



IL DIRETTORE

**SELECTION PROCEDURE N. 06/2013 FOR 1 TEMPORARY RESEARCH
ASSOCIATE POSITION
("Assegno di Ricerca")
Cat. B type II**

THE DIRECTOR

Given Law n. 168, dated 30th December 2010;

Given art . 22 of Law n. 240, dated 30th December 2010;

Given the University Statute;

Given the regulations for assigning temporary research associate positions ("assegni di ricerca") laid down in D.R. n. 4246 dated 5th December 2011 and modified and integrated with D.R. n. 4108 dated 19th November 2012;

Given D.M. n.102 dated 09th March 2011 fixing the amount 19.367,00, excluding the costs to be paid by the Administration, as annual minimum gross salary for temporary research associate positions ("assegni di ricerca"), granted according to the Law 240/2010;

Given the decrees of the Academic Senate and of Board of Directors of 12th April 2011 and of 19th April 2011, respectively;

Given the resolution of the Department Council, dated July, the 26th July 2013, which approved the publication of a selection procedure for a temporary research associate position - cat. B type II - at the Department of Physiology and Pharmacology "Vittorio Erspamer" and the resolution to increase the amount paid for the fellowship research in respect to the minimum established by the collegiate bodies for the specific duty (article 3.1 of regulation) to € 21.950,00;

Having regard to the availability of funds obtained through the Research Project: "Scientific evaluation of the conformity of a total of 800 (8 hundred) summary of product characteristics (SmPCs) of human medicines, for new MA or variations, approved through Mutual Recognition procedure, Decentralized procedures and National procedures, , and support to the production of all leaflets (SmPC and package leaflets)", granted by AIFA (Agenzia Italiana del Farmaco) to Prof.ssa Daniela Melchiorri at the Physiology and Pharmacology Department of "La Sapienza" University of Rome,

ANNOUNCES

Art. 1 - Research Project

There will be a public selection procedure based on qualifications and an interview for the assignment of 1 temporary research associate position ("assegno di ricerca") for research activity Category B – Type II at the Department of Physiology and

Pharmacology “Vittorio Erspamer” – Sapienza - University of Rome, for a period of 1 year, renewable.

Research Project: “Scientific evaluation of the conformity of a total of 800 (8 hundred) summary of product characteristics (SmPCs) of human medicines, for new marketing authorisation or variations, approved through Mutual Recognition procedure, Decentralized procedure and National procedure, and support to the production of all leaflets (SmPC and package leaflets)” - Scientific Sector: BIO/14, to be performed at the Department of Physiology and Pharmacology “Vittorio Erspamer” of “La Sapienza” - University of Rome.

Research Title: Scientific evaluation of the compliance of the product information of 230 medicinal products for human use to the type I and type II variations approved by National procedures.

Art. 2 - Duration/renewal of the temporary research associate position – “assegno di ricerca” and salary

The contract will be for a period of 1 year and is renewable with the same subject, as stated in art. 22, par. 3 of the 240/2010 Law. The overall period of the contract, including possible renewals, cannot in any case be longer than 4 years, according to the art. 22, par. 3 of the 240/2010, excluding periods coincident with the PhD studies, the latter for a period non exceeding the legal duration of the study program.

The gross salary is € 21.950,00/year and will be paid in monthly installments. The payments are subject to the fiscal conditions of art. 4 of Law 476/1984 and subsequent amendments and integrations, as well as to art. 2 par. 26 and of Law 335/1995 and subsequent amendments. Regarding mandatory maternity leave, the conditions of the Ministry of Labor Decree dated 12/07/2007 – G.U. n.247 of 23/10/2007 will be applied. Sick leave will be governed by art.1, par.788 of Law 296/2006 and subsequent amendments.

The Department guarantees equal rights and opportunities for men and women for the contracts and the protection of personal data privacy according to current legislation.

Art. 3 - General Requirements

Eligible candidates must have a PhD degree either in Pharmacology or in Experimental Physiopathology, or equivalent title granted in Italy or abroad, or a CV demonstrating extensive research record in the same field such as faculty positions in Universities, Research bodies, Applied research Institutions, private or public, abroad or, for non faculty positions, in Italy, excluding those listed in art. 22 comma 1, of the Law 240/2010.

