<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td>6</td>
</tr>
<tr>
<td><strong>ONBOARDING</strong></td>
<td>7</td>
</tr>
<tr>
<td><strong>NEW HIRE ORIENTATION</strong></td>
<td>8</td>
</tr>
<tr>
<td>Organizational Orientation Overview</td>
<td>8</td>
</tr>
<tr>
<td>Safety Orientation Overview</td>
<td>8</td>
</tr>
<tr>
<td>Department Orientation Overview</td>
<td>8</td>
</tr>
<tr>
<td><strong>EMPLOYEE HEALTH SERVICES INITIAL ASSESSMENT</strong></td>
<td>9</td>
</tr>
<tr>
<td><strong>BUSINESS MANAGER/DIRECTOR</strong></td>
<td>9</td>
</tr>
<tr>
<td><strong>IMMIGRATION SERVICES</strong></td>
<td>9</td>
</tr>
<tr>
<td>What Our Purpose Is</td>
<td>9</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>9</td>
</tr>
<tr>
<td>What We Do</td>
<td>10</td>
</tr>
<tr>
<td>Definitions</td>
<td>15</td>
</tr>
<tr>
<td>Points to Remember</td>
<td>15</td>
</tr>
<tr>
<td><strong>LABORATORY SPACE ALLOTMENT</strong></td>
<td>16</td>
</tr>
<tr>
<td><strong>TRANSFERRING A LABORATORY</strong></td>
<td>16</td>
</tr>
<tr>
<td>Hiring Staff from another Institution</td>
<td>16</td>
</tr>
<tr>
<td>Transferring/Shipping Animals to City of Hope</td>
<td>17</td>
</tr>
<tr>
<td>Transferring/Shipping Animals from City of Hope</td>
<td>17</td>
</tr>
<tr>
<td>Transfer/Shipement of Equipment</td>
<td>18</td>
</tr>
<tr>
<td>Transfer/Shipement of Hazardous Materials</td>
<td>18</td>
</tr>
<tr>
<td>Transfer/Shipement of Research Materials</td>
<td>18</td>
</tr>
<tr>
<td>Transfer of a Grant</td>
<td>18</td>
</tr>
<tr>
<td><strong>SETTING UP A LABORATORY</strong></td>
<td>19</td>
</tr>
<tr>
<td><strong>OCCUPATIONAL SAFETY AND HEALTH DEPARTMENT</strong></td>
<td>20</td>
</tr>
<tr>
<td>What Our Purpose Is</td>
<td>20</td>
</tr>
<tr>
<td>How We’e Organized</td>
<td>20</td>
</tr>
<tr>
<td>What We Do</td>
<td>20</td>
</tr>
<tr>
<td>Section</td>
<td>Page</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>RESEARCH FACILITIES AND EMERGENCY PLANNING</td>
<td>23</td>
</tr>
<tr>
<td>BIOMEDICAL INSTRUMENTATION SERVICES</td>
<td>24</td>
</tr>
<tr>
<td>INFORMATION TECHNOLOGY</td>
<td>25</td>
</tr>
<tr>
<td>SHARED RESOURCES, CORES AND SUPPORT SERVICES</td>
<td>31</td>
</tr>
<tr>
<td>CORE FACILITIES</td>
<td>32</td>
</tr>
<tr>
<td>LIBRARY SERVICES</td>
<td>36</td>
</tr>
<tr>
<td>CREATIVE SERVICES</td>
<td>38</td>
</tr>
<tr>
<td>GRANTS MANAGEMENT</td>
<td>39</td>
</tr>
<tr>
<td>OFFICE OF SPONSORED RESEARCH</td>
<td>40</td>
</tr>
<tr>
<td>OFFICE OF FOUNDATION RELATIONS</td>
<td>51</td>
</tr>
<tr>
<td>OFFICE OF FACULTY AND INSTITUTIONAL SUPPORT</td>
<td>54</td>
</tr>
</tbody>
</table>
## OFFICE OF TECHNOLOGY LICENSING

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Our Purpose Is</td>
<td>55</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>55</td>
</tr>
<tr>
<td>What We Do</td>
<td>55</td>
</tr>
<tr>
<td>Points to Remember</td>
<td>61</td>
</tr>
</tbody>
</table>

## RESEARCH FINANCE

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Our Purpose Is</td>
<td>61</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>61</td>
</tr>
<tr>
<td>What We Do</td>
<td>61</td>
</tr>
</tbody>
</table>

## COMPLIANCE

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Our Purpose Is</td>
<td>64</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>64</td>
</tr>
<tr>
<td>What We Do</td>
<td>64</td>
</tr>
<tr>
<td>Institutional Official</td>
<td>65</td>
</tr>
<tr>
<td>Conflict Of Interest</td>
<td>65</td>
</tr>
</tbody>
</table>

## RESEARCH PROTECTIONS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Our Purpose is</td>
<td>65</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>66</td>
</tr>
<tr>
<td>What We Do</td>
<td>66</td>
</tr>
<tr>
<td>Compliance Committees Under Research Protections</td>
<td>66</td>
</tr>
<tr>
<td>Institutional Animal Care and Use Committee (IACUC)</td>
<td>66</td>
</tr>
<tr>
<td>Institutional Biosafety Committee (IBC)</td>
<td>68</td>
</tr>
<tr>
<td>Occupational Safety and Biohazard Committee (OSBC)</td>
<td>71</td>
</tr>
<tr>
<td>Stem Cell Research Oversight (SCRO) Committee</td>
<td>72</td>
</tr>
<tr>
<td>Institutional Review Board (IRB)</td>
<td>73</td>
</tr>
<tr>
<td>RADIATION SAFETY COMMITTEE (RSC)</td>
<td>79</td>
</tr>
</tbody>
</table>

## ONGOING

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Our Purpose Is</td>
<td>80</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>81</td>
</tr>
<tr>
<td>What We Do</td>
<td>81</td>
</tr>
</tbody>
</table>

## OFFICE OF ACADEMIC AFFAIRS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Our Purpose Is</td>
<td>81</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>81</td>
</tr>
<tr>
<td>What We Do</td>
<td>81</td>
</tr>
</tbody>
</table>

## FINDING ADDITIONAL LABORATORY PERSONNEL

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graduate School Students</td>
<td>82</td>
</tr>
<tr>
<td>Summer Students</td>
<td>82</td>
</tr>
<tr>
<td>Human Resources Hiring Department</td>
<td>82</td>
</tr>
</tbody>
</table>

## COMMUNICATIONS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>What Our Purpose Is</td>
<td>84</td>
</tr>
<tr>
<td>How We’re Organized</td>
<td>84</td>
</tr>
<tr>
<td>What We Do</td>
<td>84</td>
</tr>
</tbody>
</table>
INTRODUCTION

I am pleased to provide a copy of the Basic Research Handbook. This document represents the results of several months of work on the part of many members of the Research Operations team and our colleagues across the City of Hope campus. Substantial time, effort, experience, and expertise have contributed to this effort and it is my hope that the faculty and operational staff will find it helpful.

This Handbook is aimed at supporting the COH community involved in the financial or operational conduct of basic research. It is not my intent for this manual to be read from cover-to-cover like a book; the goal of this document is to create a useful guidance and reference tool for the COH research and operational community in accessing both internal and external resources.

I am hopeful that this Handbook will prove to be a “living document” that will be updated over time to incorporate comments, suggestions, and ideas for best practices from you, as well as to reflect new knowledge and thereby help assure compliance and efficiency in the basic research setting.

Ashley Baker Lee
Senior Vice President, Research Operations
Beckman Research Institute at City of Hope
ONBOARDING

Human Resources (HR) initiates the search process to identify the ideal candidate for a job posting, including a thorough interview and reference check. The Office of Academic Affairs handles Professor series recruitment. Once a candidate has been selected, HR works with the department Business Manager/Director to begin the onboarding process. This section identifies all the steps needed to complete this process.
NEW HIRE ORIENTATION

Recruiting, retaining and developing an excellent workforce is key to implementing City of Hope’s strategic plan. The institution provides a comprehensive, multi-faceted program of orientation. New personnel attend Organization Orientation and Safety Orientation on their first day of employment, if possible, or the next scheduled orientation session available. Newly hired personnel are required to complete all components of City of Hope Orientation before independently performing their job duties.

Organizational Orientation Overview

Organizational Orientation assists new personnel in understanding City of Hope’s:

- Organizational history
- Culture
- Mission/vision/values
- Policies and Procedures
- Performance Development and Review Process (PDRP)
- Corporate Compliance Program
- Other work environment information

Safety Orientation Overview

Safety Orientation is comprised of four hours of safety-related presentations (PowerPoint and videos) that include:

- General laboratory safety concepts
- Hazard communication (identification of laboratory hazards)
- Fire extinguisher training
- Laboratory waste disposal procedures
- Ergonomic awareness
- Bloodborne pathogens
- General principals of biosafety
- Emergency Preparedness

Department Orientation Overview

The department orientation program assists new personnel in understanding departmental policies and procedures as well as key job responsibilities.
EMPLOYEE HEALTH SERVICES INITIAL ASSESSMENT

The Employee Health Services (EHS) Initial Assessment is required of all personnel after accepting a position at City of Hope. It consists of a brief physical exam, which includes evaluation of the personnel’s immunization status and, if working in the Medical Center or in the Animal Resource Center (ARC), a tuberculosis (TB) skin test. These evaluations are required to meet standards set by regulatory agencies. The personnel’s medical status is reviewed to identify any health issues that might occur with the new job position. Clearance by EHS is required to begin work.

BUSINESS MANAGER/DIRECTOR

The Business Manager/Director is responsible for the overall management and performance of a business unit. Management responsibilities include developing and implementing strategic plans, operating facilities and planning space, as well as overseeing and directing business unit staff to ensure successful operations. This includes working with other units to ensure organizational goals are met. Financial responsibilities include implementing and maintaining the annual budgets, research funding, capital expenditure, approve spending, and ensure profitability for the unit.

Some of the things the Business Manager/Director can do for investigators:

- Consult with Human Resources-Immigration Services (HR-IS) about the right type of immigration sponsorship
- Consult with the Office of Sponsored Research (OSR) about various funding and spending requests
- Manage and oversee research spending in consultation with Research Finance (RF) and Grant Accounting
- Work with Human Resources (HR) when additional personnel are needed for a research project

IMMIGRATION SERVICES

What Our Purpose Is

To ensure personnel are lawfully employed, City of Hope offers visa assistance and sponsors to eligible foreign nationals through Human Resources-Immigration Services (HR-IS).

How We’re Organized

Immigration Services is part of the Talent Acquisition department, which is part of Human Resources.

- Call: Extension 37575 or 83872
- Website: http://www.cityofhope.org/visa-services
What We Do

The following answers to frequently asked questions provides an overview of the assistance available through Immigration Services.

Does City of Hope sponsor foreign nationals/internationals to work/train/study at the institution?

- Yes. Each foreign national/international will be in a unique situation. The recruiter and the Business Manager/Director will consult with Human Resources-Immigration Services (HR-IS) for the right type of immigration sponsorship.

What are the most common types of visas at City of Hope?

- F-1 (Student) – For international students joining or enrolled at the Irell and Manella Graduate School of Biological Sciences.
- F-1 OPT with EAD (Student/Optional Practical Training with Employment Authorization Document) – For students who recently graduated from a US college/university that are allowed a period of training during or after completion of their degree.
- J-1 (Research Scholar/Short-Term Scholar) – City of Hope is only approved for two types of J-1s: (a) Research Scholar and (b) Short-Term Scholar. The J-1 is reserved for internationals who are at City of Hope temporarily to perform research/observe/teach. At City of Hope, this is commonly used for postdoctoral fellows, pre-doctoral fellows and visiting faculty/investigators/scientists.
- H-1B (Specialty Occupation) – For internationals employed in a regular position at City of Hope. The international requires at least a bachelor’s degree and the position to be held at City of Hope must require at least a bachelor’s degree industry-wide (e.g., a Registered Nurse will not qualify for an H-1B even if City of Hope requires its nurses to have at least a BSN since industry-wide an AA in Nursing is acceptable). At City of Hope, this is commonly used for Staff Scientists, Biostatisticians, Research Associates, Information Technology positions, etc.
- TN (Mexico and Canada Nationals) – This is similar to an H-1B but strictly reserved for citizens of Mexico and Canada. At City of Hope, this is commonly used for Nurses and Information Technology positions.

How long does immigration sponsorship take?

Processing of immigration sponsorship is complicated and varies by type of visa, where the foreign national is coming from, where the foreign national was born, whether the foreign national is in the United States (US) or outside the US, etc. The recruiter and Business Manager/Director will consult with HR-IS regarding each candidate’s specific processing time.

Examples:
- J-1 postdoc transferring from another institution may take 1 month with the following conditions: J-1 is valid, research is in the same category, postdoc is in the United States, and HR-IS has all necessary information and documents from the department and the postdoc.
• H-1B staff scientist transferring from another institution may take 6-8 weeks with the following conditions: H-1B is valid, staff scientist is in the US, and HR-IS has all necessary information and documents from the department and the staff scientist.
• New postdoc from China may take at least 3 months with the following conditions: needs new J-1, HR-IS has all necessary information and documents from the department and postdoc, and postdoc is subject to administrative processing in the US consulate in China.

What is the process for initiating immigration sponsorship for a foreign national/international candidate or personnel?

INSZoom is the web-based, case-processing system used to process visas at City of Hope. To use, contact the department Business Manager/Director who will most likely already have a log-in name, password and training to use this system.

Are there limits to the different visa types?

Yes. See the Immigration Sponsorship Guidelines below for reference. Consider the time limits when sponsoring an international/foreign national.

Is visa approval guaranteed for an international/foreign national?

No. HR-IS cannot guarantee a successful visa application or petition approval from the United States Citizenship and Immigration Services (USCIS) or the Department of State (DOS).

Once personnel are in the US, what is required for a Sponsoring Employer to maintain an international/foreign national’s status?

It is important to notify HR-IS of any significant change to an international/foreign national’s employment, including but not limited to: job duties, job title, salary decrease, transfer to another department, change in number of work hours a week (i.e., full time to part time or part time to full time), change in work location (i.e., campus to MAC or campus to Flower), paying entity (i.e., Med Center to BRI or vice versa), termination, etc. The Department of State and USCIS may conduct site visits to check employment of visa holders, so it is crucial to keep these agencies informed of changes to the international/foreign national’s employment/training at City of Hope. Internationals/Foreign Nationals may lose their US immigration status and City of Hope can be penalized for violations.

Once City of Hope sponsors a foreign national for a visa, can he or she bring family to the US?

Yes. Spouse and children under 21 years of age may apply for a dependent visa.

Can the spouse of that foreign national work or volunteer in a lab at City of Hope?

Only if that person has a valid work authorization or work status, regardless of whether the position is paid or unpaid. Dependent of J-1, called J-2, may apply for an Employment Authorization Document (EAD). However, dependents of H-1B and TN are not eligible for EAD. If the spouse wishes to gain research experience at City of Hope, the spouse should be sponsored for a visa as a principal applicant, not a dependent.
<table>
<thead>
<tr>
<th>Non-Immigrant Visa and Time Limits</th>
<th>Definition</th>
<th>Processing Time/ When to Start</th>
<th>Cost</th>
</tr>
</thead>
</table>
| **F-1** | Time limit depends on time needed to complete PhD | International Student enrolled at Irell and Manella Graduate School of Biological Sciences | If outside the US, allow at least 3 months for processing and entry to the US  
If in the US, allow 1 to 3 months for processing (depending on previous immigration status) | No cost to graduate school  
Student pays for visa and SEVIS fees |
| **F-1/Optional Practical Training (OPT)** | Limit: 12 months (17 months more if STEM graduate and will be working for BRI - an E-verify entity. Not all STEM degree are eligible, confirm with HR-IS) | “A recent graduate of a US college/ university” authorized to work using an EAD (employment authorization document) | EAD application prepared and submitted by EE (employee)  
Can start as long as EAD is valid  
EAD extension process takes at least 3 months with USCIS | No cost to department  
EAD - $380 filing fee. Paid for by EE |
| **J-1** | Limit: 5 years | “Exchange Visitor” in Research Scholar or Short-Term Scholar categories (i.e., Post-docs, Pre-docs, Trainees, Foreign MD Trainees)  
Paid or unpaid training position | If in the US, allow at least 3 weeks for J-1 transfer process  
If outside the US, allow at least 3 months for processing and entry to the US | No cost to department (J-1 forms done in-house)  
If outside the US, EE pays visa and SEVIS fee |
| **H-1B** | Limit: 6 years | “Specialty Occupation” –  
Position requires minimum bachelor’s degree and FN has at least a bachelor’s.  
Paid regular employment position | If in the US and presently holds H-1B, 6-8 weeks processing for EE to start  
If outside the US or a change of status (i.e. J-1 to H-1B, OPT to H-1B), allow 7-9 months processing for EE to enter the US or 4-5 months via premium processing | Approximately $2,425 via regular processing  
Approximately $2,425 + $1,225 = $3,650 via premium processing  
Use of outside immigration attorney and filing with USCIS |
| **TN** | Limit: indefinite with proof of non-immigrant intent | “Citizens of Mexico and Canada”  
Position on NAFTA list  
Paid position | Allow 2-3 weeks processing  
EE should travel to a US border or a US airport. Otherwise filing with USCIS will take 7-9 months. | No cost to department (TN packet done in-house)  
EE pays for TN border or visa fees |
What should be done when an international/foreign national personnel and/or colleague requests a reference letter for a self-petition green card petition?

