

NIZAM'S INSTITUTE OF MEDICAL SCIENCES

(A University Established Under the State Act)
Punjagutta, Hyderabad- 500 082 (A.P)



PROSPECTUS FOR ADMISSION INTO PG DIPLOMA IN CLINICAL RESEARCH (PART TIME COURSE) FOR THE YEAR 2013

I. Introduction

The Nizam's Institute of Medical Sciences (NIMS) is a university established by the Legislative Assembly of state of Andhra Pradesh under act. No.13 of 1989. The objects of the Institute is to provide for Post Graduate teaching and conduct of research in the relevant disciplines of modern medicine and other allied sciences, including inter disciplinary fields of physical and biological sciences.

II. Notification

Applications are invited from eligible candidates for admission into the part-time Post Graduate Diploma in Clinical Research course for the year 2013.

III. Number of seats, duration of course and minimum qualification required

Subject	Seats	Duration	Prior Qualification	Desirable
P G Diploma in Clinical Research (PGDCLR) (Part Time Course)	30	12 months	Candidates who have passed Bachelors degree in Medicine, Dentistry, Pharmacy, Life Sciences with a minimum of 50% aggregate marks in the qualifying examination.	1. Experience in Clinical Research 2. Post Graduate qualification

IV. Application Procedure

- 1.A Candidate must submit hard copy of the application form.
- 2.Application form is available at: www.nims.edu.in.
- 3.The application form may be downloaded and filled appropriately. Please note that all the columns in the application form require to be filled in. Incomplete application forms are liable to be rejected.
- 4.The filled in application form should be downloaded from the website and to be submitted to the Associate Dean, Nursing and Allied Studies, Academic Section-2 (AC2) 3rd floor, Old O.P Block, Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad 500 082 **on or before 5.00 PM on 05/02/2014** along with a) candidate's passport size

photograph **b)** all the documents mentioned in the **Annexure I** and **c)** a demand draft (see para 5 below). The candidate's signature will have to be applied in ink at the appropriate column.

5. A demand draft for Rs.1,000/- (Rupees one thousand only) drawn in favour of the Director, Nizam's Institute of Medical Sciences and dated **between 27/12/2013 to 05/02/2014** or for the same amount has to be paid in cash counter of NIMS. Cash receipt will have to be submitted simultaneously along with the filled-in application. The candidate must write his/her name and the course applied for on the back side of the Bank Draft/NIMS cash receipt. Application fee is non-refundable even if the application is rejected.

6. The filled in applications received after the prescribed date and time may not be considered. The institute will not be responsible for non-receipt of applications or delay in postal transit.

7. The in-service (NIMS) candidates should have a minimum of five years regular service. Applications should be forwarded by the competent authority.

8. The candidates who are in-service seeking admission into course shall submit their service certificate and no objection certificate issued only by the appointing authority in original along with application.

V. Screening candidates for interview

1. Percentage of marks in qualifying graduate examination.
2. Number of attempts for passing graduate qualifying examination.
3. Experience in Clinical Research.
4. Preference will be given to the students with Postgraduate qualification.

VI. Method of Selection

1. The selection shall be based on the merit (Percentage of marks in graduate examination + Marks in the oral aptitude (Interview)). No request for postponing the date of interview or request to appear at an earlier date shall be entertained. In the event a candidate fails to report for the admission at the date and time specified the seat shall be offered to the next merit candidate as per the waiting list. In case of any seat falling vacant within one month of starting of the course, shall be filled by the next candidate in waiting list only. Interview letters shall be sent to the candidates for interview.

2. Candidates have to report for admission in person on the date notified with required documents as detailed in Annexure-III. Non-attendance to the admission shall render the candidate forfeiting his/her admission.

3. In case of equality of marks in graduate examination + oral aptitude test, the following criteria will be adopted to resolve the tie:

- a) The total marks obtained in oral aptitude test (interview) followed by
- b) Candidate elder in age will be placed higher in merit list in that order followed by
- c) The total marks obtained in graduate examination

