EXTRAORDINARY

GOVERNMENT

REGISTERED NO. P.III

GAZETTE

KHYBER PAKHTUNKHWA

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GOVERNMENT OF KHYBER PAKHTUNKHWA
HEALTH DEPARTMENT

NOTIFICATION

Dated Peshawar, October 04, 2017

No.xxxx/KPBTSA/2017/xxxx.----In exercise of the powers conferred by section 30 of the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016 (Act No. XXV of 2016), the Khyber Pakhtunkhwa Blood Transfusion Authority is pleased to make the following regulations, namely:

THE KHYBER PAKHTUNKHWA BLOOD TRANSFUSION SAFETY REGULATIONS, 2017

1. Short title and commencement

(1) These regulations may be called the Khyber Pakhtunkhwa Blood Transfusion Safety Regulations, 2017.

(2) These shall come into force at once.

2. Definition

(1) In these regulations, unless there is anything repugnant in the subject or context;

(a) "Act" meansThe Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act , 2016;

(b) 'Appendix' means Appendix to these regulations;

(c) 'Authority' means the Khyber Pakhtunkhwa Blood Transfusion Authority established under section 4 of the Act;

(d) "Chairman" means the Chairman of the Authority;

(e) 'Chief Executive Officer' means the chief executive officer of the authorityappointed under section 9 of the Act;

(f) "Committee" means Committee constituted/appointedunder section 8 of the Act;

(g) "Certificate of Registration" means a certificate granted under these regulations;

(h) "Form" means a Form appended to these regulations;

(i) "Government" means the Government of Khyber Pakhtunkhwa;

(j) 'Guidelines' means National Guidelines for Quality Control & Transfusion Medicine developed in 2012 by the National Safe Blood Transfusion Programme, Pakistan;

(k) 'License' means a license granted for the operations of the blood bank/blood centre registered under regulation 5;

(l) 'Licensee' means the blood centre/blood bank to which a licence is granted;

(m) 'Manual' includes Standards and National Guidelines for Quality Control & Transfusion Medicine developed in 2012 by the National Safe Blood Transfusion Programme, Pakistan, 2nd Edition in January 2017, published first edition by the Safe Blood Transfusion Programme in 2012;

(n) 'Section' means a section of the Act

(2) The words and expressions used but not defined in these regulations shall have the meanings as assigned to them under the Act.

3. Application for Registration

(1) For the purpose of section 7(b), a blood bank or a regional blood centre shall be registered and granted licence after being inspected in accordance with these regulations.

(2) Any person intending to establish a new blood bank/blood centre shall make an application to the Authority on Form-I as set out in Appendix 'A' along with required documents and non-refundable fee (Rs. 10,000) to be fixed by the Authority with the approval of Government.

(3) Subject to making an application as provided under sub regulation (2), an existing blood bank may continue to function without registration for a period not exceeding ninety(90) days from the commencement of these regulations.

(4) Any existing Blood bank desirous of continuing with the operation may apply for registration within 45 days on Form-I, along with required documents and fee fixed by the Authority with the approval of the Government.

(5) Every blood bank or its branch running under the same name or management at different premises shall be registered and granted licence separately.

4. Procedure for Registration

(1) The Authority may, on receipt of an application under regulation 3, constitute a Committee to make enquiry/inspection if the blood bank or regional blood centre concerned fulfils and complies with the conditions mentioned in section 15 and 16 and in respect of such other matters as may be specified by it.

(2) The Committee shall submit its report to the Authority within a fortnight of the receipt by it of the application or in an extended period duly approved by the Chairman.

(3) The Authority may, subject to considering the report of the Committee in a meeting and after making such further enquiry as it considers necessary, grant or reject the application.

(4) The Authority shall invariably record reasons for granting or rejecting the application.

5. Certificate of Registration

(1) The blood bank or the regional blood centre of whom the application has been accepted shall be granted a certificate for registration in Form-II as set out in Appendix 'B' to these regulations on payment of non-refundable registration fee of rupees ten thousand in the name of the Authority.

(2) The Authority shall maintain a register in Form-III as set out in Appendix 'C', containing such particulars of the blood bank/regional blood centre, which are registered, and granted certificate for registration.

6. First time and Renewal of Licence

(1) The blood bank/regional blood centre to whom the certificate of registration is issued shall be inspected and granted a licence in form-II on payment of non-refundable fee (fifteen thousands) fixed by the Authority.

(2) The licensee shall be responsible for due compliance of the provisions of the Act, Rules and these regulations, the terms and conditions of licence and orders or instructions issued from time to time by the Authority.

(3) The licence, unless cancelled, earlier, shall be valid for one year from date of its commencement.

(4) An application for the renewal of licence shall be submitted to the Authority at least one month before expiry of the licence along with non-refundable fee of Rs. 10,000/- in the name of the Authority.

