

MINUTES OF 17TH MEETING OF CSC TO BE HELD ON 22ND DECEMBER 2020.

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The 17th CSC Meeting was held on 22nd December 2020 through Zoom under the chairmanship of Dr. Abdur Rashid, Director Pharmacy Services Division / Chairman (CSC). At the Committee Room, 4th Floor, Drug Regulatory Authority of Pakistan, Islamabad.

2. The meeting was attended by the following members: -

Sr. No.	Name	Designation
01	Dr. Abdur Rashid.	Chairman CSC / Director, Division of Pharmacy Services.

3. Following members attended the meeting online through Zoom:

01	Prof. Brig. (R), Muzammil Hassan Najmi.	Professor of Pharmacology, Foundation University, Islamabad.
02	Dr. Farhana Badar.	Biostatistician & Epidemiologist, Shaukat Khanum Memorial Cancer Hospital & Research Center, Lahore. Member CSC.
03	Dr. Naseem Salahuddin.	Director, Infectious Diseases Indus Hospital, Karachi Co-opted CSC Member.
04	Dr. Aamir Jaffary	Sindh Institute of Urology & Transplantation (SIUT), Karachi Co-opted Member.
05	Dr. Mushtaq Ahmed	Professor of Cardiology, Bach Khan Medical College. Mardan Co-opted Member.
06	Dr. Zeba Ahmed Shuja	Nominated by Pakistan pharmaceutical Manufacturer association Observer

3. Mr. Adnan Faisal Saim, Deputy Director (PS) and Mr. Ahsan-ul-Haq Athar AD were also present in committee room.

4. Meeting started with the recitation of holy verses of the Quran by Dr. Abdur Rashid, chairman CSC. Chairman, CSC welcomed all the members. Chairman, CSC also thanked members for their active participation online through Zoom.

AGENDA ITEM - I:

CONFIRMATION OF THE MINUTES OF THE 16TH CLINICAL STUDIES COMMITTEE MEETING.

1.1 Minutes of 16th CSC meeting held on 27th November 2020, are placed for confirmation of CSC members.

1.2. Submitted for perusal, discussion and decision of CSC.

1.3 **Decision of 17th CSC meeting:**

All the members confirmed the minutes of 16th CSC which was held on 27th November, 2020.

AGENDA ITEM -II:

APPLICATION FOR APPROVAL TO ACT AS CRO AT M/S PRECISION HEALTH CONSULTANTS (PHC) GLOBAL (PVT) LIMITED KARACHI. F. No.15-56/2020 DD (PS)

2.1 Application is from Muhammad Imran Khan, CEO of M/s Precision Health Consultants (PHC) Global (Pvt.) Limited, House # 241, 1st floor, Bahadurabad #03, Karachi, Pakistan. Wherein the request has been made to license their firm with DRAP to act as Clinical Research Organization (CRO), the application is on prescribed Form-I of the Bio-Study Rules 2017 along with a fee of Rs.300000/- submitted vide challan No. 2051401, dated 15th October 21, 2020.

2.2 It is submitted that application evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules 2017, summary of submitted documents is as follows:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Fee	Attached
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	SECP Registration Certificate No. A035856, with Corporate Universal Identification No. 016597 is attached
4	Details of premises including layout plan of the site.	Only layout attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not applicable as applied for CRO.
6	Names and qualifications of the above sections along with their staff.	Attached
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not applicable as applied for CRO.
8	Undertaking	Attached

2.3 The case was placed before CSC in its 16th meeting & CSC decided as follows:

Decision of 16th CSC meeting:

CSC after detailed deliberation decided to authorize the Chairman CSC for the constitution of inspection panel for the inspection of M/s Precision Health Consultant (PHC) Global (Pvt.) Limited, Karachi. The case will be again placed before the CSC for further deliberations and decisions after submission of inspection report.

