

OFFICE OF RESEARCH (OOR) SERVICE COMMITMENTS

Research and innovation are cornerstones of USC's strategic vision of academic excellence and scholarship with consequence. Our success in fulfilling this vision depends on harnessing the creative energies of our faculty, staff and students while helping them navigate regulatory, financial and contracting requirements associated with the conduct of research.

Implementation of the TARA system now affords USC the opportunity to: track service delivery; make the status of service requests visible to faculty and their departmental administrators online, in real time; and establish standards for service delivery, particularly with respect to the timeliness of support. Toward this end, the departments within the Office of Research established statements of service commitment, which follow on the attached pages, representing these areas:

Central Office: institutionally limited proposals, internal research awards, and research training programs;

Animal Resources/IACUC: protocols for animal research and support services for animal research;

Contracts and Grants: proposal submission, establishment of awards and closeout of awards;

DC Research Advancement: development of interdisciplinary and large federal proposals

Office for the Protection of Research Subjects/IRB: protocols for the conduct of human subjects research;

Research Technology Group: regulatory compliance systems for IRB, IACUC, Biosafety and Radiation Safety (iStar) and Conflicts of Interest in Research (diSClose);

USC Stevens Center for Innovation: technology licensing, patents, corporate research relations and material transfer agreements.

In all of these areas the OOR strives to provide a high level of service including

- *Professionalism:* providing reliable and consistent customer service;
- *Transparency:* maintaining open and effective communication with clearly defined procedures and guidelines posted at research.usc.edu;
- *Respect:* treating all persons with respect, fairness and courtesy;
- *Accountability:* acknowledging and assuming responsibility for actions and decisions, and
- *Responsiveness:* responding to all inquiries within one business day, including automated referrals when staff are out of office.

Should you wish to offer feedback on the statements of service commitment, please do not hesitate to contact the department heads or Silvia da Costa, Director of Faculty Research Relations (sdacosta@usc.edu).

CENTRAL OFFICE SERVICE COMMITMENT

1. “Priority Software – FBS Invoicing System”

- ***Bill for charges in any month issued by 19th day of following month, with notification to principal investigator***

FBS supports reservation, tracking, billing and payment for services and goods supplied by core laboratories and other research recharge centers. We commit to: working with the USC Financial Office to ensure that monthly invoice spreadsheets are error-free; maintaining the FBS software with the latest version provided by Priority Software; serving as the contact point between USC and Priority Software, informing them of any system or server problems that may be affecting FBS functionality; and updating the FBS website (research.usc.edu/fbs/) with educational and training materials and role-specific Quick Guides on FBS use.

We will also provide ongoing training to core managers, directors and associates until they are completely comfortable using the system, provide monthly reports of core activity to School Research Deans and update the facilities' web page (research.usc.edu/laboratoriesandservices/) with current core facility service and charge information.

To fulfill these standards, core facilities must finalize and update invoices to the Office of Research by the **18th of each month** (e.g.: services rendered during the month of July are invoiced August 19th) and must inform our office of any changes in core services, equipment, rates or contact information as soon as the information is available. Core managers are requested to submit individual invoices to core users **up to five days prior to the 18th**, to facilitate user inquiries and/or disputes of charges. Questions regarding FBS access and invoicing should be sent to **usccores@usc.edu**.

2. Institutionally Limited External Competitions and USC Research Awards

- ***Advertise limited submission solicitations at least four weeks in advance of USC deadline, with USC deadline at least three months prior to external deadline (unless OOR receives late notice)***
- ***Select limited submission award applications within four weeks of deadline (unless OOR receives late notice)***
- ***Advertise USC-funded solicitations at least two months prior to deadline***
- ***Select USC-funded research awards within three months of deadline***

The OOR will identify and advertise opportunities to relevant USC Schools, Centers and Institutes whose research deans and directors are responsible for promoting opportunities to their own faculty. In addition, we will post all institutionally-limited and USC-funded opportunities on the OOR webpages (research.usc.edu/institutionally-limited-external-competitions/ and research.usc.edu/for-investigators/funding/usc/). Limited submission solicitations are competitions for awards by outside sponsors for which USC can nominate a limited number of candidates and for which candidates must receive approval from the OOR prior to submission to the sponsor. Both USC Research Award and Limited Submission applications go through an internal review process.

We will also maintain the USC Application Submission Portal (app.wizehive.com/webform/USCgrants) for applicants and reviewers, adhere to a fair and transparent proposal review process, providing faculty with reviewer comments (when available) and serve as the authorized official on behalf of the University to provide letters of nomination and/or support, when applicable.

Investigators who independently identify limited submission solicitations must provide the OOR (vprsch@usc.edu) with the funding opportunity information as soon as it is identified – applicants may not apply directly to the external sponsor without OOR approval.