(5) The procedure for registration and grant of licence shall, mutatis mutandis, apply to the renewal of registration and grant of licence.

(6) The blood bank or the regional blood centre of whom the application has been accepted shall be granted renewal of licence after being re-inspected for one year from the date of expiry of the licence granted earlier.

(7) Licence of the blood bank or the regional blood centre under complaint or inquiry may not be renewed, unless, the Authority is satisfied by the report of blood transfusion inspector or Committee.

7. Monitoring and Inspection

(1) The working of the licensee shall be subject to monitoring by the Authority and for that purpose the Authority or any person authorized by it may inspect the blood bank or regional blood centre to satisfy itself if it is functioning satisfactorily in accordance with the Act, Rules and these regulations.

(2) The licensee shall allow inspection of the blood bank or regional blood centre with or without notice without any hindrance.

(3) Blood Transfusion Inspectors who are responsible to carry out functions assigned by the Authority in their territorial jurisdiction, are authorized to pass following orders about the inadequate discharge of responsibilities by the blood bank or regional blood centre as given in section 15 and 16 with the assistance of the local police, if so required:

(a) sealing of the premises of the blood establishment;

(b) imposition of fine of up to one hundred thousand rupees;

(c) confiscation of the equipment used and any other related materials;

(d) issuance of an adverse findings report and putting the blood establishment on probation;

(e) seizure and prevention of the release of blood or blood components which violate the prescribed rules and regulations or which are considered unsafe.

8. Cancellation or Suspension of Licence

(1) Where the Authority is satisfied that the licensee is not functioning properly, it may after giving an opportunity of being heard to the licensee, suspend or cancel the licence.

Provided that where the default is capable of being rectified, no order shall be passed unless an opportunity is provided to the licensee concerned to rectify such default within the specified (probationary) period.

(2) On the cancellation or suspension of the licence, the Authority shall issue orders in writing.

9. Appeal

Where the Authority rejects an application for registration or suspends or cancels the licence, the aggrieved person may, within 30 days from the date of the order of the Authority, prefer an appeal to the 'Grievance Redressal Committee' or to the high court under section 28.

10. Annual Report

For the purpose of clause under section 15(h) 16(j) and 18, the licensee shall furnish to the Authority, the periodic report on its activities, on blood donations, blood safety data and serious adverse reactions/events relating to donor or the patient as set out in Form – IV in Appendix 'D'

11. Meetings

(1) All the business of the Authority shall be discussed in its meetings.

(2) Meetings shall be held as often as deemed necessary by authority but at least four meetings annually under section 6.

(3) The Chief Executive Officer of the Authority under the instructions of the Chairman shall convene an ordinary meeting on such date and the time as may be fixed by the Chairman under section 6 (2).

(4) Meeting shall ordinarily be held in the head office of the Authority in Peshawar but the Chairman may, if he so thinks fit, hold a meeting at any other place under section 4 (3).

(5) Not less than five days advance notice accompanied by an agenda shall be given for each meeting.

(6) The Chief Executive Officer shall cause the agenda prepared in the following order;

(a) Decisions outcomes of minutes of the previous meeting,
(b) All matters deferred in the previous meetings,
(c) Reports of the Committee

(7) The Chairman shall preside over every meeting and in his absence by the member elected by the members present at the meeting from amongst themselves and the person so elected will exercise all the powers of Chairman under these regulations and under section 6 (2).

(8) Unless otherwise directed by the Chairman no meeting shall be adjourned till the business agenda is disposed off.

(9) Any person expert or advisor may attend a meeting on invitation of the Authority, but he/she shall not be entitled to cast a vote.

12. Quorum

The quorum of the meeting shall be one third of the membership of the Authority under section 6 (4).

13. Decisions

(1) All decisions in the meeting shall be taken by the majority of the members present and in case of a tie the Chairman shall have a second casting vote under section 6(3).

(2) Actions on the decisions shall be taken after confirmation of the minutes of the meeting, save in the exceptional cases where the Chairman may, by an order in writing otherwise direct.

14. Proceeding of the Meeting

(1) The Chief Executive Officer of the Authority shall record minutes of the meeting.

(2) The minutes shall comprise of the names of members present and the number of agenda items and their brief notes and the decisions taken in the meeting.

(3) The Chairman of the Authority shall approve and sign the minutes and a copy thereof shall be submitted to every member.

(4) Record of the minutes of the meetings shall be maintained.

15. Committees

(1) The authority shall determine the membership and terms of reference of the following committees as given below:

(a) The **Technical Committee** will comprise at least three members: Additional Secretary Health/representative DOH, Senior Haematologist, representatives of NGOs/Blood Donor Organizations. The Technical Committee shall provide advice on any matter referred to it by the Authority, including matters related to blood transfusion standards, quality assurance and haemovigilance.