2.4 Chairman CSC constituted panel for inspection and the site for inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Dr. Ali Jawa
iii.	Dr. Aamir Jaffary
iv.	Dr. Najam Us Saquib

2.5 After inspection, panel submitted report with following remarks:

M/S Precision Health Consultants (PHC) Global (Pvt.) Ltd, House # 241, 1st Floor, Bahadurabad # 03, Karachi was inspected by the panel in compliance to the instructions contained in DRAP Islamabad letter No. F.15-56/2020-DD(P.S) dated 8th December 2020 in connection with the inspection for approval to act as CRO. Panel inspected the premises in detail and report has been prepared on this check list. Based on the people met, documents reviewed and available facilities on the site, Panel recommends the approval of SITE for the purpose as referred in the afore mentioned letter.

2.6. Concluding status of inspection / application:

Recommended for approval

2.7. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC after detailed deliberation decided to approve M/S Precision Health Consultants (PHC) Global (Pvt.) Ltd, House # 241, 1st Floor, Bahadurabad # 03, Karachi to act as contract research organization (CRO) in connection with inspection and the recommendation of panel of experts/ inspectors.

AGENDA ITEM -III:

REQUEST FOR APPROVAL OF NATIONAL INSTITUTE OF BLOOD DISEASE & BONE MARROW TRANSPLANTATION, AS A CLINICAL TRIAL SITE, TO CONDUCT CLINICAL TRIAL TITLED "EXPERIMENTAL USE OF COVID IG CONVALESCENT PLASAMA FOR THE PURPOSE OF PASSIVE IMMUNIZATION IN CURRENT COVID.19 PANDEMIC IN PAKISTAN IN 2020". F. No.15-57/2020 DD (PS).

3.1. Application is from Dr. Tahir Shamsi, Professor & Chairman, National Institute of Blood Disease & Bone Marrow Transplantation, Karachi, dated 11th November 2020, wherein the application submitted for approval of subject Clinical Trial Site to conduct Clinical Trial titled "EXPERIMENTAL USE OF COVID-19 CONVALESCENT PLASAMA FOR THE PURPOSE OF PASSIVE IMMUNIZATION IN CURRENT COVID-19 PANDEMIC IN PAKISTAN IN 2020.", application is submitted in reference to this division letter number F.No.03-23/2020 DD (PS), dated

25th August 2020. The mentioned Clinical Trial was approved in 9th CSC meeting, during COVID-19 pandemic, to be conducted at following trial sites:

- i. National Institute of Blood Disease and Bone Marrow, Transplantation (NIBD), Karachi.
- ii. Liaquat University of Medical and Health Sciences, Jamshoro.
- iii. University of Health Sciences, Lahore.

3.2. Application evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules 2017, and following shortcoming observed:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Prescribed fee	Prescribed fee of Rs.100000/- deposited vide challan number 2032352, dated 31-03-2020.
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	Only NTN Certificate of applicant is attached. SECP Registration & Sindh Healthcare Commission Certificate is not provided.
4	Details of premises including layout plan of the site.	Not provided. Only flowchart of process is attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached.
6	Names and qualifications of the above sections along with their staff.	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not provided & claimed that it is not applicable as NIBD will involved in collection of convalescent plasma only.
8	Undertaking on stamp paper	Attached.

3.3. In the view of above following shortcomings were recorded:

- i. SECP Registration of the firm and/or Sindh Healthcare Commission registration Certificate is not provided.
- ii. Details of premises including layout plan is not provided.

- iii. Names and qualifications of the above sections along with their staff are not provided.
 - iv. Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc, are not provided, & claimed that it is not applicable as NIBD will involve in collection of convalescent plasma only.
- 3.3. Shortcomings communicated to applicant vide letter no.F. No.15-57/2020 DD (PS), dated 9th December 2020, still response is awaited.
- 3.4. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection and the site inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Prof. Dr. Ali Jawa
iii.	Dr. Aamir Jaffary
iv.	Dr. Najam Us Saquib

3.5 After inspection, panel submitted report with following remarks:

M/S National Institute of Blood diseases & Bone Marrow Transplantation Karachi, was inspected by the panel in compliance to the instructions contained in DRAP Islamabad letter No. F.15-57/2020-DD(P.S) dated 9th December 2020 in connection with the Inspection for approval as Clinical Trial Site. Panel inspected the premises in detail and report has been prepared on this check list. Based on the people met, documents reviewed and available facilities on the site, Panel recommends the approval of SITE for the purpose as referred in the afore mentioned letter.