4. The candidates will be called for the interview in 1:3 ratio.
5. For in-service candidates who are pursuing studies and who cannot deposit the original certificates at the time of admission are advised to bring Xerox copies of the original certificates duly attested by the controlling authorities of the Institution. They shall also produce a certificate from the institution that they have no objection to the candidate's admission to the P.G. Diploma in Clinical Research and in the event of selection of the candidate to the course he/she shall be relieved immediately. Failure to submit the above certificates shall render the candidate being ineligible.
6. Candidate appearing for the Interview test will not be paid any traveling allowance.
7. All those candidates who are selected for admission have to pay the fee as specified at rule XIII (2) and submit the original certificates on the date and time specified. Failure to submit the required certificates or pay the fee shall render the candidate in forfeiting the seat and such seat shall be allotted to the next merit candidate as per admission prospectus.
8. All the candidates joining the course shall execute a bond for an amount of Rs.10,000/- (Rupees ten thousand only) at the time of admission on a non-judicial stamped paper of Rs.100/- value along with two sureties not below the rank of Gazetted Officer to ensure completion of the prescribed period of training. The signature of the surety should be supported by seal/rubber stamp. The format of the bond to be executed may be seen at **Annexure II**.
9. In all matters relating to selections and admissions, the decision of the Institute shall be final and binding on the candidates and selection cannot be questioned after admissions are closed.

VII. Main Objectives of the Course

- To impart knowledge and experience and understanding of the basic principles of scientific method as applied to clinical research.
- To provide skills in using the necessary methodology and statistical tools and technique for designing and conducting clinical research.
- To build manpower capacity for clinical research/trial.

VIII. Educational Objective

Upon completion of this course, participants should be able to:

- (i) Distinguish the variety of clinical research/trials.
- (ii) Relate clinical trial as it applies in the new drug development process.
- (iii) Evaluate the key elements of clinical research design to assure study validity and rigor.
- (iv) Understand statistical issues involved in the protocol and data analysis.

- (v) Discuss key ethical issues arising in research involving human subjects.
- (vi) Outline key Indian DCGI/ICMR and international regulatory requirements governing clinical research/trial.
- (vii) Value the roles of the variety of professionals involved in trial conduct .
- (viii) Critically evaluate clinical research/trial protocol.
- (ix) Critically appraise results of published research/trial report.

IX. Benefits to Participants:

- (i) Learn to plan and manage a site as a coordinator.
- (ii) Develop and manage comprehensive clinical research/trials budgets.
- (iii) Learn to Analyze the initial review of a new protocol.
- (iv) Understand why and how to implement a monitoring visit.
- (v) Learn and apply basic concepts to protocol development.
- (vi) Initiate clinical research, apply monitoring methods, write documents and prepare reports, while understanding and abiding by regulations, guidelines and Good Clinical Practices.
- (vii) Describe all elements of a new drug application, focusing on clinical areas.
- (viii) Be-0come familiar with the IEC/IRB application process.

X. Course Requirement and Evaluation

The training course will be class room teaching lectures, with group discussions, tutorials and hands-on exercises. The classes will be held once in a week (every saturday between 4.00 PM to 6.00 PM). The curriculum provides comprehensive training across the entire clinical trials process, including courses from the perspective of the clinical study site as well as that of the sponsor or monitor and covers good practices, regulatory requirements and compliance, statistics and writing for clinical research.

XI. About the Course

This course uses the Principles of International Conference on Harmonization (ICH) GCP Guidelines. The course runs over a period of 12 months. A minimum of 75% attendance for classroom teaching is required for appearing in the final theory examination.

XII. Final Examination

At the end of 12 months of classroom teaching, the final theory + viva examination will be conducted, students who secure minimum 50% marks will be declared successful. DIPLOMA CERTIFICATE WILL BE AWARDED ONLY TO THOSE CANDIDATES WHO PASSED THE FINAL THEORY + VIVA EXAMINATION.

XIII. Admission

1. The original certificates submitted by the candidates shall not be returned to the candidates till they complete their course of study and appear for the final examination.

2. Fee structure

<u>Annual Fee - Rs.50,000/-</u>
Tuition fee, Cost of Teaching Material, Library fee & Examination fee.

3. The annual fee once paid is not refundable under any circumstances.
4. The course is part time and classes will be held once in a week (every Saturday between 4.00 PM to 6.00 PM)
5. The Institute shall fix duties and responsibilities of students from time to time.
6. All selected candidates must maintain a log - book recording their week-to-week academic activities, which are to be submitted to the Dean through Proper Channel once in 2 months.
7. The selection of each student will be subject to medical fitness. The Medical Board appointed by the Institute will decide the medical fitness. The decision of the Medical Board shall be final.
8. The students shall maintain strict discipline during the period of study/training program in terms of conduct rules of the NIMS. Violation of the conduct rules will result in the cancellation of the admission of the candidates apart from invoking the terms and conditions of the bond. The candidate shall not resort to any strikes during the period of their study in dereliction of their duties or air their views criticizing the policies of the Institute either before the print or electronic media or anywhere.
9. Resultant vacancies shall be offered to the next candidate in the merit list.
10. All students shall adhere to the Institutional rules and violation of rules will be viewed seriously.
11. In case of insufficient numbers of applications received from candidates, NIMS reserves the right to cancel the admission.