Foreign nationals apply for US Permanent Resident status because their non-immigrant H-1B, O-1 or J-1 status is temporary with specific time limits and restrictions. One restriction is not being eligible to apply for Federally-funded research opportunities. In addition, some positions are not eligible for company-sponsored US Permanent Resident applications, such as a Postdoctoral Fellow. Refer to the table on the following page to determine if the personnel requesting the letter qualifies for a Self-Petition Green Card.

Reference letters may be requested for self-petition US Permanent Resident/green card applications on behalf of foreign national employees or colleagues from other US institutions.

What are guidelines for writing reference letters for self-petition green card petition?

1. A standard reference letter consists of three parts:
   a. paragraph on your qualifications;
   b. section describing the foreign national's credentials, and;
   c. description of contributions the foreign national has made to the field. The purpose of this description is to provide proof that this person is a top researcher/scientist in his/her field and therefore qualifies for a self-petition National Interest Waiver or Exceptional Ability.

2. Carefully review the letter for accuracy of the information.

3. Provide factual information only. Do not exaggerate or embellish. As a representative of City of Hope and the Beckman Research Institute, it is important that you do not overstate the requestor's credentials to ensure that the US Citizenship and Immigration Services ("USCIS") continues to view our organization as a credible employer with highly qualified foreign national researchers and scientists.

4. Do not feel obliged to sign a reference letter prepared by the foreign national and/or his/her immigration attorney. You can make edits as you feel needed.
<table>
<thead>
<tr>
<th>Type of Self-Petition Green Card Petitions</th>
<th>Criteria</th>
<th>Qualified Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employment Based 2&lt;sup&gt;nd&lt;/sup&gt; Preference National Interest Waiver (EB-2 NIW)</td>
<td>Meet at least 3 of the following: Official academic record showing that you have a degree, diploma, certificate, or similar award from a college, university, school, or other institution of learning relating to your area of exceptional ability Letters documenting at least 10 years of full-time experience in your occupation A license to practice your profession or certification for your profession or occupation Evidence that you have commanded a salary or other remuneration for services that demonstrates your exceptional ability Membership in a professional association(s) Recognition for your achievements and significant contributions to your industry or field by your peers, government entities, professional or business organizations Other comparable evidence of eligibility is also acceptable.</td>
<td>Postdoctoral Fellow Research Associate Staff Scientist Professor series Research Professor series</td>
</tr>
<tr>
<td>Employment Based 1&lt;sup&gt;st&lt;/sup&gt; Preference Extraordinary Ability (EB-1 EA)</td>
<td>Meet at least 3 of the following: Evidence of receipt of lesser nationally or internationally recognized prizes or awards for excellence Evidence of your membership in associations in the field which demand outstanding achievement of their members Evidence of published material about you in professional or major trade publications or other major media Evidence that you have been asked to judge the work of others, either individually or on a panel Evidence of your original scientific, scholarly contributions of major significance to the field Evidence of your authorship of scholarly articles in professional or major trade publications or other major media Evidence of your performance of a leading or critical role in distinguished organizations Evidence that you command a high salary or other significantly high remuneration in relation to others in the field</td>
<td>Staff Scientist Professor series Research Professor series</td>
</tr>
</tbody>
</table>
Definitions

- STEM – Science, Technology, Engineering and Mathematics
- HR-IS – City of Hope’s Human Resources – Immigration Services
- USCIS – United States Citizenship and Immigration Services
- SEVIS – Student and Exchange Visitor Information System
- Premium Processing – Expedited processing at USCIS for H-1Bs for an additional fee
- NAFTA – North American Free Trade Agreement

Points to Remember

- Each international/foreign national will have a unique situation. The above table is only a guide. Always consult HR-IS for the best immigration sponsorship strategy
- Always consult HR-IS for updated fee schedule; fees are subject to change
- Due to time limits of each non-immigrant visa type, always consult HR-IS for next steps
- Due to time limits of each non-immigrant visa type, also consider the possibility of COH-sponsored US permanent resident/green card application for every international/foreign national hired

Please note: City of Hope is committed to hiring US citizens whenever possible.
LABORATORY SPACE ALLOTMENT

Space commitments are only made with investigators in the Professor Series or equivalent. Square footage of space is determined based on the level of the Professor. The allotments are subject to the terms of the faculty offer letter and are adjusted based on varying factors such as the type of work being done in the laboratory and the layout of the building:

- Full Professor is allotted approximately 1500-2000 sq ft.
- Associate Professor is allotted approximately 1000-1500 sq ft.
- Assistant Professor is allotted approximately 500-1000 sq ft.

The space allotment may also be adjusted commensurate with grant funding. Shared space is part of total space allotment. Shared space is determined per building and then divided among the number of investigators housed in that building. Office space (also known as “dry-lab”) for staff non-principal investigators (staff scientists, assistance research scientists, associate research scientists, research scientists) is provided when available and is counted in the total lab space allocation. Some buildings also have cubicle space for postdoctoral fellows. Sitting space for students/trainees and research associates is within the principal investigator’s lab space. A principal investigator’s office and administrative support are not part of the total lab space.

The location of the laboratory is determined by the recruitment entities. Request for additional space should be directed to the Chairperson of the department. If needed, the Beckman Research Institute Director and/or the Beckman Council can make a final determination based on particular criteria.

Ultimate authority for laboratory research space resides with the Beckman Research Institute (BRI) Director.

TRANSFERRING A LABORATORY

Hiring Staff from another Institution

When a research project is transferred from another institution, contact the department Business Manager/Director to discuss the possibility of City of Hope hiring staff currently working on the project.
Transferring/Shipping Animals to City of Hope

Transferring or shipping ongoing animal studies to City of Hope requires close communication and coordination between investigators and City of Hope Beckman Research Institute (BRI). Animal based studies may only be performed under an animal use protocol approved by the City of Hope Institutional Animal Care and Use Committee (IACUC).

Investigators must also contact the Division of Comparative Medicine (DCM) prior to shipping animals to City of Hope. The DCM’s Animal Resources Center (DCM/ARC) will provide assistance with shipping and receiving, quarantine, animal health assessment and animal holding space. The animal transfer process begins when the transferring investigator contacts the DCM/ARC shipping coordinator. An Animal Shipping Record form (available on the DCM secure Intranet site forms section; see E-mail User Groups regarding access) will be provided to the transferring investigator requesting animal health history, strain information, veterinary contacts at the sending institution, breeding information and billing account numbers. This information will be reviewed by the DCM veterinary staff prior to a decision to approve a transfer.

Investigators transferring breeding colonies to City of Hope are strongly advised to utilize the DCM’s core breeding service. The DCM breeding team works with investigators to determine breeding strategies that meet production goals and performs all animal manipulation including mating, weaning, tissue biopsy, animal identification and recordkeeping.

All animals arriving from non-commercial (institutional) sources are placed in a quarantine holding room. While in quarantine, they will receive preventive treatment for pin worms and fur mites. They will also be assigned a dedicated sentinel animal that will be in direct contact with dirty bedding from the animals being transferred. Sentinel animals will be euthanized and subjected to diagnostic testing 6-8 weeks after exposure. While in quarantine, the animals are unavailable for experimental purposes. If the quarantined animals are an ongoing breeding colony and must be mated because of aging or genetic issues, breeding maybe arranged while in quarantine. Upon receipt of the sentinel diagnostic report, animals will be released for use and the appropriate animal holding room assignment will be made.

Transferring/Shipping Animals from City of Hope

Any shipment of City of Hope owned animals to another institution must be described and approved in the City of Hope IACUC-approved protocol and approved by the receiving institution’s IACUC. Receiving institutions must have a current Office of Laboratory Animal Welfare (OLAW) Letter of Assurance on file and current accreditation by AAALAC International is strongly preferred.
Animal shipping arrangements must be made through the DCM/ARC shipping coordinator. An Animal Shipping Record form (available on the DCM secure Intranet site forms section) must be completed and returned to the DCM/ARC shipping coordinator prior to shipping any animals. The DCM/ARC shipping coordinator will provide any health history information required by the receiving institution, coordinate shipping and arrange delivery by laboratory animal transport specialists.

Animals may be transported locally for procedures such as imaging in private vehicles if described in an IACUC approved protocol. Animals must be transported in covered, secure transport containers, provided with feed and hydration adequate for the duration of the trip and procedure, and maintained in a climate controlled environment that meets the appropriate optimal temperature range described in the National Research Council (NRC) Guide for the Care and Use of Laboratory Animals.

**Transfer/Shipement of Equipment**

Equipment to be transferred and shipped needs to be tagged for the City of Hope asset registry. The investigator, Business Manager/Director and Research Finance will coordinate this transfer.

**Transfer/Shipement of Hazardous Materials**

An infectious substance is regulated as a hazardous material under the United States Department of Transportation’s (DOT's) Hazardous Materials Regulations. The HMR apply to any material DOT determines is capable of posing an unreasonable risk to health, safety and property when transported in commerce. An infectious substance must conform to all applicable HMR requirements when offered for transportation or transported by air, highway, rail or water.

Anyone wishing to provide materials covered under this rule to investigators outside of City of Hope must notify the Occupational Safety and Health Department (OSHD) for guidance and assistance in shipping this material away from City of Hope. Shippers must be properly trained by OSHD before shipping any hazardous material.

**Transfer/Shipement of Research Materials**

Research materials that are not available for purchase from suppliers are typically exchanged between scientists using Material Transfer Agreements (MTAs). The Office of Technology Licensing (OTL) has implemented procedural improvements to expedite MTAs.

**Transfer of a Grant**

The Office of Sponsored Research (OSR) will assist in the transfer of grants from the previous institution.
It is a strategic goal at City of Hope to build processes that are safe, efficient and effective in bringing about cures for cancer and other diseases. One such effort is assisting new investigators in getting their laboratories up and running quickly so they may begin their research with minimal delays. This section describes the processes new investigators should follow as they setup their laboratory at City of Hope.
OCCUPATIONAL SAFETY AND HEALTH DEPARTMENT

What Our Purpose Is

The Occupational Safety and Health Department is charged with developing and implementing policies, procedures and specific programs to eliminate causative risk factors from the workplace. This includes being a resource assisting directors, managers and supervisors to:

- Promote a safer / healthier work environment
- Identify and evaluate actual and potential risks
- Train and educate staff in safety and health
- Review and interpret accident Investigation Reports
- Identify areas of economic loss to the corporations
- Review safety policies and procedures to ensure they are current and responsive to the needs of our clients
- Measure the effectiveness of the program and determine cost reduction strategies.

OSHD provides expertise in areas of biological safety, chemical safety, radiation safety, ergonomics, hazardous waste disposal and emergency preparedness, as well as safety training.

How We’re Organized

- Call: Extension 63375
- Email: #safetysupport@coh.org
- Website: http://www.coh.org/safety/Pages/default.aspx
- Location: Buena Vista Facilities Logistics and Support Hub (FLASH) Building

What We Do

As stewards of City of Hope’s Safety Culture, the Occupational Safety and Health Department ensures a safe and healthy environment for our staff, patients and visitors by providing excellent programs and services, delivered with integrity and compassion. The Department’s vision is that all staff at City of Hope be aware of the potential hazards they may encounter, possess the skills to safely handle hazardous materials and equipment, respond promptly and properly in the event of an accident or emergency and make safety part of their daily work. The Department’s goal is to ensure all City of Hope safety programs are in the 90th percentile when compared to other medical centers.
Laboratories present unique hazards and must be handled properly and carefully to prevent catastrophic events that cause serious injury or property damage. The Occupational Safety and Health Department offers numerous programs for staff performing basic laboratory research including:

- Introductory Laboratory Safety Training
- Refresher training
- Specific Hazard Training
- Standard Operating Procedures
- Job Hazard Analysis
- Ergonomic Assessments
- Accident Investigations
- Maintenance of Safety Data Sheets
- Maintenance of Chemical Inventories
- Laboratory Inspections
- Review of laboratory protocols and procedures

**Evaluation of Skills and Experience Specific to a Research Project**

The Occupational Safety and Health Department supports research efforts through its involvement in several research oversight and compliance committees such as:

- Radiation Safety Committee (RSC)
- Institutional Biosafety Committee (IBC)
- Occupational Safety and Biohazards Committee (OSBC)
- Institutional Animal Care and use Committee (IACUC)

OSHD staff serves on these committees and are directly responsible for the administration of the Radiation Safety Committee. To speed up the review of research protocols OSHD staff pre-review protocols to make sure the applications are complete before review by the committees. This reduces the likelihood of delays in the approval process and allows the committees to focus on important safety and regulatory concerns instead of administrative issues. This process has greatly sped up the approval process and improved the quality of the research protocols. How each of these and other research compliance committees operate is described in the [Research Protections](#) section.

**Safety Training**

The City of Hope and Beckman Research Institute’s (COH/BRI) commitment to safety is stated in the **Injury and Illness Prevention Program (IIPP)**. Providing safety training and the responsibility of supervisors are major components of this program. The Beckman Research Institute has a mandatory training program, based on federal, state and local regulations, which requires training for all laboratory personnel to ensure that they are qualified to work with and handle biological agents,
hazardous chemicals, sharps, radioactive substances and other hazardous materials and equipment found in the laboratory environment. Employees and Supervisors must maintain safety training records. OSHD does not maintain individual employee safety training records, but they can be accessed through the Human Resources PeopleSoft database.

**Introduction to Laboratory Safety Class:** Seven hours of training covering all aspects of laboratory safety. The class is required for all new laboratory workers and is designed to educate them on how to integrate safety awareness into all laboratory activities. Material will be taught with significant use of case-studies, exercises, discussions and hands-on practice. Knowledge is demonstrated through a final lab practicum. Training includes, but is not limited to, bloodborne pathogen training, hazardous chemical training an introduction to radioactive materials as well as case studies in laboratory safety

**Web-based training programs** for areas not covered during new hire orientation (such as cart safety, infectious agent transport) are available. Small vignettes may be produced and placed on the OHSD website demonstrating the proper use of specific lab equipment and procedures. Additional interactive, web-based training will be developed to address all aspects of laboratory safety.

**Classroom Refresher Training - Review of Laboratory Safety:** This is an abridged version of the Introduction to Laboratory Safety Class. Annually, after receiving initial training, personnel must take:

- Lab Safety Refresher Training (as assigned)
- Radiation Safety Refresher Training (if assigned to an active Radioactive Material Use Permit)
- Bloodborne Pathogen Refresher Training (if working with human blood, body fluids or tissue in the laboratory or any pathogen that is infectious to humans via blood, body fluids or tissues)

**Participation of OSHD personnel in lab meetings:** Annually, an OSHD staff member may participate in a scheduled lab meeting to give brief refresher safety training and be available to answer specific safety-related questions.

**Ad Hoc Training** may be requested on specific issues communicated by laboratory staff.

**Radiation Safety Committee (RSC)**

The **Radiation Safety Committee (RSC)** is managed by OSHD. The RSC is responsible for review of all uses of radioactive materials at the City of Hope. The RSC’s purview, training requirements, submission process and review process are covered in the **Compliance** section of this handbook.
RESEARCH FACILITIES AND EMERGENCY PLANNING

What Our Purpose Is

Research Facilities and Emergency Planning provides support to investigators that includes space and equipment, maintenance, repair, personnel moves, safety, and campus projects. In addition our office supports the Beckman Research Institute in its emergency planning and disaster response management.

