Critical RTI Responses to be seen by Lawyers

Face Coverings, Masks

INCMR/A/E/21/00177 dated 24.Sep.2021

Detrimental_Effec
ace_Coverings_ICM

- **Questions**
  - Please provide scientific proof of the mechanism by which asymptomatic people spread this so-called covid disease. Peer-reviewed papers and/or official documentation from health agencies is required.
- **Answer**
  - **I am providing few links regarding possibility of asymptomatic covid-19 person, please click the following links:**
    - https://www.ncdc.gov.in/showfile.php?lid=363

General Public/care providers: There is no scientific evidence to show health benefit of using Disposable Triple layer mask for general public. In fact erroneous use of masks or continuous use of a Disposable Triple layer mask for longer than 6 hours or repeated use of same mask may actually further increase risk of infection.

- Conclusion: The last document actually states that face coverings are dangerous for the general public. Also, no scientific proof provided for spread by asymptomatic people

MOHFW/R/E/21/03259 dated 03.Sep.2021

- **Questions**
  - Mask voluntary hai ya compulsory public place par

Harmful_Effects_F
overings_MOHFW(

- **Answers**
  - **The use of mask/ face cover has been made mandatory by Ministry of Home Affairs in various orders issued from time to time under Disaster Management Act, 2005.**
  - **Prolonged use of masks (especially N-95 mask) has been found to be associated with headache, worsening of acne, skin irritation, erosions due to pressure effect etc**

- **Conclusion: Despite the ill effects of wearing face coverings, they are still being recommended. Also, they are citing WHO and claiming that face coverings do not lead to CO2 intoxication nor oxygen deficiency. No science or research is required to know that face coverings cause oxygen deficiency and CO2 intoxication**

NIOVP/R/E/21/00012 dated 11.May.2021

- **Questions**
  - What is the size of the Covid-19 virus i.e. the length of the virus end to end?
  - What is the pore size of the standard as well as surgical masks?

Pore_Size_NIOVP_ 11May2021ST

- **Answers**
  - **SARS-CoV-2 virus is round shaped virus with an average size of 70-80 nm.**
  - **Pore size of standard surgical mask and N95 mask is 0.3 - 10 µm & 0.1 - 0.3 µm respectively.**

- **Conclusion: As per NIOVP, 4 to 130 viral particles can easily get in and out of standard surgical masks. And 1 to 4 viral particles can easily get in and out of N95 masks**

INCMR/R/T/21/00237 dated 29.Apr.2021

- **Questions**
  - According to the current knowledge, the virus SARS-CoV-2 has a diameter of 60 nm to 140 nm [nanometers (billionth of a meter), while medical and non-medical facemasks' thread diameter ranges from 55 µm to 440 µm [micrometers (one millionth of a meter), which is more than 1000 times larger.
  - Due to the difference in sizes between SARS-CoV-2 diameter and facemasks thread diameter (the virus is 1000 times smaller), SARS-CoV-2 can easily pass through any facemask.
  - I would like to know the rationale for asking citizens of India to wear face coverings in public places in the light of the above.
  - **In addition, I would like to know if ICMR or its agencies have evaluated the risk to humans of wearing face coverings when it comes to hypoxia (inadequate oxygen supply at the tissue level), hpercapnia (too much carbon dioxide in the blood), and inhalation of all sorts of toxins from face coverings such as micro plastics, PolyTetraFluoroEthylene (PTFE), cobalt, among others. If yes, kindly provide links to the studies.**

INCMR/R/T/21/00237 dated 29.Apr.2021

- **Answers**
  - 1. Medical and non-medical masks are capable of filtration and retention of droplets, through which SARS-CoV-2 spreads. Masks are an important part of droplet and standard precautions and are helpful in preventing COVID-19 transmission and saving lives, along with physical distancing and hand hygiene.
  - **2. ICMR has conducted no such study.**

    The World Health Organization states that use of face mask does not cause Oxygen deficiency. This information is available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters#oxygen

- **Conclusion: ICMR has not conducted any studies on the detrimental effects of face coverings**

(This was appealed on Aug.22.2021, but no response yet)

No_Studies_Face_
erings_Detrimenta

INCMR/A/E/21/00163 dated 08.Dec.2021

- **Questions**
  - Viral particles are in nano meters and can easily pass in and out of all face coverings, whose openings are in micrometers. Please explain why droplets cannot pass through face coverings.
  - In addition, please respond to the 2nd part of the query. Hypercapnia and inhalation of all kinds of toxins is happening on a daily basis all over the country as people are wearing face coveriingss. This needs to be stopped or ICMR should provide solid evidence that face coverings do not cause any kind of damage to people's health. I have also personally seen people with lots of marks and lesions on account of wearing these face coverings.
  - Also, the WHO information (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters#oxygen) states that "While wearing a medical mask, make sure it fits properly and that it is tight enough to allow you to breathe normally." This is not possible and is contradictory. If worn loosely, there is a better chance of getting enough oxygen. Kindly explain.

INCMR/A/E/21/00163 dated 08.Dec.2021

- **Answers**

  - Transmitted for your perusal

NO RESPONSE RECEIVED – THEY DID NOT TRANSMIT ANYTHING TO US

NIOVP/R/E/21/00012 dated 11.May.2021

- **Questions**
  - 2. Please give copy of research material that proves effectiveness or ineffectiveness of masks during a pandemic.
  - 3. Please give copy of research material that proves effectiveness or ineffectiveness of hand sanitizers during a pandemic.
  - 4. Please give copy of research material that proves effectiveness or ineffectiveness of social distancing during a pandemic.

