Instructions for Completion of
EXTRAMURAL PROPOSAL APPROVAL AND SUBMISSION SUMMARY "EPASS"

This form is used for the review and approval of applications or proposals to be submitted to extramural funding agencies by the Office of Contract and Grant Administration (OCGA), Technology Development Group (TDG), and/or the DGSOM Clinical Trials Contracts and Strategic Relations (CTC&SR). This form is for campus use only and should not be forwarded to the funding agency.

In accordance with UC Policy, UCLA requires that all proposals submitted to an authorized institutional official for review and institutional endorsement, include a completed proposal approval form. The Extramural Proposal Approval and Submission Summary (EPASS) is the current UCLA proposal approval form that replaces the "Goldenrod" effective June 18, 2012. The EPASS provides: a helpful checklist of items that need to be addressed as part of proposal development and submission; approvals and certifications required in accordance with University and sponsor policies; and endorsements required from other University officials. **Please see Section 10 of the EPASS form, and Section 10 of these Instructions, for information on the required certifications and assurances made upon signature or submission of the EPASS by: Principal Investigators (PIs) and Co-PIs; Department Chairs, Unit Heads or Deans; other signators as required.**

Section 1: Principal Investigator(s)/Co-PIs (Not Co-Investigators)

Employee ID: This 9-digit number is the unique identifier assigned to each UCLA employee by the Employee Database (EDB). If you do not know this number, contact your department/unit payroll office.

Other PI: List other UCLA Principal Investigators as defined by UCLA Policy 900. If there are more than two, add additional information in **Section 9: Remarks** or attach additional copies of page 1 of the form.

Fellow: If the EPASS pertains to an individual fellowship, provide the name of the fellow, and list the mentor/advisor as PI.

Section 2: Department or Organized Research Unit (ORU)

Administering Department Name: Enter the name of the UCLA department/unit/ORU that will have primary responsibility for administering the award. This may or may not be the PI's home department.

FS Code: Provide the four-digit financial system code of the department/unit/ORU which will be administering this project if awarded.

Account #: Provide an appropriate department account number (e.g., 44XXXX, 78XXXX, 40XXXX) to be assigned if an award is issued in response to this proposal. Only one number should be listed that corresponds to the primary activity of the project.

Cost Center: List the applicable cost center if the administering department uses these designations; otherwise, enter "N/A".

Recharge ID: Provide a Recharge ID to be used in the event OCGA needs to ship documents related to the proposed project.

Department Contact Name/Extension/Email Address: Provide contact information for the departmental administrator who is responsible for the proposal, and can respond to questions from OCGA/TDG/CTC&SR regarding the proposal and/or resulting award. If the pre-award contact is different from the post-award contact, provide additional contact information in **Section 9: Remarks**.

If your department/unit has a single email address for all proposal/award related correspondence, enter here: Use this section to provide a shared email address to receive correspondence from OCGA related to proposals and/or awards.

Have the services of any campus Center of ORU been used in the development of this proposal?: If the proposal is affiliated with or uses the resources of a campus Center(s) and/or Organized Research Unit(s), select the supporting center or ORU from the drop-down list. If "Other" is selected, identify the supporting Center or ORU in the text field below. If the proposal is affiliated with more than one Center(s) or ORU(s), enter additional Center(s)/ORU(s) in **Section 9: Remarks**.

Section 3: Proposal Identification

Proposal Title: Enter the title as it appears on the proposal face page/cover sheet.

Is this COVID-19 Subject Matter? If this proposal is for the study of COVID-19 subject matter or provides services specifically related to COVID-19, check "Yes". Otherwise, check "No".

Project Begin Date/End Date: Enter the dates (month/day/year) of the proposed project period start and end based on sponsor guidelines or in consultation with the PI.