3.6. Concluding status / remarks of inspection panel:

Recommended for approval.

3.7. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC after detailed deliberation decided to approve National Institute of Blood Disease & Bone Marrow Transplantation, karachi, to act as clinical trial.

AGENDA ITEM -IV:

APPLICATION FOR APPROVAL OF DOW UNIVERSITY HOSPITAL, DUHS-OJHA CAMPUS TO ACT AS CLINICAL TRIAL SITE FOR CLINICAL STUDY TITLED “IMMUNOGLOBULIN THERAPY FOR PASSIVE IMMUNIZATION OF CRITICALLY ILL COVID-19 PATIENTS”. F. No.15-55/2020-DD (PS).

4.1. Application is from Prof. Badar Faiyaz Zuberi, CNIC No.42301-0868312-5, Dow University of Health Sciences, KDA Scheme 33, Gulzar-e-Hijri, SUPARCO Road, Ojha Campus, Karachi, dated 06th October 2020, wherein the request has been made for approval of Dow University Hospital, Karachi to act as clinical trial site for subject clinical trial under the Bio-Study Rules 2017. The application is on prescribed Form-I of the Bio-Study Rules 2017, along with prescribed fee of Rs.100000/- deposited vide challan number 2033437 dated 05th October 2020.

4.2. It is submitted that application evaluated according pre- requisites as mentioned in Form-I of the Bio-Study Rules 2017, and following shortcoming observed:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	Attached. It's a chartered university under the Dow University of Health Sciences Act 2004. Applied site is tertiary care university hospital.
3	Details of premises including layout plan of the site.	Attached. Applied site is tertiary care university hospital.
4	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached
5	Names and qualifications of the above sections along with their staff.	Attached
6	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Applied site is tertiary care university hospital.
7	Affidavit on Stamp paper	Attached
8	Prescribed Fee	Unverified challan number 2033437 of Rs.100000/- deposited dated 05 th October 2020.

4.3. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection and the site inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Prof. Dr. Ali Jawa
iii.	Dr. Aamir Jaffary
iv.	Dr. Najam Us Saquib

4.4. After inspection, panel submitted report with following remarks:

DOW University of Health Sciences KDA Scheme 33, Gulzar-e-Hijri, SUPARCO road, Ojha Campus Karachi was inspected by the panel in compliance to the instructions contained in DRAP

Islamabad letter No. F.15-55/2020-DD(P.S) dated 9th December 2020 in connection with the Inspection for approval as Clinical Trial Site. Panel inspected the premises in detail and report prepared on this check list. Based on the people met, documents reviewed and available facilities on the site, Panel recommends the approval of SITE for the purpose as referred in the afore mentioned letter.

4.5. Concluding status of inspection / application:

Recommended for approval.

4.6. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC after detailed deliberation decided to approve DOW University of Health Sciences KDA Scheme 33, Gulzar-e-Hijri, SUPARCO road, Ojha Campus Karachi, to act as clinical trial.

AGENDA ITEM -V:

APPLICATION FOR APPROVAL OF SINDH INFECTIOUS DISESES HOSPITAL & RESEARCH CENTER, KARACHI WORKING UNDER DOW UNIVERSITY HOSPITAL, DUHS-OJHA CAMPUS TO ACT AS CLINICAL TRIAL SITE FOR CLINICAL STUDY TITLED “IMMUNOGLOBULIN THERAPY FOR PASSIVE IMMUNIZATION OF CRITICALLY ILL COVID-19 PATIENTS”. F. No.15-59/2020-DD (PS).

5.1. Application is from Prof. Badar Faiyaz Zuberi, CNIC No.42301-0868312-5, Dow University of Health Sciences, Karachi, dated 17th November 2020, wherein the request has been made for approval of Sindh Infectious Disease Hospital & Research Center, NIPA, Karachi to act as clinical trial site for subject clinical trial under the Bio-Study Rules 2017. The application is on prescribed Form-I of the Bio-Study Rules 2017, along with an unverified fee deposit challan of Rs.100000/- , reference number 2033450 dated 04th November 2020.