3. Center for Excellence in Research (CER)

- ***Provide proposal review and feedback within two weeks for complete drafts that are provided at least four weeks prior to proposal deadline***

The OOR offers a peer-to-peer proposal review service for applications to external funding agencies. Educational opportunities, seminars and lectures are also supported and developed by the CER with the aim to foster personal and professional excellence in research, with a particular focus on providing investigators with insights on funding strategies and proposal preparation. Faculty-led research salons and training workshops are offered in person and online via the [Trojan Learn portal](#).

We commit to identifying reviewers and serving as the intermediary between applicant and reviewer, maintaining anonymity throughout the process, and providing the applicant with proposal comments and edits within two weeks of proposal submission to OOR. We also commit to identifying faculty experts (former federal agency officials and other experts across all fields of study) with specialized skills and knowledge in seeking funding from government, foundation, and corporate organizations to lead CER workshops during the academic year and to the printing and distribution the CER Calendar of Events twice yearly (available in hardcopy and at research.usc.edu/for-investigators/training/).

To fulfill these standards, a near-final draft of the proposal should be provided to Araceli Roach (aracelir@usc.edu) at least four weeks prior to the grant application due date. Inquiries regarding CER events should be directed to usccer@usc.edu or by phone (213) 821-8167.

3. Exceptional Terms in Agreements

- ***Provide approval within one week of request***

Approval from the Vice President of Research is required for exceptional contract terms, which may pertain to sponsored research, licenses, material transfer agreements or other types of agreements. Example exceptions requiring review:

- Waiver of limitation-of-liability term in an agreement
- Special intellectual property terms conveying exceptional rights to sponsors

Requests for approval will be reviewed based on the merits of each request. In most cases, a decision as to whether accept or reject the request will be made within seven

days. Requests that require an unusual level of investigation may require more than seven days. Investigation may include a review of prior history of investigator(s) and sponsors.

Exceptions governed by USC's International Research Policy may be referred to committee for review, which may take up to one month. These exceptions include restrictions on publication or restrictions on participation of foreign nations.

Exceptional terms may or may not be approved, depending on the outcome of the assessment.

4. Support Letters for Proposals

- ***Draft provided to Silvia da Cost (sdacosta@usc.edu) or Kendra Frank (kendrafr@usc.edu): one week prior to deadline if no resources are requested***
- ***Any request for provost cost-share must be submitted at least one month in advance of deadline***

The Vice President of Research is pleased to provide letters of support or letters of acknowledgment for external research sponsors. Principal investigators should submit requests in this form:

- A draft letter must be provided at least one week in advance of deadline if no resources are requested
- Letters must be addressed to the program officer. Letters should not be addressed to investigators.
- The letter should explain the significance of the work, the unique characteristics of the proposal, and the qualifications of the PI to lead the proposal.
- If the letter offers commitments of resources from a school, center or department, then an endorsement is required from the school's research dean committing to provide the stated resources.

Any request for provost cost-share must be submitted at least one month in advance of deadline. Such commitment is limited to exceptional cases, where cost-share makes a difference in proposal selection and the proposal demonstrates strong inter-disciplinarity among a team of faculty in multiple schools. Please see core instrumentation program for information on cost-share on equipment proposals.

DEPARTMENT OF ANIMAL RESOURCES AND IACUC SERVICE COMMITMENT

The Department of Animal Resources (DAR) is the university-wide department that provides support for USC programs using animals in research and teaching. The DAR provides daily animal care, veterinary care, scientific support, business services, and administration of the Institutional Animal Care and Use Committee (IACUC).

The DAR serves as a resource for knowledge and technical expertise and provides an atmosphere of mutual respect and cooperation with our research staff members. We ensure that USC remains in compliance with all federal, state, and local regulatory agencies and we are committed to continuous accreditation by the Association for the Assessment and Accreditation for Laboratory Animal Care, International.

The DAR Customer Service Commitment describes our pledge to provide high quality service and how you can help us achieve it.

1. Support from IACUC

Preparation of Protocol Submissions

DAR will provide consultation with a laboratory animal veterinarian on research animal model development and experimental methodologies for any IACUC protocol or research proposal.

Protocol Review

- ***Submission to approval status decision within 60 days for protocols that do not require major revisions and that have addressed all stipulations from the IACUC***

When IACUC protocol approval forms are submitted through the iStar system, they will be reviewed during each calendar month based on submission deadlines published on the IACUC web site. The IACUC meeting and approval of protocols for each month normally occurs within 30 days of the deadline for that month. The protocol review process involves assignment of the protocol to a subset of IACUC members for review. A pre-review meeting is held, and after that meeting, a list of questions and stipulations to be addressed is sent to the Principal Investigator with a deadline for response prior to full IACUC meeting. If all questions and stipulations are answered to the committee's satisfaction, IACUC approval will be granted by electronic notification.