Section 4: Award/Proposal/Program Type

Award Type: Select the anticipated type of funding mechanism from the drop-down menu based on the descriptions provided below:

Grant	A financial assistance mechanism to support the conduct of research or other activities as described in a general scope of work.
Contract	Agreement to provide support for research or other activities in return for a set statement of work or deliverables.
Subgrant	Agreement under a prime grant award to another entity that provides financial assistance to UCLA to support the conduct of research or other activities as described in a general scope of work.
Subcontract	Agreement under a prime contract to another entity that provides support to UCLA for research or other activities in return for a set statement of work or deliverables.
Cooperative Agreement	An award in which the funding agency remains involved in the research or project during its performance by the receiving entity.
Other Transaction Agreement	A research award that is not a grant, cooperative agreement or contract, using Other Transaction Authorities.
OTA Subaward	Agreement under a prime contract to another entity that is not a grant, cooperative agreement or contract, using Other Transaction Authorities.

Proposal Type: Select the appropriate Proposal Type from the drop-down menu based on the descriptions provided below:

New	A new proposal.
Competitive Renewal	A competitively reviewed proposal requesting additional funds and an additional project period beyond the current project period.
Preliminary Proposal	A brief description, usually 2-10 pages, of research plans and estimated budget that is sometimes submitted to determine the interest of a particular sponsor prior to submission of a formal proposal. Also termed "pre-proposal."
Resubmission - New	A proposal that is a resubmission of a new proposal previously declined proposal.
Resubmission - Competing Renewal	A proposal that is a resubmission of a competitive renewal that was previously declined.
Supplement	A separate proposal for additional funding and scope to be added to a fully-executed grant or contract.
Modification/Amendment	Modification to an existing fully-executed grant or contract.
Transfer (In)	An award that is being transferred from another institution to UCLA.

Program Type: Select the type of sponsored project activity from the drop-down menu based on the descriptions provided below:

Applied Org Research	Research to determine and expand the potential of new scientific discoveries or improvements in technology, materials, processes, methods and devices, and attempts to advance the state of the art.
Basic Org Research	Research directed toward an increase of knowledge where the primary aim of the investigation is a fuller knowledge or understanding of the subject under study rather than a clear or direct practical application.
Capital Program	Conceptualization, planning, design and construction of capital improvement projects, including financial strategies, architectural design, review of plans and specifications, environmental reviews, construction contracts and agreements, and staging plans.
Clinical Research	Medical science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.
CT Device	Industry funded or device provided by Sponsor, controlled, clinical testing in human subjects of investigational device(s)/equipment/contrast agent(s) to assess safety, efficacy, benefits, costs, adverse reactions, and/or outcomes.
CT Drug	Industry funded or drug provided by Sponsor, controlled, clinical testing in human subjects of investigational new drug(s) to assess safety, efficacy, benefits, costs, adverse reactions, and/or outcomes.
CT Gene Therapy	Industry funded, controlled, clinical testing in human subjects of gene therapy to assess safety, efficacy, benefits, costs, adverse reactions, and/or outcomes.

CT Gov./Non-profit	A Government/Non-Profit funded, controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. See Common Rule definition of research at 45 CFR 46.102(d) See Common Rule definition of human subject at 45 CFR 46.102(f) The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo or other control) of the clinical trial. An *intervention* is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related processes and/or endpoints. Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and, treatment, prevention, and diagnostic strategies. A *health-related biomedical or behavioral outcome* is defined as the pre-specified effect of an intervention on the study subjects. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); disease processes; health-related behavior; and, well-being or quality of life Biomedical clinical trials of an experimental drug, treatment, device, or behavioral intervention may proceed through four phases: **Phase I.** Tests a new biomedical intervention in a small group of people (e.g. 20-80) for the first time to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects). **Phase II.** Study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and further evaluate safety. **Phase III**. Study to determine efficacy of the biomedical or behavioral intervention in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the interventions to be used safely. **Phase IV.** Studies conducted after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.
CT In Kind	Test article (i.e. drug or device) without funding.
CT PI	A clinical trial where the PI authors the protocol and industry is funding to study drug(s) and/or device(s).
CT Other	Industry funded, controlled, clinical testing in human subjects to assess safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. This option is used when other CT options do not apply, could include but is not limited to core lab services agreement, registry agreements.
Dev Org Research	Research concerned with the systematic use of scientific and technical knowledge in the design, development, testing or evaluation of potential new products or services.
Equipment	An award for the purchase or fabrication of tangible nonexpendable property and having a useful life of more than one year.
Individual Fellowship	A financial and intellectual reward for a student's personal and academic achievements, as well as the recognition of future potential. These awards generally include a stipend paid to the student and may also include payment of fees and other educational costs.
Other Org Research	Research that does not meet the definition of Basic, Applied, or Development.
Other Service	An agreement for services which the University provides or makes available which do not fit within the categories of training or public service, such as the use of University facilities by for-profit entities.
Personnel Agreement/IPA	A funding reimbursement mechanism to enable UCLA personnel to perform activities at a non-UC agency for a defined period of time.
Public Service	An award that provides support for the purpose of organizing, establishing, providing, or enhancing the delivery of services to a particular community or non-university audience.
Research Training	Training of UCLA students and/or employees in the scientific techniques used while conducting research (e.g. NIH Diversity Supplements and K-awards, NSF REU Supplements).
Training	An award for the instruction of university students and/or employees in research or in the techniques or practices pertinent to a particular academic discipline.
Visiting Scientist	Agreement that details the conditions under which a scientist/academic from another entity will visit a department or school within UCLA for scholarly work.