Non-Italian citizens from EU countries must hold a qualification recognized as equivalent on the basis of international agreements, or as described by art. 332 of the “Testo Unico” dated 31/8/1993, n. 1592. This equivalence should be demonstrated by suitable certification issued by the competent authorities.

Alternatively, qualifications obtained abroad that are not considered equivalent, according to the current legislation, will be evaluated by the selection committee only for the aims of this selection and should be translated, legally certified and have a

declaration of value issued by the appropriate Italian diplomatic Authorities and attached to the application, also as photocopies.

Candidates should have these requisites before the deadline for the submission of the applications.

Art. 4 –Applications and deadlines

Applications, on plain paper, should follow the structure of **Appendix A**, be signed by the applicant, and sent by email to: bandidipfisiopharm@uniroma1.it within the deadline of 20 days starting from the day after publication of this notice following the guidelines given in this document.

Candidates must indicate an e-mail address to which all communications will be sent including the invitation to the interview. Any change of the address should be immediately communicated to the Department of Physiology and Pharmacology “Vittorio Erspamer”.

If the deadline is on a holyday, it is automatically moved to the next working day.

The Administration will not take any responsibility if the candidate is not reachable or for late or lost mail due to changes of email address, late or wrong communication of the email address by the candidate.

Applicants must state, under their own responsibility and liability, the following facts. Failure to do so will result in exclusion from the selection procedure.

- surname and name;
- date and place of birth;
- residence;
- citizenship;
- possession of political rights;
- a declaration that the candidate does not have any criminal record nor is currently under any criminal prosecution; should there be a criminal record or prosecution, the candidate must report it, together with the date of any sentence passed and the legal authority that passed it;
- Master degree with grades, as well as the date and the University that granted the degree;
- equivalence of the titles, if obtained abroad /declaration of value of qualifications if not considered equivalent;
- to have obtained a PhD degree in Pharmacology or in Experimental Physiopathology or equivalent title granted in Italy or abroad, or a CV demonstrating extensive research record such as faculty positions in Universities, Research bodies, Applied research Institutions, private or public, abroad or, for non faculty positions, in Italy;
- Not to be a relative of any Professor of the Physiology and Pharmacology “Vittorio Erspamer” Department (up to 4th degree included) or of the Rector, General Director, or any member of the Administrative Council of the University.

The application should include, if this is the case, a declaration of the enrolment in a PhD school without grant and/or of any activity performed as “assegnista di ricerca” (**Attachment B**), a photocopy of an identification document and everything listed in art. 5 of this document.

Art. 5 - Qualifications and CV

In the application, candidates must include the following items in PDF format:

- substitutive declaration of certification or notarial act of certificate of their Master degree with the final grade and with the grades of the individual exams;
- substitutive declaration of certification or notarial act of PhD degree certificate or equivalent title even if obtained abroad.
- substitutive declaration of certification or notarial act of documents and qualifications deemed useful for the selection procedure (diplomas of specialization, certificates of attendance to post-graduate, advanced courses in Italy or abroad, grants or research assignments both in Italy and abroad);
- curriculum of their scientific and professional activity dated and duly signed;
- eventually scientific publications, with the indication of the impact factor.

As stated by the modifications introduced by art. 15, par. 1 of Law n. 183/2011 to the discipline of certificates and declarations in substitution of notarial acts, contained in the D.P.R. 445/2000, Public Administrations cannot either request nor accept acts or certificates containing informations which the P.A. Is already in possess of. **Therefore, only the declarations in substitution of certifications and/or notarial acts which are stated according to articles 46 and 47 of the D.P.R. 445/2000 have value and can be accepted.**

With reference to the publications considered relevant for this selection procedure, candidates must include a declaration, in substitution of a notarized act, certifying that the copies are in conformity with the originals, according to art.47 del D.P.R. n. 445/2000 (**Attachment C**).

Titles/qualifications written in a foreign language must be presented with a translation in Italian that must be certified by the competent Authority as being in conformity with the original text. No such certified translation is required for titles/qualifications written in English.

Foreign citizens resident in Italy can self-certify the above as far as situations, facts, or personal qualities that can be certified or supported by public officials or private Italian citizens are concerned (art. 3 DPR 445/2000).

Foreign citizens who are not resident in Italy cannot use self-certification in any way . Within 3 months from the conclusion of the selection procedure, the candidates must take action to collect the originals/copies of the qualifications and publications presented (at their own expenses). After this deadline, the Department of Physiology and Pharmacology "Vittorio Erspamer"; will not be responsible of storing these documents.