5.2. It is submitted that application evaluated according pre- requisites as mentioned in Form-I of the Bio-Study Rules 2017, and following shortcoming observed:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	It is described that the site is a part of Dow University of Health Sciences, Karachi. Whereas Dow University of Health Sciences, Karachi is a chartered university

		under the Dow University of Health Sciences Act 2004.
3	Details of premises including layout plan of the site.	Attached. Applied site is an especially designed facility to deal with COVID-19 patients and the facility is working under the Dow University of Health Sciences, Karachi.
4	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached
5	Names and qualifications of the above sections along with their staff.	Attached
6	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Attached. Applied site is an especially designed facility to deal with COVID-19 patients and the facility is working under the Dow University of Health Sciences, Karachi.
7	Affidavit on Stamp paper	Attached
8	Prescribed Fee	Unverified challan number 2033450 dated 05 th October 2020, of Rs.100000/- is attached.

5.3. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection and the site inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Prof. Dr. Ali Jawa
iii.	Dr. Aamir Jaffary
iv.	Dr. Najam Us Saquib

5.4. After inspection, panel submitted report with following remarks:

Sindh Infectious Disease Hospital & Research Center, Near NIPA, Karachi was inspected by the panel in compliance to the instructions contained in DRAP Islamabad letter No. F.15-59/2020-

DD(P.S) dated 9th December 2020 in connection with the Inspection for approval as Clinical Trial Site. Panel inspected the premises in detail and report has been prepared on this check list. Based on the people met, documents reviewed and available facilities on the site, Panel recommends the approval of SITE for the purpose as referred in the afore mentioned letter

5.5. Concluding status of inspection / application:

Recommended for approval.

5.6. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC after detailed deliberation decided to approve Sindh Infectious diseases Hospital & Research Center, Near NIPA, Karachi, working under DOW University Hospital, DUHS-OJHA Campus, to act as clinical trial site.

AGENDA ITEM -VI:

APPLICATION FOR LICENSE TO ACT AS BA/BE STUDIES SITE AT INSTITUTE OF BIOLOGICAL BIOCHEMICAL & PHARMACEUTICAL SCIENCES (IBBPS), AT DOW UNIVERSITY OF HEALTH SCIENCES, KARACHI. F. No.15-10/2019-DD (PS)

6.1. Application is from Dr. Sadia Asim, Director, Institute of Biological, Biochemical and Pharmaceutical Sciences (IBBPS), Dow University of Health Sciences, Karachi, dated 07th July 2020, wherein the FR is an application for approval of BA/BE Studies Center at Institute of Biological, Biochemical and Pharmaceutical Sciences (IBBPS), Dow University of Health Sciences, Karachi.

6.2. Application scrutinized & evaluated as per prerequisites of the Bio-Study Rules 2017, details of the submitted documents is as under;

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	Attached
3	Details of premises including layout plan of the site.	Layout of ground & first floor attached.
4	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Attached
5	Names and qualifications of the above sections along with their staff.	Attached

6	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	No details provided
	Prescribed Fee	Prescribed fee of Rs.300000/- deposited vide challan number 1932885, dated 08 th July 2020.
	Undertaking on stamp paper	Attached

6.3 The case was placed before CSC in its 4th meeting held on 17th July 2019 & CSC decided as follows:

Decision of 4th CSC meeting:

The CSC after deliberation, deferred the application for six months for improvements, and after the six months when the firm submit compliance report then re-inspected by the same panel of inspectors as nominated in the 3rd CSC meeting.

6.4. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection and the site inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Dr. Ali Jawa
iii.	Dr. Aamir Jaffary
iv.	Dr. Najam Us Saquib

6.5. After inspection, panel submitted report with following remarks:

Institute of Biological, Biochemical & Pharmaceutical Sciences (IBBPS) at Dow University of Health Sciences, Karachi was inspected by the panel in compliance to the instructions contained in DRAP Islamabad letter No. F.15-10/2019-DD(P.S) dated 8th December 2020 in connection with the Inspection for approval to act as BA/BE Studies Center. Panel inspected the premises in detail and report has been prepared on this check list. Based on the people met, documents reviewed and available facilities on the site, Panel recommends the approval of SITE for the purpose as referred in the afore mentioned letter.