In addition to timely response to protocol submissions, IACUC staff members will confirm protocol submissions, respond promptly to questions and relay approval status based on published deadlines. IACUC staff members and veterinarians will also promptly answer questions on protocol submissions, stipulations from the IACUC, or approval status.

Reminders

Courtesy communication from an IACUC staff member regarding deadlines for animal use protocol renewals will be sent beginning 90 days before expiration.

2. Support from DAR

DAR will provide a clean and safe working environment within animal research facilities, and minimize unwanted experimental variation by the control of the animal environmental, animal health and animal wellbeing.

DAR staff members will make every effort to respond by telephone and/or email, normally within one work day. During absences, an automated message will indicate whom to contact.

Utilizing FBS software, DAR will provide accurate billing for services and timely response to questions about financial issues, offer convenient ordering and convenient transfer of animals and supplies for their care and use.

In the event of facility problems affecting animal studies and in the event of routine animal health problems, DAR veterinarians and staff will provide expert assessment and communication, normally within one working day. In emergencies, veterinary staff will normally respond to the problem within one hour (including weekends and holidays), with communication to the researcher within one working day.

Veterinarians will train any research staff member needing assistance with an experimental method in animals. Group retraining by a veterinarian for laboratory staff members may be scheduled at a laboratory meeting.

For new faculty, DAR will meet with research staff and students, review and consult on draft IACUC protocols, schedule training, establish financial accounts, and tour animal research facilities.

DAR will also promptly disseminate information about changes in federal regulations, guidelines, IACUC policies, and DAR services.

3. How You Can Help

- Respect animal welfare and others using and supporting our facilities;
- Follow appropriate procedures for animal facility and equipment use, animal handling, research procedures, and workplace safety;
- Adhere to policies emphasized in training materials, our website, and newsletters;
- Ensure that animal research procedures are fully understood by all laboratory staff members and are approved by the IACUC before implementation;
- Request training or retraining for research staff when needed;
- Be mindful of deadlines for submitting IACUC protocols, renewals, and amendments;
- Provide feedback by telling us what we are doing well and how we can improve.

DEPARTMENT OF CONTRACTS AND GRANTS SERVICE COMMITMENT

The Department of Contracts and Grants (DCG) supports USC's investigators from proposal development to award closeout, ensuring that our grants and contracts are consistent with university standards for academic freedom, research ethics and fiscal responsibility.

The Department of Contracts and Grants:

- Reviews, approves and submits proposals to extramural sponsors;
- Negotiates and accepts awards on behalf of the University;
- Executes subcontracts;
- Coordinates pre-award and post-award actions;
- Develops and maintains positive sponsor relationships;
- Ensures institutional compliance with federal and state regulations, sponsor policy and University policy.

1. Support for Proposal Review

DCG is committed to supporting USC investigators by assuring timely review and submission of complete and accurate proposals that have the best chance possible of success in the sponsor review process. To succeed in this goal, DCG offers an enhanced review for proposals ready for submission three business days in advance of the sponsor's deadline.

Proposals Received Three Business Days in Advance: Enhanced Review

For proposals where (1) All Kuali Coeus (KC) approvals are in place and (2) the proposal is final and ready for submission at least three business days in advance of the sponsor's deadline or the USC Deadline, if earlier, the Principal Investigator may request the Enhanced Review. The Enhanced Review will include:

Comprehensive proposal review in comparison to the sponsors' guidelines, including:

- Font type and size;
- Margins;
- Page limits for sections and proposal;
- Completeness for inclusion of all required sections;
- Non-technical review of proposal for grammatical and spelling errors

Institutional Information:

- Verify institutional information (e.g., DUNS, contact information, etc.);
- Check and clear errors generated by Grants.gov and/or Sponsor's proposal submission system;
- Verify completeness and accuracy of KC Proposal eDoc;
- Verify regulatory reviews (e.g., human/animal subjects, conflict of interest).

Budget Review:

- Verify budget calculations, rates and cost-sharing;

- Verify that all costs are categorized correctly and have appropriate justification;
- Verify that there are unallowable costs are not included.

Subawards:

- Verify that we have received a scope of work, budget and budget justification;
- Verify that we have received a subawardee institutional commitment;
- Verify compliance with FCOI, when applicable.

Proposals Received Two Business Days in Advance: Standard Review

For proposals where (1) All KC approvals are in place and (2) the proposal is final and ready for submission at least two business days in advance of the sponsor's deadline or the USC Deadline, if earlier, DCG will perform a Standard Review. The Standard Review will include, at a minimum:

Adherence to sponsor proposal solicitation

Institutional Information:

- Verify institutional information (e.g., DUNS, contact information, etc.);
- Check and clear errors generated by Grants.gov and/or Sponsor's proposal submission system;
- Verify completeness and accuracy of KC Proposal eDoc;
- Verify regulatory reviews (e.g., human/animal subjects, conflict of interest).

