Name: Enrolment No:	

UNIVERSITY OF PETROLEUM AND ENERGY STUDIES

End Semester Examination, May 2022

Course: Good Clinical Practice: Conducting Clinical Trials **Semester: II**

Program: M Sc. Clinical Research **Time: 03 hrs.**

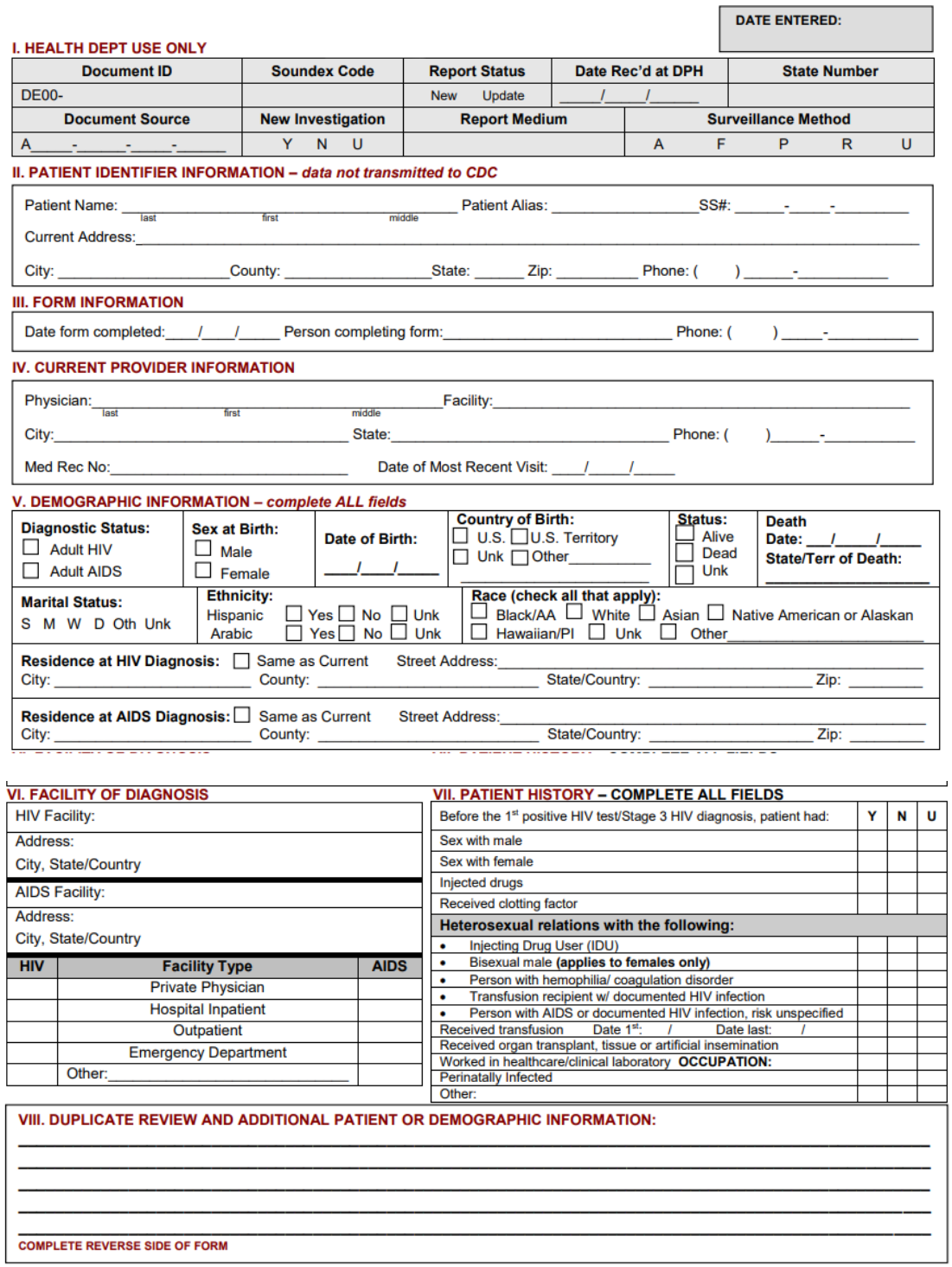
Course Code: HSCR7010 **Max. Marks: 100**

Instructions: All the sections are compulsory.