6.6. Concluding status of inspection / application:

Recommended for approval.

6.7. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC decided to approve Institute of Biological Biochemical and Pharmaceutical Sciences (IBBPS) at Dow University of Health Sciences, Karachi, to act as BA/BE Studies Center” on recommendation of panel of experts/ inspectors in their inspection report.

AGENDA ITEM -VII:

REQUEST FOR APPROVAL OF CHILDREN'S HOSPITAL KARACHI AND RESEARCH INSTITUTE FOR BLOOD, GENETIC & BONE MARROW TRANSPLANT, KARACHI TO ACT AS CLINICAL TRIAL SITE.F.No.15-47/2020 DD (PS)

7.1. Application is from Dr. Saqib Hussain Ansari, Children's Hospital Karachi and Research Institute for Blood, Genetic & Bone Marrow Transplant, Karachi, dated 9th June 2020. Wherein the request has been made to license their hospital with DRAP to act as Clinical Trial Site. Application is on prescribed form along with prescribed fee paid vide challan number 1954317, dated 4th June 2020.

7.2. It is submitted that application evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules 2017, and following shortcoming observed:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached.
2	Fee	Attached.
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	Particulars regarding the legal status of Children's Hospital Karachi. (Page 83-89/corr.) i. Sindh Health Care Commission Certificate No.612/SHCC/DC. ii. ISO 9001:2015 Certificate.
4	Details of premises including layout plan of the site.	Attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not provided.
6	Names and qualifications of the above sections along with their staff.	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Attached.
8	Undertaking on stamp paper	Attached.

7.3. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection and the site inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Prof. Dr. Ali Jawa
iii.	Dr. Aamir Jaffary
iv.	Dr. Najam Us Saquib

7.4. After inspection, panel submitted report with following remarks:

Children's Hospital Karachi and Research Institute for Blood, Genetic and Bone Marrow Transplant Karachi, was inspected by the panel in compliance to the instructions contained in DRAP Islamabad letter No. F.15-47/2020-DD(P.S) dated 9th December 2020 in connection with the Inspection for approval as Clinical Trial Site. Panel inspected the premises in detail and report has been prepared on this check list. Based on the people met, documents reviewed and various discrepancies observed in the facilities on the site, Panel concludes to defer this Hospital SITE for improvements for the purpose as written in afore mentioned DRAP Letter.

7.5. Concluding status of inspection / application:

Deferred for improvements.

7.6. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC decided to defer the Children Hospital, Gulshan e Iqbal park, karachi to act as Clinical Trial Site” on recommendation of panel of experts/ inspectors in their inspection report.

AGENDA ITEM -VIII:

APPLICATION FOR LICENSE TO ACT AS CRO, BY M/S CYNTAX HEALTH PROJECTS ISLAMABAD. F. No.15-52/2020 DD(PS)

8.1. Application is from Madeeha Malik of M/s Cyntax health Projects PVT LTD Apartment No. 6, 4th Floor, Plaza No. 129, Civic center, Phase IV, Bahria town Islamabad, wherein the request has been made to license their company with DRAP to work as Clinical Research Organization (CRO). The application is on prescribed Form-I of the Bio-Study Rules 2017 along with fee of Rs.300000/- deposited for CRO vide challan no.2039292.

8.2. It is submitted that application evaluated according pre- requisites as mentioned in Form-I of the Bio-Study Rules 2017, and following shortcoming observed:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Fee	Attached
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners	Readable documents required.

	and in the case of company the name and address of the company and its directors).	
4	Details of premises including layout plan of the site.	Layout plan does not justify sitting capacity of provided staff.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	Not provided. Applied for CRO.
6	Names and qualifications of the above sections along with their staff.	Attached staff is not as per decision of 2 nd CSC meeting.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Not Provided. Applied for CRO.
8	Undertaking on stamp paper	Attached.

8.3 The case was placed before CSC in its 4th meeting held on 17th July 2019 & CSC decided as follows:

Decision of 14th CSC meeting:

CSC after detailed deliberation decided to authorize the Chairman CSC for constitution of inspection panel for the inspection of facilities as per criteria laid down CSC in its 2nd meeting. The case will be again brought before the CSC for further deliberation and decision after inspection.