Art. 6 – Selection procedure

The Committee will decide how to assign the scores in percent; the scoring system adds up to 100/100, and will take into account, appropriately weighted:

- the Master degree grade;
- scientific publications;
- diplomas of specialization and certificates of attendance at post-graduate courses according to their relevance to the research to be carried out;
- Awards and recognitions for scientific activities

- other activities carried out under contract, study grants or posts within National or International Research Agencies; the dates and periods of service must be certified in detail as well as the activity conducted.

- interview.

The results of the assessment of the qualifications will be made known to the candidates prior to the interview. They will be posted on the notice-board and on the website of the Department of Physiology and Pharmacology “Vittorio Erspamer”.

Art. 7 – Interview

The selection procedure includes an interview that will focus on the program indicated in art. 1 of this call and on:

- The European and National regulation on product information for medicinal products
- The European regulation on type I and type II variations of the marketing authorization of medicinal products;
- The organization and function of the Italian Medicines Agency (AIFA) and of the European Medicines Agency (EMA);
- The scientific guidelines of the European Medicines Agency
- Clinical Pharmacology
- Clinical Pathology
- Clinical Physiopathology
- Pharmacovigilance activities
- Biostatistics applied to clinical trials; Bayesian statistics
- Design of clinical trials

Notification of the interview will be given to individual candidates using the e-mail address provided in the application at least 20 days before the interview, unless written waiver of all interested parties.

This notice is equivalent to notification in all respects regarding the candidates and therefore will not be given again in any other communication.

For the interview, candidates need to show a valid Identification document.

During the interview, the Committee will verify the ability of the candidate to deal with the subject of the project. The interview is public. At the end of each step of the selection process, the Committee will make the results public.

Art. 8 – Committee

The examining Committee will be nominated by the Director of the Department of Physiology and Pharmacology “Vittorio Erspamer”, following the recommendations of the Council of the Department. It will consist of three members: a full Professor, who will act as President and two members selected from the “Sapienza” Professors or Researchers (also fixed terms) or Researchers from Research Institutes having an official agreement with the Sapienza University. One of these will act as the Secretary of the committee.

The decision of the Committee is final.

Art. 9 – Procedure results

The Committee, in the first meeting, will establish the criteria to be used for the evaluation and scoring of the qualifications and of the interview, formally ratifying them in a report.

The final marks are obtained by summing the scores of the qualifications and of the interview. The ranking will list the final marks for each candidate in decreasing order. The Director of the Department approves the results established by the Commission. The results will be publicized on the web sites of the Department of Physiology and Pharmacology "Vittorio Erspamer" and of the University and notifies the candidates. If she or he will not accept the position or will resign, the position will be offered to the next ranked candidates.

Candidates who will not declare their acceptance of the contract or who will not start their activity within the established deadline will be disqualified. Requests of delaying the beginning of the contract will only be accepted when due to certified health problems, obligatory maternity leave or by proven force majeure.

Art. 10 - The Temporary Research Associate Contract – "Assegno di Ricerca"

The temporary research associate position – "assegno di ricerca" will take the form of a temporary contract drawn up under civil law. This temporary, fixed-term contract does not, in any way, represent a permanent contract of dependent work and does not give any right to permanent positions within the University.

According to articles 46 and 47 of D.P.R. n. 445 dated 28/12/2000, the winning candidate must produce, within 20 days of being notified of the granted "assegno di ricerca", a declaration on plain paper, stating:

- a) date and place of birth;
- b) citizenship;
- c) possession of political rights in his/her country;
- d) freedom from any criminal convictions or current criminal proceedings.

The Administration reserves, according to articles 43, par. 5, 71 and 72 of D.P.R. n. 445/2000, and to the modifications given by art. 15 of Law 183/2011, the right to verify the truth and authenticity of the titles and qualifications produced by declarations in substitution of notarial acts, according to articles 46 and 47 of D.P.R. 445/2000. In case of false declarations, the proceedings laid down in art. 75 and 76 of D.P.R. n. 445/2000.

The winner must also comply with the requirements described in the University Regulations, for awarding temporary research associate positions - "assegni di ricerca". A copy of the D.R. in which the above mentioned regulations are issued will be provided to the winner.