No_Info_Mask_Effeness_NIOVP_May

- **Answers**
  - This information is not part of our records. For more information you may visit the Ministry of Health and Family Welfare, ICMR websites on www.mohfw.gov.in or www.icmr.gov.in

- **Conclusion: No information available on effectiveness of masks, hand sanitizers, and distancing**

VCRCP/R/E/21/00002 dated 19.May.2021

- **Questions**
  - 2.Please give copy of research material that proves effectiveness or ineffectiveness of masks during a pandemic.
  - 3.Please give copy of research material that proves effectiveness or ineffectiveness of hand sanitizers during a pandemic.
  - 4.Please give copy of research material that proves effectiveness or ineffectiveness of social distancing during a pandemic.
- **Answer**
  - VCRCP has no studies to prove effectiveness of face coverings, sanitizers, and distancing (response to questions 2 through 4)
- **Conclusion: No studies done on effectiveness of the various so-called health measures being imposed on the population**

No_Studies_Effect
ness_Masks_Sanit_I

MOHFW/R/E/21/03781 dated 01.Jul.2021

- **Questions**
  - 1. How much funding has gone into the research that Covid-19 is contagious and spreads from person to person when infected person breathes out air?
  - 2. How much funding has gone into the research that masks are effective to control spread of Covid-19?
  - 3. How much funding has gone into the research on the side-effects of masks on the health i.e. effect on lungs, heart, brain, teeth etc?
- **Answer**
  - The information is not available with ICMR for point no. 01 to 03.
- **Conclusion: No funding has gone into fundamental research (contagion, effectiveness and detrimental effects of face coverings)**

No_Funding_Cont
nMasksICMRJul20

INCMR/R/E/21/00655 dated 11.Aug.2021

Question

- Following details of research done by ICMR on side-effect of masks is requested.
  - 1. ICMR public domain (icmr.gov.in) website link giving this research details or copy of the research material on the side-effects of masks.
  - 2. Amount of funding spent by ICMR on this research.

Answer

- This information is not available with ICMR.

Conclusion: No studies done on the detrimental effects of face coverings

No_Research_Mas
:ffects_ICMRAug2(

CDSCO/R/T/21/00823 dated 07.Oct.2021

- **Question**
  - What is the side effect of disposable blue mask surgical mask.
- **Answer**
  - CDSCO has no such specific information.
- **Conclusion: No information on harmful effects of wearing face coverings from CDSCO also**

No_Info_Harmful_
ts_MasksCDSCO_C

INCMR/R/E/21/00436 dated 16.Jun.2021

Question

- Face masks, hand sanitizers and social distancing are currently mandated to prevent spread of Covid-19. Request for scientific evidence and research material that prove that face masks, hand sanitizers and social distancing are effective measures for Covid-19.

Answer

- The WHO's interim guidance on Mask Use in the context of COVID-19 dated 1 December 2020, reviews significant published literature on mask use to prevent COVID-19 and provides guidance. The studies reviewed are listed in the WHO document. The studies were carried out in different settings (community as well as healthcare settings) and helped formulate the guidance provided by WHO on mask use. This information is available at: https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

Conclusion: No information shared in the Indian context.

No_India_Researc
althMeasuresICMF

Testing, Asymptomatic Individuals (that is, healthy individuals), Delta Variant Testing, Emergency Use

INCMR/R/E/21/00609 dated 11.Aug.2021

- **Question**
  - Request information whether there are adverse effects or side effects of the RT-PCR tests and if ICMR has conducted studies on the same.
- **Answer**
  - Repeated testing at very frequent intervals **can lead to injury in nasal cavity and throat.**
  - Conclusion: Direct admission of possibility of injury

Detrimental_Testi
sym_Skew_ICMR_A

INCMR/R/E/21/00609 dated 11.Aug.2021

Question

- Request count of Covid-19 tests done all over India. Request split of this data between the different kinds of tests and between the symptomatic status.

Answer

- Symptomatic status count of people who tested Covid-19 positive –Data

Symptomatic status count of people who tested Covid-19 positive -Data		
	Count of symptomatic people who tested positive	Count of asymptomatic people who tested positive
RT-PCR	8047959	232861528
Rapid Antigen	4255956	206382651
Other Tests	454275	11361871

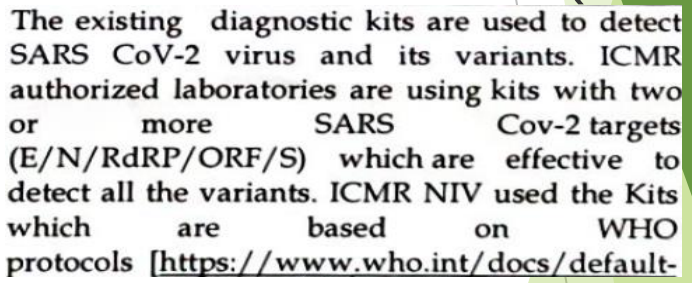
Detrimental_Testi
sym_Skew_ICMR_A

- **Conclusion: 97.2% of the people who tested positive were asymptomatic (that is, they were healthy).**

NIOVP/R/E/21/00065 dated 01.Oct.2021

- **Question**
  - Please provide official documents / scientific papers / test specifications for the testing procedures that are being followed by ICMR-authorized labs and institutions for identifying individuals infected with the delta variant (VoC B.1.167)

No_Test_For_Delta
NIOVP_Oct01_2021


The existing diagnostic kits are used to detect SARS CoV-2 virus and its variants. ICMR authorized laboratories are using kits with two or more SARS Cov-2 targets (E/N/RdRP/ORF/S) which are effective to detect all the variants. ICMR NIV used the Kits which are based on WHO protocols [https://www.who.int/docs/default-

- **Answer**
  - The existing diagnostic kits are used to detect sars cov-2 virus and its variants. Kits being used are based on early 2020 protocols!
- **Conclusion: No specific test available for the so-called delta variant as is apparent. This was appealed (next few slides)**

NIOVP/A/E/21/00012 dated 29.Oct.2021

No_Change_Test_
ocol2021ForDeltaN

- **Question**
  - I am asking for specific testing procedures issued by NIOVP/ICMR to identify positive cases 'infected' by the so-called delta variant of concern (B.1.167). If existing test kits can identify delta 'cases', please provide specific testing procedures issued by NIOVP or ICMR to various labs in India to identify delta 'cases'. I am not asking for generic documents and papers, that too from early 2020 which do not and cannot possibly have any reference to the delta variant of concern.
- **Answer**
  - It is to inform that the test protocol did not change in 2021. The one used during 2020 is still in use for detection of delta variant
- **Conclusion: This is ridiculous. As it is the RT-PCR test is under Emergency Use Authorization (EUA) and these people say they are using it to detect all of nature's variants**

CDSCO/R/E/21/00422 dated 24.Sep.2021

Questions

- 1. Kindly inform if the RT-PCR test kits currently in use in India are fully approved or approved under emergency use authorization or if there is some other kind of approval.
- 2. If not fully approved, then request the steps taken so far, and the steps needed to be done for full approval of RT-PCR test.
- 3. Request all documentation including minutes of meetings towards decision making for the full approval of RT-PCR test kits.