SECTION A

S. No.	CO	MCQ's /Fill in the blanks/ T&F (1.5 marks each)	Marks (30)
1.	**CO1**	The GCP guideline ensure clinical data generated are a) Verifiable b) Accurate c) Reproducible d) All of the above	**1.5**
2.	**CO1**	Vulnerable groups that face discrimination include a) Women b) Schedule caste c) Schedule tribe d) All of the above	**1.5**
3.	**CO1**	Research must be justified on the basis of a favorable risk/benefit assessment. True/False Justify the comment	**1.5**
4.	**CO2**	FDA 21 CFR 820 refers to……	**1.5**
5.	**CO2**	Differentiate between ISO 13485 and 21 CFR 820.	**1.5**
6.	**CO2**	Investigator`s brochure is a compilation of …… data.	**1.5**
7.	**CO3**	Source documents data is considering as the original data. Justify the statement.	**1.5**
8.	**CO3**	The responsibility of sponsor/investigator/IRB is to maintain the Quality Assurance documents (chose the correct one)	**1.5**
9.	**CO3**	Responsibility for investigational product(s) accountability at the trial site(s) perform by ……	**1.5**
10.	**CO3**	There are ……..types of source documents.	**1.5**

11.	**CO4**	Does Institutional Review Board need to register with FDA before approving studies?	**1.5**
12.	**CO4**	An institution must establish its own Institutional Review Board. True/False Justify the comment.	**1.5**
13.	**CO4**	The fundamental purpose of IRB review of informed consent is to assure that the rights and welfare of subjects are protected. True/False	**1.5**
14.	**CO4**	Sponsors allowed access to review board to access written procedures, minutes and membership rosters. Yes/No	**1.5**
15.	**CO5**	If an IRB disapproves a study submitted to it, and it is subsequently sent to another IRB for review, should the second IRB be told of the disapproval? Give reason.	**1.5**
16.	**CO5**	List some role and responsibilities of Institutional Review Board.	**1.5**
17.	**CO5**	Does FDA expect the IRB chair to sign the approval letters?	**1.5**
18.	**CO5**	IRB member can have diverse membership? True/False (justify your comment)	**1.5**
19.	**CO5**	IRB/IEC should include at least ……..members	**1.5**
20.	**CO5**	The investigator may provide information on any aspect of the trial, but should not participate in the deliberations of the IRB/IEC or in the vote/opinion of the IRB/IEC True/False	**1.5**
SECTION B (5 marks each question)			
Q	**CO**	Short Answer Type Question (5 marks each) Word limit (100-120)	**Marks(20)**
1.	**CO4**	Write a short note on ethical and conceptual basic of Vulnerable Populations.	**5**
2.	**CO5**	Does FDA require the signature of children on informed consent documents?	**5**
3.	**CO1**	Read the following paragraph and answer the following questions Human research study should be justified scientifically and presented in a clear, detailed in a prescribed format documents. The document must be carefully designed to generate statistically and scientifically sound answers to the questions that are being asked and meet the objective(s) of the study. The trial perform on human should generate useful results. The document followed to achieve such trial is unobtainable by other methods. Investigation should not be random and haphazard. a) What is meant by “scientifically justified”? b) In this paragraph what refers to document? Give an example of such methodology format.	**2+3**

4.	**CO5**	Discuss the role and responsibilities of Institutional Review Board.	**5**
		SECTION C 30 marks	
Q	**CO**	Two case studies 15 marks each subsections	**Marks**
1	**CO3**		**15 (2+3+10)**

DATE ENTERED:

I. HEALTH DEPT USE ONLY

Document ID	Soundex Code	Report Status	Date Rec'd at DPH	State Number
DE00-		New Update	____/____/____	
Document Source	**New Investigation**	**Report Medium**	**Surveillance Method**	
A____-____-____-____	Y N U		A F P R U	