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Budget Review:

- Verify budget calculations, rates and cost-sharing
- Verify that all costs are categorized correctly and have appropriate justification;
- Verify that there are unallowable costs are not included.

Subawards:

- Verify that we have received a scope of work, budget and budget justification;
- Verify that we have received a subawardee institutional commitment;
- Verify compliance with FCOI, when applicable.

For Proposals Received Less Than One Business Day in Advance

Due to time constraints, proposals received less than 24 hours (or one business day) in advance of the sponsor's deadline or the USC Deadline, if earlier, will receive a minimum review with the goal to ensure that it is not rejected from the electronic submission vehicle. Unfortunately, proposals received by DCG less than 24 hours in advance risk rejection by sponsors, or potentially late submission.

In the event a proposal is submitted due to time constraints or because the proposal was submitted to the sponsor without going through DCG, DCG will conduct a

Standard Review after submission. DCG will work with the PI and the School to secure any additional approvals and make any additional corrections that are identified after submission.

For all proposals, DCG staff will communicate with the Principal Investigator and his/her research administrator when a proposal will receive less than a Standard Review due to time constraints.

Confirmation of Proposal Submissions

DCG will forward electronic confirmation to the Principal Investigator and his/her research administrator once the proposal is received and accepted by the sponsor.

2. Tips to Facilitate the Proposal Approval Process

The following are some tips to facilitate the proposal approval process:

1. Your proposal should be circulated for approvals within the KC system at least five business days in advance of the proposal deadline. Please allow more time if your proposal requires reviews and approvals by multiple schools, departments, centers or divisions;
2. Include the proposal guidelines and/or solicitation in the KC Proposal so DCG staff can review the proposal along with the solicitation guidelines;
3. Allow time for corrections. Allowing time for corrections helps to ensure the proposal is at its best when it is submitted to the sponsor;
4. Ensure a point of contact is available to make corrections. The Principal Investigator and/or a departmental contact should be available to make corrections until the proposal is ready to submit to the sponsor.

3. Negotiation of Sponsored Research Agreements

Sponsored Research Agreement negotiation timelines vary depending on agreement and sponsor; however, the DCG staff is committed to facilitating and completing negotiations in a professional and timely manner. Once DCG has (1) a complete and correct KC record containing the submitted proposal and Principal Investigator and School approvals and (2) the draft agreement, we are committed to initiating negotiations with the sponsor within five business days.

4. Communication with DCG Staff

DCG staff make every effort to be available to communicate with investigators and research administrators by telephone and email during heavy deadlines. When away from the office for more than 24 hours, staff will provide an out of office message indicating whom to contact during their absence. Staff will otherwise normally respond to inquiries within 24 hours of when they are contacted, and usually much sooner.

In addition, during the negotiation of any sponsored research or non-industry clinical trial agreement, DCG is committed to providing a biweekly status update to the Principal Investigator and department/center research administrator.

5. Additional Resources and Questions

The Department of Contracts and Grants offers a comprehensive online training program developed to meet the needs of today's evolving research environment. The [C&G Curriculum](#) is a valuable resource for proposal preparation and award management and ensures an overall standard level of expertise for research administrators working at a program, department or dean's office level.

The Office of Research through the [Center of Excellence in Research](#) also offers proposal writing workshops and resources.

In addition, the Grants Management Training programs for Faculty and Staff are online training modules required for new faculty, Principal Investigators, Co-Principal Investigators, and Research Administrators. The GMT consists of three training programs:

[Grants Management for Faculty](#): Required for all new faculty hired after 7/1/2015

[Grants Management for Faculty Refresher](#): Required for PI/Co-PI who completed training prior to 7/1/2015

[Grants Management for Staff](#): Required for staff seeking approval privileges on sponsored project accounts

The [Office of Research](#) and [DCG](#) websites provide additional information on procedures for processing grants and contracts, support available from different research administration units of the University, and information tailored for both sponsors and investigators.

For any questions regarding the DCG Service Commitment, please contact Jeri Muniz, Executive Director, Department of Contracts and Grants (jerimuni@usc.edu).

DC OFFICE OF RESEARCH ADVANCEMENT SERVICE COMMITMENT

The DC Office of Research Advancement is committed to helping USC faculty initiate or expand sponsored research programs. Specifically, the office strategically pursues funding opportunities with a targeted focus on large, multidisciplinary research endeavors. To achieve these goals, the DC Office of Research Advancement has established the following Service Commitment to all USC faculty.

