प्रतिभागी के सूचना पत्रक को सटीक रूप से पढ़ कर सुनाया है, और मेरी जानकारी के अनुसार प्रतिभागी यह सुनिश्चित करता है कि उसके साथ निम्नलिखित परीक्षण किये जायेंगे:

1. सीडी 4+ टीसेलकाउंटऔरसीडी 8+ टीसेलकाउंटकेआकलनकेलिएप्रतिभागीकेरक्तकेनमूनेकोलियाजाएगा।

2. प्रतिभागीकोबीसीजीवैक्सीनका टीकाफिरसेलगायाजाएगा।

मैं पुष्टि करता/ करती हूं कि प्रतिभागी को अध्ययन के बारे में प्रश्न पूछने का अवसर दिया गया है, और प्रतिभागी द्वारा पूछे गए सभी प्रश्नों का सही उत्तर दिया गया है और मैं पुष्टि करता/ करती हूं कि व्यक्ति को सहमति देने में मजबूर नहीं किया गया है, और सहमति स्वतंत्र रूप से और स्वेच्छा से दी गई है।

इस आईसीएफ की एक प्रति प्रतिभागी को प्रदान की जाएगी।

जाँचकर्ता का नाम / सहमति लेने वाले व्यक्ति का नाम - डॉ

जाँचकर्ता के हस्ताक्षर / सहमति लेने वाले व्यक्ति के हस्ताक्षर_____

तारीख _____

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PROJECT'S ESTIMATED COST

Cost of 1 test = Rs. 1500

No. Of tests for each person = 02

Cost of total 2tests for 1 person = 1500 x 2=Rs. 3000

Cost for 200 participants of study = Rs. 600000

BCG Vaccine and Syringe = Rs. 15 / person

BCG Vaccine and syringe for 200 perons = Rs. 15x 200= Rs. 3000

Total Estimated Budget = Rs 6,03,000

	Price per Unit	Qty	Total (in Rs.)
CD4+ T cell count and CD 8+ t cell counts	1500	400 (2 tests / person)	6,00,000
BCG Vaccine & Syringe	15	200	3000
Estimated Total Cost			6,03,000

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