Art. 11 – Rights and duties

Grantees must carry out their research activity within the research programs approved by the Department to which they belong; their duties should be related to research and not be limited to technical support. Grantees can collaborate to research activities of students who are working on their Master thesis; can participate to seminars and practices for students and be part of exam committees as experts.

To perform their research activities, grantees can take advantage of the instrumentations of the Department where they work and of all the services available to researchers according to the current legislature and to the Department rules.

If explicitly authorized by the Scientific Principal Investigator to travel, the grantee will be reimbursed expenses according to the current legislature.

Grantees are required to provide the Department where they work with a written yearly report of their research activity, together with a written evaluation of their activities by the Scientific Principal Investigator.

The research activity can be partially performed in a different University of Research Institution in Italy or abroad, provided this is coherent with the program and objectives of the assigned research activities; the period abroad must be explicitly authorized by the Department in advance following a motivated request by the Scientific Principal Investigator.

Art.12 –Incompatibility

The temporary research associate position “assegno di ricerca” cannot be combined with other grants or fellowships intended for similar purposes, with the exception of those assigned by national or foreign institutes to integrate, during stages abroad, the research activity of the selected candidate.

Grantees cannot enroll in Degree Courses, Master degrees, PhD or specialization schools with fellowships, in Italy or abroad, University post-graduate Masters.

The temporary research associate position “assegno di ricerca” can be granted to Public employees, if they are on unpaid leave during the period of the contract.

The temporary research associate position “assegno di ricerca” is personal. The selected candidates can conduct free-lance work, provided that written notice is given to the Department in advance and that the activity is recognized by the Department as compatible with the funded research activity; that there is no conflict of interest with the specific research carried out by the selected candidate for the University; that the University reputation is safeguarded at all times. The Responsible Scientist and the selected candidate must declare that they do not have a professional relationship.

Provided that the funded research activity is guaranteed, and in agreement with the Department, the grantees can take part in research and consultancy work for third parties on behalf of the Sapienza University according to art. 66 of D.P.R. 382/80, and can be entitled to related gains according to the regulations governing such work.

Grantees who want to work or continuing working in unpaid activities in voluntary associations or non-profit cooperatives or cultural Institutions can do so, provided that they comply with all their research duties.

The activity is suspended in cases of obligatory leave for maternity, parental leave and illness and it can be extended, according to the current legislation. Authorized leave periods shorter than 30 days in a year are not considered suspensions.

Art. 13 – Contract resolution

A procedure for resolution of the contract of a grantee is started when, after having started his activity, does not continue it regularly and without interruptions for the whole period without justified motivation, or who will be responsible of severe

failures or defaults. The procedure is initiated following the request of the Scientific Principal Investigator and approved by the Department Council.

Causes for resolution of a contract are:

- Failure to start the activities or unjustified delay in starting the;
- Unjustified suspension of the activity for a period that jeopardizes the research program;
- Violation of the incompatibility rules as stated in art. 6 if repeated after a first warning
- Negative evaluation of the Department Council or of the Administrative and managerial body of the same Department.

Art. 14 - Making the selection procedure public

This selection procedure will be made public by posting it on the notice board of the Department of Physiology and Pharmacology "Vittorio Erspamer", as well as on the Department website and on the websites of the University, MIUR and the European Union.

<http://dff.uniroma1.it/dipartimento/bandi>

www.uniroma1.it/organizzazione/amministrazione/ripartizionepersonale/concorsi/asogni/

www.miur.it

<http://ec.europa.eu/euraxess/>

What is not explicitly stated in this notification, is regulated by current laws.

Rome, 18th September 2013

THE DIRECTOR
Prof. Paolo Nencini



APPENDIX A

EXAMPLE OF THE APPLICATION TO BE SENT ON PLAIN PAPER BY E-MAIL

To the Director of the
Department of Physiology and Pharmacology "Vittorio Erspamer"
Sapienza – Università di Roma
Piazzale Aldo Moro 5
00185 ROMA
MAIL: bandidipfisiopharm@uniroma1.it

I, the undersigned
born in state on, resident in
..... Street ZIP code
asks to take part in the selection procedure, via qualifications and interview, for the temporary
research associate position – "Assegno di Ricerca" (n. 1), Research Project.....
.....
Scientific Sectorin the Department of Physiology and Pharmacology "Vittorio Erspamer",
Sapienza, University of Rome. Selection Procedure n..... /2013