1. Support for Proposal Development

Requests for Guidance Received More Than 60 Days Prior to Due Date

The DC Office of Research Advancement will provide: 1) a review of the solicitation; and 2) a competitive assessment of potential for funding. The review and competitive assessment findings will be conveyed directly to the potential PI. If the PI decides to proceed and submit a full proposal, the DC Office of Research Advancement can provide some or all of the services listed below:

Team Building

- Provide strategic input related to team composition and expertise;
- Identify USC faculty as potential collaborators;
- Identify faculty from other universities and individuals from other organizations as potential collaborators.

Proposal Organization and Planning

- Organize conference calls and face-to-face meetings;
- Develop outlines of application components;
- Create timelines for preparing and submitting applications;
- Conduct comparative analyses of existing USC assets;
- Conduct analyses of existing projects funded under the targeted program to determine optimal team composition and leadership.

Writing & Copy-Editing

- Review drafts for organization and responsiveness to solicitation;
- Copy-edit drafts for grammar, clarity, and completeness;
- Write *de novo* text for non-technical aspects of the proposal, e.g., outreach, administrative organization, USC assets;
- Creation of graphics, organizational charts, and timelines;
- Review summary statements and previous reviewer reports to provide guidance on resubmissions;
- Generate drafts of support letters from consultants, advisory committee members, and other partners;
- Generate drafts of supplementary documents required for submission.

Budget Preparation

- Assist PIs and school/departmental staff to develop and revise budgets;
- Prepare budget justifications;
- Identify potential strategies for cost sharing.

Administrative & Logistical Activities

- Coordinate collection of required documents from participating collaborators (including subcontractors), such as biosketches and letters of support;
- Complete application forms for electronic or paper submission;
- Ensure PIs obtain required governmental IDs and corresponding accounts (e.g. eRA Commons, NIH ASSIST);
- Ensure adherence to internal procedures and requirements prior to submission (e.g. disclose, Conflict of Interest).

Proposal Submission

- Facilitate department approvals as required by USC Department of Contracts and Grants;
- Coordinate the final on-time submission with USC Department of Contracts and Grants and other relevant USC offices.

Requests for Guidance Received Less Than 60 Days Before Due Date

The DC Office of Research Advancement will internally review all requests made less than 60 days before due date. Requests will be evaluated and prioritized based on various factors including:

- Extent to which the proposal involves multiple schools internally at USC and externally with other universities;
- Degree to which the proposed research crosses multiple scientific domains;
- Probability of proposal success;
- Current and projected workload of office staff;
- Feasibility of completing requested tasks in advance of proposal deadline.

If approved, the DC Office of Research Advancement can provide some or all of the services listed above as requested by the PI.

Post-Submission Assistance

Federal research sponsors may occasionally request additional information and/or proposal adjustments prior to making a funding decision. The DC Office of Research Advancement is available to assist with post-submission/pre-award requests including:

- Drafting responses to sponsor questions and/or criticisms in order to potentially improve the proposal's chance of success;
- Revising budgets based on feedback;
- Assisting with the coordination of site visits.

2. Notification of Funding Opportunities

The DC Office of Research Advancement tracks current and emerging funding priorities among federal agencies. The office will continue to monitor newly released federal funding opportunities on a daily basis. Faculty will be notified of these new potential funding opportunities via customized email messages.

New funding announcements are also posted weekly via Twitter and can be accessed via twitter.com/usc_dcresearch.

3. Federal Outreach

The DC Office of Research Advancement maintains and strengthens ties between USC investigators and federal research sponsors. In addition, the staff also promotes USC research breakthroughs and findings to relevant agencies. Federal program officers have a large amount of discretion in making funding decisions; thus, it is useful to establish a relationship with them before considering applying for federally funded grants.

For faculty interested in connecting with a federal agency, DC Office of Research Advancement staff will provide guidance as requested. Dr. James Murday (murday@usc.edu), Associate Director for Physical Sciences in the DC Office of Research Advancement, is the point of contact for these requests concerning all agencies except NIH. Dr. Steven Moldin (moldin@usc.edu), Executive Director of the DC Office of Research Advancement, is the point of contact for NIH.

4. Strategy Sessions

Upon request, the DC Office of Research Advancement will meet with individual faculty or collaborative research groups to discuss proposal development strategies. Topics include how to assemble a large multidisciplinary team, agency interests, and potential agency matches.

In addition, the Office will conduct a comprehensive search for relevant funding opportunities.

5. Submission Procedures

The USC Department of Contracts and Grants (DCG) reviews and submits proposals, negotiates and accepts contract and grant agreements, and ensures compliance with sponsor and university policies. DCG is the only USC office authorized to submit proposals on behalf of faculty. As requested, the DC Office of Research Advancement will work closely with DCG throughout the pre-award process.

In order to ensure an on-time submission, the DC Office of Research Advancement will finalize and transfer all proposal files to DCG **no later than two business days prior to the sponsor's deadline**. If a proposal is not completed two business days prior to the sponsor's deadline and provided to the Office, it is the responsibility of the PI and school/departmental staff to coordinate submission with DCG.

