General Definitions and Guidelines for Program Director/Project Director/Principal Investigator, Co-Investigator, Collaborator, Consultant and Consortium Agreement Associated with an Application

In order to address various questions associated with subject and what constitutes one role from the other, I have provided general definitions along with general guidelines that are to be used in determining the type of role associated with an individual and how these roles are used in applications.

Program Director/Project Director/Principal Investigator: An individual designated by the recipient to direct the project or program being supported by the grant. He or she is responsible and accountable to recipient organization officials for the proper conduct of the project or program. The organization is, in turn, legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported activity.

Co-Investigator: An individual involved with the principal investigator in the scientific development or execution of a project. The co-investigator may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement.

A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the principal investigator's roles and responsibilities as specified in this policy statement.

Collaborator: An individual involved with the principal investigator in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as key personnel. The Collaborator is employed by, or affiliated with the grantee organization.

Referring to the definition and taking this definition and role a step further in comparing the language with that of the Co-Investigator, a "Collaborator" is an individual employed by TUC with minimal involvement (4% or less effort) with the PI in the scientific development or execution of the project. If an individual, as stated in the definition, is "involved" with the PI in the scientific development or execution of the project and a specific percent of effort is requested (5% or more), this individual needs to be identified as a "Co-Investigator". This individual may or may not have a primary appointment with the College, Department and/or Unit submitting the application. The key differences between the Co-Investigator and the Collaborator are the degree of involvement in the scientific development or execution of the project and the effort associated with his/her involvement. Both, the Collaborator and the Co-Investigator are employees of Touro University.

Consortium or Contractual Agreement: An agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. In this arrangement, the grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization's principal investigator and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including Facilities and Administration costs.

If the individual is employed outside the university and is involved in the scientific development or execution of the project, then this individual should be identified as a Co-Investigator and a formal Consortium or Contractual Agreement needs to be utilized.
Consultant: A consultant is an individual retained to provide professional advice or services on a project for a fee but usually not as an employee of the requiring organization (TUC). The term "consultant" also includes a firm that provides paid professional advice or services. Grantees must have written policies governing their use of consultants that are consistently applied regardless of the source of support. In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee as long as those separate services are not related to the same project and are not charged to the same project. In order to prevent apparent or actual conflicts of interest, grantees, consortium participants, and contractors under grants must establish written guidelines indicating the conditions, if any, under which the payment of consulting fees to employees is proper.

Under no circumstances can an individual be paid as a consultant and an employee under the same NIH grant.

In unusual cases and with authorization as indicated below, consulting fees paid by an educational institution to a salaried faculty member that represent extra compensation above that individual's base salary are allowable, provided the consultation is across departmental lines or involves a separate or remote operation and the work performed by the consultant is in addition to his or her regular departmental workload. In all other cases, consulting fees paid to employees of a grantee, a consortium participant, or a contractor in addition to salary may be charged to NIH grant-supported projects only when all of the following conditions exist:

- The policies of the grantee, consortium participant, or contractor permit such consulting fee payments to its own employees regardless of whether Federal grant funds are received;

- The consulting services are clearly outside the scope of the individual's salaried employment;

- It would be inappropriate or not feasible to compensate the individual for those services through payment of additional salary; and

- Authorization is obtained as specified below.

Authorization for consulting fees paid to individuals serving as both employees and consultants of the same party must be provided in writing, on a case-by-case basis, by the head of the recipient organization, consortium participant, or contractor incurring the costs, or his or her designee. If the designee is personally involved in the project, the authorization may be given only by the head of the recipient organization, consortium participant, or contractor. This authorization must include a determination that the required conditions are present and that there is no apparent or actual conflict of interest.

For additional clarification on the allowance and appropriateness of consulting fees, refer to the NIH Grants Policy Statement (03/01) Part II: Terms and Conditions of NIH Grant Awards Subpart A: General – Part 4 of 7

This definition and the role is the most complex. The first sentence reads, "A consultant is an individual retained to provide professional advice or services on a project for a fee but usually not as an employee of the requiring organization." Therefore, this individual should not be a Touro University employee. When referring to a TUC employee, identify the individual as a "Collaborator" (minimal effort) or a "Co-Investigator" (significant input and involvement; effort 5% or >). If the individual is involved in the development or execution of the project and is not
employed by TUC, then TUC needs to have a Consortium or Contractual Agreement with the Co-Investigator identified from the outside entity.

In Summary, a Consultant is not a TUC employee and is not intimately involved in the development or execution of the project. If there is a fee associated with this individual, the fee should be minimal (i.e. generally a fee less than 10% of the total direct costs or effort less than 10%) and the letter of Intent to Consult should not be on the letterhead of another Institution of Higher Learning (unless we are consulting with the Institution and not with the specific individual). The letter of intent should be from the individual or from the consulting firm. The letter of Intent to Consult should outline specifically, the duties associated with his/her role as a consultant for the project. Using the aforementioned general definitions and guidelines along with some common sense will constitute identifying this individual as a “Consultant” or as possibly a “Co-Investigator”. If questions/concerns exist after reading the Letter of Intent to Consult, please contact your OSP representative. Please note that letters of Intent to Consult need to be obtained early on in the process since people have different perceptions as for the type of role these individuals may perform for their research project.

Well, I hope I have clarified the differences regarding these terms and their applicable roles for any given project. Please understand that sponsored activity is seldom “black and white”. The majority of issues that we deal with can be very “gray”. The bottom line is that OSP will work with you, but time is the critical factor. The earlier these issues surface in the application process, the more time everyone will have to fully express their intentions and objectives, which in turn, will provide the opportunity to achieve the objectives of the application, both scientifically and administratively.