Special Program Type: Select "Not Applicable" or special program types from the drop-down menu based on the descriptions provided below. NOTE: If more than one applies, provide additional types in **Section 9: Remarks**.

Not Applicable	Indicates the award or proposal does not have a special program type.
SBIR	Small Business Innovative Research - Federal program designed to support small business concerns conducting innovative research/research & development with potential for commercialization in partnership with a large business or educational institution. The small business is the prime grantee or contractor and the university is the subgrantee/subcontractor.
STTR	Small Business Technology Transfer - Federal program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. The small business or research institution can be the prime grantee or contractor.
Tobacco Industry	Indicates proposal is to be submitted in Tobacco Industry sponsor, which requires special review and reporting to UCOP.
UC Discovery	A former UCOP-funded program that matched industry funding against UCOP funding.
UC Program	Any UC-funded program.
Limited Submission	Indicates this proposal is the one or one of only a few that was nominated for submission from UCLA. These proposals must be approved for submission, as the sponsor accepts a limited number from each institution.
CDA/NDA	A formal agreement between UCLA and an outside entity that protects the confidential information generated at UCLA and/or that of our outside collaborators.
Master Agreement	An agreement that details the terms and conditions that will govern and be referenced in future contracts between two parties.
MOU	Memorandum of Understanding is an agreement that details the terms and conditions that will govern and be referenced in future contracts between two parties.
DUA or DTUA	Data Use Agreement or Data Transfer and Use Agreement is an agreement that details the conditions under which data may be shared between parties.
Teaming Agreement	An agreement that details the conditions under which the parties will collaborate. For example, a collaborative proposal development effort. Generally, not a funding mechanism.

If this EPASS relates to an existing Award or Master Agreement, select the appropriate Action Type: From the drop-down menu based on the descriptions provided below:

Continuation	A non-competitive continuation of an existing award, sometimes known as progress report.
Supplement	A separate award with additional scope and funding that is issued by the sponsor as an addition to a current award. In most cases, a separate proposal was submitted in order to request these funds.
Modification/Amendment	Modification to an existing fully-executed grant or contract.
Option	A priced and scoped component of a contract that is negotiated at the time of contract execution but is not committed funding. Sponsor may "exercise the option" by formally modifying the agreement after execution to fund a particular option.
Master Agreement/Task Order	*Master Agreement:* A contract where the parties agree to terms and conditions that will govern future transactions. *Task Order:* A discrete, project-specific agreement that generally includes a scope of work and budget, but not other terms and conditions as those would have been agreed to in the master agreement.

Current Sponsor Award/ID #: Provide Sponsor's unique identification number indicated on the SNAPSHOT for the current award.

Section 5:

Sponsor Information (Entity which will provide funding directly to UCLA)

Sponsor Name: Indicate the name of the entity to which UCLA is submitting the proposal

Sponsor Due Date/Time (Pacific): Indicate the date and time that the application is due to the sponsor. For subawards, the sponsor is defined as the entity to which UCLA is submitting the proposal. If no deadline or "ASAP" is indicated, a standard deadline of five business days from date of receipt will be used.

Deadline Type: Select the applicable deadline type from the drop-down menu. If sponsor requires both electronic and hard-copy submission, provide additional information in **Section 9: Remarks**.