6. Additional Resources and Questions

USC Center of Excellence in Research – DC Office of Research Advancement staff frequently participate in the USC Center of Excellence in Research. This university-wide resource offers proposal guidance and advice on obtaining federal research funding. Additional information, including the most recent schedule of workshops, can be accessed via this URL: <https://research.usc.edu/about/vp/cer/>

For any questions regarding the DC Office of Research Advancement Service Commitment, please contact the Office's Executive Director, Dr. Steven Moldin (moldin@usc.edu).

OPRS/IRB SERVICE COMMITMENT FOR REVIEW OF HUMAN SUBJECTS RESEARCH

The Office for the Protection of Research Subjects (OPRS) and the USC IRBs are committed to supporting USC Investigators by assuring timely review of all human subjects research proposals submitted to the IRBs. It is our goal to assist researchers with their submissions by offering study-specific guidance by OPRS and IRB staff as well as by providing an abundance of educational materials. To succeed in this goal, OPRS commits to the following standards for Proposal Submission, Review, and Approval of exempt, expedited and full board review studies.

1. Human Subject Proposal Review

Full Board Studies:

- ***Number of days until approval unless contingencies: 60 days***

Proposals submitted for review are screened by IRB staff for completeness; if necessary, staff will request revisions/clarifications from the investigator. The staff review is available on iStar, the online IRB submission system. IRB staff schedules the study for the next available IRB meeting. The IRB Chair or IRB Director selects primary and secondary (and tertiary when applicable) reviewers. The reviewers' comments, questions, and contingencies are posted in the iStar system and discussed during the Full Board meeting. Study materials and reviewer comments are available to all committee members. Outcome of the meeting will be communicated to the researcher. Changes, if required, must be satisfied before final approval is granted.

Expedited Studies

- ***Number of days until approval unless contingencies: 30 days***

IRB staff initially evaluates all submissions and may request changes/ clarifications from the investigator. IRB staff then prepares a staff review that is forwarded to an expedited reviewer for review and approval. In the staff review, the reasons why the submission meets expedited review criteria are noted by citing the appropriate expedited review category. The expedited reviewer is prompted to either concur or disagree with the staff recommendation for expedited processing and any related contingencies or necessary revisions. Outcome of the review will be communicated to the researcher. Changes, if required, must be satisfied before final approval is granted.

Exempt Studies

- ***Number of days until approval unless contingencies: 10 days***

Reviewers of exempt determinations conduct a review of the project to determine if it qualifies for exempt status. The study is reviewed according to IRB policy, human subjects research regulations, and ethical standards. Additional revisions may be requested by the reviewer. Once approved, the PI is notified and, unless changes are made to the study, no further IRB review is required.

Submissions after Initial Project Approval

In addition to initial review of a study, amendments, continuing review and reportable events are handled in the most expeditious manner commensurate with risk level.

2. Additional Customer Enhancements

Not Human Subjects Research (NHSR) Submission

- ***Number of days until approval unless contingencies: 10 days***

A Not Human Subjects Research (NHSR) submission is USC-created information request to determine if a project is subject to IRB review and approval. Its purpose is to streamline the system to exclude projects that do not meet the regulatory definitions of human subjects research (not applicable for projects involving FDA-regulated products). If the IRB determines that a project is NHSR, the investigator receives documentation that the project does not meet the definition of human subjects research. However, if the IRB determines that the project is human subjects research, a new study application will be requested by the IRB.

Flex Studies

- ***Number of days until approval unless contingencies: 10 days***

Research that involves no greater than minimal risk and is not federally-funded may qualify for review under a novel USC Flexibility Policy. The Policy was created to provide administrative flexibility in the review of eligible studies without compromising subject protections. Flex studies include projects that do not fit specifically within one of the federally-defined categories of exempt research and involve no greater than minimal risk to subjects. Additionally, the Policy also provides three-year approvals for nonexempt, no greater than minimal risk projects.

Ceded Review

USC has established agreements to simplify the IRB review process for projects taking place between USC and partner sites. Under the Memoranda of Understanding (MOU), one Institution will cede the IRB review process and the other Institution will provide the IRB review. USC's agreements with CHLA, Hebrew Union College, Rancho, RAND Corporation, and Cedars may be found at oprs.usc.edu/initiatives/agreements.

3. Creative Education for Research Community

Education Sessions

OPRS staff offer regular classroom education as guest lectures to discuss human subjects protections. Researchers can contact OPRS to schedule ad hoc educational sessions for their research team and/or department. Additionally, town hall meetings will be scheduled several times a year to discuss changes affecting the research community such as important changes in Policies, significant modifications to the IRB electronic submission system and accreditation preparation and updates.