To this end, according to articles 46 and 47 of D.P.R. n. 445, dated 28/12/2000, and being fully
aware that false declarations are punished under Criminal Law and by specific laws, I declare that
I:

- 1) graduated in (Master degree) (Univ.)
with the following grade.....;
- 2) hold a PhD degree in (Univ.)..... or to be a
researcher with extensive experience also because has held the following previous faculty
positions in Universities, research bodies, Applied research Institutions, public or private, abroad
or, for non permanent positions, in Italy
- 3) am a citizen ofand am in possess of political rights;
- 4) have no criminal convictions and am not involved in current criminal proceedings; OR have a
criminal conviction forfromdate
..... OR being involved in current criminal proceedings
- 5) am not the recipient any other fellowship of any sort or that I am prepared to renounce to such
grant should I be selected in this procedure; am not enrolled in any degree course, Mater
course, PhD school or specialization school with a fellowship in Italy or abroad, in University
post-graduate Masters;
- 6) am not a member of staff of bodies listed in art.. 22, comma 1, of Law 240/2010;
- 7) not to be a relative of any Professor of the of Department of Physiology and Pharmacology (up
to 4th degree included) or of the Rector, General Director, or any member of the Administrative
Council of the University;
- 8) want to receive notifications regarding this selection procedure at the following e-mail address
.....
- 9) to waive the right to a twenty-day notice before the actual day of the interview.

According to the Law n. 104, dated 5/2/1992 disabled candidates should make a specific request if
assistance is needed to take part in the interview.

I, the undersigned, include in this application (in PDF format):

- 1) copy of a valid identification document
- 2) declaration of the enrolment in a PhD program without fellowship and/or activity as “assegnista di ricerca”, when this is the case;
- 3) substitutive declaration of certification or notarial act of my Master degree with the place and date in which it has been obtained and the final grade;
- 4) substitutive declaration of certification or notarial act of Ph.D. title or equivalent title obtained also abroad;
- 5) substitutive declaration of certification or notarial act of all the documents and scientific qualifications I consider useful for this selection;
- 6) CV of my scientific and professional activity dated and signed;
- 7) Scientific publications with attached substitutive declaration of notarial act in which he certifies conformity with the original.

In addition, I consent that my personal information can be handled, for the purposes for this procedure according to D.Lgs. n. 196/2003,

Date Signed.....

(Not requiring authenticity certificate, art, 39 of the D.P.R. 28.21.2000 no. 445)

APPENDIX B

**SUBSTITUTIVE DECLARATION OF CERTIFICATION
(ART. 46 D.P.R. n. 445, DATED 28/12/2000)**

I, the undersigned born on in(state) tax code identification, fully aware of the penal sanctions in the case of false declarations and false documents, art. 76 D.P.R. n. 445, dated 28/12/2000 and according to art. 22 of Law 240/2010

DECLARE

- to be enrolled in thePhD program without fellowship fromto..... (total months/years) by

- to have received temporary research associate positions “assegni di ricerca” according to the law 240/2010:
from to (total months/years)
by
from to (total months/years)
by
from to (total months/years)
by

- I have never received research temporary research associate positions “assegni di ricerca” according to the law 240/2010;

- to have been Research Assistant (fixed term) according to art. 24 of the Law 240/2010:
from to (total months/years)
by
from to (total months/years)
by

- to have never been Research Assistant (fixed term) according to art. 24 of the Law 240/2010

Indicate leave of absence periods for maternity leave or illness according to the current legislature:
.....

In addition, I declare to be informed, according to D. Lgs. n. 196/2003, that my personal information will be handled, also via electronic storage and transfer, exclusively for the purposes for which this declaration has been made.

Place and date

(SIGNATURE)

SUBSTITUTIVE DECLARATION
(given according and with the consequences of D.P.R. n. 445/2000)

I, the undersigned Dr, born on
in..... resident in
Street ZIP code

being aware that, according to articles 75 and 76 of D.P.R. 28.12.2000 n. 445, in case of false declarations, false acts or use of false acts, will incur in the penal sanctions and there will immediately be the resolution of the temporary research associate position - "assegno di ricerca",

DECLARE

that the documents, certificates and publications presented correspond to the original

.....
.....
.....
.....

Information according to D.Lgs n. 196/2003

Personal informations will be handled, also electronically, exclusively for the purposes for which this declaration has been made

Place and date

(SIGNATURE)

.....

(a not authenticated photocopy of the identity document of the applicant is included)