How We’re Organized

Research Facilities and Emergency Planning is run by a manager in Basic Research Operations.

- **Call:** Extension 62589
- **Page:** (626) 423-5679
- **FAX:** (626) 301-8136

What We Do

The Laboratory Compliance questionnaire covers basic laboratory activities and helps to determine the skill and experience level of personnel. Based on answers provided to the questionnaire, the investigator/research staff will be contacted if further training is required. Individual personnel will be directed to web-based modules covering both general laboratory safety concepts as well as specific modules that address chemical safety, radioactive substance use and biosafety.

As part of the support provided to investigators, Research Facilities and Emergency Planning has established “shared” equipment areas throughout the institution which house various pieces of basic research laboratory equipment such as centrifuges, plate readers and other data gathering instrumentation for all investigators to use. Posting in these areas identifies which equipment is “shared” and provides contact information.

In addition, there are two facilities similar to the research cores, the PCR Facility and the Imaging Facility, which are free of charge to the user. In the case of the PCR facility, required training sessions are scheduled on a regular basis.

An investigator needing to use equipment that is department specific should seek the advice of a lab member that has been properly trained in the use of the identified equipment. When this is not
possible, the investigator should contact his or her supervisor in order to arrange for proper training. If training cannot be arranged within the department, the user can place a request to Biomedical Instrumentation Services (BIS).

**BIOMEDICAL INSTRUMENTATION SERVICES**

**What Our Purpose Is**

Biomedical Instrumentation Services (BIS) provides equipment repair and maintenance support and plays an important role in meeting regulatory and other organizational requirements. BIS also arranges training on shared equipment.

**How We’re Organized**

Biomedical Instrumentation Services (BIS) is part of Facilities Maintenance Services.

- **Call:** Facilities HelpDesk – Extension 32245
- **Hours:** Monday - Friday 7:00 a.m. - 4:30 p.m.
- **After Hours Emergencies:** Call the PBX office (Extension 55) to have the BIS On-Call Staff paged. Be sure to leave contact information and reason for call
- **BIS Service Request:** [http://facprod.City of Hope.org/Eforms/Forms/BISRequest.aspx](http://facprod.City of Hope.org/Eforms/Forms/BISRequest.aspx)
- **Website:** [http://www.coh.org/bis/Pages/default.aspx](http://www.coh.org/bis/Pages/default.aspx)

**What We Do**

- Oversight of equipment repair and service
- Scheduled equipment inspections
- Safety inspections for new equipment and devices obtained for short-term use
- Maintaining an equipment inventory and service documentation
- Pre-purchase evaluations and recommendations
- Equipment service contract review and processing
- User support and training

When needed, an investigator may call BIS to arrange training on shared equipment or to request contact information for appropriate vendor support.
INFORMATION TECHNOLOGY

What Our Purpose Is

Information Technology Services (ITS) ensures that investigators and staff have the information technology tools and infrastructure necessary to carry out City of Hope’s mission. ITS provides the resources that enable leading-edge research and improved productivity.

How We’re Organized

Research Computer Services (RCS) is responsible for coordinating all aspects of IT services for the research community at City of Hope. Other areas covered by ITS include information security, wireless services, access to City of Hope computer systems, systems development, training, equipment support and other technical services.

- Call: ITS HelpDesk - Extension 64357
- E-mail: researchit@COH.org
- Website: http://www.coh.org/its/Pages/default.aspx

What We Do

Services provided by Research Computer Services (RCS) include requests for new research computers, replacement of research computers, advice on computer-related purchases, and software purchases, licensing and installation.

Standard Software Provided at No Cost

- Microsoft Windows Operating System
- Microsoft Office Pro (Word, Excel, PowerPoint, Outlook, Access)
- Anti-virus software
- Cisco VPN Client
- Credant encryption program
- Endnote

This software is provided on computers assigned to personnel for individual use. It is not provided free on computers that are purchased for general lab or shared use. It is not provided free on computers provided directly by vendors to run lab equipment.

File and Data Storage

ITS maintains a large system for file storage and special systems for very large data storage. A request to access these systems is submitted through AccessNET.
Additional software/Resources Available at No Cost If Needed

- HopeBoard (Learning Management System)
- ChemBioOffice
- ImagePro
- RedCap

Software available on Citrix

To gain access to Citrix an AccessNET request will need to be submitted and approved. The following software is available on Citrix and is not installed on individual computers:

- Graphpad Prism
- Transfac
- Nexus
- CLCBio Workbench
- Genomics Workbench
- Ingenuity Pathways
- Matlab
- Partek
- NextGene
- Genome Studio

Use of the above software may require chargeback.

Purchasing Other Software

To purchase software not listed above, request a quote by completing a Request for Service (RFS) online or by calling the ITS HelpDesk (extension 64357). In general, such requests should come from individuals in supervisory positions. Once the software is received, request installation using the same ITS Helpdesk system.

Additional Services

Contact Research IT for:

- Programming
- Training
- Troubleshooting
- Assistance in determining needs and required specifications for computer equipment and/or software included in grant proposals; involving Research IT early in the process is recommended
ITS maintains a High Performance Computing (HPC) system and a General-Purpose Computing on Graphics Processing Units (GPGPU) system for heavy analytical processing. For questions or access to either system, contact Research IT.

E-Mail User Groups

All investigators need to have their e-mail listed in the #BRI user group in order to gain access to secure SharePoint sites such as the Department of Comparative Medicine, the Institutional Animal Care and Use Committee (IACUC), and Stem Cell Research Oversight (SCRO) Committee, as well as, to receive announcements of lecture series, research equipment training sessions, new resources and services available, changes in research-related procedures and policies and other information of interest to investigators. In order to be added, call the ITS HelpDesk (extension 64357).

AccessNET

AccessNet is used to request and monitor personnel access to various City of Hope information systems. To use the system, go to the AccessNet page.

Depending on role, the following functions are available:

- Request username and password for available systems.
- Request password reset for available systems.
- View list of available systems.
- View list of current system access.
- Request access for another personnel.
- View list of current system access for another personnel.
- Process requests for access to systems that the personnel administers.
- Modify system information descriptions.

Virtual Private Network (VPN)

The Virtual Private Network (VPN) Online allows City of Hope personnel to connect to City of Hope’s Intranet, File Servers, and E-mail using approved web browsers. VPN allows occasional and frequent telecommuters to connect to the City of Hope network through the Internet using any internet connection in a secure encrypted format. Access to VPN is requested through AccessNET.

Information Systems

ECRT (Electronic Certification and Reporting Technology)

As recipients of federal research funding, City of Hope is required to maintain after-the-fact personnel activity certification for the purpose of properly allocating salary charges and effort to federal projects. The City of Hope extends the effort reporting requirement to all sponsored projects. ECRT (Electronic Certification and Reporting Technology) is City of Hope’s on-line effort reporting tool that is used to facilitate the process of effort reporting.
• Access ECRT from the City of Hope home page or the OSR home page, which includes the ECRT calendar, login, FAQ, policies and procedures, tutorials and reference materials.
• ECRT login: same Username and Password as the City of Hope login.
• For assistance, contact ecrtsupport@coh.org.

**EHS Assistant (Employee Health and Safety Assistant)**

The **Occupational Safety and Health Department** has an information system called the EHS Assistant. This system allows staff to perform many key tasks including managing Radiation Use Permits, managing chemical inventories, requesting hazardous waste pickups, requesting ergonomic assessments, accessing injury reports and reviewing and responding to facility inspection findings.

• Access EHS from [EHS Assistant Login](#).
• The [EHS webpage](#) includes troubleshooting tips for users.

**Enterprise Resource Planning (ERP)**

Enterprise Resource Planning (ERP) integrates information across multiple functional areas, including Finance, Grants, Human Capital Management (HCM) and Supply Chain Management (SCM). ERP facilitates the flow of data between these functions and across the City of Hope organization, providing a central repository for information shared by several ERP modules. Requisitions, expense reimbursement requests, check requests and workflow approval are all done through ERP.

• Access ERP from [ERP PeopleSoft NEW](#) with the City of Hope username and password.
• The [ERP Webpage](#) provides instructional tools for completing tasks in PeopleSoft.
• For assistance, contact #ERPHelp@coh.org.

**iLab (Core Facility Management software)**

iLAB is an online system designed to streamline the process of ordering and billing for core facility service requests. iLab is intended to increase core facility utilization and awareness, improve core financial management, and enhance core user experience. Specific features include:

• A search feature for all cores across the institution that ensures researchers can find all institution-supported resources and services available to them in one central location.
• One consistent interface for searching resources, requesting services and updating project progress.
• The ability to view core landing pages from outside the City of Hope Intranet, allowing researchers external to the institution to view available services.
• The ability for core facilities to automatically generate recharges and invoices and post charges directly to the general ledger, eliminating data re-entry and improving data accuracy.

The following core facilities are on iLab with more cores to be added in the future:

• [Analytical Cytometry](#)
• [Animal Tumor Model Program](#)
• Clinical Immunobiology Correlative Studies
• Design and Fabrication Lab
• Electron Microscopy
• Integrative Genomics
• Light Microscopy
• Mass Spectrometry
• Small Animal Imaging Core
• Survey Research
• Transgenic/Knockout Animal Program
• Veterinary Pathology Program
• X-Ray Crystallography

To request access to the iLab system:

• Access https://coh.ilabsolutions.com with the City of Hope username and password.
• Upon successful authentication, complete the registration form by selecting the appropriate PI/lab from the pull-down list and providing a phone number.
• Submit the completed registration form to notify the department Business Manager/Director of the iLab membership request.
• An email with basic instructions on using the system will be sent, however, orders cannot be placed until the iLab request has been approved and cost centers have been assigned by the Business Manager/Director.

Please note:

• Payment information must be supplied for all reservations and/or requests when working with the core facilities. Contact the Business Manager/Director for appropriate information.
• iLab works best in Firefox or Chrome browser.
• For assistance, contact support@ilabsolutions.com.
• For detailed information on standard cores, see basic manual.
• For detailed information on scheduling cores, see scheduling manual.

**iRIS™ (Integrated Research Information Systems)**

iRIS™ provides investigators with a framework to electronically submit and track information regarding research projects at City of Hope as required by the following entities:

• Institutional Review Board (IRB)
• Cancer Protocol Review and Monitoring Committee (CPRMC)
• Protocol Review and Monitoring Committee (PRMC)
- Data and Safety Monitoring Committee (DSMC)
- Office of Clinical Trial Finance (OCTF)
- Biospecimen Repository Committee (BR)
- Office of IND Development and Regulatory Affairs (OIDRA)
- Conflict of Interest and Commitment Committee (COICC)
- Institutional Animal Care and Use Committee (IACUC)
- Stem Cell Research Oversight Committee (SCRO)

Additional modules are being configured for:

- Institutional Biosafety Committee (IBC)
- Occupational and Biohazards Committee (OSBC)
- Radiation Safety Committee (RSC)

Submissions are automatically routed electronically, either sequentially or simultaneously, to the appropriate committee(s). This approach eliminates the need for duplicate data collection and provides real-time tracking of how a project is progressing through regulatory and other review at City of Hope. iRISTM allows research staff to initiate, review, edit and version submission applications and associated documents. Electronic signature, role-based security access and transaction auditing facilitates 21 CFR Part 11 compliance.

- Use AccessNET to request access.
- Access https://iris.coh.org with the City of Hope username and password.
- For training or other assistance, contact extension 3-IRIS(x34747) or e-mail iRISHelp@COH.org.

**MediTract**

City of Hope enters into many different kinds of transactions with outside parties that create obligations either on the part of City of Hope or the outside party — whether to receive or spend funds, provide or receive goods or services, or otherwise commit resources. City of Hope’s standardized contract management system is called MediTract. MediTract is also the depository for all electronic copies of all grants and progress reports. MediTract is housed in the legal department.

Use the Request for MediTract access to obtain a login for the MediTract website.

Processing steps for using MediTract:

- Obtain proposed contract from vendor or use an approved City of Hope contract template
- Enter the contract into Workflow in MediTract to obtain the approval of the appropriate personnel, including the Authorized Employee (AE) per the Signature Authority/Hierarchy Policy and Legal, if Legal review is required (see Contracts Exempt From Legal Review).
- Print the Workflow Summary Page (“printer friendly”) to include in the Contract Package.
- Send the contract to the vendor for signature. If the vendor make changes to the City of Hope approved template, the agreement information workflow will need to be submitted and legal department’s approval will need to be obtained.
- Make sure contract is signed by an AE(s) for City of Hope.
City of Hope shared resources offer access to a wide array of cutting-edge technologies, high-end instrumentation, technical support and training needed to conduct high-quality research. These shared resources perform a highly valuable role in facilitating basic, clinical and translational research. Other shared resources include Library Services and Creative Services. This section describes City of Hope entities that provide services to investigators and their staff, postdoctoral fellows and graduate students.
CORE FACILITIES

What Our Purpose Is

To facilitate scientific progress, City of Hope provides investigators and their laboratory teams access to sophisticated support services and state-of-the-art equipment through many core facilities.

How We’re Organized

Core directors and lab personnel are highly trained experts in their field who provide technical expertise, consultation, and training.

- **Website**: [http://www.cityofhope.org/research/support/Pages/shared-resources.aspx](http://www.cityofhope.org/research/support/Pages/shared-resources.aspx)

What We Do

The following is a summary of the services provided by the scientific cores that pertain to basic research:

- **Analytical Cytometry Core (ACC) Facility** provides investigators with high-quality flow cytometry instrumentation, as well as expertise in analyzing and/or sorting sample populations of interest via interpretation of their physical, fluorescent and/or light-scattering properties. Request service using iLAB.

- **Analytical Pharmacology Core Facility (APCF)** conducts pharmacokinetic and pharmacodynamic studies for both chemotherapy clinical trials and peer-reviewed preclinical studies. Request service using iLAB.

- **Animal Resources Center (ARC) Super Core** is responsible for the care and use of animals in research and teaching programs at the City of Hope/Beckman Research Institute and the facilities in which the animals are housed. Services provided include the procurement of animals and animal husbandry supplies, provision of veterinary medical care, animal care and use, training, use of ARC surgical facilities and surgical support program, polyclonal antibody production program, rodent breeding colony core program, and technical support services.
- **Animal Tumor Model Program (ATMP)** supports in vivo drug therapeutic efficacy assessment, drug pharmacokinetic, pharmacodynamic, toxicological and pathological studies, teratoma formation assays, establishment of primary tumor xenografts, alive tumor tissue banking as well as in vivo-related procedure training, protocol documentation and grant applications. Request service using iLAB.

- **Transgenic/Knockout Animal Program (TKAP)** covers all procedures utilized in the start-up phase of producing genetically engineered mouse models. Investigators utilizing the core protocol are free to focus on the experimental use of animals rather than the production of models. The shared resource provides a range of production-related services including embryo transfer re-derivation and cryopreservation of strains. Request service using iLAB.

- **Veterinary Pathology Program (VPP)** provides research pathology, diagnostic pathology (to assess research-related morbidity or mortality), necroscopy and/or tissue collection and trimming, and toxicology/toxicologic pathology consultation. Request service using iLAB.

- **Bioinformatics Core (BIC) Facility** provides investigators with high-throughput biological data analysis tools, data management, unified cyber-infrastructure, training, as well as trained staff working within a multidisciplinary team to facilitate experimental design, information management, data integration, annotation, dissemination and visualization. BIC actively supports Image Analysis, Genomic Analysis, Computer-Assisted Molecular Design, and Molecular Imaging and provides Laboratory Information Management System (LIMS) support for user data and software support for BIC subscribers.

- **Biostatistics Core Facility (Information Sciences)** is a group of statisticians who collaborate in basic, translational and clinical research. Areas of statistical expertise include clinical trials; clinical epidemiology; genetic epidemiology; gene expression and functional genomics; pharmacokinetic modeling; assays, bioassays, and diagnostics; toxicology; and general statistical methods for data summary, inference and prediction. Core members can help with study design, grant proposals, clinical protocols, data analysis and manuscripts. Consulting generally consists of one or two meetings and is without cost. The core can provide HIPAA-compliant identification of stored tissue samples and medical data meeting defined characteristics. Statistical Computing is provided in conjunction with collaboration.

