



SECRETARÍA JUNTA ADMINISTRATIVA

2014-15

Certificación Número 167

YO, NYDIA BONET JORDAN, Secretaria Ejecutiva de la Junta Administrativa del Recinto de Ciencias Médicas de la Universidad de Puerto Rico, **CERTIFICO**:

Que la Junta Administrativa en reunión ordinaria celebrada el martes, 27 de enero de 2015, consideró y evaluó la solicitud de enmienda al documento llamado "**Office of Research Development and Compliance (ORDEC)**" que forma parte de la Certificación 92, 2013-2014 de la Junta Administrativa del Recinto de Ciencias Médicas. Luego de amplia discusión y dialogo de rigor, la Junta Administrativa, **ACORDÓ**:

Que se dé por recibido y aprobado en su totalidad el documento enmendado y revisado llamado "*Center for Research Compliance and Development (CRECED)*".

Que se derogue el documento anterior llamado "*Office of Research Development and Compliance (ORDEC)*" que en español se denominó Oficina de Desarrollo de Investigación y Cumplimiento (ODIC) y que forma parte de la Certificación 92, 2013-2014, JA-RCM.

Que acepta en el día de hoy el cambio de nombre de dicha oficina para que sea "*Center for Research Compliance and Development (CRECED)*".

Que el director de la Oficina de **CRECED** rinda un informe de progreso de los trabajos realizados y los resultados de los mismos ante la Junta Administrativa en la reunión ordinaria de enero de 2016.

Copia del documento enmendado, revisado y aprobado se haga formar parte de esta certificación.

Y para que así conste, para conocimiento del personal y de las autoridades universitarias que corresponde, expido esta Certificación bajo el sello del Recinto de Ciencias Médicas de la Universidad de Puerto Rico, hoy veintiocho de enero del año dos mil quince.

Vo. Bo.:

Noel J. Aymat Santana, DMD, FAAPD, JD
Rector

NBJ/NJAS/ynr

Nydia Bonet Jordan, MD
Secretaria Ejecutiva



**Center for Research Compliance & Development
(CRECED)**



Date of Ammendment: January 21, 2015

Effective Date: January 27, 2015

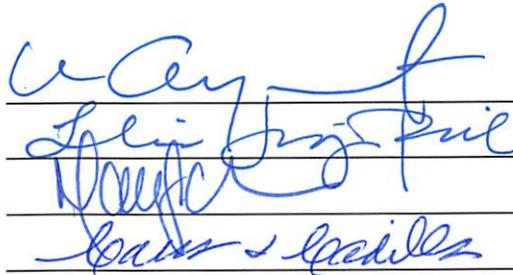
Proponents for ammendment:

Noel Aymat, DMD, JD

Lilia Figueroa, JD

Marcia Cruz-Correa, MD, PhD

Carmen Cadilla Vazquez, Ph.D.



Handwritten signatures of the four proponents listed on the left, written in blue ink on lined paper. The signatures are: Noel Aymat, Lilia Figueroa, Marcia Cruz-Correa, and Carmen Cadilla Vazquez.

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HISTORICAL BACKGROUND

In 1999, in an effort to improve research infrastructure, the Administrative Board of the University of Puerto Rico - Medical Sciences Campus (UPR-MSC) modified its distribution of indirect costs to provide the Office of Contracts, External Funds and Financial Administration (OFCA) with 12% of the indirect costs received at our institution (Cert 30, 1999). These funds would be used to extend the services provided by OFCA to include a subdivision of Human Resources, Purchasing and Travel.

In 2006 the Office was renamed as Office of Sponsored Programs (OSP). Its mission was to provide administrative support to externally funded research projects and programs. The main objectives were to: (1) Provide support to researchers and project administrators in the processing and revision of proposals. (2) Coordinate trainings related to the submission of grant proposals and grant administration. (3) Revise and submit electronic proposals, particularly through "grants.gov; NSF Fastlane, Department of Defense, Department of Education, etc. In order to achieve its mission and objectives, the OSP was divided into three divisions: Sponsored Programs Development (DSPD), Financial Administration (DFA) and the Center of Administrative Resources for Scientific Research (CARSR).

The OSP presently functions as an administrative unit under the Chancellor's Office with the responsibilities of submitting grants proposals and provides partial administrative support to federally funded research grants. OSP is the liaison between the federal agencies and the investigators. It creates research accounts, prepares invoices, financial, cash and status reports, monitors cash transactions, assists in the hiring and preparation of personnel contracts and drawdown of external funds among others.