Answer

- It is stated that due to surge in Covid-19, the RT-PCR test kits intended to detection of Covid-19 is approved under expedited review and accelerated / fast approval process as per International practices (Emergency Use Authorization) based on validation of the kit at ICMR designated labs, as per ICMR Guidance document and after examining all requisite documents under the provisions of Drugs & Cosmetics Act, 1940 and Medical Devices Rules-2017.

Conclusion: **Responses not provided for 2 and 3. So, this was appealed (next slide)**

CDSCO/A/E/21/00114 dated 03.Nov.2021

- **Question**
  - Questions 2 and 3 of the RTI asked for steps taken to test RT-PCR kit so that it gets full authorization. These questions are not answered in the RTI reply. If this information is not available kindly state so.
- **Answer**
  - (2) As per conditions, the licenses issued would be effective until control of covid19 outbreak in the country and evaluated for continuation based on the emerging data
  - (3) CDSCO has no information

RT-PCR_StillUnder
_CDSCONov03_20

- **Conclusion: This is alarming. After 20 months, the concerned agencies have not made any effort to put in place a fully validated test. The RT-PCR test is still under Emergency Use Authorization (EUA)**

Injections, Clinical Trials, Informed Consent, Privacy, Safety, Deaths, AEFIs:

CDSCO/R/E/21/00573 dated 27.Dec.2021

- **Questions**
  - Please provide detailed information on the trials of covid19 vaccines conducted in children below the age of 18 in India.

1. Please include information on the number of Informed Consent Forms (ICFs) collected during these trials for each of the covid19 vaccines (either from children or their guardians).

2. Please provide information on the number of non-healthy Indian children who participated in these trials. Non-healthy indicates children with chronic conditions such as eczema, asthma, ADD, ADHD, autism, and so on resulting from previous vaccinations or other causes.

3. Please provide information on Absolute Risk Reduction ARR) observed in these clinical trials and not Relative Risk Reduction (RRR).

4. Please provide information on whether these covid19 vaccines trials were sponsored by the manufacturers themselves and/or by any Foundation (such as the Bill and Melinda Gates foundation or the Rockefeller foundation or other) and/or any government agency/institution.

Continued

CDSCO/R/E/21/00573 dated 27.Dec.2021

- **Answers**
  - CDSCO has granted the permissions to conduct following clinical trials in children & adolescents (age –group):

1. Phase II/III clinical trial of Nanoparticle Vaccine (Liquid) (COVOVAX) manufactured by M/s Serum Institute of India Pvt. Ltd. in 2 to 17 years age group.

2. Phase II/III clinical trial of Whole-Virion Inactivated SARS-CoV-2 Vaccine manufactured by M/s Bharat Biotech in 2 to 18 years age group.

3. Phase II/III clinical trial of RBD of SARS-CoV-2 gene manufactured by M/s Biological E Limited in ≥5 to <18 years age group.

  - Further, all the above clinical trials are being conducted in healthy participants.

Continued

CDSCO/R/E/21/00573 dated 27.Dec.2021

- **Answers**
  - The details of number of subjects, age group, inclusion and exclusion criteria, clinical trial objectives and endpoints, sponsors are also available publically and may be seen through CTRI website i.e. www.ctri.gov.in.
  - As of now, these clinical trials are ongoing for evaluation of safety of the vaccines and complete safety data may be available after conclusion of clinical trial results as per approved clinical trial protocol.
  - Further, this office has given global trial permission in Form CT-17 on 13/10/2021 to M/s Johnson and Johnson Private Limited, L.B.S. Marg, Mulund West, Maharashtra (India) – 400080 with protocol title- “A Randomized, Double-blind, Placebo-controlled, Phase 2/3 Adaptive Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Different Dose Levels of Ad26.COV2.S Administered as a One-or Two-dose Regimen in Healthy
  - Adolescents From 12 to 17 Years Inclusive” - HORIZON 2, Protocol Number: VAC31518COV3006, Amendment 1, dated 13-July-2021.
  - Further, the above clinical trial is being conducted in healthy adolescents from age 12 to 17 Years.

Continued

CDSCO/R/E/21/00573 dated 27.Dec.2021

- **Conclusion**
  - Trials involving children are still ongoing – they are being done *only* on a few hundred children and *only* on seronegative healthy children

CT_Ongoing_Chil
en_CDSCODec2021

Clinical Trial Information from all 3 manufacturers appears below

Serum Inst - From
RI Children Dec. 2

Covaxin Children
Dec 2021

Corbevax_Biologi
lE Children Dec 20

INCMR/R/T/21/01388 dated 13.Dec.2021

- **Questions**
  - The published literature related to AZD1222 (Covishield - University of Oxford/AstraZeneca vaccine, also known as ChAdOx1 nCoV-19) clinical trials, ' Safety and efficacy of the ChAdOx1 nCoV-19 vaccine (AZD1222) against SARS-CoV-2: an interim analysis of four randomised controlled trials in Brazil, South Africa, and the UK' involved only healthy participants. The link to this study is here https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2932661-1
  - The study is sponsored by the manufacturer themselves (at least in part).
  - The study compares relative risk reduction and not absolute risk reduction. If we look at this result from the study “Overall vaccine efficacy across both groups was 70·4% (95·8% CI 54·8–80·6; 30 [0·5%] of 5807 vs 101 [1·7%] of 5829).”. This is just a relative risk reduction which has no meaning.
  - The absolute risk reduction is just 1.2% (101/5829 minus 30/5807).

Continued

INCMR/R/T/21/01388 dated 13.Dec.2021

- **Questions**
  - Please provide proper scientific basis for approving this vaccine for the public at large when the clinical trials:

1. Were sponsored in part by the manufacturer themselves,

2. Were conducted only on healthy individuals, and

3. Had a negligible benefit (of 1.2%) for reduction in the occurrence of symptoms

  - Please provide specific proof and basis (not general statements) for approving this vaccine for people with pre-existing health conditions, pregnant, and lactating women.
  - Please provide details of clinical trials involving Covishield done using Indian citizens.