- **Chemical Good Manufacturing Practices (GMP) Synthesis Facility (CGSF)** is a state-of-the-art manufacturing facility for small and large molecule therapeutics for clinical trials. The CGSF provides services for
drug discovery, process research, development and early clinical manufacturing of pharmaceutical drug substances (APIs) that meet Food and Drug Administration (FDA) requirements. With its significant capabilities, the CGSF plays a key role in bridging basic science and translational medicine at City of Hope.

- **Clinical Immunobiology Correlative Studies Laboratory (CICSL)** has developed and has available a variety of assays that are based on molecular, functional and biochemical platforms. The laboratory operates under principles of Good Laboratory Practices (GLP) to support clinical trial protocols in the Cancer Center. Request service using iLAB.

- **Cytogenetics Core Laboratory** provides classic and molecular cytogenetics (fluorescence in-situ hybridization (FISH)) services to Beckman Research Institute investigators, as well as non-City of Hope investigators. FISH testing has proved invaluable as a diagnostic tool in many types of malignancies and is useful in determining both prognosis and course of treatment. The equipment in the Cytogenetics Core Laboratory is available to investigators on an appointment basis. The laboratory also provides training and consultation services in molecular cytogenetic testing.

- **Design and Fabrication Lab** provides the COH medical and research community with design and fabrication services, including mechanical and 3D design, electronic and optical design, and instrument modification. This core works with simple devices like radiation shields and electrophoresis units, to fully automated, computer-controlled instruments such as sequencers and synthesizers. Fabricating services cover all basic machine operations such as turning, CNC milling, drilling and sheet metal forming. Request service using iLAB.

- **Drug Discovery and Structural Biology Core (DDSB)** was established to provide the necessary technical and scientific resources to facilitate drug discovery efforts consistent with the cancer center’s translational research goals. An important focus of the DDSB is on cancer drug discovery in the area of molecular-targeted therapeutics, as well as chemical biology probes. The core comprises four major service components that work together in a complementary and cohesive manner to provide a full array of early-phase drug discovery services and chemical probes for biological systems.
  - **DNA/RNA Peptide** services include design and synthesis of highly specialized siRNA-aptamers and DNA-peptide hybrid derivatives and peptides greater than 100 amino acids in length.
  - **High Throughput Screening (HTS)** assists investigators in identifying novel lead compounds for anticancer drug development and chemical probes useful for biochemical mechanistic studies via sophisticated high throughput screening assays of synthetic compound and natural product libraries. A team of medicinal chemists, pharmacologists, structural biologists, bioinformaticians and clinicians help to optimize some of these small molecules for drug development and translate them into clinical evaluation in cancer patients. Request service using iLAB.
  - **Synthetic and Biopolymer Chemistry Core (SBCC)** provides both biopolymer and small-molecule synthetic services to scientists at City of Hope.
- **X-ray Crystallography Core Facility** provides structural information to understand mechanisms of biological systems at the atomic level, validates binding sites of lead compounds of therapeutic interest, and facilitate leads discovery through co-crystallization of therapeutic targets and small molecule libraries. Request service using iLAB.

- **Electron Microscopy Core** provides equipment to define ultrastructural details in their experimental systems. The EM Core assists with all aspects of studies brought to the lab including training, experimental design and interpretation of results. A variety of preparation methods are available for transmission and scanning electron microscopy including ultra-thin sections of conventionally fixed samples, immunogold labeling, plunge-freezing cryo-EM and tomography. Request service using iLAB.

- **Integrative Genomics Core** provides high quality, efficient, comprehensive and cost effective services using microarray and high-throughput sequencing technologies as well as basic and advanced data analysis services to make complex data biologically interpretable for clinical and basic investigators. Request service using iLAB.

- **DNA Sequencing/Next Gen Sequencing** provides convenient, rapid and cost effective DNA analysis for all investigators. The laboratory is equipped with state-of-the-art Illumina Genome Analyzer II systems, including a Cluster station and a Paired-end module. The core also has a state-of-the-art Hitachi AB model 3730 48-capillary DNA Analyzer with the capacity to analyze 4,000 to 8,000 samples per week.

- **Microarray Core Facility** provides microarray analysis of both DNA and RNA samples, including transcript level expression, Exon level expression, miRNA expression, transcription factor binding, DNA methylation, and histone modification.

- **Light Microscopy Digital Imaging Core** provides widefield light microscopes, confocal microscopes and makes available the latest research platforms for automated microscopy experiments, advanced observation techniques and sophisticated digital image processing and analysis. Request service using iLAB.
• **Mass Spectrometry and Proteomics** provides high-quality mass analysis of biomolecules – proteins, glycoproteins, peptides, oligonucleotides, nucleic acids, lipids and small-molecule metabolites – for a variety of biomedical investigations. The facility offers supporting techniques as well as scientific consultation. Request service using iLAB.

• **Nuclear Magnetic Resonance (NMR) Core** applies high resolution NMR spectroscopy to the structural characterization of biomolecules, small organic compounds, natural products and biomolecular complexes, including protein-protein, protein-nucleic acid and protein-ligand complexes.

• **Pathology Core** provides access to optimally preserved tumors and normal tissues. Over ten thousand samples of diverse neoplasms are currently available in the frozen tumor bank, along with many samples of normal tissue. Periodic inventories and sample testing are conducted to ensure quality of preserving DNA/RNA/protein integrity. All entries are recorded in a computerized database in the tumor bank.

• **Small Animal Imaging Core (SAIC)** provides equipment for optical bioluminescence imaging, fluorescence imaging, gamma camera, PET scanner and CT scanner to allow non-invasive monitoring of the dynamic biodistribution of therapeutic agents as well as vital processes such as gene expression, cell trafficking, cell viability, cell proliferation, tissue hypoxia and angiogenesis in the intact animal. Request service using iLAB.

• **Survey Research Core (SRC)** provides a wide range of services in the areas of study design and sampling, survey instrument development and evaluation, data coding, collection, management, analysis and reporting. Request service using iLAB.

• **Translational Biomarker Discovery Core** is currently under development. Request service using iLAB.

• **Translational Research Laboratory (TRL)** supports basic science investigators, clinical investigators, population investigators and clinical science collaborations to ensure the inclusion of scientifically sound correlative studies in clinical trials and to enable and assist research studies using clinical samples from clinical trials.

---

**LIBRARY SERVICES**

**What Our Purpose Is**

The Department of Library Services serves the information needs of the City of Hope community, supporting the institution’s clinical, scientific and educational missions.

**How We’re Organized**

- **Call:** Extension 68497
- **E-mail:** library@COH.org
- **Website:** [http://www.cityofhope.org/library](http://www.cityofhope.org/library)
- **Location:** Lee Graff Medical and Scientific Library
- **Hours:** Monday - Friday 8 a.m. - 6 p.m.
What We Do

For the basic investigator, the library offers:

**Expert Help Finding and Managing Information and Complying with Funder Requirements**

- One-on-one consultations to help find relevant information to support research as well as strategies for keeping up with new developments in the investigator’s field.
- Assistance with managing information and publishing research: using EndNote to manage citations, finding the right journal for the publishing the research paper, evaluating and increasing the impact of the research
- Customized classes for the investigator and research team on a variety of topics.
- Support for grant reporting and compliance with the National Institutes of Health (NIH) Public Access Policy: help setting up My NCBI My Bibliography, submitting and tracking publications through the NIH PAP workflow and generating lists of publications for grant progress reports.

**Databases, Journals, Books and Historical Materials**

- [Databases](#) in a variety of scientific fields
- A customized version of [PubMed](#) with links to full text from the library’s collections and commonly used filters for limiting searches
- An extensive collection of [journals](#), most available electronically
- An extensive collection of [books](#), many available electronically
- [The Career and Professional Development Collection](#), featuring print and electronic books on grant writing, lab management, developing CVs, giving presentations and more
- 24/7/365 access to databases and electronic books and journals from any computer anywhere via VPN
- [Interlibrary loan and document delivery service](#) to deliver articles and book chapters directly to the investigator, either from City of Hope collections or from other libraries.
- [The City of Hope Archives](#), which can supply historical photos and other materials.
Space to Read, Work and Relax:

- 24/7/365 access to the Lee Graff Medical and Scientific Library, which offers quiet study and relaxation space as well as print books and journals, computers, and two walking stations to exercise while reading/working.

CREATIVE SERVICES

What Our Purpose Is

Creative Services is the resource for designing research presentations.

How We’re Organized

- **Call:** Extension 26384 or Extension 62447 for Design and Photography
- **Call:** Extension 65080 for Print Services
- **E-mail:** #Traffic@coh.org subject line “Design - New Users” to register as a new user to receive log-in information for the “Instant Web Publishing” request site accessible from the Creative Services website
- **Website:** [http://www.coh.org/creative-services/Pages/default.aspx](http://www.coh.org/creative-services/Pages/default.aspx)

What We Do

Areas of expertise include conceptualization, graphic design, typography, photography and production. Creative Services maintains electronic templates for both internal and external scientific meeting and conference presentations as well as templates for research posters of varying dimensions. Turnaround time is usually three to five business days for basic jobs and up to two weeks for larger projects. Events require one to two months’ lead-time depending upon complexity of elements.

The following tools are available on the Creative Services Intranet page:

- Research poster templates
- City of Hope branding style guides
- Writing style cheat sheets
As a first step, investigators should discuss their project with their department chair and determine what resources are needed. Investigators who are knowledgeable about what internal support may be available are in a better position to seek external support.

This section describes the services and procedures of offices that help investigators identify, apply for and manage grants as well as other types of agreements related to basic research. The following chart identifies the offices that help administer and provide support to investigators and their research and administrative staff. These offices work closely together to determine the appropriate City of Hope office to administer the funding, contract and/or licensing aspects of a project and provide assistance to investigators and department administrative staff.

<table>
<thead>
<tr>
<th>Office of Sponsored Research (OSR)</th>
<th>All research, scholarly activities and projects funded in whole or in part by a governmental agency (federal, state or local) are processed through the Office of Sponsored Research (OSR).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office of Foundation Relations (OFR)</td>
<td>Research, scholarly activities or projects supported by individuals or private foundations are administered through the Office of Foundation Relations (OFR).</td>
</tr>
<tr>
<td>Office of Faculty and Institutional Support (OFIS)</td>
<td>Assistance in finding grant funding opportunities, writing proposals and editing manuscripts is provided by the Office of Faculty and Institutional Support (OFIS).</td>
</tr>
<tr>
<td>Office of Technology Licensing (OTL)</td>
<td>Negotiation of non-disclosure agreements (NDAs), confidential disclosure agreements (CDAs), material transfer agreements (MTAs) and licensing of intellectual property and facilitation of collaborations between City of Hope and outside institutions and industry is provided by the Office of Technology Licensing (OTL).</td>
</tr>
<tr>
<td>Grant Accounting</td>
<td>Business Managers/Directors deal directly with Grant Accounting on behalf of investigators as far as invoicing, adding chart of accounts and financial reporting required by several agencies.</td>
</tr>
<tr>
<td>Research Finance</td>
<td>Oversight and management of expenditures of research institutional budgets and discretionary cost centers is the responsibility of the Research Finance Department.</td>
</tr>
</tbody>
</table>
OFFICE OF SPONSORED RESEARCH

What Our Purpose Is

The Office of Sponsored Research (OSR) provides the necessary support to improve the effectiveness of sponsored programs and ensure that grants and contracts comply with City of Hope’s standards for academic freedom, research ethics and fiscal responsibility.

OSR is the central administrative office responsible for submitting proposals and accepting awards on behalf of City of Hope. Sponsored project proposals may only be submitted, and awards accepted, by individuals authorized in OSR to sign the necessary documents. Investigators and administrative staff are not authorized to submit proposals, accept grants or execute contracts on behalf of City of Hope.

How We’re Organized

The Office of Sponsored Research (OSR) is under Basic Research Operations.

- **Call:** For contact information, see: [http://www.coh.org/OSR/Pages/contact-us.aspx](http://www.coh.org/OSR/Pages/contact-us.aspx)
- **E-mail:** [OSR@COH.org](mailto:OSR@COH.org)
- **Website:** For OSR assignments by administrator, business manager/director or department; forms; policies and procedures, see: [http://www.coh.org/OSR/Pages/default.aspx](http://www.coh.org/OSR/Pages/default.aspx)
- **Grants Calendar:** [http://www.coh.org/grants-calendar/Pages/default.aspx](http://www.coh.org/grants-calendar/Pages/default.aspx)

What We Do

OSR supports research faculty and staff by providing pre-award and post-award grant administration. OSR liaises with grant sponsors on behalf of investigators and acts internally as the intermediary between the Office of Foundation Relations, Office of Technology Licensing, Grant Accounting, Legal Office, Corporate Compliance Office and auditors, both internal and external. OSR staff assist investigators by reviewing grant proposals to ensure compliance with sponsors’ terms and conditions, as well as, City of Hope policy and federal regulations and requirements.

OSR responsibilities include, but are not limited to:

- Acts as the liaison between City of Hope and extramural sponsors
- Provides guidance to faculty and staff regarding proposal preparation
  - Assists with the review of the proposal content and format
  - Assists with the review of the application forms
- Reviews and endorses all proposals to extramural sponsors
  - Institutional review focuses on commitment of institutional resources and compliance with City of Hope and sponsor policies
• Reviews award terms and conditions and accepts on behalf of City of Hope and investigator by approving budget and requesting the appropriate Project ID(s)

• Coordinates sponsor requests for additional information
  – Just-in-Time requests
  – Administrative Supplements
  – Change in SOW
  – Changes in key personnel
  – No-cost extensions
  – Budget revisions
  – Requests to carry forward funding from one year to the next

• Ensures compliance with relevant City of Hope policies and procedures governing the conduct of research and other extramural activities, including:
  – Protection of human and animal subjects (IRB and IACUC)
  – Use of City of Hope facilities and appropriateness of the research activity
  – Adherence to personnel policies and compensation plans
  – Technology Transfer
  – Conflicts of Interest
  – Recovery of direct and indirect costs
  – Liability insurance and indemnification/medical malpractice coverage

Transferring A Grant From Another Institution

To transfer a grant from the previous institution, contact the assigned OSR Grants and Contracts Administrator. The transfer requires these actions:

1. Relinquishment: Investigator will inform the funding agency of their desire to transfer the agreement to City of Hope. The grants office of the previous institution will inform NIH that it has agreed to relinquish responsibility.

2. Proposal and Award to City of Hope: The investigator will need to prepare a proposal for the remaining funds, following City of Hope proposal procedures. Business Manager/Director will prepare PDAF for assignment of a GEMS number via RDMA. The OSR Grants and Contracts Administrator will assist the investigator in submitting this proposal, along with any other letters of support and other documentation, to the sponsor.

3. Transfer of Equipment: Based on sponsor approval, an agreement from the previous institution to release equipment purchased on the grant to be transferred to City of Hope will be completed. This is coordinated through Research Finance.