The Office of Research Development and Compliance (ORDEC) was approved by the Administrative Board from the UPR-MSC, under Certification No. 92 (January 28, 2014). However, ORDEC has not been implemented at the UPR-MSC. Our ammendment will enable the implementation of the approved office, but modification to a Center, keeping the same scope, goals and organizational structure as the original proposal. We have eliminated elements of reassignment of personnel included in the approved document, as they were too specific. It is specified in the revised document that the Director will be responsible of evaluating and

performing decisions of resources and personnel to respond to the goals and needs of CRECED.

NEED FOR THE RESTRUCTURING OF OSP

The crash of the economy has had a negative impact on the availability of research funds. This situation is worsened by an increase in research compliance requirements, resulting in an excessive administrative burden for researchers, and creating constraints on the time available to meet their teaching, research and service commitments. In addition, UPR processes are numerous, complex and bureaucratic, requiring a colossal amount of time and effort from the investigators and their staff.

The OSP was created to provide assistance to faculty and graduate students in their efforts to obtain external funds for their research and teaching endeavors and to expedite and improve efficiency of all procedures related to the management and expenditures of research funds. History has demonstrated that OSP as presently structured lacks operational links to other essential administrative areas thus hindering its efforts to fulfill its mission. To accomplish its goals, OSP must be restructured, modernized, and accounting and finance structures expanded (procurement, purchasing, invoicing, property, and inventory) to facilitate the hiring of prospective research personnel and processing of their documents, provide editorial assistance during proposal preparation, oversee compliance issues and provide technical and statistical support for research projects, among others. Presently these activities are processed by different administrative units, which lack effective communication among them. In addition, the Office of Contracts, that manages contracts and sub-contracts stemming from grants and contracts, will be integrated into the new structure as a collaborative unit. Furthermore, adequate support is needed in the pre-award state of the proposal submission to become more competitive. With the restructuring the UPR-MSU expects that the efficient and adequate administration of research funds will expand the amount of support received by investigators and contribute to the development and growth of the university. To this avail, we propose the creation of a new center called “*Center for Research Compliance & Development*”(CREDED). This step, although necessary for the development of research, is the first one in a structured plan to create the new Deanship of Research. This Deanship for Research is part of the MSU’s Chancellor work plan and based on this reorganization will be pursued through the channels necessary such as the Academic Senate and the UPR Governing Board.

CRECED GOALS

The goals of CRECED are to administer and support the development of research and compliance activities at the UPR-MSC, in accordance with institutional, local and federal regulations and in coordination with the Office of the Vice President for Research and Technology and the Compliance Office of the UPR Central Administration.

To achieve these goals CRECED will establish efficient administrative structures, with rules and regulations of operation to expedite and allow flexibility in the administrative procedures involved in the submission, management and expenditures of research funds, hiring of research personnel, processing of personnel documents and contracts, purchase of research supplies and equipment, negotiation of grants and contracts with public and private entities, preparation and management of grant budgets, and financial transactions with the granting agencies.

VISION

CRECED will be a model sponsored project administration office. CRECED fosters proposal development for research at the UPR-MSC; promotes and sustains sound business practices; and provides the highest quality of administrative management and financial services to support the UPR MSC's mission.

MISSION

CRECED's mission is to maximize success of investigators in the attainment of external funds, and facilitate and optimize their research, training, educational and community service endeavors. The procurement of grants, contracts and endowments from private and government sources provide financial resources that sustain the continued development and growth of the university. CRECED will be the point of convergence of the UPR-MSC in ensuring that their researchers are successful in obtaining external funding sources for their projects, as well as in the efficacious management and execution of the sponsored activities after they are awarded.

CRECED will work closely with the compliance institutional units, Human Research Subjects Protection Office (HRSPO), Institutional Animal Care and Use Committee

(IACUC), Institutional Biosafety Committee (IBS), and Radiation Safety Committee (RSC) as well with the UPR Compliance Unit at the Vice-President Office for Research and Technology.

FUNCTIONS AND SERVICES OF CRECED

CRECED will be an important part of the UPR-MSC support structure and will seek to assist faculty and staff members in a variety of ways. It will assist investigators in identifying funding sources; collaborate in the development of proposals and facilitate the administration of grant/contract award activities. This assistance may range from acting as the project manager, assist in the monitoring and control of finances, manage and track information on policy and regulations, facilitate the preparation and submission of required reports, and assure that milestones are met in a timely manner.

In addition, CRECED will serve as an advocate for the research community, ensuring that the administration provides a campus environment that is conducive to the research enterprise. It will also advise the administration on regulatory compliance issues and other scholarly activities related to research endeavors.