XIV. Discontinuation of the course

Candidates are permitted to discontinue the course under the following conditions by forfeiting their annual fee and without any penalty against the bond executed by them.

1. Illness certified by the Medical Board of the Institute.
2. If a candidate is absent for more than 30 days without approval he/she shall be treated as deemed to have discontinued.

XV. Closure of Admissions

The admissions shall stand closed within one month from the date of commencement of the course. The duration of the course shall be calculated from the date of commencement of the course without any reference to the date of joining of any individual.

XVI. Termination of Training and Dismissal

A candidate admitted to the course shall be liable for dismissal at any time before completion of the course on account of negligence, failure to attempt to the prescribed studies and duties, insubordination, misconduct or any other offences amounting to moral turpitude on the part of the candidate which in the opinion of the Head of the Institute makes it undesirable to continue the candidate in the Institute.

XVII. Powers of Dean

Notwithstanding anything contained in these prospectus, the Dean of the Faculty of the Institute may at any time before completion of the course either on his/her own motion or on the application of any person after due and proper enquiry and after giving the person 2 weeks time from the date of receipt of the show cause notice to submit the written explanation and on personal hearing order the cancellation of admission to the course, if in his/her opinion, such candidate has furnished incorrect particulars/or false information in the application or in the document attached thereto or in the statements made either before the authority in charge of admissions or the Dean or any other manner. Against any such order of the Dean, the appeal shall be with the Director, NIMS, Punjagutta, Hyderabad.

XVIII. These rules are subject to change in accordance with the decisions of the Institute taken from time to time.

XIX. Anti Ragging Act:

Ragging is prohibited in the Educational Institutions in the State of Andhra Pradesh, vide. Act.No.26 of 1997, dated 21-08-1997 and amendments made from time to time. If any incident of ragging comes to the notice of the authority, the concerned student shall be given liberty to explain and if his/her explanation is not found satisfactory, the authority would expel him/her from the Institution.

DIRECTOR
NIMS

ANNEXURE-I**List of documents to be submitted in person or by post along with hardcopy of web generated application, duly signed.**

1. Original bank demand draft/NIMS cash receipt (please write the name of the candidate and course applied for on the back side of draft/receipt).
2. Attested copy of Marks Memo of 10th class/Proof of date of birth
3. Attested copy of Marks Memo of degree
4. Attested copy of Provisional/Final certificate of Degree
5. Attested copy of Study& Conduct Certificate of degree course issued by the Principal of the college where last studied.
6. Attested copy of Transfer/Migration certificate of degree
7. Service certificate and No Objection Certificate from the appointing authority in original (in case of in-service candidates).
8. Experience certificate (in case of employee) issued by the appointing authority in original
9. Attested copy of Post Graduate degree, if any

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ANNEXURE-II**FORM OF BOND TO BE EXECUTED BY A CANDIDATE JOINING PGDCLR COURSE, WITH SURITY (on Non Judicial Stamped paper Rs.100/-)**

This Bond is executed on this ___day of_____2014 by Mr/Ms.._____

S/o/Do _____ R/o _____
 hereafter called as "STUDENT" in favour of the Executive Registrar, Nizam's Institute of Medical Sciences, (NIMS), Punjagutta, Hyderabad hereafter called as the "NIMS Institute". WHEREAS the said student selected for the P G Diploma in Clinical Research (Part Time Course) for the year 2013, in the NIMS.

WHEREAS the NIMS Institute has prescribed/stipulated the condition in admission regulations that the student selected for course have to execute bond for Rs.10,000/- (Rupees ten thousand only) in favour of the Executive Registrar, NIMS promising that he/she will complete the course. In case of cancellation/discontinuation of the said course by the student will be liable to pay the said bond amount.

Whereas the student selected has agreed to the said conditions and executing this bond. The bond will come into force from date of selection.

This Bond is executed in the presence of the following witness.

Witness:1) _____ signature of the student
 Full name with address
 2)
 Full name with address

We, the gazetted officers/faculty
 1) _____ S/o _____ R/o _____
 working as _____
 2) _____ S/o _____ R/o _____
 working as _____

We hereby stand as sureties to the Bond executed by Mr/Ms. _____ in favour of Executive Registrar, NIMS, Punjagutta, Hyderabad. We undertake the liability of the above bond amount to an extent of bond amount as well as the stipend if any received by the student/executor of the Bond. If the student/executor of the said bond fails to discharge his/her obligations under the said bond, we will pay the said amount as and when the NIMS demand.