Continued

INCMR/R/T/21/01388 dated 13.Dec.2021

- **Answers**
  - Trials are usually sponsored by manufacturer but approved is given only after data has been reviewed by independent subject matter expert committee.
  - Vaccine trials are conducted on healthy individuals as vaccines are usually expected to stop people from getting infected.
  - After second wave of COVID-19 in India in April-May, 2021 the National technical advisory group on immunization recommended COVID vaccine for people with pre-existing health condition, pregnant and lactating women. https://pubmed.ncbi.nlm.nih.gov/34870133/

NTAGI_Reco_With
utTrials_Dec2021S

- **Conclusions: This is appalling. They have recommended these vaccines for people with pre-existing conditions, pregnant, and lactating women without any trials. And their response with respect to CT being done only on healthy individuals is absurd**

DTOFW/R/2021/60017 dated 21.May.2021

- **Question**
  - How many vaccine receivers till date have developed adverse reactions? Kindly provide details, out of which how many had serious complications? Needing ICU care kindly provide details. How many deaths are reported till date after covid19 vaccination? Kindly provide details. Is there any compensation provided for vaccine injury or adverse reactions, deaths. If yes, please provide details of the same.
- **Answers**
  - Total 48,66,462 doses have been administered till 19 May 2021 (Source Co-WIN) and 35 serious AEFI cases have been reported which includes 9 deaths and 9 severe AEFI cases have been reported as on 19 May 2021.
  - There is no provision for compensation after Adverse Reaction.

DFW_PurelyVolun
Deaths_AEFIs_May

- Conclusion: They are admitting to deaths and AEFIs in just NCT and just till May 19 2021.

INCMR/R/X/21/00128 dated 27.Aug.2021

- **Questions**
  - What safety studies have been done to ascertain effects of vaccine on human (male and female) reproduction.
  - Have there been safety studies to determine if Covid vaccines will cross-react with the syncytin and reproductive proteins in sperm, ova, and placenta, leading to impaired fertility and impaired reproductive and gestational outcomes.
- **Answer**
  - This information is not available with ICMR
- **Conclusion: No fertility studies done**

No_FertilityStudies_ICMRAug2021ST

CDSCO/R/T/21/00487 dated 04.Aug.2021

- **Questions**
  - Has the MoHFW/DGCI set up data safety monitoring boards (DSMB) and event adjudication committees (EAC).
- **Answer**
  - Currently, the trials are ongoing. the safety of the vaccines is assessed under the provisions of the NDCT rules, 2019 and the conditions of approval. This office has not set up the Data Safety Monitoring Board (DSMB) & Event adjudication committees (EAC). There is no such requirement under the provisions.
  - However, as per condition of clinical trial permissions, applicants conducting clinical trials of COVID-19 vaccines are required to constitute DSMB for review of safety data during conduct of various phases of clinical trials .
- **Conclusion: No DSMB set up by CDSCO. Applicants are required to do it by themselves. Seems odd.**

No_DSMB_CDSCO_Aug2021ST

MOHFW/R/E/21/04552 dated 08.Aug.2021

- **Questions**
  - Please let me know the document format used to obtain informed consent for each vaccine recipient in India. Please provide information on the number of informed consent documents/forms signed and collected from vaccine recipients across India
- **Answers**
  - If anyone is concerned for any specific health reason **before COVID Vaccination, please consult a doctor/Health Care Provider**.
  - It is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, **but this in no way implies that any person can be forced to be vaccinated against her/his wishes. Covid Vaccination is voluntary.**
  - As per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid Vaccination on COWIN or visit Covid Vaccination Center for vaccination. if a person above the age of 18 years visits a Covid Vaccination Centre by his/her choice for vaccination, it implies that she/he is voluntarily coming to the center to get the benefit of Covid Vaccination. Hence, **no separate written consent should be required from the person who has voluntarily come to the Covid Vaccination Center, to get the Vaccination**.

NoForce_MOHFW_02Aug_2021ST

MOHFW/R/E/21/05398 dated 13.Sep.2021

- **Questions**
  - Please provide documentation / minutes of meetings of official meetings held by various government agencies and bodies in which they discussed deleterious consequences of administering covid19 injections to people who are already suffering from the following conditions:
    - Autism
    - Polio
    - Vaccine damaged
    - High blood pressure, uncontrolled type 2 diabetes
    - Morbid obesity
    - Who have had organ transplants
    - Cancer
    - Heart ailments
    - Allergies
    - Other chronic conditions

Continued...

MOHFW/R/E/21/05398 dated 13.Sep.2021

ConsultDoc_Volu
loComp_MOHFW_

- **Answers**
  - COVID Vaccines like other drugs are licensed after due deliberations and consideration of safety data by Drug Controller General of India (DCGI). **If anyone is concerned for any specific health reason before COVID Vaccination, please consult a doctor/Health Care Provider. Vaccination for COVID-19 is voluntary. There is no provision of financial assistance/compensation for adverse event following COVID-19 Vaccine, if any. However, severe and serious Adverse Events Following Immunization (AEFI) cases may be reported to and treated at Government Hospital/facilities.** You may refer COVID-19 vaccine operational guidelines (28.12.2020) https://www.mohfw.gov.in/covid_vaccination/vaccination/dist/images/documents/COVID19VaccineOG111Chapter16.pdf (Page no. 105 specifically for Adverse Events Following Immunization).
  - **Conclusion: They are admitting to the possibility of severe and serious AEFIs**

CDSCO/R/X/21/00010 dated 09.Jun.2021

- **Question**
  - Please provide copy, scientific proof, or evidence of covid -19 Vaccine is safe and effective.