CRECED aims to be a positive stimulus for the advancement of research of the UPR-MSC. The Center must be active in ensuring that funding agencies are aware of, and familiar with, UPR-MSC capabilities and interests. CRECED must also ensure that the university responds to funding opportunities which are compatible with its mission, and for which it is positioned to compete. This entails identifying key opportunities for the university, communicating them to the faculty and staff, organizing and facilitating competitive proposals, and maintaining a current database of faculty capability and interests. Among the services to be provided are:

Identification of External Funding Services

- Maintain a library of newsletters, publications, and electronic sources on funding opportunities and of instructional materials related to external funding.
- Subscribe to computerized databases that provide information on government and private sources of funding, such as *Grants.gov* and the *Federal Register*.

Identify Faculty and Staff Capabilities

- Compile a list of research and scholarly interests for faculty and research staff.
- Request yearly updates of faculty interests using an online survey.
- Match interests of researchers with potential funding sources.

Faculty and Staff Grantsmanship Skills Development

- Provide workshops on research marketing and sponsor relationships.
- Provide workshops on policies and procedures related to contracts and grants.
- Provide training in proposal planning and writing.
- Provide training in project management and systems used for this purpose.

Dissemination of Funding Information

- Publish and distribute annual reports of proposal submissions, awards and other funding related topics.
- Notify faculty of relevant funding mechanisms that become available in federal and private funding agencies in a timely fashion.

Proposal Development

- Consult with faculty and staff on proposal drafts.
- Provide technical assistance in completing application forms.
- Develop a proposal preparation guide.
- Maintain an Institutional Fact Sheet.
- Provide editorial assistance for language and scientific writing.
- Provide editorial assistance in manuscript submissions.

Budget Preparation

- Ensure that the proposal budget adheres to university and sponsor guidelines.
- Review budget justification
- Review cost share and indirect cost allocation.
- Ensure that proper and accurate information is entered into the proposal budget

(personnel salaries and fringe benefits, etc).

Award Negotiations

- Review and negotiate budgets.
- Review and negotiate indemnifications.
- Review and negotiate contract/agreement execution.

Administration of Funded Programs

- Assist the Principal Investigator (PI) in managing projects, clarifying agency regulations and policies.
- Advise on grant revisions.
- Review and approve expenditures on grant/contract accounts.
- Acts as a liaison between PI and the sponsoring agency regarding modifications of funded projects (no cost extensions, budget revisions).
- Prepare invoices and other billings.
- Prepare and submit financial reports.
- Develop, negotiate and administer all subcontracts.
- Provide contractual guidance (interpreting the sponsor's regulations and guidelines).
- Coordinate accounts closeout, including all financial, property and invention reports.
- Act as a liaison for all audits involving sponsored projects.
- Monitor and document cost share requirements.
- Oversee and certify the time and effort reports (Form 125 B).
- Manage all award budgets of the UPR-MSC.
- Process budget modifications.

Compliance

Verify that all Institutional compliance requirements of proposals are met before the submission to funding agencies.

- Institutional Review Board.

- **Institutional Animal Care and Use Committee**
- **Biosafety Committee**
- **Radiation Safety**

CRECED Organizational Chart (see Appendix)

CRECED will respond directly to the chancellor of UPR-MSU and will have four main components:

- Proposal and Scientific Development (PRE-AWARD)
- Financial Administration, management, and personnel transactions of Grants and Contracts (POST-AWARD)
- Research Regulatory & Compliance
- Agglutinate MSU Research Units previously allocated within the Chancellors office and/or other Deanships

CRECED PERSONNEL (see Appendix C)

In order to offer an effective and efficient structure with minimal fiscal impact in times of fiscal constraints, the establishment of CRECED requires restructuring of current human resources and moreover, setting-up new/key positions.

Each division will have an Assistant Director, with the exception of Personnel Transactions and Management of Grants and Contracts, for which there will be one Assistant Director. All Assistant Directors report to the newly created position of Director, a faculty member, who will be responsible for executive leadership, policy creation and execution of CRECED's program; and who will report directly to the Chancellor.

CRECED Director

The Director will be responsible for establishing and developing the mission, vision and program of CRECED. He/She will be responsible for increasing grants collaborative agreements and contracts activity in UPR-MSU by identifying relevant grants, subcontracts, and collaborative agreements for faculty and staff members. He/She will advise faculty and staff on the appropriate funding mechanisms and on grants management strategies. The Director will also work with support staff, offices, granting and government agencies and others to assure compliance with all required guidelines and regulations.