The Sureties are signed this bond in the presence of the following witness on this day ___ of _____2013

Witness:1 _____ Sureties: 1

2. _____ Sureties: 2

NB: Sureties should be not below the rank of two permanent Gazetted Officers. The signature of the surety should be supported by seal/rubber stamp.

ANNEXURE III**List of Original Certificates to be submitted at the time of Admission:**

1. Marks Memo of 10th class/Proof of date of birth
2. Marks Memo of degree
3. Provisional/Final certificate of Degree
4. Study& Conduct Certificate of degree course issued by the Principal of the college where last studied.
5. Transfer/Migration certificate of degree
6. Relieving order from the employer (in case of in-service candidates).
7. Fee to be paid:

Annual Fee - Rs.50,000/-
Tuition fee, cost of teaching material, library fee and examination fee

8. Post graduate degree certificate, if any
9. Bond as per annexure II

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IMPORTANT DATES TO REMEMBER

1	Last date for receipt of applications	05/02/2014 (Wednesday)
2	Issue of interview letters for eligible candidates through E-mail	12/02/2014 (Wednesday)
3	Date of Oral Aptitude Testing/ Interview (venue as indicated in the interview letter)	18/02/2014 (Tuesday)
4	Display of merit list and names of candidates provisionally selected for admission	24/02/2014 (Monday)
5	Date of admission, payment of fee and submission of certificates and bond	27/02/2014 (Thursday)
6	Commencement of classes	15/03/2014 (Saturday)
7	Closure of admission	14/04/2014 (Monday)

IMPORTANT NOTE

1. No individual correspondence will be made for selection/admission. Candidates are requested to follow the instructions/information displayed at NIMS notice board/website: www.nims.edu.in as per the scheduled programme.
2. NIMS is not responsible for any postal delay for the receipt of the completed application after the prescribed closing date.
3. For enquiries contact:
Associate Dean Allied and Nursing Studies
Academic Section – 2 (AC2)
3th floor, Old O.P. Block, NIMS
Phone No:040-23489350
4. Candidates are requested to visit the website regularly for any updates.



NIZAM'S INSTITUTE OF MEDICAL SCIENCES

(A University established under the State Act)
PUNJAGUTTA::HYDERABAD -500 082, A.P.

Application Form for the Post Graduate Diploma in Clinical Research (Part Time Course) for the year - 2013

Registration Number

(To be filled by the office)

1. The application form to be downloaded and filled appropriately.
2. Read page no.1 of the prospectus for details of the applications procedure.
3. Fill in all the columns using drop boxes wherever provided.
4. Print the form and review all the Data. Sign, attach a passport size photograph and submit the form in person or by post along with all the documents mentioned in the prospectus so as to reach Associate Dean Allied and Nursing Studies, Academic Section-2 (AC2) 3rd floor, Old O.P Block, Nizam's Institute of Medical Sciences, Punjagutta, Hyd - 500082, **before 5.00 P.M. on 05/02/2014.**
5. The applications form has to be accompanied by Demand Draft favoring Director, NIMS or NIMS cash receipt for Rs.1,000/-

Affix self
attested Latest
Passport Size
Photograph

Course Applied	P.G. Diploma in Clinical Research (Part Time Course)	
Surname		
Name		
Sex		Date of Birth:

Address for Communication:-

Line 1		
Line 2		
Line 3		
Town/City		Pin Code
Phone Number		Mobile Number.
E – Mail Address (Mandatory)		
Father' Name		
Mother's Name		
Identification of Marks-1		
Identification of Marks-2		

Nationality		In Service status :	
Degree Qualification		Month & Year of Passing:	
Total marks obtained in Degree		Out of :	Average:

Number of attempts for passing Graduate qualifying Examination

P.G. Degree qualification		Month & Year of Passing		
Total marks obtained in P.G. Degree		Out of		Average
Year of Experience in Clinical Research (Submit Experience Details with Hardcopy)				
Mode of payment		Amount Rs.1000/-		
Demand Draft/NIMS Cash Receipt Number				
Name of the Bank				
Name of the Branch (Type "NIMS" if paid at NIMS cash counter)				

DECLARATION OF THE CANDIDATE:-

I declare that the particulars given above are correct. I agree to abide by the admission prospectus issued by the Institute. I also declare that in the event that information provided is incorrect or false. I may be prosecuted as per law.

Signature of the Candidate

Date:	
Place :	