(b) The **Licensing Committee** will comprise at least three members: Chief Executive Officer of the Authority, senior Haematologist/Blood Transfusion Inspector and a legal expert.

The Licensing Committees hall:

i. review all inspection reports and decide on the issuance of the licence to blood bank, regional blood centers and specialized blood transfusion services in both public and private sector.

ii. categorize non-compliances observed as critical, severe, and significant.

iii. refer the case to the inspectors/local police and relevant courts to deal with cases referred by the licensing committee, if the non-compliance(s) constitutes critical or severe, or other violations of this Act which pose a direct/indirect risk to the blood donor or the patient safety.

(c) The **Grievance Redressal Committee** will comprise at least three members, Chairman of the Authority/representative of DOH, haematologist/blood transfusion expert and member of the Authority representing civil society/NGO/BDO. The Grievance Redressal Committee shall: redress any grievances caused by any decision of the Chief Executive Officer of the Authority. The grievances, however, shall not constitute Prohibitions / Offenses mentioned under Section 11 of this Act.

(d) **Hospital Blood Transfusion Committees** shall have multidisciplinary composition with members which truly reflects the key staff groups involved in transfusion, including the blood bank incharge, prescribers (which frequently use blood components, such as haematologist, Oncologist, Surgeon, Anesthesiologist, Obstetrician-Gynaecologists, Clinicians/Paediatrician), Incharge nurse, pharmacist and hospital administrator. The Hospital Transfusion Committee shall ensure haemovigilance, safe blood transfusion practices and rational use of blood and blood components.

(e) **District Blood Transfusion Committees** shall comprise philanthropists, social workers, district health officer and Vice Chancellor of a University/Principal of a college in a district, blood bank representative. These Committees may assume any function as delegated by the Authority, including creating awareness about voluntary blood donations.

(2) The business of every Committee shall be conducted in such manner as it may decide.

(3) Every committee shall be headed by a convener appointed by the Chief Executive Officer of the Authority.

(4) In the absence of the convener, the members of the Committee shall elect one of them to preside and the member so elected shall exercise all powers of the convener under these regulations.

(5) The proceedings or report of the Committee shall be submitted to the Chief Executive Officer as early as possible for placing it before the Authority.

16. Quality assurance in maintenance of an effective anti-HIV, hepatitis B, hepatitis C, Syphilis, Malaria and other viruses and infective agents screening

For the purpose of clause (f) of section 15,and clause (g) of section 16 of the Act, a registered regional blood centre and a blood bank (respectively) shall follow the general instructions given at Chapter 7 of the manual.

17. Standard operating procedures for evolving quality system of blood and blood products

For the purpose of clause (b) & (k) of section 7 of the Act, a registered blood bank or a regional blood centre shall follow the minimum standards and establish quality control and quality assurance mechanism involving processes from blood collection to transfusion given in the manual and national guidelines for QC and QA.

18. Rational use of blood

For the purpose of section 3 of the Act, the prescribers and other members of hospital transfusion committees shall follow the guidelines for component therapy.

19. Phasing in voluntary non-remunerated blood donation and phasing out replacement donation

For the purpose of section 15(b) of the Act, Authority may delegate responsibility to regional blood centre in coordination with district blood transfusion committees for creating awareness and motivation about voluntary blood donations. Blood banks shall discourage replacement donations.

20. Safety measures to be adopted by the Blood banks and Regional Blood Centres

For the purpose of clause (j) of section 7 of the Act, the blood bank and the regional blood centre, to which the license for registration has been issued, shall notify a responsible person under intimation to the Authority for performing the following:

a) Demonstrate the bio-safety measures specified in the Appendix 'E' to all staff members.

b) Inform and explain all members, on periodical basis, the hazards encountered working in the blood bank and regional blood centres and the necessary precautions to be taken.

c) Give instructions regarding cleaning of different areas and make arrangements for the safe and documented disposal of waste.

d) Record any accidents or incidents involving possible escape of potentially infective material even if there has been no personal injury in a register maintained specially for that purpose.

21. Distribution of copies of manual and instructions

(1) The blood bank and the regional blood centre to whom the Authority grants license shall be provided with at least two copies of the manual (Standards and Guidelines for Blood Transfusion Services).

(2) On reviewing the instructions under regulations 16, 17 and 18 from time to time, the Authority shall provide the revised instructions to the licensee during the preceding year and such information relating to its activities as may be required by the Authority.