Applying for a New Grant

Sponsored Projects are externally funded research, scholarly activities or projects that have a defined scope of work, deliverables or a set of specific objectives which provide a basis for sponsor expectations, including, but not limited to financial reporting, specific project outcomes or intellectual property rights.
1. Determining the Type of Project/Activity:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
</table>
| Research                    | **Basic**: Research directed toward increasing knowledge of the subject being studied. Includes activities that seek to increase the understanding of fundamental phenomena.  
                              | **Translational**: Facilitates the translation of findings from basic science to practical applications that enhance human health and well-being. Basic research (bench-side) that can be directly applied to or closely related to the patient care (bedside).  
                              | **Clinical**: Research 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.                                                                                                             |
| Research Training/          | Funding received in order to train or provide subsistence during training, to either graduate students or post doctoral candidates training in research techniques.                                                                                                                                                                               |
| Fellowships                 |                                                                                                                                                                                                                                                                                                                                            |
| Clinical Trials             | An agreement typically with a for-profit drug company (but not always) in which, with FDA approval, investigators are testing drugs, devices or therapies on human subjects.                                                                                                                                                                         |
| Equipment Grant             | Typically funded purely to purchase equipment to enhance the research infrastructure.                                                                                                                                                                                                                                                        |
| Conference Grant            | Funding received for a conference/scientific meeting. For a gathering, symposium, seminar, scientific meeting, workshop or any other organized, formal meeting where persons assemble to coordinate, exchange, and disseminate information or to explore or clarify a defined subject, problem, or area of knowledge.                                                                                                    |
| Travel Grant                | Funding to help full-time faculty to attend regional, national, or international professional affairs in order to present or perform scholarly activities.                                                                                                                                                                                           |
| Instruction                 | Given to develop or enhance curriculum.                                                                                                                                                                                                                                                                                                   |

2. Determining the Type of Application:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Application</td>
<td>Refers to an application not previously proposed or one that has not received prior funding.</td>
</tr>
<tr>
<td>Renewal (a.k.a. Competing Continuation)</td>
<td>A request for additional funding that is intended to extend, or results in the extension of, a project beyond the originally approved project period.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Continuation (Non-competing)</td>
<td>The sponsor requires submission of a continuation or progress report in order that the sponsor can monitor the progress of a project with a funding commitment of the entire project period.</td>
</tr>
<tr>
<td>Supplement</td>
<td>A request for additional funds to support an existing project during that same project period.</td>
</tr>
<tr>
<td>Revision /Resubmission</td>
<td>A proposal submitted to make a significant change to a previously submitted proposal not yet funded by the sponsor.</td>
</tr>
</tbody>
</table>

3. **Determining the Type of Funding Mechanisms/Types of Award**:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gifts</td>
<td>Gifts are contributions made to City of Hope for which the donor receives nothing in exchange. Gifts may be restricted to a specific purpose, or they may be unrestricted and used by City of Hope for any purpose consistent with City of Hope’s mission and not-for-profit status. Other than restricting the purpose of the gift, the donor may not impose terms and conditions on the use of the gift funds or require deliverables from City of Hope.</td>
</tr>
<tr>
<td>Grants</td>
<td>Grants are usually made in support of basic research, training, or workshop support, requiring technical and financial reports rather than specifying definite services or product deliverables. Grants require City of Hope and its investigators to abide by certain terms and conditions. Federal, state and local government agencies, for-profit entities, and private not-for-profit organizations distribute funding through grants, contracts and cooperative agreements, each associated with terms and conditions.</td>
</tr>
<tr>
<td>Contracts</td>
<td>Government agencies and for-profit, commercial entities may use a procurement mechanism, such as a contract or purchase order, to fund research or other programs of importance to the sponsoring organization. Basically, one party is buying a service or product from the other in exchange for payment. Contracts assume the production and delivery of a specific product that can be an instrument, device or technical report. Consequently, contract requirements are more specific and less flexible than grants.</td>
</tr>
<tr>
<td>Cooperative Agreements</td>
<td>Cooperative Agreements are an arrangement where both parties are involved in carrying out a portion of the research. Cooperative agreements generally stipulate the responsibilities of both parties.</td>
</tr>
</tbody>
</table>
### Subawards and Subcontracts
Subawards and Subcontracts are formal written agreements made between a research institution that applies for the funding and City of Hope that provides collaborators to perform a portion of the work. When funded by a grant or cooperative agreement, the applying institution (Prime Recipient) will issue a Subaward to City of Hope (Subawardee) providing funding from the prime award. If the prime award is a contract, the award to City of Hope will be a Subcontract. Applicable terms and conditions of the prime award will flow to City of Hope.

### Fellowships
Fellowships are awards of financial support to individually named students or postdoctoral scholars or to City of Hope on behalf of individually named students or postdoctoral scholars. The funds are treated as a research training grant, a type of sponsored research project.

### 4. Identifying Funding Opportunities
The Office of Faculty and Institutional Support (OFIS) is available to assist faculty and staff in locating potential external funding opportunities.

**Federal Funding Sources (see: Grants.Gov)**

- Department of Defense
- National Cancer Institute – Extramural Funding Opportunities
- National Institutes of Health – Office of Extramural Research
- National Science Foundation
- U.S. Army Medical Research and Material Command

**State and Local Government Funding Sources:**

- California Institute for Regenerative Medicine
- University of California – Tobacco-Related Disease Research Program
- University of California – California Breast Cancer Research Program
- University of California – California HIV/AIDS Research Program

**Non-Federal Funding Sources:**

- American Cancer Society
- Juvenile Diabetes Research Foundation
- Margaret E. Early Research Trust
- National Comprehensive Cancer Network
- Susan G. Komen for the Cure
**Internal Funding Administrative Sources:**

- **Office of Foundation Relations** – website posts grant opportunities from other groups
- **Office of Faculty and Institutional Support** – e-mails “Grant Bulletin” weekly
- **City of Hope** – Enhancement programs as announced via email

5. **Obtaining A GEMS Number:** A GEMS Number is required in order for OSR to maintain organization of all proposals that enter the department. To obtain a GEMS Number, the following steps should be followed at least 7 business days prior to the deadline:

<table>
<thead>
<tr>
<th>Step 1</th>
<th>The investigator submits the following documents to <a href="mailto:OSR@COH.org">OSR@COH.org</a>:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>A.</strong> Proposal Data and Approval Form (PDAF)</td>
</tr>
<tr>
<td></td>
<td>1) Due to continuing updates/changes to the PDAF, it is highly recommended that you download a new PDAF from the OSR forms page for every use.</td>
</tr>
<tr>
<td></td>
<td>2) Documents to assist in using the PDAF:</td>
</tr>
<tr>
<td></td>
<td>a. PDAF Signature Instructions</td>
</tr>
<tr>
<td></td>
<td>b. Assurance of Compliance</td>
</tr>
<tr>
<td></td>
<td><strong>B.</strong> Abstract (Scope of Work)</td>
</tr>
<tr>
<td></td>
<td><strong>C.</strong> Budget – Documents to assist in preparing the budget:</td>
</tr>
<tr>
<td></td>
<td>1) PHS 398 Face Page (Word Format)</td>
</tr>
<tr>
<td></td>
<td>2) PHS 398 Excel Spreadsheet with Consortium Calculation (For Internal Use Only)</td>
</tr>
<tr>
<td></td>
<td>3) Percent Time and Effort to Person Months (PM) Conversion Table</td>
</tr>
<tr>
<td></td>
<td>4) Salary Cap Summary (Updated 2/9/2012)</td>
</tr>
<tr>
<td></td>
<td><strong>D.</strong> Budget Justification</td>
</tr>
<tr>
<td></td>
<td><strong>E.</strong> Facilities and Resources (If applicable)</td>
</tr>
<tr>
<td></td>
<td><strong>F.</strong> Guidelines (If applicable)</td>
</tr>
<tr>
<td></td>
<td><strong>G.</strong> PI Exception Form (If applicable)</td>
</tr>
<tr>
<td></td>
<td><strong>H.</strong> IDC Waiver Form (if applicable)</td>
</tr>
</tbody>
</table>

| Step 2 | A confirmation email will be sent providing the assigned GEMS Number and identifying the OSR Grants and Contracts Administrator who is responsible for future communication regarding the proposal. |

| Step 3 | After receiving a confirmation email, the final complete application is passed on to the OSR Grants and Contracts Administrator for their review. |

**Filling Out Forms Related to Grants**

Contact the OSR Grants and Contracts Administrator assigned to your department for assistance with forms related to grants. [Contact information can be found on the OSR website](#).
1. **The Proposal Data and Approval Form (PDAF):** The PDAF is used to identify key elements of the proposal and to secure required signatures and, as appropriate, department approvals for use of City of Hope resources. The PDAF form and instructions can be found on the OSR website.

2. **Request for Approval to Spend Funds (RAS):** The Director of the Office of Sponsored Research must approve any budgetary commitment for pre-award costs on a new or competing grant award. To obtain approval, the following steps should be followed:

| Step 1 | The **Business Manager/Director** of the Department/Division shall prepare a “Request for Approval to Spend Funds” (RAS) and provide a line-item budget (not to exceed 25% of the yearly budget requested in the proposal). Information provided on the RAS includes:
|        | A. The GEMS Number that was assigned when the proposal was submitted.
|        | B. Award specific information.
|        | C. Requested budgetary amount.
|        | D. Justification of need to incur costs prior to receipt of official notice of award.
|        | E. Identification of a non-sponsored cost center for cost recovery if (1) the award is ultimately not made or (2) the award start date is later than anticipated resulting in expenses being incurred beyond the 90-day approved pre-award window.

| Step 2 | The following signatures are required:
|        | A. Signature of the Department Business Manager/Director to acknowledge request being made.
|        | B. Signature of the investigator accepting responsibility for any expenses as a result of the sponsor’s (1) failure to make the award entirely or (2) make the award with a delayed start date.
|        | C. Signature of the Division/Department Chair in recognition of the requested action and, as necessary, provision of a non-sponsored activity cost center to guarantee the financial risk where the investigator does not have sufficient discretionary funds to guarantee the 90-day pre-award project expenses.
|        | D. If neither the investigator nor the Division/Department Chair can provide guarantee funds, the signature of the Director of BRI is required.

| Step 3 | The completed RAS form and supporting documentation (clearly scanned signed documents) shall be submitted to the OSR Grants and Contracts Administrator for final review and approval. The OSR Grants and Contracts Administrator will verify the following with the sponsor:
|        | A. That the sponsor will fund the grant or award a subcontract to City of Hope.
|        | B. That in the case of City of Hope as Sub-recipient, verify that (1) Prime Recipient has confirmed that the award will be made from the sponsor, and (2) the Prime Recipient intends to award a subcontract to City of Hope.
|        | C. The expected start date of the project.
|        | D. The expected award amount.
|        | E. The pre-award period that the sponsor recognizes.
|        | F. That the sponsor allows pre-award costs.
**Step 4**  
In addition, the OSR Grants and Contracts Administrator will:

A. Confirm that all institutional approvals are in place (as appropriate to the proposed research), including:
   1) PDAF is completed.
   2) IRB protocol is approved, current and has received concordance review.
   3) IACUC protocol is approved, current and has received concordance review.
   4) COI review has been performed.
   5) Other institutional reviews as required.

B. Review the requested budget to ensure it is 25% or less than the amount requested in the proposal.

C. Verify the identification of a City of Hope or Medical Center non-sponsored activity project for cost recovery if (1) the award ultimately is not made or (2) the award start date is later than anticipated resulting in expenses being incurred beyond the 90 day pre-award window.

D. Verify with the Business Manager/Director that adequate funds are available in the alternate cost center.

E. Verify that the investigator has signed the RAS form indicating acceptance of responsibility for pre-award costs if funding is (1) not subsequently awarded or (2) the actual start date of the award is later than the anticipated start date, i.e., greater than 90 days from the pre-award approval date.

F. Verify that the Department/Division Chair has reviewed and signed the request indicating his/her approval. If necessary, the Department/Division Chair has provided a discretionary cost center as the financial guarantee.

**Step 5**  
Upon approval of the Director of OSR and verification that conflicts of interest and concordance reviews by the IRB and IACUC have been completed, the OSR Grants and Contracts Administrator will prepare a “Project Costing Maintenance Form” and forward it with the RAS and the requested line item budget to RDMA in order to establish a new Project ID.

**Step 6**  
Grant Accounting will establish the Project ID and forward the Grants File Maintenance Form (GFM) to RDMA, who will inform the OSR Grants and Contracts Administrator. Upon receipt of IRB and IACUC clearance, the OSR Grants and Contracts Administrator will notify the investigator and the Department Business Manager/Director of the Project ID.

**Preparing Proposals**

1. Once a faculty member has formulated an idea for a project and determined a potential sponsor, the Department Business Manager/Director and OSR will assist the faculty member to ensure that the proposal satisfies both the sponsor’s application guidelines and City of Hope’s regulations.

2. A proposal requesting support from any sponsor will most often consist of the following components:
<table>
<thead>
<tr>
<th>Title Page</th>
<th>For those sponsors that do not provide application packages or have other specific requirements, the investigator must construct some form of title page.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table of Contents</td>
<td>List of proposal sections including page numbers.</td>
</tr>
<tr>
<td>Abstract</td>
<td>A brief description covering the purpose, important features and significance of the project.</td>
</tr>
<tr>
<td>Research Plan</td>
<td>A detailed description of the project.</td>
</tr>
<tr>
<td>Budget and Justification</td>
<td>A reasonable estimate of the resources necessary to conduct the project. Most sponsors require a detailed breakdown of the budget into certain defined budget categories and a detailed budget justification. The budget justification should clearly explain what costs will be paid for by the sponsor and how the expense was calculated.</td>
</tr>
<tr>
<td>Biosketches (CV)</td>
<td>Biographical sketches for all key project personnel.</td>
</tr>
<tr>
<td>References</td>
<td>List of all references cited in proposal.</td>
</tr>
<tr>
<td>Facilities and Resources</td>
<td>If applicable.</td>
</tr>
<tr>
<td>Current and Pending Support</td>
<td>If applicable.</td>
</tr>
<tr>
<td>Appendices</td>
<td>If applicable.</td>
</tr>
</tbody>
</table>

**Submitting Proposals**

1. **Reviewing and Submitting the Proposal**: OSR is the central administrative office responsible for submitting proposals and accepting awards on behalf of City of Hope. Investigators and departments should allow adequate time for proposal review.

   *Important* PDAF should be submitted to OSR seven to ten days prior to the sponsor deadline.

2. **Processing a Paper Proposal**: The following steps should be followed when processing a paper proposal.
Step 1
The Departmental Administrator emails OSR@COH.org to request an GEMS number and includes the statement “This proposal will be a paper submission” along with the following:
1) Recipient
2) Address
3) Phone number
4) Date to be mailed
5) Dimensions and type of box
6) Estimated weight
7) Investigator
8) Department
9) Business Manager/Director

Step 2
When the department receives the assigned GEMS number, a copy will be sent to the OSR Grants and Contracts Administrator.

Step 3
The day before the anticipated mailing date, the OSR Grants and Contracts Administrator will prepare the FedEx mailing label and notify the department that it will be ready no later than 9am the following day. The label will be saved as a PDF and emailed to the department. The originating department is responsible for packing and mailing the grant.

Step 4
When preparing the shipping label, the OSR Grants and Contracts Administrator will include the GEMS number, as well as, the department name and Business Manager/Director in the reference field(s).

3. Processing an Electronic Proposal (Please refer to funding opportunity guidelines to determine funding submission mechanism.)

- **Grants.gov**: A source to search for funding opportunities and to download application packets. This website is used by OSR to apply for grants and track applications.
- **eRA Commons**: A new user who needs access to eRA Commons can obtain a username by contacting RDMA. New users include, but are not limited to, investigators that transfer to City of Hope from another institution.
- **RPPR**: A federally mandated reporting format for all federal grant agencies (NIH, NSF, DoD, etc.) designed to provide consistent information on the progress of federally funded research and research related activities.
- **proposalCENTRAL**: An e-grantmaking website shared by many government, non-profit and private grant-making organizations.
Negotiating and Accepting Awards

1. **Negotiating the Award:** OSR is the central administrative office responsible for negotiating and accepting awards on behalf of City of Hope. As needed, OSR consults with the investigator, Department/Laboratory/Center Administrators and other administrative offices, such as the Legal Department and Office of Technology Licensing.

2. **Accepting the Award:** A Notice of Grant Award, also known as NOGA, NGA, Sponsor Notice or Award Letter, is the official notification from the sponsor indicating that a proposal has been funded. Notice of Grant Awards are usually received by OSR, although in some circumstances, investigators may be notified directly.

3. **Setting-Up the Award Account:** Prior to award setup, IRB and IACUC protocol approvals and grant concordance reviews need to be completed, as well as all COI for key personnel identified on a project. Otherwise, account set-up may be delayed. Upon receipt of a sponsor award notice or update to an award, the OSR Grants and Contracts Administrator initiates the account set-up/modification process by completing the PCMF. OSR Grants and Contracts Administrator sends the PCMF to Grant Accounting to request a new or extend an existing cost center number. Grant Accounting sends confirmation of the account set-up via a Grant File Maintenance (GFM).

   Subawards (outgoing) are defined as funding to an outside vendor under an agreement received by City of Hope which may include, but is not limited to, the following:

   - Account set-up: This should occur at the time of the parent grant’s PCMF
   - Budget set-up
   - Terms and Conditions
   - Separate file for record keeping
   - Subrecipient Commitment Form
   - OSR Request Form

4. **Entering Awarded Budgets and NOGA’s in GEMS and MediTract:** The awarded budget is entered into Grants Electronic Management System (GEMS) by the RDMA. This maintenance is mandatory for all grants and contracts. Budgets will be entered according to their budget period over the span of the awarded project period.