8.4. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection and the site inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Dr. Rizwana Chaudhry
iii.	Farhana Badar
iv.	Dr. Gul Shehnaz
v.	Rana Ahsan Ul Haq Athar

8.5. After inspection, panel submitted report with following remarks:

Keeping in view the currently available Human Resources, their previous experience in the operational research in the field of pharmacy, premeds, the panel recommends the Cyntax Health Projects as Contract Research Organization. However, Cyntax was advised that technical persons should be available permanently available after approval.

8.6. Concluding status of inspection / application:

Recommended for approval.

8.7. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC decided to approve Cyntax Health Projects Pvt. Ltd. Office No.06, Floor 4, Plaza 129, Civic Centre, Phase iv, Bahria Town, Islamabad, as Contract Research Organization on recommendation of panel of experts/ inspectors in their inspection report.

AGENDA ITEM -IX:

APPLICATION FOR LICENSE TO ACT AS CLINICAL TRIAL SITE FROM NATIONAL INSTITUTE OF HEALTH F.No.15-58/2020 DD (PS)

9.1. Application is from Mst.Ghazala Perveen Chief BPD, national Institute of Health sciences, Islamabad, wherein the major General prof. dr. Aamer Ikram SI (M), Executive Director, NIC number 51401-0924270-9 application has requested for grant of license to act as a Clinical Trial Site. The application is on Form-I of the Bio-Study Rules 2017 with fee of Rs.100,000/-

9.2. It is submitted that application evaluated according pre-requisites as mentioned in Form-I of the Bio-Study Rules 2017, and as following are observations:

S. No.	Required Documents / Information	Remarks
1	Application on prescribed Form-I of The Bio-Study Rules 2017.	Attached
2	Fee	Fee challan of Rs.100,000/- attached submitted vide slip No. 2003111.
3	Particulars regarding the legal status of the applicant i.e. in case of proprietorship the names of proprietors and their addresses, in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors).	The establishment of NIH Islamabad was conceived during early 1960s. In July 1967 the nucleus of this activity started functioning with the name of National health center in newly established capital, Islamabad. Various independently working organization like Bureau of laboratories and directorate of Nutrition survey and research were shifted in the premises of NHC. Later, during 1974 proper integration of all these independently working units took place under the name of national health laboratories, Islamabad. The NIH has five major Divisions i.e. Public Health Laboratory division, Biological Production Division, Nutrition division, drugs Control and traditional

		Medicine Division and field Epidemiology & Disease Surveillance Division. Beside this a college of Medical Laboratory Technology, Allergy Centre and support departments facilitate financial, administrative and engineering functions of the institute.
4	Details of premises including layout plan of the site.	Attached.
5	Details of the section wise equipment and machinery required for the analytical or bio-analytical and clinical studies.	List of testing equipment Attached. But details of treatment/ patient handling facilities of trial center not provided.
6	Names and qualifications of the above sections along with their staff.	Attached.
7	Details of the allied facilities associated with the trial center including ambulatory services, emergency handling etc.	Islamabad hospital Isolation Hospital and infectious treatment center Detail are provided.
8	Undertaking on stamp paper	Not provided.

9.3 The case was placed before CSC in its 16th meeting held on 27th November 2020 & CSC decided as follows:

Decision of 16th CSC meeting:

CSC after detailed deliberation decided to authorize the Chairman CSC for the constitution of inspection panel for the inspection of NIH to act as clinical trial site and Islamabad Hospital, off Jinnah Avenue, Islamabad for COVID-19 Vaccine Phase III Trial. The case will be again placed before the CSC for further deliberations and decisions after submission of inspection report.

9.4. As power conferred by CSC to Chairman CSC for constitution of inspection panel, Chairman CSC constituted panel for inspection and the site inspected by following panel:

i.	Dr. Abdur Rashid (Coordinator)
ii.	Dr. Rizwana Chaudhry
iii.	Farhana Badar
iv.	Brig. Rtrd. Muzzammil Hasan Najmi.