SECRETARY HEALTH/CHAIRMAN
BLOOD TRANSFUSION SAFETY AUTHORITY
KHYBER PAKHTUNKHWA

APPENDIX 'A'
FORM – I
See regulation 3(2)

OFFICE OF THE CHIEF EXECUTIVE OFFICER,
KHYBER PAKHTUNKHWABLOOD TRANSFUSION SAFETY AUTHORITY, STREET ADDRESS XXXX, PESHAWAR

PH # 091-9211486 FAX # 091-XXXXXXXX

SECTION I: REGISTRATION FORM FOR LICENCING OF BLOOD BANKS AND REGIONAL BLOOD CENTRES (*)

(*) under section 4 of the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016 "blood bank" and 'regional blood centre' includes private, public blood banks and regional blood centres maintained for the purpose of receiving/collecting, preserving, storing, analysing, screening, processing, distributing/issuance of blood and blood products.

Name of Blood Bank/Regional Blood Centre

.....

Address/Location

.....

Type of Blood Bank/ Regional Blood Centre	□ Public	□ Private for Profit	□ Private Non Profit
	□ Stand-alone Blood Centre	□ Part of Pathology Laboratory	□ Hospital Blood Bank

Name of Hospital (s) / Facility (ies) linked with the blood bank/centre

1. ..... 2. ..... 3. .....

4. ..... 5. ..... 6. .....

Processes Carried out in the Blood Bank/Regional Blood Centre	□ Blood Collection/Receiving	□ TTI Screening	□ Processing (component preparation)
	□ Immunohaematology	□ Storage	□ Distribution
	□ Issuance	□ Transfusion	□ Others
Paid Fee Receipt No.			

SECTION II:

Name of in-charge/designated person of the Blood Bank/Centre

.....

Qualification			
PMDC Registration No		Last Renewal	Expiry
Contact Details	Phone & Cell No.	E-mail:	Fax No.

CERTIFICATE BY THE BLOOD INCHARGE /DESIGNATED PERSON(*)

**Under section 16 (2) of the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act 2016 'designated person' means the person notified by the blood bank or regional blood centre to the authority.*

Dr.....s/o-d/o-w/o.....

Do hereby solemnly affirm that I am working as the officially designated person/in charge of Blood Bank/Regional Blood Centre and the information provided above is correct. I accept full responsibility to implement the standards and to ensure all instructions laid down by the Khyber Pakhtunkhwa Blood Transfusion Safety Authority andshall be complied with and proper documentation shall be maintained. Further that I have not lent my name or interest in absentia to any other blood bank/centre intending to apply for registration. I also understand that in an event of any lapse in compliance, I shall be liable to penalization as prescribed by the law.

Date.	Name	Signature
	Designation	
	CNIC No.	
	PMDC Registration No.	

Following documents attached with registration form:

1. Copy of CNIC
2. Two photographs
3. Policy Manual
4. Standard operating procedures
5. List of staff with qualification
6. Job description.
7. List of equipment with specifications.
8. Attested copies of degrees and certificates of all staff.
9. Original Challan after depositing the registration fee Rs. 10,000/- in Treasury / Scheduled Bank in Head of Account xxxx
10. Application along with enclosure may be submitted in all District Health Offices and in the office of Authority at (street address), Peshawar.

OFFICE OF CHIEF EXECUTIVE OFFICER,

KHYBER PAKHTUNKHWABLOOD TRANSFUSION

SAFETY AUTHORITY

Street address, Peshawar
Ph.091-xxxxxxxx Fax # 091-xxxxxxxx

SECTION III: STAFF INFORMATION AND INSPECTION CHECK LIST

Name of Blood Bank/Regional Blood Centre

Address:

Name of Incharge (Designated person):

Name of Incharge (Technical person):

Telephone No: _____ Cell No: _____

E-mail Address: _____ Fax No: _____

DETAILS OF TECHNICAL STAFF			
S. No:	Designation	Experience	Qualification/Training

(Detail of Staff: along with their qualification with certificates & job description must be attached).

BUILDING

i. Is the location/approach/premises to the blood bank as per work load? ☐

ii. Are sign boards/direction boards installed for donor/patient guidance? ☐

iii. Is the building well maintained i.e. white washing etc? ☐

iv. Is Lighting, Ventilation, general cleanliness satisfactory? ☐

v. Is power back up available? ☐

vi. Are procedures displayed for patients? ☐

vii. Are procedures displayed for donor guidance? ☐

viii. Are safety and hygiene instructions displayed? ☐

Is the building suitable for a Blood Bank? -

_____

SPACE MANAGEMENT

- Is Donor Management area available ☐
- Is Blood Testing /Screening area available ☐
- Is Processing/Component Preparation area available ☐
- Is Storage area available ☐

BLOOD DONOR MANAGEMENT UNIT

Is Counselling in privacy available? ☐
Are history/physical examination/donor consent forms in use. ☐
Is Post Donation care provided ☐

BLOOD GROUPING

- Slide method/Tile method ☐ Tube method ☐
- Forward Grouping ☐ Reverse Grouping ☐

SCREENING

- HBs Ag ☐ HCV ☐ HIV ☐ Syphilis ☐ Malaria ☐

BLOOD COLLECTION

- Is Venipuncture done properly ☐
- Is proper Collection of Blood being done ☐
- Is proper sealing of tubes and labelling done ☐
- Is blood shaker equipment available ☐

COMPONENT PREPRATION/ STORAGE

- RBC Concentrates ☐ Cryoprecipitate ☐ FFP ☐ Platelets ☐
- Temperature Monitoring of stored Blood ☐

ISSUANCE OF BLOOD

- Standard Requests form & Issuance register ☐
- Cross matching procedure.