Restricted_Use_E
ncy_CTOngoing_C

- **Answer**
  - Further, it is mentioned that as per the provisions of New Drugs and Clinical Trials Rules, 2019 and considering COVID pandemic, CDSCO in consultation with Subject Expert Committee (SEC) has approved three COVID-19 vaccines **for restricted use in emergency situation and the clinical trials are still ongoing for conclusion of results of complete safety, immunogenicity and efficacy.**

  - Conclusion: They are admitting that these injections are only for restricted use, that too in emergency situations. Experiments are still ongoing (presumably on the public at large) and nothing is sure in terms of safety and efficacy

MOHFW/R/E/21/04550 dated 03.Sep.2021

- **Questions**
  - Please share raw data that SII and Bharat Biotech had to make available to the committee approving covid-19 vaccines. Did this committee look at the raw data and/or discuss it? Please share data provided by SII and Bharat Biotech related to the following from their trials:
  - 1. Teratogenicity (risk of harm to foetus)
  - 2. Genotoxicity (gene mutations)
  - 3. Carcinogenicity (risk of cancer)
  - 4. Fertility
  - 5. Death

Continued...

MOHFW/R/E/21/04550 dated 03.Sep.2021

- **Answers**
  - The brief of interim clinical trial results/information containing safety, immunogenicity and efficacy results along with side-effects, contraindications precautions and instructions for use of Covishield & Covaxin COVID-19 vaccines are available in Summary of Product Characteristics (SmPC) & factsheet which along with recommendations of Subject Expert Committee are publicly available on CDSCO website i.e. www.cdsco.gov.in.
  - Further, the sought information is exempted under Sec 8(1) (d) and (e) of RTI Act 2005 & consent is required for disclosure from such information

- **Conclusion:** **They are not sharing vital data. They are hiding behind Sec 8 (1) (d) and (e), which clearly state the following:**

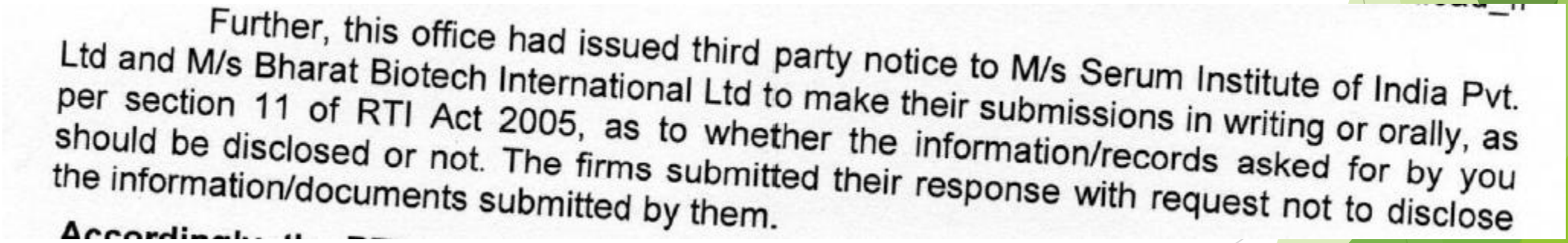
- (d) information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information;
(e) information available to a person in his fiduciary relationship, unless the competent authority is satisfied that the larger public interest warrants the disclosure of such information;

SO THIS WAS APPEALED (next slide)

CDSCO/A/E/21/00120 dated 29.Nov.2021

Not_Revealing_CTaCDSCO_29Nov20

- **Question**
  - Sec 8 (1) (d) and (e) state the following:
    - (d) information including commercial confidence, trade secrets or intellectual property, the disclosure of which would harm the competitive position of a third party, unless the competent authority is satisfied that larger public interest warrants the disclosure of such information;
    - (e) information available to a person in his fiduciary relationship, unless the competent authority is satisfied that the larger public interest warrants the disclosure of such information;
  - The information that I am seeking is of utmost public interest as Teratogenicity, Genotoxicity, Carcinogenicity, Fertility, and Death are serious consequences of these vaccines (and any vaccine for that matter). **The clinical trial data that I am asking should be sent to me and should be made public.**
- **Answer**



Further, this office had issued third party notice to M/s Serum Institute of India Pvt. Ltd and M/s Bharat Biotech International Ltd to make their submissions in writing or orally, as per section 11 of RTI Act 2005, as to whether the information/records asked for by you should be disclosed or not. The firms submitted their response with request not to disclose the information/documents submitted by them.

- **Conclusion: They are still not sharing vital data. They are hiding behind Sec 11 which also states that disclosure may be allowed if the public interest in disclosure outweighs in importance any possible harm or injury to the interests of such third party.**

MOHFW/R/E/21/06059 dated 18.Oct.2021

- **Questions**
  - Covaxin and Sputnik manufacturers clearly mention contraindications for pregnant women. Given this, please provide scientific basis/evidence for **MOHFW recommending these covid-19 shots for pregnant women despite these contraindications.**
  - Also, the Covishield manufacturer mentions that not enough studies have been done on pregnant women. Given this, please provide scientific basis/evidence for **MOHFW recommending this covid-19 shot for pregnant women despite the dearth of studies involving pregnant women**

Pregnant_NoScie
BasisMOHFWOct2

- **Answer**

You may visit the MoHFW's website (https://www.mohfw.gov.in) for Operational Guidance for COVID-19 Vaccination of Pregnant Women or refer link
https://www.mohfw.gov.in/pdf/PostersonvaccinationofpregnantwomenEnglish.pdf (14.07.2021)

https://www.mohfw.gov.in/pdf/CounsellingbookletforFLWsEnglish.pdf (14.07.2021)

https://www.mohfw.gov.in/pdf/OperationalGuidanceforCOVID19vaccinationofPregnantWoman.pdf (02.07.2021)

- **Conclusion: They are asking us to refer to booklets, posters, and guidelines. Absolutely no scientific basis or studies presented.**

CDSCO/R/T/21/00263 dated 29.Jun.2021

- **Questions**
  - Please reply if research has been undertaken on vaccination post disease. Does the study rule out possibility of cytokine storm post disease consequent to increased levels of antibodies post vaccination?

NoCTPermission_ Diseased_CDSCO_.

- **Answers**
  - As of now, **CDSCO has not granted clinical trial permission for use of approved covid-19 vaccines in post diseased individual.**
  - Conclusion: They are admitting that they have not even granted permission for trials in people who have recovered from the alleged covid disease

CDSCO/R/T/21/00761 dated 30.Sep.2021

Questions

- As per CDSCO, they have not granted clinical trial permission for use of approved covid-19 vaccines in post-diseased individuals. I received this information via RTI CDSCO/R/T/21/00263 on June 29 2021. My original question was 'Please reply if research has been undertaken on vaccination post disease. Does the study rule out possibility of cytokine storm post disease consequent to increased levels of antibodies post vaccination.'