Sponsor Guidelines and/or FOA/RFA/RFP: Check "Yes" or "No" to indicate whether the sponsor has issued guidelines and/or an opportunity number. If "Yes", check the appropriate box below. If "URL (Section 9)" is checked, provide the URL in the "9. Remarks".

Contact/Email Address/Phone #: If known, enter the name, e-mail address and phone number of the individual to whom the proposal

should be directed. If this application requires hard-copy submission, enter the mailing address in the remarks section. Note that all applications that are shipped via private carrier require a phone number and street address.

Prime Sponsor Information (Complete this section when UCLA is a subrecipient). When UCLA is a subrecipient, the same information is required for the prime sponsor, as for the Sponsor (see *Sponsor Information*, above).

Section 6: Proposal Checklist

Answer "Yes" or "No" for each line item:

PI Exception Required? Use the "Check Requirements" hyperlink on the form to review UCLA Policy 900 and determine if the individuals listed in Section 1 as PI, Other Co-PI, or Multiple PI are eligible to serve as PI on extramurally supported projects as outlined in section III.B of the policy. If "No", attach a signed PI approval.

On Campus Space? If "Yes", enter the *Building* and *Room* in the text fields provided. If "No", leave the blank.

Of Campus Space? If "Yes", indicate the location including full address in the text field provided. If "No", leave blank.

Note: The answer to one or both of the questions, above, can be "Yes", but only one of the two can be answered "No".

Outgoing Agreements? If the proposal includes any outgoing subawards (subawards issued by UCLA to a collaborator), provide the necessary forms and information for each collaborating entity. Review Outgoing Subawards Overview for details on required forms and documents.

Does this project involve activities outside the U.S. and/or partnership with foreign collaborators, whether or not funded? Check "Yes" if any part of the project involves activities or partnerships outside of the U.S. or with foreign collaborators and indicate the country(ies). In addition, carefully review and answer the "Export Control" questions below.

Is any Mandatory Cost Sharing/Matching proposed in this application? This can include cash, unfunded effort, or in-kind contributions, but *should not* include salary cap differential. If "Yes" provided the mandatory cost chare amount in the text field. Note: Voluntary cost sharing is discouraged under UC Policy.

Is any unfunded effort proposed in this application? If any effort is proposed for UCLA personnel that is not fully funded by the sponsor, effort must be reported in ERS in accordance with UC Policy. This does not apply to salary cap differential.

Do you anticipate Program Income? If yes, specify: Indicate type and anticipated amount.

> Program income is gross income—earned by a grantee, a consortium participant, or a contractor under a grant—that was directly generated by the grant-supported activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed; charges for the use or rental of real property, equipment or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; and license fees and royalties on patents and copyrights. (Note: Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements.)

Does this proposal involve the use of significant IT resources (beyond basic academic infrastructure); the generation of datasets or digital assets; or a budget with over $10,000 in IT-related hardware, software, or staff expenditures? If yes, please indicate.

Human Subjects? If yes, enter IRB protocol number or 'Pending'. If the proposed use of human subjects is anticipated within the period of award, but definite plans are not yet known to submit a protocol application to the Institutional Review Board until initial work begins under a funded award, check the box labeled 'Delayed Onset'.

NIH Funded Clinical Trial? Carefully review the definition of an NIH Funded Clinical Trial. If "Yes", provide the names of all individuals involved in the conduct, oversight, or management of clinical trials, as well as their Good Clinical Practice completion date(s) on the next page. Use the CITI Training Completion Tool on the ORA Portal to look-up training completion dates. Note: non-completion of training will not prevent submission of the proposal, but is required for Just-in-Time and award acceptance.

Will the clinical research study utilize UCLA Health System resources, including but not limited to, any patient care costs? If "Yes" Coverage Analysis is required. Carefully review UCLA Policy 915 and contact coverageanalysis@mednet.ucla.edu with questions.

Animal Subjects? If yes, enter ARC approval number or "pending". If the proposed use of animal subjects is to be defined after award as part of the proposed scope of work, describe this clearly in the scope of work and in the proposal narrative section describing use of animal subjects, and check the box labeled "Delayed Onset."

Human Embryonic Stem Cell Research? If yes, refer to information provided via the hyperlink.