  Emergency ☐ Routine ☐ Albumin Phase ☐ Coombs Phase ☐
- Are instruction for transport of Blood given ☐
- Is post transfusion feedback mechanism present ☐
- Is there an adverse reaction register being maintained ☐

EQUIPMENT DATA

S #	Name of Equipment	Number	Working	Out of order
1	Blood Collection Mixer			
2	Tube Sealer			
3	Weighing Scale			
4	Equipment for HB Estimation			
5	Safety Equipment and Supplies			
6	Blood Storage Refrigerator			
7	Plasma Freezer (FFP)			
8	TTI Screening Equipment			
9	Agglutination viewer Lamp			

10	Serofuge/Cell washer			
11	Water Bath			
12	Refrigerated Centrifuge			
13	Plasma Extractor			
14	Blood Cell Separator			
15	Blood Cell Irradiator			

REAGENTS & CONSUMABLES USED *(please specify methodology and company)*		
1	Grouping sera	
2	Haemoglobin reagent	
3	Albumin/LISS	
4	Reagents for screening of Hepatitis B	
5	Reagents for screening of Hepatitis C	
6	Reagents for screening of HIV	
7	Reagents for screening of Syphilis	
8	Reagents for screening of Malaria	
9	Blood lancets	
10	CPDA triple/Double blood bags	
11	CPDA single blood bags	
12	Gloves	
13	Test tubes for grouping/screening tests	
15	Others (please specify and use additional sheets)	

RECORDS Are record computerized. ☐

Is each entry authenticated with signatures of the official concerned ☐

S #	Record Type	Yes / No.	S #	Record Type	Yes / No.
1	Donor Record		5	Cross-match Record	
2	Blood Grouping record		6	Transfusion Reaction record	
3	Blood Collection Record		7	Blood Products Record	
4	TTI Screening Record		8	Shift Taking over Register	

PERFORMANCE (WORKLOAD) OF PREVIOUS YEAR

S #	Procedure	NO	S #	Procedure	No
1	Blood Group Testing		4	Storage	
2	Blood Collection		5	Distribution	
3	TTI Screening		6	Cross match performed	

OTHER

1. Is there evidence of constitution of Hospital Transfusion Committee? meeting schedule of HTC.

   YES ☐ NO ☐

2. Is there a documented system available for the recall of any component(s) causing adverse effects and all other components linked with that component(s)?

   YES ☐ NO ☐

3. Are there Hazards management (fire, electricity, etc, safety and hygiene) instruction displayed? YES ☐ NO ☐

4. Standard Waste Management practices followed?

   YES ☐ NO ☐

5. Is there any mechanism of quality control/TQM/Accreditation?

   YES ☐ NO ☐

APPENDIX 'B' **FORM – II** See regulation 5(1)

LICENSING REPORT

Name of BB/RBC visited_____ **Date of visit:** _____**2017**

The Inspection report, Checklist and compliance report by the concerned bank/centre, has been reviewed in the light of decision made by the licensing committee in its meeting dated 0x.0x.2017. The deficiencies pointed out by the Technical Committee have been rectified. The compliance report is attached.

The observations made are as follows:

Sr. No	Standard requirements	Comments of Technical Committee
1	**Premises** The service area for a blood bank must be capacious, neat and clean. The directional signs should be given for facilitation of the donors/patients. There should be designated areas for registration/donor selection, phlebotomy, rest and laboratory work.	•
2	**Staff** A Blood Bank/Blood Centre should be supervised by a qualified (MBBS) doctor. All the areas need to be manned by qualified and skilled staff. Professional, administrative and ancillary staff must be in adequate numbers according to workload.	
3	**Procedures** a. The principle of voluntary non-remunerative donations should be applied and practiced.	
	b. All procedures of vein to vein management such as donor selection, ABO grouping and Rh typing and cross matching/antibody screening should be done with standard methods. Screening/ processing of blood, storage and issuance, transfusion of blood and haemovigilance are performed as per guidelines/SOPs.	
	c. All blood collected must be subjected to screening for TTIs as defined by the authority.(Presently five TTIs to be screened)	
	d. Quality management reviews conducted and documented regularly.	
	e. All blood and blood products should be quarantined until screening results are available and should be accordingly stamped.	
	f. Basic equipment for storage of blood should include a blood storage cabinet with a reliable temperature control system with backup power supply.	