   The budget entry, the notice of award, agreement, modifications to agreement and progress report are entered into MediTract by the OSR staff.
5. **Spending (Pre-award) Sponsored Funds**: Many federal sponsors allow grantee institutions to incur pre-award costs up to 90 days prior to the start date of a grant award. Any pre-award costs the City of Hope incurs may not be reimbursed by the sponsor if an official award is not granted. Therefore, such costs incurred during the pre-award phase of a grant are the financial risk of the investigator and the institution. However, there is also a risk in making cost transfers onto a sponsored project, when the cost center for that sponsored project has not been set up due to a delay in receiving the official notice of award.

Look on the OSR website for information regarding the procedures and guidelines for obtaining **Pre-Award Spending Authorization (RAS)**.

The Director of Sponsored Research must approve any budgetary commitment for pre-award costs on a new or competing grant award.

**Grant Award Policies and Federal Regulations**

City of Hope uses the following federal requirements in establishing procedures for administering all awards for research and other sponsored agreements:

- NIH Grants Policy Statement
- OMB Circular A-122: Cost Principles for Nonprofit Organizations
- OMB Circular A-110: Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other non-Profit Organizations
- OMB Circular A-133: Audits of Institutions of Higher Education and Other Non-Profit Institutions
- FAR: Federal Acquisition Regulations: Contracting Requirements

**OFFICE OF FOUNDATION RELATIONS**

**What Our Purpose Is**

The Office of Foundation Relations manages relationships with private philanthropic foundations to advance City of Hope’s mission to conquer cancer, diabetes, HIV/AIDS and other life-threatening diseases.

**How We’re Organized**

- **Call**: Extension 26224
- **E-mail**: foundations@COH.Org
- **Website**: [http://www.coh.org/foundations/Pages/default.aspx](http://www.coh.org/foundations/Pages/default.aspx)
What We Do

The Office of Foundation Relations (OFR) works collaboratively with City of Hope investigators and staff to ensure that communication with foundations is strategic and coordinated. Investigators need to contact OFR before making any contact with private sources. Services include:

- Identifying, posting and alerting investigators via e-mail to foundation funding opportunities and deadlines for proposal submission
- Communicating with potential funding agencies to discuss projects
- Assisting with proposal development and submission
- Planning and executing foundation site visits
- Monitoring award requirements
- Coordinating post-award reports and stewardship

For investigators who come to OFR to discuss their research interests, OFR may:

- Put investigators in touch with others at the institution and elsewhere who are involved in similar projects or related research
- Help identify, research and qualify foundation prospects for individual projects
- Share knowledge about various foundations not available through or up-to-date on public websites
- Assist investigators in strategizing their approach to foundations
- Work with investigators to determine the best initial contact with the foundation and who at the institution needs to be involved
- Contact investigators when new foundation funding opportunities arise that dovetail with their projects
- Consult with investigators on writing the proposal, preparing the budget and reporting results

The following answers to some frequently asked questions provides an overview of the assistance available through OFR.

What are some of the steps to finding the right foundation to fund a research project?

The Private Funding Opportunities webpage provide links to sites describing foundations that fund the types of research conducted at City of Hope.
When considering possible donors, keep in mind the following:

- Foundations fund initiatives that align with their core mission and rarely make exceptions to their pre-stated priorities. They typically have pre-determined programmatic and geographic focus areas.
- Many foundations favor programs that are multi-institutional, interdisciplinary and/or involve community partnerships.
- Many foundations provide funding opportunities to innovative or “risky” projects that are ineligible for government funding.
- Foundations often prefer to support projects that will have an impact beyond the initiating institution and/or projects that will develop new solutions to persistent problems.
- Many foundations provide support for a limited time (typically one to three years). Therefore, foundations often want to see institutional support as well as plans to secure additional funding after the foundation’s support is over.

**What are some of the steps to writing a foundation proposal?**

Each foundation has its own procedures and most maintain websites providing guidance to applicants. Study these carefully, but contact OFR to ask for additional information that may not be available or may not be up-to-date on these websites. Foundations want to bestow their grants where the funds will yield the greatest results. In writing a proposal, investigators should consider:

- What is the problem to be addressed? Can the project be framed in the context of a larger issue? What data demonstrates how the project will address that issue?
- Why is City of Hope the ideal institution to address this issue?
- Why is the foundation a good fit for the project?
- What qualifies the investigator to accomplish the research objectives?
- What key activities of the project will accomplish these objectives?
- What measurable outcomes will be used to evaluate success?
- What resources are needed in regard to time, money, facilities, and personnel?
- How will the project be sustained once the foundation’s funds have been expended?

**What are RFPs and Limited Applications?**

A Request for Proposals (RFP) is a foundation’s announcement inviting proposals for a specific program or issue and providing a specific deadline. These RFPs may be released publicly or only sent to pre-selected institutions identified by the foundation. OFR serves as a clearinghouse for many RFPs and distributes them as appropriate within the institution. If an RFP limits the number of applicants per institution, an internal scientific selection committee decides on the final candidate(s).
OFFICE OF FACULTY AND INSTITUTIONAL SUPPORT

What Our Purpose Is

The Office of Faculty and Institutional Support (OFIS) develops and supports an extramurally funded research environment that assures integrity and compliance with appropriate regulations, and facilitates communications among faculty and administrators.

How We’re Organized

- **Call:** Extension 62597 or 60277 to schedule scientific writing services

*Please Note.* Grant applications are given priority over manuscripts.

What We Do

**Grant Bulletin**

OFIS sends a weekly “Grant Bulletin” e-mail to the Duarte campus listing funding opportunities and announcements from the National Institutes of Health (NIH), other government agencies and major foundations. OFIS can also assist investigators in locating potential external funding opportunities.

**Scientific Writing Services**

The focus of Scientific Writing Services is to provide free writing and editing to investigators in writing grant proposals and manuscripts. All of the scientific writers have a background (Ph.D.) in the biological sciences. Investigators should contact the scientific writers well in advance of deadlines to ensure that the writers can reserve adequate time to provide assistance. Services include:

- Reviewing grant proposals and manuscripts for grammar, consistency and the logical flow of presented data
• Ensuring proposals are responsive to the purpose of a Request for Application (RFA) or Request for Proposal (RFP) or to reviewer’s comments in cases of resubmissions
• Reviewing response letters to editors/reviewers, abstracts, etc.

Documents are edited using the tracking tool in Word so that authors can easily accept/reject the changes made.

**OFFICE OF TECHNOLOGY LICENSING**

**What Our Purpose Is**

The Office of Technology Licensing (OTL) protects faculty interests while advancing discoveries toward commercial development.

**How We’re Organized**

• **Call:** Extension 65600
• **E-mail:** mta@COH.org to request a Material Transfer Agreement (MTA)
• **Website:** [http://www.coh.org/otl/Pages/default.aspx](http://www.coh.org/otl/Pages/default.aspx)

**What We Do**

Research at City of Hope often leads to important innovations or discoveries. Many times these discoveries result in new inventions. These new inventions, while scientifically significant, may or may not be considered “inventive.” Identifying which discovery or innovation is also an invention and protecting them is the mission of the Office of Technology Licensing (OTL).

OTL handles non-disclosure agreements (NDAs), confidential disclosure agreements (CDAs), material transfer agreements (MTAs) and licensing of intellectual property and provides input to produce effective collaborations between City of Hope staff and outside institutions and industry.

OTL will assist the investigator to:

• Generate collaborations with industrial and academic partners
• Identify and protect intellectual property while preserving academic values
• Evaluate whether research results are patentable
• Guide the investigator through the patenting process
• Effectively transfer discoveries and inventions from the laboratory into commercial development
• Comply with City Of Hope policies and procedures as they relate to materials, confidentiality and intellectual property, along with input from other teams at City of Hope
• Explore entrepreneurial and company start-up activities.
The following answers to some frequently asked questions provide an overview of the assistance available through OTL.

**What is intellectual property and who owns intellectual property developed at City of Hope?**

“Intellectual property” includes inventions of new products, materials, designs, processes, methods, techniques or algorithms, whether or not such inventions are actually patentable. Determination of whether City of Hope will apply for a patent or protect the invention in another manner is performed by OTL in consultation with the inventors. City of Hope owns intellectual property developed at City of Hope. City of Hope intellectual property includes inventions conceived by those employed by, or using resources owned by, City of Hope. This includes works that were developed under grants, sponsored research or other agreements, or using City of Hope funds or facilities. Inventors must formally give (“assign”) City of Hope the rights and ownership (“title”) to all inventions. Inventions made at any time or place that are in anyway related to the field of work for which you were specifically hired for or is consistent with the mission of City of Hope are considered the property of City of Hope. This includes inventions conceived or developed at home or on weekends.

**Who is covered by City of Hope’s Intellectual Property Policy?**

All investigators, scientists, physicians, nurses, post-docs, students and others working at City of Hope, including everyone engaged in medical, scientific, administrative or support work. Everyone is subject to the City of Hope Intellectual Property Agreement. Creation of any invention while working at City of Hope triggers three main obligations:

1. Disclosure — Inventor’s obligation to disclose to OTL any inventions
2. Cooperation — Inventor’s obligation to cooperate with OTL in the protection of the invention, for example by a patent application(s)
3. Financial — City of Hope’s obligation to share royalties/income with the inventor(s)

**What is a patent?**

A patent is a property right granted by the government to “exclude others from making, using, selling or importing the invention” in the country where the patent is issued. Companies wishing to practice a patented City of Hope invention should seek a license from City of Hope to obtain suitable rights.
What can be patented?

There are three types of patents: utility patents, design patents and plant patents. City of Hope inventions are primarily protected as utility patents. Utility patents are granted for any new material, method, machine, manufacturing process or improvements to any existing inventions of these types. At City of Hope, examples of patentable inventions include new molecules, methods of synthesis, methods of use, assays, gene associations, protein interactions, screening methods, computer algorithms, medical devices and drug formulations.

What makes an invention patentable?

For an invention to be patentable, it must be:

1. **Novel** — The invention must be a novel or new idea. An invention cannot be patented in the United States if it has been described in a printed publication, has been in public use or offered for sale in the US for more than one year before a patent application is filed. An invention cannot be patented in any foreign country if it was described in a printed publication or has been in public use at any time prior to submitting a patent application.

2. **Non-obvious** — The invention should not be obvious to a person having ordinary skill in the area of technology at the time the invention was made. For example, the substitution of one material for another is not patentable unless there is an unexpected effect.

3. **Useful** — The invention must have some useful effect or purpose.

4. **Enabled** — The invention must be clearly described so that a person of ordinary skill in the art can make and use the invention. Occasionally this means demonstration of activity in an animal model or human clinical trial.

Who are inventors?

- An inventor is a person who contributed to the “creative spark” — the conception — of an invention. In some cases inventorship may require an intricate legal determination by City of Hope’s patent attorney who is handling the case.
- A person who contributed only labor and/or the supervision of routine techniques, but who did not contribute to the idea, is not considered an inventor.
- Inventorship is determined in accordance with US patent law. The criteria for inventorship are different from that of authorship.

Are investigators always inventors?

Not necessarily. Inventorship comes from having, or meaningfully contributing to, the “creative spark.” However, inventions often arise from or through close mentoring and discussions with investigators. So, provided they meet all the requirements of inventorship, investigators can be co-inventors.
What steps need to be followed to document research?

The following procedures are recommended to maintain good laboratory notebooks.

1. Use ink, not pencil when recording ideas and experiments.
2. Keep all records in bound notebooks with all pages numbered permanently in ink.
3. Keep lab notebooks intact and free from mutilation.
4. Make no erasures; cancel mistakes by drawing a line through them and writing the correct data in the margin, with initials and the date after each such correction.
5. Make no changes or insertions on a page at any date later than that shown. If it is necessary to make insertions, indicate by adding initialed and dated marginal note indicating when the change and insertion are made.
6. Leave no blank pages between successive entries in the notebook. If a page or partial page is skipped, draw lines through the unused portions with the word “cancel,” and add initials and date in the margin along such areas.
7. Use the past tense of verbs to describe actions and experiments that were actually completed.
8. Label ideas or proposals or suggestions as such so that they may be differentiated from work actually performed.
9. State in detail how a proposed idea is to be carried into actual practice. If the indicated method turns out to be inoperative, then the record will prove only the conception of a problem, not the conception of an invention.
10. Be explicit about what was actually done.
11. When using abbreviations or terms, make sure they are “standard abbreviations or terms.” Use of terms and abbreviations should be explained in a table at the front or back of the notebook.
12. Record all experiments contemporaneously with the performance of the actual events. Do not use loose slips of paper to record data for subsequent entries.
13. Sign and date each page of the notebook as it is completed. For pages relating to ideas or laboratory work which may lead to important inventions, be sure to have each such page witnessed and dated as soon as possible after completion of the page.
14. In selecting a witness for the notebook, choose someone who is not likely to be an inventor or a co-inventor but who will understand the experiment when it is explained and who is able to read the relevant section in the notebook.

To document the invention, these steps should also be taken:

1. Try to preserve the “first samples” of new products or of products produced by a new method. To each sample, attach a permanent label dated and signed and witnessed.
2. Whenever an experiment or apparatus is new, it would be very helpful to photograph the project. All such photographs should be signed and dated and attached firmly to the relevant page of the notebook.

Contact OTL with any questions regarding notebooks and other documentation of research.

*When and how should an invention be disclosed to OTL?*

Ideally, OTL should be contacted to discuss an invention after there is some evidence that it works but prior to any public disclosure. Following discussion with OTL, may request submission of an invention disclosure form. An invention disclosure should fully describe the invention and its relevance so that OTL can properly assess its patentability and commercial potential and pursue patent protection if applicable.

Allow at least 30 days prior to any public disclosure to ensure adequate time to review and prepare a meaningful patent application.

*When constitutes public disclosure of an invention?*

Public disclosure may include:

- Oral or poster presentation at a scientific conference, to a company or to a non-federal grant funding agency
- Publication of a manuscript or abstract
- Sharing detailed information with investigators from other institutions.

*Does every invention disclosed to OTL result in a patent application?*

No. The substantial expense of obtaining patent rights — roughly up to $25,000 for a US patent and possibly over $100,000 for worldwide coverage — warrants critical examination of the commercial potential of each invention disclosure.

*What factors are used when deciding whether to file a patent?*

If OTL determines the invention has potential commercial value and is adequately supported by documentation from the inventor(s), City of Hope will initially file a provisional patent application in the United States. Within eight to nine months after filing the provisional application, OTL will ask the investigator for additional data that may have been generated since filing the provisional application and review any commercial interest in the invention. Commercial value will be reassessed as well as the likelihood the United States Patent and Trademark Office will allow a patent before a decision is made whether to file a regular (non-provisional) US patent application. At that time, OTL will also assess whether to file patent application(s) in foreign countries. Filing in foreign countries is very expensive and is reserved only for intellectual property that is expected to result in significant income for City of Hope or which is about to enter testing in clinical trials or is licensed to third parties willing to bear the financial expense.
When will OTL start marketing an invention?

As soon as possible with the inventor’s help. The inventor’s professional contacts can be very useful in bringing the technology to the attention of a commercial enterprise’s decision makers. The inventor’s active involvement can dramatically improve the chances of success.

How can the inventor assist OTL in marketing an invention?

The inventor can help OTL staff identify candidate companies that have the expertise and resources to bring the technology to the market. The inventor is asked not to approach companies without the participation of OTL. If companies approach the inventor, contact information should be obtained and brought to the attention of OTL immediately. OTL will coordinate the relationship and put in place a confidentiality agreement to ensure that any confidential information is preserved. The inventor may be asked to participate in telephone calls or meetings with companies to help explain the invention and its potential merits. OTL staff will help prepare the inventor for these discussions.

What is a license?

Intellectual property can be licensed to other parties. A license is a legal agreement, subject to federal, state and local regulatory authorities, by which a patent owner promises not to take action to exclude the licensed party from making, using or selling a potential invention. An exclusive license limits the use of the invention to a single group or entity, while a nonexclusive license allows for use by multiple concerns. A license may be for patented, patent pending technology or for unpatented biological materials. A license may be for patented, or patent pending technology, or for unpatented biological materials.