Non-UCLA materials/equipment to be used? If yes, describe the type and source of the non-UCLA materials/equipment in the text fields

Human or primate cells, tissue, or fluids; recombinant or synthetic nucleic acids; potentially infectious materials; exotic plants or plant pathogens; select agents or toxins? Refer to the UCLA Research Safety & Animal Welfare Administration (RSAWA), Institutional Biosafety Committee (IBC) website.

Use of UC IP? If UC-protected Intellectual Property is to be used, indicate the IP disclosure case number.

Export Control: See Research Policy and Compliance website.

Section 7: Additional Forms Required – See links on EPASS for additional information needed.

Section 8: Funds Requested

Excluded Direct Costs: Indicate the amount of direct costs that ***are not*** subject to/assessed F&A.

F&A Base Type: Select the appropriate Facilities and Administrative (F&A) Cost Base Type from the drop-down menu based on the descriptions provided below:

Lump Sum	Indicates the F&A is awarded as a lump sum and not as a percentage of the direct costs.
MTDC	As defined in UCLA's federally-negotiated F&A rate agreement, indicates F&A is being calculated on a portion of the total direct costs. MTDC excludes equipment, capital expenditures, charges for patient care, student tuition remission, rental/lease costs of off-site facilities, scholarships and fellowships, as well as a portion of each subgrant and subcontract in excess of $25,000.
Other	Indicates a non-standard F&A Rate is being utilized on this award. This includes alternates to the MTDC base described below.
Salary and Wages	Indicates F&A is only charged on Salary expenses. All other expenses (including benefits) are excluded from the F&A calculation.
Salary and Wages (with Benefits)	Indicates F&A is charged on Salary and benefits expenses. All other expenses are excluded from the F&A calculation.
TADC (Federal Training)	TDC base excluding tuition and fees and equipment expenditures.
TC	Indicates F&A is calculated based on a percentage of Total Costs (e.g., if F&A Rate = 10% of Total Cost, F&A on $100,000 Total Costs would be $10,000).
TDC	Indicates F&A is being calculated on total direct costs with no exclusions.

Section 9: Remarks: Provide additional information as needed.

Section 10: Approvals

In accordance with UC Policy, the following required certifications and assurances are made upon signature or submission of the EPASS by: Principal Investigators (PIs) and Co-PIs; Department Chairs, Unit Heads or Deans; other signators as required.

The Principal Investigators (PIs) and Co-PIs, by signing and submitting a hard copy of this form, or by each forwarding this form from his/her personal or UCLA email account, make the certifications that follow:

> *The Investigator(s) certifies to the following: (1) that the information submitted within this application is true, complete and accurate to the best of their knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Investigator(s) to criminal, civil or administrative penalties; (3) agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application; and (4) that you are not currently debarred, suspended or ineligible to receive federal or non-federal funds*; (5) all Clinical Trials based upon FDAAA 801, will be registered in ClinicalTrials.gov. *When multiple investigators are named in Section I, above, this assurance must be obtained by all named Investigators.*

The Chair/ORU Director/Dean by signing and submitting a hard copy of this form, or by each forwarding this form from his/her personal or UCLA email account, thereby confirm and assure the appropriateness of any commitments of University resources required by the proposed project, as well as the appropriateness of the project in accordance with University Regulation No. 4 (see detail below*). Such commitments may include laboratory space, computer facilities, cost of renovations, personnel and cost sharing. The Principal Investigator's proposed effort, salary and any leave or release time in the proposal require the approval signatures of the Department Char, Unit Head or Dean, as applicable within each School or Department.

* 2-130 *ACADEMIC POLICY - UNIVERSITY REGULATION NO. 4*

University Regulation No. 4, set forth in APM 020, states the general policy of the University concerning professional or scholarly services to external individuals or organizations including business, industry, governments, or other educational institutions. This Policy describes, in part, the types of such services which the University considers appropriate for its faculty to undertake. "Routine tests of a commonplace type" are specifically proscribed. The full text of APM 020 can be found in Chapter 1, Sections 1-320 and 1-330, of this *Manual* and in the *Academic Personnel Manual Section APM 020, Special Services to Individuals and Organizations.*