4	**Others** 1. Regular review meetings of Hospital Transfusion Committee and documentation of minutes of meeting (for blood banks located inside the hospital).	
	2. Standard measures for bio-safety and waste management should be practiced.	
	3. Emergency tray to deal with any reaction during v2v procedure must be readily available.	
	4. The SOPs are displayed/ available at hand for ready reference.	
	5. Consent for blood donation/ transfusion taken and documented.	
	6. All data of blood bank performance is provided to the authority after every three months.	

Issuance of license to (name)_____Blood Bank/Regional Blood Centre for one year is recommended which will be extended, if the blood bank continues to maintain the standards.

Or

License rejected on the basis of critical compliances

Or

Corrective measures proposed

FOR OFFICE USE ONLY	
Date application received: New Applicant.....	Renewal Case..... Old Licence No.....
Identification Code No.	
Charges received	Rupees:
Charges received for the purpose:	
Bank Challan / Bank draft No.	
Inspection Date	
Name(s) of the Inspector(s)	
Date of Inspection Report's submission	
Date of meeting of Authority to consider the Application No.....	
Decision of the Authority on the Application No:.....	

Member Licensing Committee/Chief Executive Officer
KP Blood Transfusion Authority
Peshawar

KHYBER PAKHTUNKHWA BLOOD TRANSFUSION SAFETY AUTHORITY

Street address, Peshawar
Ph.091-xxxxxxxx Fax # 091-xxxxxxxx

LICENCE CERTIFICATE FOR OPERATIONS OF BLOOD BANKS

According to the Powers and Functions vested under Section 7of the Khyber Pakhtunkhwa Blood Transfusion Safety Authority Act, 2016, the KP Blood Transfusion Authority, hereby allows the.....Blood Bank/Regional Blood Centre to conduct the following Blood Banking operations for a period of one (01) year, starting with effect from.....

Collecting blood/donor draw	Yes		No	
Receiving blood and blood components	Yes		No	
Preserving	Yes		No	
Storing	Yes		No	
Analysing	Yes		No	
Screening	Yes		No	
Processing blood and blood products	Yes		No	
Distributing blood and blood products	Yes		No	

The Licence shall function in accordance with the KP Blood Transfusion Safety Authority Act, 2016, Rules and regulations framed there under and the instructions issued from time to time by the Authority.

This registration will expire on.....and the Blood Bank/Regional Blood Centre should apply for licence renewal for the operations at least one month in advance.

Secretary
Khyber Pakhtunkhwa Blood Transfusion Safety Authority
Dated:.....

APPENDIX 'C' **FORM – III** See regulation 5(2)

REGISTRATION AND LICENCE RECORD

S.#	Name of registered Blood Banks/Regional Blood Centres	Name of Licenced Blood Banks/Regional Blood Centres	Address/Location with telephone	Date of Expiry of Licence	Details of the owner and management of Blood Bank	Remarks
1	xx	xx	xx		xx	xx

APPENDIX 'D' FORM-IV see regulation 10

	Status of BB/RBC Operation- Year 2017	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	%
1.	**Blood Donation Collection**														
1.1.	Total Blood donation Collection (all type)														
1.2.	Number of voluntary donors														
1.3.	Number of replacement/family donors														
1.4.	Total number of donors (both gender)														
1.5.	Number of male donors														
1.6.	Number of female donors														
1.7.	Number of donation collected at RBC														
1.8.	Number of Blood donations collected thorough camps/hospital														
2.	**Blood Processing**														
2.1.	Total number of units processed into components														
2.2.	Number of Units kept as whole blood														
2.3.	Number of Red cell concentrates														
2.4.	Number of Fresh Frozen Plasma (FFP)														
2.5.	Number of Platelets														
2.6.	Platelet concentrates														
2.7.	Platelet Apheresis														
3.	**Blood Group Serology**														
3.1.	Group														
3.2.	Number of donor sample tested for forward blood group														
3.3.	Group														

3.4.	Number of patients sample tested for forward group only														
3.5.	Number of Blood groups tested on tile method														
3.6.	Number of blood groups tested on tube method														
4.	**TTI Screening**														
4.1.	Blood bags screened for TTIs (all 5)														
4.2.	Number of Blood Bags screened for HCV by CLIA/Elisa														
4.3.	Number of Blood Bags screened for HCV by Rapid ICT														
4.4.	Number of Blood Bags Positive for HCV														
4.5.	Number of Blood Bags screened for HBV by CLIA/Elisa														
4.6.	Number of Blood Bags screened for HBV by Rapid ICT														
4.7.	Number of Blood Bags Positive for HBV														
4.8.	Number of Blood Bags screened for HIV by CLIA/Elisa														
4.9.	Number of Blood Bags screened for HIV by Rapid ICT device														
4.10.	Number of Blood Bags Positive for HIV														
4.11.	Number of Blood Bags screened for syphilis by CLIA/Elisa														
4.12.	Number of Blood Bags screened for syphilis by Rapid ICT device														
4.13.	Number of Blood Bags Positive for syphilis														
4.14.	Number of Blood Bags screened for Malaira by Rapid ICT device														
4.15.	Number of Blood Bags Positive for Malaria														
5.	**Blood Stock Inventory**														
5.1	Number of HBB(s) whose blood demand covered fully														
5.2	Number of HBB(s) whose blood demand covered Partially														