Research Coordinator Education

OPRS hosts education sessions for research coordinators at quarterly intervals to discuss and address coordinator needs, share best practices, and provide coordinators a networking opportunity.

IRB Student Mentor

A graduate assistant serves as a UPIRB liaison to meet with student researchers and provide one-on-one assistance with IRB submissions. The mentor also represents USC student interests by participating in IRB deliberations as a full-voting IRB member.

Not-for-cause Assessments

OPRS and IRB personnel conduct assessments of research studies, IRB documentation and the iStar system to identify trends and issues related to researcher and IRB operations. Deficiencies identified in these assessments often drive changes and/or creation of new policy, process and educational materials.

Booklets

OPRS creates many booklets available in hard copy and online to educate researchers and students on various human subjects research topics. Booklets are updated routinely to ensure researchers have up-to-date best practices and guidance. To access OPRS booklets, go to <http://oprs.usc.edu/education/booklets/>.

iStar Videos

OPRS and IRB personnel created video tutorials for iStar, the online IRB application system. The videos were created to assist researchers with the intricacies of an expedited or full board review study submission. To access the videos, go to <http://vimeo.com/scctsiecde/istar-training-videos>.

Model IRB Applications

IRB applications selected for accuracy and completeness of actual USC studies are available to assist investigators with their submissions. Model applications include those of exempt, expedited and full board review studies as well as those involving coded data/specimens and Not Human Subjects Research (NHSR) projects. To access the model applications, go to <https://oprs.usc.edu/review/modelirb/>.

4. Communication and Outreach Activities

The latest information on human subjects research, including guidance, consent templates, policies, educational resources, and contact information can be found at oprs.usc.edu. OPRS also distributes a periodic newsletter to keep the USC research community informed of updates in regulations, policies, best practices, and relevant research news, as well as a bulletin for research coordinators and other research support staff.

August 25, 2018

The IRBs at University Park and the Health Sciences Campus have designated office hours to encourage researchers to general and study-specific human subjects research issues. For more information, contact your local IRB.

OPRS and the IRBs encourage researchers to provide feedback on how to improve the IRB review process anonymously by completing the annual IRB survey. OPRS utilizes these data to create educational opportunities, policy changes and iStar system process changes. Researchers are provided results of the survey via the OPRS listserv and can access these on the OPRS/IRB website.

RESEARCH TECHNOLOGY GROUP SERVICE COMMITMENT

The Research Technology Group is committed to serving USC faculty, students, and staff by continually enhancing and improving the iStar and diSClose systems and ensuring effective and timely support for technical issues users might experience in using iStar.

1. **Support for USC faculty, students, and staff in their use of the iStar system**

This commitment is characterized by:

- **Issue Resolution**

We commit to respond to user queries within one business day. This usually results in the issue being resolved within that time frame. There are times, however, that the issue raised does not admit to a quick fix and must follow good development practices. In such cases, the user will be informed of this and be updated (as applicable) of the status of the request.

- **User Training and Education**

Users (both individuals and groups) who wish to have training to use the iStar or diSClose systems may contact the [help desk](#) and request training. Training sessions are scheduled with the person(s) requesting them. Additionally, the Research Technology Group staff will conduct information sessions for users (usually once or twice a year) to inform faculty, students, and staff of recent or planned changes. General reference guides for iStar are available, as well as specific guides for IACUC and IBC.

- **System Availability and Performance**

We commit to ensuring that the system is available and functional at all times. There are specific times when the system will have maintenance outages, but all foreseen outages will be identified and notification to system users will be made.

- **Reasonable Disaster Recovery Policies**

We understand that researchers spend a good amount of time completing forms and are committed to maintaining the data they have entered. To that end, we have automated procedures in place to back up data, at off site locations, every 30 minutes.

2. **Continuing development/improvement of the iStar and diSClose systems**

We recognize that policies, procedures, and regulations change. We support this by convening development/change control committees for each of the groups (IRB, IACUC, IBC, RSC, and COI). Committees meet monthly. We are committed to having a minimum of three upgrade cycles per year for changes to the systems. We also are committed to transparent changes. Each change goes to the committee twice to ensure that (a) the problem area/issue is agreed upon by the committee and (b) the implementation of the change solves the problem/issue identified by the committee. We

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commit to following good software development practices to ensure that the changes work properly and resolve the problems identified. We also are committed to maintaining the system and framework with updates and upgrades to improve the systems generally.

USC STEVENS CENTER FOR INNOVATION SERVICE COMMITMENT

USC Stevens Center for Innovation is committed to advancing the creative thinking and breakthrough research at USC for societal impact beyond traditional academic means. We focus on the licensing of technologies, expanding industry collaborations, and supporting start-ups.