II. PATIENT IDENTIFIER INFORMATION – *data not transmitted to CDC*

Patient Name: _____ Patient Alias: _____ SS#: ____-____-____
(last first middle)

Current Address: _____

City: _____ County: _____ State: _____ Zip: _____ Phone: ( ) ____-____

III. FORM INFORMATION

Date form completed: ____/____/____ Person completing form: _____ Phone: ( ) ____-____

IV. CURRENT PROVIDER INFORMATION

Physician: _____ Facility: _____
(last first middle)

City: _____ State: _____ Phone: ( ) ____-____

Med Rec No: _____ Date of Most Recent Visit: ____/____/____

V. DEMOGRAPHIC INFORMATION – *complete ALL fields*

Diagnostic Status: ☐ Adult HIV ☐ Adult AIDS	**Sex at Birth:** ☐ Male ☐ Female	**Date of Birth:** ____/____/____	**Country of Birth:** ☐ U.S. ☐ U.S. Territory ☐ Unk ☐ Other_____	**Status:** ☐ Alive ☐ Dead ☐ Unk	**Death Date:** ___/____/____ **State/Terr of Death:** _____
Marital Status: S M W D Oth Unk	**Ethnicity:** Hispanic ☐ Yes ☐ No ☐ Unk; Arabic ☐ Yes ☐ No ☐ Unk	**Race (check all that apply):** ☐ Black/AA ☐ White ☐ Asian ☐ Native American or Alaskan ☐ Hawaiian/PI ☐ Unk ☐ Other_____			

Residence at HIV Diagnosis: ☐ Same as Current Street Address: _____
City: _____ County: _____ State/Country: _____ Zip: _____

Residence at AIDS Diagnosis: ☐ Same as Current Street Address: _____
City: _____ County: _____ State/Country: _____ Zip: _____

VI. FACILITY OF DIAGNOSIS

HIV Facility:
Address:
City, State/Country

AIDS Facility:
Address:
City, State/Country

HIV	Facility Type	AIDS
	Private Physician	
	Hospital Inpatient	
	Outpatient	
	Emergency Department	
	Other:_____	

VII. PATIENT HISTORY – COMPLETE ALL FIELDS

Before the 1st positive HIV test/Stage 3 HIV diagnosis, patient had:	Y	N	U
Sex with male			
Sex with female			
Injected drugs			
Received clotting factor			
Heterosexual relations with the following:			
• Injecting Drug User (IDU)			
• Bisexual male **(applies to females only)**			
• Person with hemophilia/ coagulation disorder			
• Transfusion recipient w/ documented HIV infection			
• Person with AIDS or documented HIV infection, risk unspecified			
Received transfusion Date 1st: / Date last: /			
Received organ transplant, tissue or artificial insemination			
Worked in healthcare/clinical laboratory **OCCUPATION:**			
Perinatally Infected			
Other:			

VIII. DUPLICATE REVIEW AND ADDITIONAL PATIENT OR DEMOGRAPHIC INFORMATION:

_____

_____

_____

_____

_____

COMPLETE REVERSE SIDE OF FORM

Observe the above figure and answer the following questions:

a) The above sample format represents which documents?
b) The format is traditional/electronic. Justify your answer.

		c) Discuss the basic principles to design such format.	
2	**CO2**	Increased health awareness, a growing middle class, and government health efforts are projected to propel India's medical device market forward in the next years. With the publication of the Medical Device Rules in 2017, Indian authorities revised the medical device regulatory process. The rules came into force in January 2018. The government has already notified and given time to all the medical device industry to register 'voluntarily'. a) Who is regulating such medical device rule in India? b) Discuss the need to register medical device by the industry voluntarily. c) Write the essentials principles for safety and performance of medical device guidelines.	**15 (2+6+7)**
SECTION D 20 marks			
Q	**CO**	Long Answer Type Questions. 10 marks each Word limit 200-250	**Marks (20)**
1	**CO1**	Discuss the WHO principles of Good Clinical Practice.	**10**
2	**CO4**	Write in details about the role and responsibilities of Institutional Review Board	**10 (5+5)**