- Given the above, please provide information, scientific papers, minutes of meetings for deciding not to explicitly exclude post-diseased individuals from the ongoing vaccination drive in India. If the direction is to exclude post-diseased individuals, please provide inserts, publicity material, and so on mentioning this caution/alert/caveat/exclusion.

CT_PD_Ambiguity
CDSCOSep30_2021

Answers

- CDSCO has given various permissions to conduct clinical trials of covid-19 vaccines. The details of the clinical trial such as objectives, endpoints, inclusion and exclusion criteria etc are available on the website of the ctri.nic.in. **Further, CDSCO has no role in conduct of research in post diseased individuals.**

- **Conclusion: First they said no permission given (previous slide), here they have evaded the question by saying they have no role in conduct of research**

CDSCO/R/T/21/00670 dated 17.Sep.2021

- **Questions**
  - Please provide documents of all safety trials conducted on the Covid vaccines which shows its safety for people with existing conditions, pregnant women and breast feeding women. **Please provide peer reviewed scientific research showing, beyond reasonable doubt that Covid vaccines are safe for people with preexisting conditions, pregnant women and breast feeding women**
- **Answers**
  - **CDSCO has not granted permission to conduct clinical trials on pregnant women and breast feeding women.**

- **Conclusion: They are admitting (on Sep. 17 2021) that they have not even given permission to conduct clinical trials on pregnant and lactating women.**

No_CT_Permissio
gLactatingCDSCO

CDSCO/R/E/21/00423 dated 08.Oct.2021

Questions

- Request documents concerning all phases of all Covid-19 vaccine trials on comorbid people, pregnant women and breast-feeding women.
- Request information on the nature of tests being done including tests for side-effects.
- Request information on adverse effects observed so far on Covid-19 vaccine trials on comorbid people, pregnant women and breast-feeding women.
- Please provide peer reviewed scientific research showing, beyond reasonable doubt that Covid vaccines are safe for people with preexisting conditions, pregnant women and breast feeding women.

PregLactatingWo
xcludedFromTrials

Answers

- As per information available, the applicants have enrolled healthy participants in the various clinical trials of COVID-19 vaccines and as per exclusion criteria, Pregnant and lactating/ breast-feeding women were excluded.

Conclusion: They are admitting (on Oct. 08 2021) that only healthy individuals are/were part of clinical trials and that pregnant and lactating women are/were excluded.

CDSCO/R/E/21/00515 dated 15.Nov.2021

Questions

- Please provide details of any safety trials conducted on pregnant women and breast feeding women for the following Covid 19 Vaccines:
  - 1. Covishield
  - 2. Covaxin
  - 3. ZyCoV-D

No_Preg_Lact_Tria
:DSCO_Nov15_202

Answers

- As per information available, the firm have enrolled healthy participants in the various clinical trials of COVID-19 vaccines and as per exclusion criteria, Pregnant and lactating/ breast-feeding women were excluded.

Conclusion: More proof that pregnant and breast-feeding women were excluded. They are also emphasizing that only healthy individuals were enrolled.

MOHFW/R/E/21/06705 dated 21.Dec.2021

Questions

- Please provide state-wide and all-India information and statistics on the number of pregnant and breastfeeding women who have received 1 dose of any of the covid19 vaccinations.
- Please also provide the same details for the number of pregnant and breastfeeding women who have received 2 doses of any of the covid19 vaccinations.

No_Tracking_Preg
abStatusMOHFWD

Answers

- **Such category wise (Pregnant & Breast Feeding Women) vaccination data is not available with the CPIO/office.**

Conclusion: They are not even keeping track of pregnant and lactating women who have chosen to get injected. Since the clinical trials were bypassed, the least they should be doing is keeping track of this demographic for short and long-term effects.

CDSCO/R/T/21/00341 dated 08.Jul.2021

- **Question**
  - Are vaccine trial participants counselled about risks of these vaccines and is informed consent obtained?
- **Answers**
  - Clinical Trials are conducted as per the provisions of New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940 wherein as per Table 3 of Third Schedule, **the investigator is required to inform description of any reasonably foreseeable risks or discomforts to the subject and obtain informed consent from trials participants.**
  - Conclusion: Informed consent is a must, but it is not at all being practiced. The next RTI has more

Informed_Consen
_Must_CDSCO_Jul2

CDSCO/R/T/21/00776 dated 23.Sep.2021

- **Questions**
  - Chapter 5 in the NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS that was published by ICMR in October 2017 has a very clearly defined Informed Consent Process with several conditions and requirements.
  - As the ongoing covid injections are in clinical trials and experimental in nature, all recipients are test subjects and must be made an integral part of the Informed Consent Process.
  - Please provide information/ data / statistics on the number of patient/participant information sheets (PIS) and the number of informed consent forms (ICF) collected from all over India since the beginning of the drive in January 2021 involving these experimental injections.

Continued...

CDSCO/R/T/21/00776 dated 23.Sep.2021

- **Answer**
  - No such information/database is maintained by CDSCO

- **Conclusion: They are admitting to not having any database of informed consent forms**

No_InformedCon
Database_Sep23_2(

INCMR/R/E/21/00792 dated 17.Sep.2021

- **Questions**
  - As per section 5.1.5 in the NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS that was published by ICMR in October 2017, 'Informed Consent Process - It is necessary to maintain privacy and confidentiality of participants at all stages.
  - As the ongoing covid injections are in clinical trials and experimental in nature, all recipients are test subjects and have the right to privacy and confidentiality.
  - Given this, on what basis is the vaccination status of individuals being asked by various government institutes and bodies and private companies?
  - Which is the authorized body/agency in India that is responsible for ensuring this stringent privacy and confidentiality requirement across India?

Continued...

INCMR/R/E/21/00792 dated 17.Sep.2021

- **Answer**
  - Vaccination status is different from the clinical trial data.