The Chancellor of the UPR-MSU will appoint the CRECED Director. He/She will have a doctoral level educational background and proven experience in obtaining federal research grants. The Director will have at least 5 years of research experience and publications in peer reviewed national and international journals. The Director will oversee all CRECED divisions and will be an ex-officio member of the Research Compliance Committee and the Research Advisory Committee.

The Director will conduct strategic planning meetings with staff to successfully manage a dynamic workload that meet researchers, faculty and students' changing demands/expectations. He/She will foster a positive relationship with staff, management, customers and campus administrators to encourage regular and open dialogue. She/He represents CRECED on campus and system-wide committees and in professional meetings and associations and will exercise delegated signature authority.

CRECED Associate Director

To assist and enhance the Director's efforts, the position of an Associate Director is required. The Associate Director will supervise the various administrative components of CRECED. The Associate Director will be responsible for the establishment of priorities and the day-to-day operation of the office. He/She will make the maximum use of resources, and conduct business in an open and transparent manner with the goal of achieving CRECED's mission, vision, and values. He/She will develop and set team metrics to ensure operational efficiencies, maximum productivity, customer satisfaction, and employee proficiency. He/She will supervise the efforts to implement written Standard Operating Procedures for all aspects of CRECED.

The Associate Director will help the Director to conduct strategic planning meetings with staff to successfully manage a dynamic workload that meet researchers, faculty and students' changing demands/expectations. Together they will foster a positive relationship with staff, management, customers and campus administrators to encourage regular and open dialogue.

To best serve the community of researchers, the reorganization involves creating and reassigning several other positions:

New positions

Director – (see above)

Associate Director – (see above)

Editorial and Statistical Services – CRECED will outsource editorial and statistical services to assist in the development of research proposals, as well as of scientific manuscripts to be submitted to peer-reviewed journals. (\$3,000 per proposal and \$1,500 per manuscript for editorial services, \$1,500 per proposal for statistical advice. A maximum of \$60,000 per year will be budgeted each year). The Director will developed the procedures for these services.

Reassignments

Evaluation of personnel and institutional resources will be an integral part of CRECED to maximize efficiency, provide leverage, and enhance the MSC Research Enterprise. The Director will work with the Associate Director and Administrative Director and staff to establish goals/outcomes within CRECED and will report to the Chancellor.

Budget and Finance

CRECED will have an operational fund derived from the facilities and administration fees (F&A costs) as described in (Cert. #30, 1999-2000). The Chancellor will assign CRECED's additional budget if necessary. Operational costs will be subject to internal and external UPR audits.

KEY RESOURCES OF THE CRECED

Research Compliance

Research projects in clinical, biomedical and behavioral fields require that the Institution where the research is conducted certify that the Projects comply with all federal and local regulations. To this avail, the following committees serve this purpose:

IACUC: The Institutional Animal and Care and Use Committee (IACUC) revises, approves monitors and certifies that the project complies with institutional, USDA and NIH regulations regarding the use of animals in biomedical research.

IRB: The Institutional Review Board (IRB) revises, approves, monitors and certifies

that all biomedical and behavioral research involving humans complies with all local and federal regulations such as the NIH.

RSC: The Radiation Safety Committee (RSC) revises, approves, monitors and certifies that all biomedical and clinical research, as well as all clinical procedures, that involve the use of radioactive material, comply with institutional, the Nuclear Regulatory Committee (NRC), the Health Department, the Environmental Protection Agency (EPA) and Junta de Calidad Ambiental (JCA) regulations.

IBC: The Institutional Biosafety Committee (IBC) revises, approves, monitors and certifies that all research that involves the use of recombinant or synthetic DNA molecules complies with the Food and Drug Administration (FDA) guidelines as well as those from the Department of Health and Human Services and the National Institutes of Health (NIH). It also oversees experimentation that involves the use of biological materials (infectious agents) and other potentially hazardous agents (cancerogens).

DATABASE OF INVESTIGATORS

CRECED will maintain a list of: (1) investigators, (2) their research interests, (3) letters of approval by IRB, IACUC, RSC, and IBC of all research protocols (4) IACUC, IRB, RSC and IBC training certificates and (5) submitted proposals, contracts and continuing reports.

RESEARCH AND GRANT OPPORTUNITIES

Early identification of funding opportunities and cultivation of the funding sources are key attributes of institutions that are highly successful in obtaining external funding. CRECED will obtain the resources and tools to allow early identification of funding opportunities to permit early preplanning and preparation as soon as a formal announcement is published. CRECED will monitor potential sponsor's websites for early recognition of research opportunities. It will also make a concerted effort to maintain funding agencies aware of the university's interests and capabilities.