5.3	Total number of blood components distributed to HBBs														
5.4	Previous balance of RCC (Red cell concentrates) stock														
5.5	Number of RCC distributed														
5.6	Number of RCC expired														
5.7	Previous balance of FFP stock														
5.8	Number of FFP Distributed														
5.9	Number of FFP expired														
5.10	Previous balance of platelets stock														
5.11	Number of platelets distributed														
5.12	Number of platelets expired														
5.13	Total number of blood bags discarded due to TTI Positive														
5.14	Total Number of blood bags discarded due to expiry														
5.15	Total Number of blood bags discarded due to other reason														

APPENDIX 'D' FORM – IV see regulation 10

LIST OF DONOR ADVERSE EFFECTS

1. VASOVAGAL REACTION

- Cold extremities/chills
- Convulsions
- Feeling of Warmth
- Hypotension
- Light headedness/Dizziness
- Urination/Loss of bladder/bowel control
- LOC<60 seconds
- LOC > 60 seconds
- Nausea/Vomiting
- Pallor (pale skin or lips)
- Rapid pulse
- Slow pulse
- Sweating
- Tetany
- Twitching
- Weakness

2. SYSTEMIC ALLERGIC REACTION/ANAPHYLAXIS

- Anxiousness, restlessness
- Arrhythmia
- Cyanosis
- Generalized hives
- Generalized rash
- High blood pressure
- Laryngeal edema with stridor (noisy breathing)
- Low blood pressure
- Pulmonary edema
- Rapid Pulse
- Slow pulse
- Scratchy feeling in throat
- Shortness of breath
- Sneezing and nasal congestion
- Swollen throat, tongue, eyes and face
- Wheezing

3. HYPERVENTILATION

4. MEDICAL EMERGENCY

- Cardiac
- Respiratory
- Stroke

5. LOCAL SITE REACTION

- Itching at insertion or bandage site
- Rash/hives at insertion or bandage site
- Redness at insertion or bandage site
- Multiple pricks
- Bruising or Haematoma

LIST OF RECIPIENT ADVERSE REACTIONS, SIGNS AND SYMPTOMS

List of Adverse Reactions

1. Immunological haemolysis due to ABO incompatibility
2. Immunological haemolysis due to allo-antibody
3. Post -transfusion Purpura
4. Allergic Reaction
5. Anaphylactic/hypersensitivity reaction
6. Transfusion related acute lung injury (TRALI)
7. Graft versus host disease
8. Transfusion associated HIV-1/2 infection
9. Transfusion associated HBV infection
10. Transfusion associated HCV infection
11. Other transfusion associated viral infection
12. Sepsis due to bacterial contamination of the donor unit
13. Transfusion associated malaria infection
14. Other transfusion associated parasitical infection
15. Transfusion associated circulatory overload

Clinical Symptoms

1. Discomfort
2. Chills/rigors/flushing
3. Itching
4. Urticaria Isolated/Extensive
5. Redness
6. Rash
7. Jaundice
8. Low back pain
9. Chest/abdominal pain
10. Nausea/vomiting
11. Dyspnoea/Wheeze/stridor/Pulmonary Oedema/Cough/Hypxaemia
12. Acute renal failure
13. Shock
14. Loss of consciousness

Biological Signs

1. Positive DAT/Direct Coombs
2. Hyperbilirubinemia
3. ALT>2N
4. Transfusion refractoriness
5. Haemoglobinurla
6. Haematuria
7. Fever
8. Raised JVP
9. Hypertension/Hypotension
10. Arrhythmia
11. Respiratory Rate

RECIPIENT ADVERSE REACTION REPORTING FORM

Patient	Sex: M ☐ F ☐ Age: ..... years File number: ..... Date of transfusion (dd/mm/yy): ..... /..... /..... Appearance of reaction after transfusion : ....min / ....hour(s) / ....day(s) / ....year(s) (all other information is confidential and appears only on the hospital forms/patient record)
Transfused blood component (BC)	Type of BC : ☐ Whole Blood ☐ Red cells ☐ Platelets ☐ Plasma/FFP Additional modification of BC: ☐ Leucocyte-poor ☐ Leucocyte-depleted/filtered ☐ Plasma-depleted/washed ☐ CMV negative ☐ Irradiated ☐ Other (specify): .....
Place of BC issue	