A license is a contract between a company and City of Hope to grant rights in the intellectual property to the company (licensee) in exchange for income for City of Hope. That income can include cash license fees and a percentage royalty on any future sales of products. A license agreement can be entered into with an established company or, under certain circumstances, with a new business venture (a “start-up” company). City of Hope seeks licensees that can demonstrate a clear and reasonable plan to make the technology broadly available in the marketplace. In every license agreement, City of Hope always retains the right to continue using the licensed intellectual property for internal research.
What do the inventors receive from a license agreement?

Under City of Hope’s Intellectual Property policy, City of Hope shares income from license agreements with the relevant inventors. Inventors get a share of all licensing fees and royalties received by City of Hope. Please review the City of Hope Intellectual Property Policy and contact OTL for additional details.

Points to Remember

- If in any doubt, ask OTL about any request to enter into an agreement or provide a signature
- If contacted by a commercial entity about your research, obtain contact information for OTL to follow up
- Maintain good documentation of all research
- Talk to OTL in advance of any public disclosure (e.g., talk, poster, paper submission) if the presentation includes important new scientific findings or ideas

RESEARCH FINANCE

What Our Purpose Is

The Research Finance Department is responsible for oversight and management of expenditures of the research institutional budgets and discretionary cost centers (80/90/92/98).

How We’re Organized

- **Call:** Extension 62373
- **Website:** Forms and Applications used by Research Finance and other business entities at City of Hope: [http://www.coh.org/forms-and-applications/Pages/default.aspx](http://www.coh.org/forms-and-applications/Pages/default.aspx)

What We Do

The department collaborates with department administrators on annual budgets, identifies and resolves budget variances and processes and tracks all research capital expenditures and investigator recruitment packages. Additionally, the department manages the financial activities of the cancer center support grant and the shared resource facilities.

The department reviews business expense reports, check requests, purchase requisitions, Human Resources requisitions and hierarchy change requests for adherence to established City of Hope policies and procedures.
Research Finance Orientation of Business Managers/Directors

The Research Finance Department provides training for new business managers/directors on the policies and procedures, processes and systems available to assist with the management and oversight of department financial activities. The business manager/director in the investigator’s department is a good resource for navigating the requirements and processes under the purview of the Research Finance Department.

Research Finance Policies, Procedures and Forms

The following forms, policies and procedures available via the City of Hope Intranet and are directly related to the business performed within the Research Finance Department.

- Business Manager/Director – Daily Period Range – All Years (Excel)
- Capital Expenditure Form
- Check Requests
- Contract Management
- Hierarchy Matrix
- Invoice Approval System
- International Travel Request Form
- Purchase Requisition System
- Virtual Account Manager

Research Finance Signature Requirements

Expense transactions against research institutional budget accounts or discretionary accounts (cost centers beginning in 80/90/92/98) require additional approval by Research Finance. This requirement is in addition to the hierarchy. Check Requests and Online Purchase Requisitions less than $500 do not require additional approval from Research Finance. All expense reimbursements, regardless of dollar amount, need Research Finance Approval.
COMPLIANCE

It is the policy of City of Hope to comply consistently and fully with applicable federal and state laws and regulations and to conduct all of its dealings ethically. This policy applies to all City of Hope Board members, Medical and Allied Health Professional Staff members, personnel and volunteers. This section covers some of the entities responsible for providing guidance to investigators and staff to ensure compliance with ethical and legal standards.
CORPORATE COMPLIANCE OFFICE

What Our Purpose Is

The Corporate Compliance Office coordinates City of Hope’s efforts to comply with the complex laws and regulations governing health care and research activities.

How We’re Organized

The Compliance Program is directed by City of Hope’s Chief Compliance Officer, who is assisted by Compliance Officers and a staff of associate or assistant compliance officers, managers and assistants.

- Call: Extension 64205 Compliance Office
- Call: (877) COH-COH8/(877) 264-2648 Anonymous Compliance Hotline
- Website: http://www.coh.org/corporate-compliance/Pages/default.aspx

What We Do

In September 1999, City of Hope’s Board of Directors adopted City of Hope’s Corporate Compliance Plan. This Plan is modeled after the US Department of Health and Human Services, Office of Inspector General’s Compliance Program Guidance for Hospitals, which was initially issued in February 1998 and updated with Supplemental Guidance in January 2005. The Corporate Compliance Office is responsible for the implementation of the Plan and does so through City of Hope’s Corporate Compliance Program entitled “A Matter of Integrity.”

Key elements of “A Matter of Integrity” are found in the Code of Conduct, which is a summary of City of Hope’s policies regarding ethical conduct and workplace behavior. It provides general guidance on subjects of wide interest within City of Hope and is required to be reviewed upon hire and annually thereafter as part of the performance evaluation process.

“A Matter of Integrity” includes an “open communication policy” which encourages personnel to come forward with compliance questions and concerns. A variety of avenues are available for this purpose, including an anonymous toll free compliance hotline. The Program also includes regular, mandatory compliance training for all City of Hope Board members, personnel, investigators, physicians and on-campus volunteers. The Program’s monitoring and auditing policy provides for regular reviews of operations to assure regulatory compliance and to address any errors or the possibility of any unethical or illegal conduct.

The Corporate Compliance Department is also assisted by the Corporate Compliance Committee and its sub-committees, standing committees that meet regularly to assist in assuring the effectiveness of the Compliance Program by ensuring that the objectives of the Program are reflected in City of Hope governance, risk management, information management and financial and operational activities.
Institutional Official

The Institutional Official (IO) is designated by City of Hope to ensure that research at City of Hope has the resources and support necessary to comply with all federal and state laws and regulations that govern research.

The IO is legally authorized to represent City of Hope in signing Assurances and assuming the obligations of City of Hope under those assurances. IO is responsible for:

- Overseeing the research review boards and committees including:
  - Institutional Animal Care and Use Committee (IACUC)
  - Institutional Biosafety Committee (IBC)
  - Institutional IND Quality Systems Committee (IIQSC)
  - Institutional Review Board (IRB)
  - Stem Cell Research Oversight Committee (SCRO)
  - Radiation Safety Committee (RSC)
- Assuring that the research review board and committee members have the appropriate knowledge to review research in accordance with ethical standards and applicable regulations
- Assuring that all investigators have the appropriate knowledge to conduct research in accordance with ethical standards and applicable regulations
- Facilitating investigator relationships with research components
- Overseeing the conduct of research performed by City of Hope’s investigators
- Overseeing the development and implementation of an educational plan for research members, staff and investigators

Conflict Of Interest

As part of City of Hope’s continuing efforts to identify and manage Conflicts of Commitment and Conflicts of Interest, the Board of Directors has established the Conflict of Interest and Commitment Committee (COICC). The COICC is an independent committee charged with serving as the representative of the Board in preserving the independent decision-making of the governance, operations and research mission of City of Hope pursuant to City of Hope COICC Policies.

RESEARCH PROTECTIONS

What Our Purpose is

Research Protections provides institutional oversight to ensure that all research at City of Hope is ethical, scientifically justified, performed with appropriate safeguards for safety and privacy, and conforms to Federal and State laws and guidelines.
How We’re Organized

Research Protections oversees the activities of the following committees:

- **Institutional Animal Care and Use Committee (IACUC)**
  - **Call:** Extension 80022
  - **E-mail:** RACCeSubmit@coh.org
  - **Website:** http://www.coh.org/iacuc/Pages/default.aspx
- **Institutional Biosafety Committee (IBC)**
  - **Call:** Extension 83371
  - **E-mail:** IBCeSubmit@coh.org
  - **Website:** http://www.coh.org/ibc/Pages/default.aspx
- **Occupational Safety and Biohazard Committee (OSBC)**
  - **Call:** Extension 83371
  - **E-mail:** OSBCeSubmit@coh.org
  - **Website:** http://www.coh.org/osbc/Pages/default.aspx
- **Stem Cell Research Oversight (SCRO) committee**
  - **Call:** Extension 83371
  - **E-mail:** SCRO@coh.org
  - **Website:** http://www.coh.org/scro/Pages/default.aspx
- **Institutional Review Board (IRB)**
  - **Call:** Extension 82700
  - **E-mail:** IRBeSubmit@coh.org
  - **Website:** http://www.coh.org/irb/Pages/default.aspx

Research Protections also oversees three committees not covered in this handbook: the Cancer Protocol and Review Monitoring Committee (CPRMC), the Protocol Review and Monitoring Committee (PRMC), and the Data and Safety Monitoring Committee (DMSC).

What We Do

Depending on the proposed research activities, submission to and review and approval from more than one committee may be required before work may commence.

_Compliance Committee Submission Deadlines and Meeting Dates_

Submission deadlines and meeting dates are listed on the Research Committees Calendar. Calendar features include adding meetings to the investigator's calendar and requesting e-mail reminders.

Compliance Committees Under Research Protections

_Institutional Animal Care and Use Committee (IACUC)_

The Institutional Animal Care and Use Committee (IACUC) is responsible for assuring that animal research, testing, and/or training protocols conducted at City of Hope involving live, vertebrate
animals are ethical, humane, scientifically justified and have the potential for advancement of science, medical knowledge and/or animal health.

The IACUC is also responsible for assuring that the City of Hope Institutional Animal Care and Use Program for the procurement, housing, and care and use of animals maintains full accreditation with the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and conforms to the Institute for Laboratory Animal Research (ILAR) Guide for the Care and Use of Laboratory Animals; all regulations of the United States Department of Agriculture (USDA) which implement the Animal Welfare Act (AWA) of 1966 and its amendments (9 CFR, Chapters 1, 2, 3); and the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals.

Investigators are required to secure IACUC approval prior to initiating research involving live animals.

**IACUC Training Required:** Regardless of previous training/work experience, all personnel listed on an IACUC protocol must complete the mandatory IACUC Animal User Training Program:

1. **CITI Online courses**
   - Investigators, Staff and Students (if listed on an IACUC protocol)
   - Reducing Pain and Distress in Laboratory Mice and Rats (if listed on an IACUC protocol)
   - Aseptic Surgery (if working with live animals)
   - Working with Mice in Research (if working with mice)
   - Working with Rats in Research Settings (if working with rats)
   - Working with the IACUC-Refresher (at 3 year anniversary of completing CITI courses)

2. **Introduction to City of Hope and Beckman Research Institute Animal Care and Use Program** (if listed on an IACUC protocol)

3. **Hands-on training sessions provided by the Animal Resource Center (ARC)**
   - Rodent Handling Restraint and Biomethodology (if working with rats or mice)
   - Rodent Aseptic Surgical Technique and Anesthesia (if working with rats or mice)
   - Rodent Survival Surgery Training (if conducting survival surgery)

**IACUC Submission Process:** All projects that include research activities under IACUC purview must be submitted through the Integrated Research Information Systems (iRIS). iRIS is the electronic system utilized by the IACUC to assist in the review and management of research projects.

Submissions must be made for:

- New Protocols
- Amendments to Ongoing Protocols, including changes in personnel
- Annual Continuing Review
- 3rd year Renewals (every 3rd year, the entire protocol is reviewed as if it were new)
- Unanticipated Problems
- Closures
IACUC Review Process: Once received, an IACUC protocol submission may require multiple review steps, including administrative review, attending veterinarian pre-review, assigned primary reviewer’s review and full committee review. Therefore, requests for submission of annual continuing reviews and 3rd year renewals should be addressed promptly to allow sufficient time for the submission process from review to approval.

At a convened meeting of a quorum of the members, the IACUC will review the submission and take one of four possible actions: (1) Approved/Approved with Comments; (2) Approval pending the conditions are met; (3) Deferred; (4) Disapproved. All IACUC review outcomes will be sent in writing to the investigator.

Lack of a prompt response to IACUC conditions will delay approval of new protocols or amendments. Lack of a prompt response to conditions regarding annual continuing review or 3rd year renewal that cause a delay in re-approval past the expiration of the previous approval will result in closure of the protocol. If the protocol is closed, no animal work described in the protocol will be permitted.

Investigators with approved IACUC protocols are responsible for the following:

1. To make sure that all research staff involved in the conduct of the animal research project have read, and have a clear understanding of, the IACUC approved protocol procedures and requirements.
2. To obtain IACUC approval prior to initiating any changes in the protocol. (No changes can be initiated until IACUC approval has been secured.)
3. To report to the IACUC any unexpected problems involving animals as soon as the investigator is aware of them.
4. If concordance review of an associated grant application is required, to contact the Director of Office of Laboratory Research Subjects Protection.

Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) is responsible for review of all research involving the use of recombinant or synthetic nucleic acid molecules (i.e., DNA, RNA), including the use of transgenic animals and plants. The IBC ensures all such research conducted at or sponsored by City of Hope is conducted in accordance with NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules regardless of funding source.
General responsibilities include review of research projects for compliance with NIH Guidelines in areas such as physical and/or biological containment levels, facilities, procedures, practices, training and expertise of personnel, as well as, institutional procedures and practices.

**IBC Training Required:** City of Hope does not offer any specific courses regarding use of recombinant or synthetic nucleic acid molecules. Investigators completing IBC Protocol Review Forms will be asked to provide a summary of experience and training of all personnel to demonstrate that the research team includes personnel with competency to safely perform the work described in the protocol.

**IBC Submission Process:** All research projects that include research activities under the purview of the IBC must be submitted to the IBC according to the submission requirements and using the Word protocol review forms posted on the IntraNet.

Prior to completing the IBC Protocol Review Form for a new research project, send an email to IBCeSubmit@COH.org to obtain an IBC protocol number. Include the assigned protocol number where indicated in the IBC Protocol Review Form.

Submissions must be made for:

- New Protocols
- Amendments to Ongoing Protocols, including changes in personnel
- Annual Continuing Review
- 3rd year Renewals (every third year the IACUC reviews the entire protocol as if it were a new project)
- Unanticipated Problems
- Closures

**IBC Review Process:** Investigators are required to secure IBC approval prior to experimentation using recombinant DNA materials and ordering or transport of genetically altered cells or materials that fall in the category of requiring IBC approval (review categories III-A, III-B, III-C and III-D). The IBC Protocol Review Form must be completed and submitted for research falling into categories III-E and III-F, but experiments may be initiated after the form has been submitted prior to receiving an acknowledgement from the IBC.
### III-A
Experiments that Require Institutional Biosafety Committee (IBC) Approval, Institutional Review Board (IRB) Approval, NIH Recombinant DNA Advisory Committee (RAC) Review, and NIH Director Approval **Before** Initiation. Example of experiments are (1) Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally.

### III-B
Experiments that Require NIH/OBA (Office of Biotechnology Activities) and IBC Approval **Before** Initiation. Example of experiments are (1) cloning of toxin molecules with LD$_{50}$ of less than 100 ng/kg.

### III-C
Experiments that Require IBC, IRB Approvals and NIH/OBA Registration **Before** Initiation. Example of experiments are (1) Deliberate transfer of rDNA, DNA or RNA derived from rDNA, into a human research participant.

### III-D
Experiments that Require IBC Approval **Before** Initiation. Example of experiments are (1) Using Risk Group 2 (RG2), RG3, RG4 or Restricted Agents as Host-Vector Systems (2) DNA from RG 2, 3, 4 or Restricted organisms is cloned into nonpathogenic prokaryotic or lower eukaryotic host vector systems. (3) Use of infectious DNA or RNA viruses in tissue culture (TC) systems. (4) Use of defective DNA or RNA viruses in presence of helper virus in TC systems. (5) Experiments involving whole animals. (6) Experiments involving whole plants. (7) Experiments involving 10 liters or more of culture.

### III-E
Experiments that Require IBC Notice **Simultaneous** with Initiation. Example of experiments are (1) Experiments involving the formation of rDNA molecules containing less than 2/3 of the genome of any eukaryotic virus.

### III-F
**Exempt** Experiments. Example of experiments are (1) Experiments that use rDNA molecules which are not conducted in organisms or viruses. (2) use of rDNA molecules that consist entirely of DNA segments from a single nonchromosomal or viral source, one or more segments may be synthetic. (3) rDNA derived entirely from a prokaryotic host including indigenous plasmids when propagated only in that host or closely related strain. (4) rDNA that derives entirely from a eukaryotic host including indigenous chloroplasts, mitochondria, plasmids but not viruses when propagated only in that host or closely related strain. (5) Experiments using only synthesized small interfering RNA’s (siRNA) to study gene expression.