9.5. After inspection, panel submitted report with following remarks:

Keeping in view the currently available Human Resources, Infrastructure, equipment & machinery, other facilities, national & international collaborations the panel unanimously recommended the clinical trial site of National Institute of Health park. Panel also visited the Hospital also and appreciated the facilities NIH will conduct also COVID-19 vaccine trial along with already approved centers on Corona-19 vaccine.

9.6. Concluding status of inspection / application:

Recommended for approval.

9.7. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC after detailed deliberation decided to approve M/S National Institute Health, Park road, Chack Shahzad, Islamabad, to act as Clinical trial site along with already approved centers on Covid-19 vaccine on the recommendation of panel of experts/ inspectors in inspection report.

AGENDA ITEM -X:

PROTOCOL AMENDMENTS IN RIFASHORT CLINICAL TRIAL.
F.No.03-06/2018 DD (PS).

10.1. Application received from Dr. Bushra Jamil, Co-P.I. RIFASHORT Trial, Aga Khan University, Karachi, wherein request is for amendments in already approved protocol of clinical trial titled, “An international multicenter controlled clinical trial to evaluate 1200mg and 1800mg rifampicin daily in the reduction of treatment duration for pulmonary tuberculosis from 6 months to 4 months (RIFASHORT)”.

10.2. Summary of Amendments:

Version No.	Date	Summary of minor changes
8.0	30/09/2019	<ul style="list-style-type: none">• Inclusion of baseline culture negative but GeneXpert positive patient to trial.• Removal of Bolivia as site and addition of Indus Hospital (Pakistan).• Updated details of new Trial Manager/Clinical Trial Coordinator.• Note on follow-up period for patients recruited towards end of enrolment period.

10.3. Copy of amended protocol with summary of track changes is attached.(Annex-I)

10.4. After scrutiny of the FR following shortcomings observed:

- i. Prescribed fee of Rs25000/- for miscellaneous request as per S.R.O. 1047(I)/2019, dated 12th September 2019, is not provided.
- ii. Ethical approval from NBC-PHRC for amended protocol is not provided.

10.5. Applicant informed regarding shortcomings vide letter number F.No.03-06/2018 DD (PS), dated 30th November 2020, but yet response is awaited.

10.6. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC after detailed deliberation decided to deffer the case of protocol ammendments in Rifashort Clinical Trial for the fulfilment of following shortcomings;

- i. Prescribed fee of Rs25000/- for miscellaneous request as per S.R.O. 1047(I)/2019, dated 12th September 2019, may be provided.
 - ii. Ethical approval from NBC-PHRC for amended protocol shall be furnished by the Agha Khan Hospital Karachi.
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AGENDA ITEM -XI:

**CONVALESCENT PLASMA TREATMENT IN COVID-19 PATIENTS:
NON-RANDOMISED OPEN LABEL CLINICAL TRIAL AT A TERTIARY
CARE CENTER IN PAKISTAN. F.No.03-28/2020 DD (PS).**

11.1. Appliation from Dr. Natasha Ali (Co-Principal Investigators), Associate Professor Hematology, Department of Pathology & Laboratory Medicine/Oncology, Aga Khan University, dated 22nd April 2020, forwarded by Dr. Masud Ur Rehman, Secretary CSC / Additional Director, Division Pharmacy Services through email, wherein request has been made for registration & approval of subject clinical study, which will be carried out at Section of Hematology & Transfusion Medicine, Department of Pathology and Laboratory Medicine, Aga Khan University Hospital, Karachi. Application is not on prescribed Form-I & II of the Bio-Study Rules 2017 and prescribed fee for approval & registration of Clinical Trial Site & Clinical Studies is not provided.

11.2. The study carried out under the supervision of Dr. Muhammad Hasan (PI).

11.3. The primary objective of the study “To investigate the efficacy and safety of transfusing convalescent plasma collected from patients who have recovered from COVID-19 disease to patients admitted at Aga Khan University Hospital for the management of active COVID-19 disease”.

11.4. Due to COVID-19 pandemic application was placed in the 10th CSC meeting, held on 28th April 2020. CSC approved the study subject to fulfilment of all prerequisites.