SignsBefore tx After tx	*Clinical Symptoms (1)*	*Clinical Symptoms (2)*	*Biological Signs*
Temperature °C .... Blood pressure (systole/diastole In mm Hg) ...../..... ...../..... Pulse (beats/min.) .... Haemoglobinurea☐☐ Cardiac arythmia☐☐ Others:	☐ Discomfort ☐ Chills ☐ Itching ☐ Urticaria ☐ Redness ☐ Rash ☐ Jaundice Others:	☐ Lower back pain ☐ Chest/abdominal pain ☐ Nausea/vomiting ☐ Dyspnea ☐ Acute renal failure ☐ Shock ☐ Loss of consciousness Others:	☐ Positive DAT / Direct Coombs ☐ Hyperbilirubinemia ☐ ALT > 2N ☐ Transfusion refractoriness Others: .....

Patient's primary diagnosis	☐ Surgical ☐ Medical ☐ Obstetric ☐ Oncologic ☐ Haemotologic ☐ Other:.....	Details:

Indication for blood transfusion:	Specify:

Conclusions on RECIPIENT AR (Adverse Reaction to Transfusion) (only one for each report):

Immunological

- ☐ Haemolysis due to ABO incompatibility
- ☐ Haemolysis due to irregular antibody
  Specify:.....
- ☐ Immunisation to :
  - ☐ Red cells ☐ Platelets
  - ☐ HLA ☐ IgA
- ☐ PTP (post-transfusion purpura)
- ☐ Allergic reaction (mild)
- ☐ Anaphylactic reaction (severe)
- ☐ TRALI (transfusion related acute lung injury)
- ☐ TACO (Transfusion associated circulatory overload)

Severity

- ☐ 0. no effect
- ☐ 1. immediate, no vital
- ☐ 2. immediate, vital
- ☐ 3. long term morbidity
- ☐ 4. death

Imputability

- ☐ 0. excluded
- ☐ 1. possible, dubious
- ☐ 2. likely, probable
- ☐ 3. certain, proven

Other relevant clinical information on the tx patient:

(e.g. prior condition of the recipient, medication, ...)

Infectious

- ☐ Blood component (BC) with bacterial contamination
  Microorganism(s): .....
- ☐ HIV
- ☐ HBV
- ☐ HCV
- ☐ CMV
- ☐ Malaria
- ☐ Other infectious agent: .....

Others

- ☐ NHFTR (Non haemolytic febrile transfusion reaction)
- ☐ TA-GVHD (tx associated graft versus host disease)
- ☐ Pulmonary oedema (due to cardiac failure, circulatory overload)
- ☐ Haemosiderosis
- ☐ Unspecified: .....

Transfusion process	Location:	☐ Operation Theatre ☐ Intensive Care Unit ☐ Medical ☐ Paediatric ☐ Outpatient Clinic ☐ Other unit/ward:
	Time:	☐ Working hours ☐ Night shift ☐ Weekend
Incorrect blood component transfused (IBCT):		Yes ☐ No ☐ Where in the process did the error occur? ☐ Regional Blood Centre ☐ hospital blood bank ☐ clinical unit/ward ☐other: ..... ☐ at production of blood component ☐ at cross-matching ☐ at distribution/issuing ☐ at transfusion (administration of BC to patient) ☐other:..... Describe the error: ....
Associated involvement		☐Materiovigilance / medical devices failure ☐Reactovigilance / laboratory reagents failure ☐ Pharmacovigilance / medical products, medicines failure Describe .....

APPENDIX 'E'

BIOSAFETY MEASURES

(1) Hands to be washed before and after each procedure, especially for donor draw and transfusion to patient

(2) Use gloves for all procedures

(3) No work inside the blood bank laboratory shall be carried with exposed skin, cuts and lesions.

(4) Blood shall be drawn through new disposable, properly sterilized syringes and needles.

(5) Blood shall not be pipetted by mouth.

(6) A freshly prepared solution of 01 % sodium hypochlorite should always be available in the blood bank for sterilization of re-usable equipment e.g. pipettes, scissors, beakers, flasks and other equipment.

(7) Needles and other sharp instruments shall always be kept in rigid plastic, glass or metallic containers.

(8) Needles shall be properly capped.

(9) Decontaminated material shall be autoclaved or burnt and buried at a scientific landfill site.

(10) Contaminated laboratory and other clothing be autoclaved before sending them for washing.

(11) Work surfaces shall be decontaminated with 10% sodium hypochlorite solution, bleach and soap at the end of each day.

(12) At the end of the work, hands shall be washed with soap or disinfectant.