- **Conclusion: This is a ridiculous response. They have insulted our intelligence with this response. So, this was appealed (next slide)**

Continued…

INCMR/A/E/21/00185 dated 23.Sep.2021

Questions

- The following are some important privacy-related clauses (they clearly include the protection of the identity of the individual as also protection of privacy and confidentiality during and after completion of research) from the NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS document:
- 1.1.5. Principle of ensuring privacy and confidentiality whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized.
- 2.3.3 Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published.
- 4.7.9 The EC should ensure that privacy of the individual and confidentiality of data including the documents of EC meetings is protected.
- 6.2.12 Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.
- 7.1.5 At all times, the privacy of a participant must be maintained and any information gathered from the participant be kept strictly confidential.
- Given the above, the response provided on 17/Sep/2021 by ICMR is incorrect. The protection of the identity of all individuals vaccinated by experimental covid19 vaccines is non-negotiable. This is applicable during conduct of research/experiment and even after its completion.
- Given all this, on what basis is the vaccination status of individuals being asked by various government institutes and bodies and private companies?
- Which is the authorized body/agency in India that is responsible for ensuring this stringent privacy and confidentiality requirement across India?

Continued...

INCMR/A/E/21/00185 dated 23.Sep.2021

- **Answer**
  - The reply given by the CPIO is in order. ICMR follows ethical guidelines for all its publications.

Privacy_Confident
ty_AbsurdReply_IC

- **Conclusion: This is an absurd response. The reply has absolutely no relation to the protection of the identity of the individual as also protection of privacy and confidentiality during and after completion of research**

CDSCO/R/T/21/00800 dated 18.Oct.2021

- **Questions**
  - As the covid19 vaccines are experimental and highly sensitive in nature (research and trials are still ongoing and mortality and morbidity issues are abundant all across India), please let me know the following:
    - A. The document format used to obtain informed consent for each vaccine recipient in India
    - C. Please provide information on the number of informed consent documents/forms signed and collected from vaccine recipients across India
    - D. Please provide the number of tests conducted across India (for understanding the contents and background of the study) and the number of repeat tests conducted due to failure to understand the issues the first time.

Continued…

CDSCO/R/T/21/00800 dated 18.Oct.2021

ICF_MaintainedCDSCOOct2021ST

- **Answers**
  - Reply A & B: Informed Consent Document/Format is provided in Schedule 2, Table no 3 of New Drugs and Clinical Trials Rules 2019 under Drugs and Cosmetics Act, 1940 which is publically available on CDSCO website www.cdsco.gov.in
  - Reply C, D: As per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetics Act 1940, Informed Consent documents/forms are obtained and maintained by Principal Investigators of concerned participating clinical trial site to safeguard the rights, safety and well beings of the study participants along with their privacy and confidentiality as per Good Clinical Practices (GCP) and other applicable guidelines
- **Conclusion: Here they are saying principal investigators maintain ICFs. But, we know that they are not collecting forms from the general populations**

Miscellaneous:

Disaster Management,
Vaccination Status of MPs,
Herd Immunity,
Dose Interval,
Effectiveness of Health Measures
Effect of 5G

NDMAU/R/T/21/00101 dated 27.Dec.2021

- **Questions**

1. Please provide list of circumstances that need to exist in a country like India (considering the diversity of the land and the nature of rural, semi-urban and urban pockets) when the National Disaster Management Act (NDMA) can be invoked

2. Please provide information on the maximum amount of time when the NDMA can be in effect

3. Please provide information on the conditions and circumstances that need to exist in a vast country like India to revoke the NDMA

NDMAU/R/T/21/00101 dated 27.Dec.2021

- **Questions**

4. Please provide detailed information and minutes of meetings held wherein it was decided to invoke the NMDA during the early stages of the covid era

5. In the Covid era, what are the conditions that need to be met to revoke the NDMA.

6. The NMDA tramples on a lot of fundamental constitutional rights (articles 21 and 359 to name two). Please provide information on how this is circumvented

NDMAU/R/T/21/00101 dated 27.Dec.2021

- Answers

4. **There is no objective criteria in the Disaster Management (DM) Act, 2005 for invoking provisions** of the DM Act, 2005. The DM Act, 2005 contains definition of Disaster. Government invokes provisions of the DM Act,2005 when it deems fit as per the provisions of the DM Act, 2005.

- **Conclusions: NDMAU is clearly admitting that they have no objective criteria for invoking the DM Act. It is based purely on the whims and fancies of the government.**

No_Objective_Crit
_Disaster_NDMAU_

MOHFW/R/E/21/06551 dated 22.Dec.2021

- **Questions**

  Please provide the names of Lok Sabha MPs who have received both doses of covid19 vaccination (covishield, covaxin, or sputnik, or other). Also Rajya Sabha MPs

- **Answers**

  Such specific data of COVID Vaccination (profession wise vaccination data) is not maintained and not available.

MPs_NoTrackingJ
atusMOHFWDec2(

MP_Jab_Status_LS
MOHFWDec2021S

- **Conclusion: It is clear that they are not tracking the jab status of MPs. This obviously means that it is not a requirement to enter parliament. Two relevant RTIs embedded here. More similar RTIs are available with us**

MOHFW/R/E/21/05261 dated 03.Sep.2021

- **Questions**
  - Pls provide flwg India specific details
    - What is the natural herd immunity for respiratory diseases?
    - What is the natural herd immunity for Covid-19?
    - Has India achieved natural herd immunity?
    - How many Covid-19 deaths per million are expected based upon natural herd immunity levels achieved?
    - What are the factors that determine natural herd immunity?
    - Who determines natural herd immunity? Pls provide all communication received by ICMR pertaining to natural herd immunity.