To achieve this goal, USC Stevens offers a service commitment for commercialization activities, including timely communication with the inventors of the technology, and clearly articulated processes and procedures.

1. Communication with Inventors

USC Stevens is committed to communicating our procedures and processes to the research USC research community in a clear and concise manner. Information about our processes can be found here: stevens.usc.edu/researchers/commercialization-process/. In addition, the USC team is committed to in person meetings with faculty and their research teams to discuss the processes and answer questions.

2. Review of Invention Disclosures

- ***Review within 30 days of receipt***

USC Stevens is committed to reviewing all complete disclosures within 30 days of receipt. In order to facilitate the disclosure process, USC Stevens launched an online disclosure portal earlier this year. A link to this portal for disclosing new inventions can be found on the USC Stevens Website: <http://stevens.usc.edu/>.

The disclosure review process shall include a conversation between the assigned Licensing Officer from USC Stevens and the Inventors of the technology. During that conversation, the Licensing Officer will gather additional information to help us evaluate the market opportunity, as well as potential partners. Based on the information that is gathered during this conversation, as well as our own research regarding potential commercial value and prior art, USC Stevens will decide whether to file an initial patent application covering the technology. This decision will be communicated to the inventors within one business day. For decisions regarding the ongoing prosecution of patents, USC Stevens will commit to informing the inventors of go/no go decisions at least 60 days in advance of any deadlines, provided that USC Stevens has received notice at least 90 days in advance of such deadline.

3. Negotiation of License and other Agreements

USC Stevens will conduct all negotiations in a professional and expeditious manner. We are committed to the education of USC Stevens' staff and to completing our negotiations using best practices established by professional societies such as the Association of University Technology Managers (AUTM). The time to complete negotiations varies depending on agreement and partner. USC Stevens will provide information on the status of negotiations in [Sophia](#), and notify inventors on important milestones.

4. Material Transfer Agreements

- ***Draft agreement to other party within three day of receipt of all required information***

USC Stevens is committed to completing Material Transfer Agreements in a timely manner, utilizing our online portal: <http://stevens.usc.edu/researchers/mta-cda/>. Once USC Stevens has all of the required information from the requestor, we are committed to preparing a draft agreement and sending it to the other party within three business days.

5. Sponsored Research Agreements

Industry Engagement

USC Stevens is committed to increasing industry engagement with USC faculty through:

- Development of an understanding of the research capabilities of USC faculty in order to build mutually beneficial relationships with industry;
- Communication of industry needs and strategic areas of interest to USC faculty and to work with faculty to develop an action plan for industry engagement;
- Coordination of in-person meetings and crafting partnering strategies that reflect shared interests to facilitate corporate research funding agreements;
- Interface with the Department of Contracts and Grants, the General Counsel's Office and USC Steven's legal team to expedite funded research agreements.

For more information, contact Lawrence Lau (lau@usc.edu).

Intellectual Property Terms Review

- ***Review and redline IP terms within five business days***

USC Stevens reviews unusual intellectual property terms in sponsored projects agreements and service agreements originating from the Department of Contracts and Grants, the Clinical Trials Office and the General Counsel's Office. IP review is ordinarily completed in parallel with other contract review steps. USC Stevens is committed to review and redline the IP terms in agreements within five business days of receipt, provided that USC Stevens has received any required input from third parties.

6. Education of Faculty and Researchers

- USC Stevens is committed to providing seminars relating to technology commercialization for USC faculty and students. USC Stevens will hold seminars on topics such as working with USC Stevens, the patent prosecution process, and venture capital;
- USC Stevens is also committed to holding meetings with its faculty and researchers. Upon request, we will set up a meeting with a faculty member, a lab or other group to give a presentation regarding our procedures and to answer questions;

- USC Stevens provides a service called “Legal Office Hours” for the USC research community, which provides complimentary legal assistance, counseling and information materials to all USC innovators (faculty, staff, students and alumni) and start-up companies. Our services are on-campus and are provided by qualified corporate and intellectual property attorneys. More information on Legal Office Hours can be found here: <http://stevens.usc.edu/about-us/programs/legal-office-hours/>.

Legal assistance currently available includes, but is not limited to:

- Patent searches and provisional/non-provisional patent applications;
- Patent processing;
- Patent protection;
- IP ownership;
- Trademark and Copyright applications;
- Drafting articles of incorporation;
- Drafting bylaws for Corporations (for profit and non-profit);
- Contract drafting and contract review;
- Creating Limited Liability Companies and Corporations;
- Reviewing business plans.

Additional information regarding our services and procedures can be found on the USC Stevens Website: stevens.usc.edu/.

For any questions regarding the USC Stevens Service Commitment, or to provide feedback regarding our service, please contact Jennifer Dyer, Executive Director, USC Stevens Center for Innovation (jennifer.dyer@stevens.usc.edu).