11.5. Shortcomings communicated on 27th July, 2020, 26th August 2020, 16th October 2020 & a final reminder issued on 27th October 2020. Applicant also contacted telephonically and informed regarding shortcoming, but response is yet awaited and following shortcomings still need to be fulfilled:

- i) Prescribed processing fee of Rs.200000/- as per S.R.O.1047(I) /2019, dated 12th September 2019 is not deposited yet.
- ii) Investigator Brochure is not provided.
- iii) Provided study protocol is not as per ICH-GCP Guidelines.
- iv) Phase of trial is not described.
- v) Summary of Protocol & Investigator’s brochure is not provided.
- vi) Sample of label for the investigational product / drug is not attached.

11.6. Submitted for perusal, discussion and decision of CSC.

Decision of 17th CSC meeting:

CSC after detailed deliberation decided to deffer the study entitled as Convalescent Plasma Treatment in Covid-19 Patients: Non-Randomised Open Label Clinical Trial at A Tertiary Care Center In Pakistan till report is submitted by Dr. Tahir Shamsi of his approved study of convalescent plasma and for fulfillment of following shortcomings

- i) Prescribed processing fee of Rs.200000/- as per S.R.O.1047(I) /2019, dated 12th September 2019 is not deposited yet.
- ii) Investigator Brochure is not provided.
- iii) Provided study protocol is not as per ICH-GCP Guidelines.
- iv) Phase of trial is not described.
- v) Summary of Protocol & Investigator's brochure is not provided.
- vi) Sample of label for the investigational product / drug is not attached.

ITEM XII:(Additional Agenda)

PROGRESS REPORT SUBMISSION AND APPROVAL FOR PHASE II TRIAL OF OPEN LABELLED RANDOMIZED I & II CLINICAL TRIAL TO ACCESS THE SAFETY AND EFFICACY OF IODINE COMPLEX (RENESSANCES).

Dr. Ghias-Un-Nabi Tayyab, Department of Medicine, Post Graduate Medical Institute Lahore General Hospital, Lahore, dated 8st December 2020 and MTI-Medical (Pvt.) Ltd, Lahore, have stated that phase-I clinical trial subject enrollment has been completed. Till date, 24 subjects have completed 5 days stay in hospital and 13 patients completed 21 days in the study as per approved protocol. Only 11 patients will be left to complete their 21st day milestone and 6th week visit only be pending then. During the entire course of study, no serious adverse event observed.

2. In the wake of second wave of covid-19, it is anticipated use of Renessans product in Covid-19 patients as per approved protocol phase-II trial, may help the patients to recover speedily from the disease and product efficacy may be evaluated to make it available for general public after completion of its next stage.

3. They have requested to allow them to commence the phase-II trial based on initial safety data and pandemic condition of Covid-19 in Pakistan at their approved site.

4. **Decision of 15th CSC meeting:** CSC after detailed deliberation decided to approve the Lahore General hospital, Lahore, Post Graduate Medical Institute, Lahore to act as Clinical trial site. As well as CSC decided to approve the Clinical trial titled "**OPEN LABELLED RANDOMIZED PHASE-I & II CLINICAL TRIAL TO ASSESS THE SAFETY AND EFFICACY OF IODINE**

COMPLEX (RENESSANS)” under Bio-Study Rules 2017. As per recommendation of NBC-PHRC it is suggested that after completion phase-I safety report shall be immediately submitted to CSC before commencing the phase-II clinical studies. Further as per conditions of “approval to conduct the Clinical Trial Study” as per the recommendation of NBC-PHRC it is suggested that after completion of phase-I safety report shall be immediately submitted to CSC before commencing the Phase-II clinical studies. Applicant has NBC approval for phase-II.

The request of applicant is placed before the Clinical studies Committee for further deliberation and decision. Submitted please.

Decision of 17th CSC meeting:

CSC being satisfied by the submitted safety report by the principal investigator allowed to continue phase-II trial. CSC further directed to submit progress report monthly basis. In case of any amendment in the original protocol or any adverse event immediatrly inform pharmacovigilance center of DRAP along with steps taken under intimation to this division.