No_Herd_Immuni
InfoICMRSep2021

- **Answer**
  - The requested information is not available with ICMR
- **Conclusion:** Startling to note that they have no information on natural immunity for any respiratory disease

MOHFW/R/E/21/04547 dated 31.Jul.2021

- **Questions**
  - This is the first vaccine which is being administered in India in 2 doses. Please make available the scientific basis for this. What is the exact number of days one has to wait between the 1st and 2nd doses? What is the scientific basis for this?
- **Answer**
  - It is recommended that the 2nd dose of COVAXIN should be administered in the interval of 28 days to 42 days after the 1st dose. The 2nd dose of COVISHIELD should be administered in the interval of 84 days to 112 days after the 1st dose. The second dose of SPUTNIK V should be administered in the interval of 21 days to 90 days after the 1st dose.
- **Conclusion: No scientific basis provided for intervals. So, this was appealed (next slide)**

MOHFW/A/E/21/00663 dated 17.Sep.2021

- **Questions**
  - Please provide documentation and information on studies conducted for the intervals recommended for the various products in your reply. Please provide scientific basis for these intervals.
- **Answer**
  - The First Appellate Authority has been informed by the CPIO that additional information is not available with him.
- **Conclusion: No scientific basis/studies for dose intervals available with MOHFW**

Dose_Intervals_No
ntificBasisMOHFW

MOHFW/R/E/21/03781 dated 01.Jul.2021

- **Questions**
  - 1. How much funding has gone into the research that Covid-19 is contagious and spreads from person to person when infected person breathes out air?
  - 2. How much funding has gone into the research that masks are effective to control spread of Covid-19?
  - 3. How much funding has gone into the research on the side-effects of masks on the health i.e. effect on lungs, heart, brain, teeth etc?
- **Answer**
  - The information is not available with ICMR for point no. 01 to 03.
- **Conclusion: No funding has gone into fundamental research (contagion, effectiveness and detrimental effects of face coverings)**

No_Funding_Cont
nMasksICMRJul20

VCRCP/R/E/21/00002 dated 19.May.2021

- **Questions**
  - 2.Please give copy of research material that proves effectiveness or ineffectiveness of masks during a pandemic.
  - 3.Please give copy of research material that proves effectiveness or ineffectiveness of hand sanitizers during a pandemic.
  - 4.Please give copy of research material that proves effectiveness or ineffectiveness of social distancing during a pandemic.
- **Answer**
  - VCRCP has no studies to prove effectiveness of face coverings, sanitizers, and distancing (response to questions 2 through 4)
- **Conclusion: No studies done on effectiveness of the various so-called health measures being imposed on the population**

No_Studies_Effect
ness_Masks_Sanit_I

INCMR/R/E/21/00657 dated 24.Aug.2021

Questions

- Following details of research done by ICMR on effect of Elecrromagne c Fields (EMF) on the human body is requested.

1. ICMR public domain (icmr.gov.in) website link giving this research details OR copy of the research material on Elecrromagne c Fields (EMF) effect on human body.

2. Amount of funding spent by ICMR on this kind of research, with breakup of funding per research material.

3. All the research done since 2000 is requested, this includes research done on effect of 4G and 5G radia on on the human body.

4. Also give the names of other organiza ons in India that do this kind of research.

No_5GStudiesHuBody_ICMRAug20

Answer

Above mention studies are designed and conducting on 2G, 3G and 4G network of cellular communication technology. Though 5G network of cellular communication technology still not launched in India, therefore no study is done on effect of 5G radiation on human body.

- **Conclusion: No studies done on the effect of 5G on the human body, yet they are rolling it out in several cities in early 2022**

Virus Isolation

NIOVP/R/T/21/00011 dated 24.Sep.2021

- **Question**
  - Please provide scientific papers clearly detailing the purification and isolation of the so-called Delta variant.
- **Answer**
  - There is no specific protocol for purification and isolation of the sars-cov-2 Delta variant
- **Conclusion: All this talk of variants has no scientific backing**

Delta_Not_Isolate
urified_NIOVP_Sep

NIOVP/R/E/21/00085 dated 06.Dec.2021

Questions

- Please provide all studies and/or reports in the possession, custody or control of ICMR or NIV or other affiliated bodies/agencies describing the purification of the alleged “COVID-19 virus” (aka “SARS-COV-2”, including any alleged “variants”) directly from a sample taken from a diseased human, where the patient sample was not first combined with any other source of genetic material (i.e. monkey kidney cells aka Vero cells; fetal bovine serum).
- Clarification of Request:
- Please note that I am NOT requesting studies/reports where researchers failed to purify the suspected “virus” and instead:
- 1. cultured something, and/or
- 2. performed an amplification test (i.e. PCR), and/or
- 3. fabricated a genome from sequences detected in an impure substance, and/or
- 4. produced electron microscopy images of unpurified things.

Continued

NIOVP/R/E/21/00085 dated 06.Dec.2021

Questions

- I am already aware that according to virus theory a “virus” requires host cells in order to replicate, and am not requesting records that describe replication of a ‘virus’ without host cells. Nor am I requesting records that describe a strict fulfillment of Koch’s Postulates (or Rivers's criteria), or records that describe a suspected “virus” floating in a vacuum, or private patient information.
- I simply request records that describe purification (separation of the alleged virus from everything else in the patient sample, as per standard laboratory practices for the purification of other very small things). This would normally involve maceration, filtration, and ultracentrifugation.
- Please note that my request includes any study/report matching the above description, authored by anyone, anywhere.
- If any records match the above description of requested records and are currently available in the public domain, please provide enough information about each record so that I may identify and access each one with certainty (i.e. title, author(s), date, journal, where the public may access it). Please provide URLs where possible.

Continued

NIOVP/R/E/21/00085 dated 06.Dec.2021

Questions

- Please do not point me to or send me papers such as the following:

- 1 Abraham Priya, Cherian Sarah, Potdar Varsha. Genetic characterization of SARS-CoV-2 & implications for epidemiology, diagnostics & vaccines in India. 2020,152 (1), 12-15.

- 2 Sarkale P, Patil S, Yadav PD, et al. First isolation of SARS-CoV-2 from clinical samples in India. Indian J Med Res. 2020;151(2 & 3):244-250. doi:10.4103/ijmr.IJMR_1029_20.

- These are not what I am looking for.

Continued

NIOVP/R/E/21/00085 dated 06.Dec.2021

- **Answer**
  - As per our knowledge, there is no methodology available to purify the SARS-COV-2 directly from the clinical specimens of the patient until the virus is isolated using in vitro or in vivo methods.
  - Considering the biosecurity aspects, the records of the clinical specimens, isolates of SARS-COV-2 in possession, custody, or control of ICMR-National Institute of Virology, Pune cannot be shared publicly.
- **Conclusion: It is abundantly clear that virologists do not separate any ‘virus’. What they mean by isolation is the exact opposite of isolation. They assume without any proof that the ‘virus’ is buried in a soup in a dish in the lab and triumphantly state that they have separated the ‘virus’ from all surrounding material.**

Can'tPurifyWitho
olating_Humorous