CRECED will provide assistance to faculty and staff in researching, identifying, and matching funding and research opportunities with specific areas of interest and/or

specialization. CRECED will maintain a research profile of each investigator. A weekly search of solicitations notices such as Request for Applications (RFA) and Program Announcements (PA) will be conducted in the NIH and NSF databases, as well as in databases of pertinent Foundations every week. Those interested in having CRECED provide this information must complete the Research Profile Interest Form and submit it electronically to the CRECED. Funding Alert e-mails will be sent when funding opportunities become available.

An updated list of Government funding Agencies and Foundations, as well as the types of activities they are interested in supporting, will also be maintained in the CRECED website. This information can be very useful in identifying sources for unsolicited proposals that match the research interest of the university.

Advisory Committees

Two advisory committees will provide guidance to the UPR Chancellor in research development and administration:

Chancellor's Board for Institutional Compliance Committee – composed by the directors of institutional research oversight committees (IRB, IACUC, Biosafety and Radiation Safety)

Chancellor's Research Advisory Committee – Composed of researchers from each of the Schools of the MSC and of the research Institutes of UPR-MSC. The Deans of each School nominate members to the Chancellor.

PRE-AWARD

PROPOSAL DEVELOPMENT AND PREPARATION

Proposal Development

1. Assists investigators in identifying the appropriate funding sources and mechanisms to provide support to their educational, clinical and research endeavors.
2. Sends out weekly notices of available funding opportunities.
3. Maintains an updated list of Foundations and government agencies that provide research funds.

Proposal Preparation

1. Meets with investigators to discuss proposal requirements and qualifications of investigator for a successful response to solicitation.
2. Provides guidance to the investigator on the steps to follow for proposal submission.
3. Helps investigators develop a timeline for proposal preparation.
4. Provides assistance in budget requirements and preparation, as well with recruitment and job descriptions of proposal personnel. Assists with budget justification preparation.
5. Provides editorial assistance for grant proposals and manuscripts.
6. Provides statistical counseling in the preparation of the experimental design.
7. Enrolls investigators in eRA Commons or other pertinent database.

8. Assists the investigator with the preparation of the Internal Transmittal Form for proposal submission.
9. Receives a copy of the proposal from the investigator and revises for administrative errors.
10. Checks that the proposal complies with all institutional (Chair and Dean Signatures) and federal requirements (IACUC, IRB, etc).
11. Obtains the Chancellor's signature in the Internal Transmittal Form certifying that he/she agrees with the terms and conditions of the grant proposal.
12. Submits the proposal to the appropriate agency.
13. Assists the investigator in addressing the errors that occur during the submission process.
14. Keeps a copy of all submitted proposals.
15. Assists with submission of progress reports, Just in Time reports, etc.
16. Responsible for communications and transactions with the granting agency regarding administrative and financial issues.

PROPOSAL REVIEW AND EVALUATION GUIDELINES

Generally, a grant proposal is reviewed from several perspectives. First of all, it needs to fulfill the criteria outlined in the program announcement. A grant proposal is also evaluated for the accuracy and validity of the scientific content, the clarity in which the material is presented, grammatical and typographical errors, the suitability of the PI and of the environment to conduct the research project, etc.

CRECED will assist the investigator to ensure that it complies with the criteria outlined in the program announcement and, if requested, will provide scientific and language editorial assistance. Editors will review the proposal from the perspective of the reviewers and potential sponsors and will provide detailed comments to improve and fine-tune the proposal to maximize its potential for success.

CRECED will verify the grant proposal prior to submission, to guarantee that no critical elements have been left out or overlooked. The Director will do this and/or staffs who are knowledgeable of the requirements for the specific solicitation being addressed and who also

have a general knowledge of proposal preparation and submission procedures. These include ensuring that:

1. All explicit evaluation criteria are addressed.
2. The document is complete.
3. All document format requirements are met.
4. The proper forms are filled-out, signed and attached.
5. All required signatures are on the proposal transmittal form.

The proposed plan will bring to bear an administrative organization that will deliver information, direction and technical assistance services to faculty and staff in obtaining external funds. With an emphasis on improving the efficiency, productivity and a comprehensive support service, CRECED will serve as the keystone of the existing research capabilities while enhancing and developing new capabilities and resources.

Appendix. Center for Research Compliance & Development
(CRECED)
Overall Organizational Chart