At a convened meeting of a quorum of the members, the IBC will review the submission. The review outcome may include conditions that the investigator will be required to address to secure approval. For research in categories III-A through III-D, the IBC will take one of four possible actions: (1) Approved/Approved with Comments; (2) Approved with Conditions; (3) Deferred; (4) Disapproved. For research in categories III-E and III-F, the review outcome may be acknowledged or may include conditions that the investigator will be required to address first. All IBC review outcomes will be sent in writing to the investigator.

Lack of a prompt response to IBC conditions will delay approval of new protocols or amendments. Lack of a prompt response to conditions regarding annual continuing reviews or 3rd year renewals that delay re-approval past the expiration of the previous approval will result in closure of the protocol. If the protocol is closed, no work involving recombinant DNA molecules described in the protocol will be permitted.
Investigators with approved IBC protocols are responsible for informing the committee of any unexpected problems related to recombinant DNA research as soon as they are aware of them and not making any changes in review categories III-A through III-D until an amendment has been submitted, reviewed and approved by the IBC.

**Occupational Safety and Biohazard Committee (OSBC)**

The Occupational Safety and Biohazards Committee (OSBC) is responsible for review of all research involving the use of biohazardous materials (other than recombinant DNA under the purview of the IBC and radioisotopes under the purview of the RSC), chemicals, carcinogens, infectious agents and other safety hazards not covered by other institutional committees. The OSBC ensures that appropriate safety precautions for the conduct of research using such materials are in place and conform to regulatory and accrediting agency standards and guidelines.

Investigators are required to secure OSBC approval prior to conducting research activities under the committee’s purview.

**OSBC Training Required:** Investigators completing OSBC Protocol Review Forms will be asked to state the number of years experience each personnel has with the science described in the protocol. They will also be asked to indicate each personnel’s training status regarding the following:

- Hazardous Material Training
- Agent/Physical Specific
- Biosafety Level
- Bloodborne Pathogens
- Dangerous Goods Shipping

The research team must include personnel with the competency to safely perform the work described in the protocol.

**OSBC Submission Process:** All research projects that include research activities under the purview of the OSBC must be submitted to the OSBC according to the submission requirements and using the Word protocol review forms posted on the IntraNet.

Prior to completing the OSBC Protocol Review Form, send an email to OSBCeSubmit@COH.org to obtain an OSBC protocol number. Include the assigned protocol number where indicated in the OSBC Protocol Review Form.

Submissions must be made for:

- New Protocols
- Amendments to Ongoing Protocols, including changes in personnel
- Annual Continuing Review
• 3rd year Renewals (every third year the IACUC reviews the entire protocol as if it were a new project)
• Unanticipated Problems
• Closures

**OSBC Review Process:** At a convened meeting of a quorum of the members, the OSBC will review the submission. The review outcome may include conditions that the investigator will be required to address to secure approval. The OSBC will take one of four possible actions: (1) Approved/Approved with Comments; (2) Approved with Conditions; (3) Deferred; (4) Disapproved. All OSBC review outcomes will be sent in writing to the investigator.

Lack of a prompt response to OSBC conditions will delay approval of new protocols or amendments. Lack of a prompt response to conditions regarding annual continuing reviews or 3rd year renewals that delay re-approval past the expiration of the previous approval will result in closure of the protocol. If the protocol is closed, no work described in the protocol involving biohazardous materials and other physical hazards can be performed.

Investigators with approved protocols are responsible for informing the OSBC of any unexpected problems related to work described in the protocol as soon as they are aware of them and not making any changes until an amendment has been submitted, reviewed and approved by the OSBC.

**Stem Cell Research Oversight (SCRO) Committee**

The Stem Cell Research Oversight (SCRO) committee is responsible for providing oversight of human pluripotent stem cells and certain neuronal stem cell research activities. SCRO ensures that research proposals involving human stem cells are ethical and scientifically justified, and that they conform to California Institute for Regenerative Medicine (CIRM) Regulations regardless of funding source.

Investigators are required to secure SCRO approval prior to conducting research activities under the committee’s purview.

**SCRO Training Required:** City of Hope does not offer any specific courses regarding use of stem cells. Investigators completing SCRO Protocol Review Forms will be asked to provide a summary of experience, training and qualifications of all personnel to demonstrate that the research team includes personnel with competency to safely perform the work described in the protocol.

**SCRO Submission Process:** All research projects that include research activities under the purview of the SCRO must be submitted to the SCRO through the Integrated Research Information Systems (iRIS). iRIS is the electronic system utilized by the SCRO to assist in the review and management of research projects.

Submissions must be made for:

• New Protocols
• Amendments to Ongoing Protocols, including changes in personnel
• Annual Continuing Review
• Unanticipated Problems
• Closures

SCRO Review Process: At a convened meeting of a quorum of the members, the SCRO will review the submission. The review outcome may include conditions that the investigator will be required to address to secure approval. The SCRO will take one of four possible actions: (1) Approved/Approved with Comments; (2) Approved with Conditions; (3) Deferred; (4) Disapproved. All SCRO review outcomes will be sent in writing to the investigator.

Lack of a prompt response to SCRO conditions will delay approval of new protocols or amendments. Lack of a prompt response to conditions regarding Annual Continuing Review that delays re-approval past the expiration of the previous approval will result in closure of the protocol. If the protocol is closed, no work described in the protocol involving stem cells will be permitted.

Investigators with approved SCRO protocols are responsible for not making any changes until an amendment has been submitted, reviewed and approved by the SCRO.

Institutional Review Board (IRB)

The City of Hope Institutional Review Board (IRB) is required to review and approve all research projects involving human subjects prior to the initiation of research activity. The IRB ensures that research proposals involving human subjects conform to federal Office of Human Research Protections (OHRP) Title 45 Code of Federal Regulations Part 46, Food and Drug Administration (FDA) Title 50 Code of Federal Regulations Part 21, and Health Information Portability and Accountability Act (HIPAA) as applicable to research, regardless of funding source.

Investigators conducting projects involving human subjects are responsible for ensuring that appropriate IRB approval is obtained and for complying with the requirements of City of Hope policies and procedures governing human subjects research.

Human Subjects Research Training Required: Prior to participating in any research project involving human subjects, all key personnel are required to complete the training courses listed below. Failure to complete any of the training courses will result in the inability to participate in research studies involving human subjects and/or a possible delay in the approval of a submission. Please note that courses can be completed in parallel with completing the IRB application.

1. Clinical Research Certification Training (CRC)

   The CRC gives an overview of basic human subject principles and must be completed and renewed every 3 years to continue conducting research involving human subjects. For instructions on completing this training, visit the Clinical Research Training Office Intranet site.

2. Adverse Event and Unexpected Problem (AE/UP) Training

   This course provides an overview of City of Hope’s policy regarding reporting of adverse events and unanticipated problems. This training is completed once and does not require renewal.
IRB Submission Process: All research projects that include research activities under the purview of the IRB must be submitted to the IRB through the Integrated Research Information Systems (iRIS). iRIS is the electronic system utilized by the IRB to assist in the review and management of research projects.

Submissions must be made for:

- New Protocols
- Amendments to Ongoing Protocols, including changes in personnel
- Annual Continuing Review
- 5th Year Renewals (every third year the IRB reviews the entire protocol as if it were a new project)
- Unanticipated Problems
- Closures

IRB Review Process: The IRB review process is generally separated into four processes. For basic science investigators, the most common review processes used will generally be non-human subjects, exempt and expedited.

The diagrams below illustrates the IRB workflow of a submission through final approval:
CPRMC/PRMC and IRB Decision Tree

Does my project involve research or the use of an FDA regulated article?*

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(d)

YES

Does it involve human subjects?

Human subject means a living individual about whom an investigator conducting research obtains:
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information. 45 CFR 46.102 (f)

YES

The project meets the definition of 'research' or involves the use of an FDA regulated article and 'human subjects'. You must submit an application in IRIS for IRB and CPRMC/PRMC review.

NO

No submission necessary to either CPRMC/PRMC or IRB.

NO

Does it involve Cancer Center resources?

YES

Submit to CPRMC by completing the non human subjects IRIS application. The IRB will release a Non Human Subjects Research determination.

NO

Submit to PRMC by completing the non human subjects IRIS application. The IRB will release a Non Human Subjects Research determination.

* Quality improvement and quality assurance activities may or may not constitute 'research.' See OHRP website for additional guidance and contact the Office of Human Research Subjects Protection at x62700 for guidance.
**Non Human Subjects Determination**: In order for a project to require review by the IRB, it must meet the definition of research and involve human subjects as defined by the *Common Rule (45 CFR 46)*:

- **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(d)
- **Human subject** means a living individual about whom an investigator conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. 45 CFR 46.102(f)

To fall under *Food and Drug Administration (FDA) regulations*, projects must involve a regulated FDA article, meet the definition of a clinical investigation and involve human subjects.

To determine if your project needs requires IRB review, use the decision tree below:

**Exempt Review**: Submissions meeting the exempt criteria do not need to be reviewed at a fully convened IRB meeting. OHRSP is responsible for determining whether a submission qualifies for exempt review. Common examples of research activities which may qualify for exempt review are:

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

**Expedited Review**: Submissions meeting the expedited process criteria do not need to be reviewed at a fully convened IRB meeting. OHRP is responsible for determining whether a submission qualifies for expedited review. Common examples of research activities which may qualify for expedited are:

- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
• Prospective collection of biological specimens for research purposes by noninvasive means. Examples include
  - hair and nail clippings in a non-disfiguring manner;
  - deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - permanent teeth if routine patient care indicates a need for extraction;
  - excreta and external secretions (including sweat);
  - uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
  - placenta removed at delivery;
  - amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques:
    - mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
    - sputum collected after saline mist nebulization.

• Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

**Waiver of Informed Consent and HIPAA Authorization**: Examples of research studies that may qualify for a waiver of informed consent and HIPAA authorization include retrospective chart reviews and retrospective specimen collections. Any project requesting a waiver must meet these requirements:

• **Waiver of Informed Consent**: Federal regulations permit a waiver of informed consent when the investigator can justify the waiver as meeting the following criteria outlined at 45 CFR 46.116(d) and 45 CFR 164.514(e):
  - The research involves no more than minimal risk to the subjects.
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects.
  - The research could not practicably be carried out without the waiver or alteration.
  - Whenever appropriate, the subjects will be provided with additional information after participation.

• **Waiver of HIPAA Authorization**: To qualify for waiver of HIPAA Authorization, investigators must indicate:
  - An adequate plan exists to protect protected health information (PHI) identifiers from improper use and disclosure.
  - An adequate plan exists to destroy those identifiers at the earliest opportunity, consistent with the research, or as otherwise required by law.
  - There is adequate written assurance that the PHI will not be reused or disclosed to any other person or entity except as required by law; for authorized oversight of the research project; or for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.
Review of Use of Specimens from the City of Hope Biorepository. One of the main objectives of the Pathology Core is to provide investigators access to optimally preserved tumors and normal tissues. For information about how to use and draw down specimens from City of Hope’s Biorepository, see the workflow on the following page. This workflow demonstrates how to navigate through the regulatory systems at City of Hope and obtain specimens.
RADIATION SAFETY COMMITTEE (RSC)

The Radiation Safety Committee (RSC) is administrated by the Occupational Safety and Health Department (OSHD). The RSC is responsible for review of all uses of radioactive materials at City of Hope. This includes all radioactive material and radiation emitting machines and devices. The RSC ensures that guidelines and practices are established for the protection of the health care and research staff from radiation exposure that is consistent with keeping radiation exposure “as low as reasonably achievable” (ALARA). The RSC also ensures the safety and comparable care for patients receiving diagnostic and therapeutic doses of radioactive materials; and ensures the safety of visitors and families of patients receiving therapeutic and diagnostic doses of sealed and unsealed radioactive materials. These activities are conducted in accordance with Nuclear Regulatory Commission Regulations at Title 10 Code of Federal Regulations Part 20, Title 17 of the California Code of Regulations (CCR), the City of Hope Radioactive Materials License and the City of Hope Radiation Safety Manual.

RSC Training Required: The State of California, in agreement with the Nuclear Regulatory Commission (NRC), requires that every individual that works with radioactive materials receive initial training on the protection and proper handling of isotopes and radiopharmaceuticals in their workplace, as well as annual refresher training.

The Radiation Safety Committee will suspend the Radioactive Material Use Permit where Authorized Users or their Technical Staff are found to be delinquent in completing the annual refresher training requirements following a 30 day grace period from the assigned date. The permit will be reinstated once the Radiation Safety Committee has been provided with appropriate documentation of training.

RSC Submission Process: All research projects that include work under the purview of the RSC must be submitted to the RSC according to the submission requirements and using the Word forms posted on the Radiation Safety Forms Intranet page. Submissions must be made for:

- Non-human use of radioactive material
- Use of radioactive materials with animals
- Use of radiation-producing devices with animals
- Human use of radioactive material
- Facility use of radioactive material
- Machine use of radioactive material
- Amendments to previously approved uses

RSC Review Process: At a convened meeting of a quorum of the members, the RSC will review the proposals and take one of four possible actions: (1) Approved/Approved with Comments; (2) Approved with Restrictions or Recommendations; (3) Deferred; (4) Disapproved. All RSC actions and reasons for their decisions will be sent in writing to the investigator.
City of Hope is committed to creating a great work environment. This section covers additional resources for investigators to manage and enhance their career at City of Hope.
OFFICE OF ACADEMIC AFFAIRS

What Our Purpose Is

The Office of Academic Affairs (OFA) is responsible for the management of academic activities in the Beckman Research Institute and City of Hope Medical Center. This includes oversight of faculty appointments, promotions, evaluation, recruitment and grievances. Policies and Procedures for Academic Appointments and Promotions defines the policies and procedures for faculty, in terms of appointments and promotions.

How We’re Organized

The Office of Academic Affairs (OFA) is an independent office under the direction of the Dean for Faculty Affairs. The staff consists of the Program Manager assisted by an Academic Personnel Coordinator and a Project Specialist.

- **Call:** Extension 62238, 60737 or 31252
- **Website:** [http://www.coh.org/faculty-affairs/Pages/default.aspx](http://www.coh.org/faculty-affairs/Pages/default.aspx)
- **Website:** [http://www.coh.org/faculty-senate/Pages/default.aspx](http://www.coh.org/faculty-senate/Pages/default.aspx)

What We Do

The OFA oversees the academic activities of the following appointment titles in one of three series Assistant, Associate and Full:

- Professor
- Research Professor
- Clinical Professor
- Adjunct Faculty
- Visiting Faculty

The office oversees the activities of the following committees:

- Executive Committee of the Faculty Senate
- Full Senate or Members at Large
- Appointments and Promotions
- Nominating Committee
- Grievance Committee

The Faculty Senate consists of all members in the Professor, Research Professor and Clinical Professor series. Senate members have voting rights and participate in the quarterly meetings and functions as described in the Bylaws of the Faculty Senate of City of Hope.
FINDING ADDITIONAL LABORATORY PERSONNEL

Graduate School Students

Each first year student at the **Irell & Manella Graduate School of Biological Sciences** is required to have a minimum of three lab rotations. The purposes of the rotations are (1) to help students find the research area and lab in which they want to conduct their thesis research, (2) to learn experimental techniques, and (3) to expose students to a broad range of intellectual and technical approaches to address current research challenges. Each lab rotation is carried out in a different lab and lasts from ten to twelve weeks. The student is expected to spend a minimum of 20 to 25 hours per week in the lab during a rotation. It is also expected that the student perform at an exceptional level in advanced coursework during this time and thus should be allowed some leeway to study during weeks when they have examinations.

Summer Students

City of Hope’s **Eugene and Ruth Roberts Summer Student Academy** gives curious and hardworking students the opportunity to learn about science by actually doing it. Selected participants then spend 10 weeks working full-time as a member of a biomedical research team. Investigators serve as mentors who guide students in their research, while helping them develop their critical thinking skills.

Human Resources Hiring Department

A staffing need might come about as the result of personnel turnover, the creation of a new position, or increased workload. Contact the **Business Manager/Director** prior to posting or hiring for a position. The chart below provides an overview of the significant hiring process activities.
Department Hiring Process – Flow Chart

1. Dept identify staffing need
2. Identify funding support
3. Define and write up job description
4. Complete “Request for Hire”
5. Forward job description to HR
6. Regular hire?
   - Yes
     - HR hiring process
   - No
     - NES hiring process

HR hiring process

Candidate is selected

Visa sponsorship?
- Yes
  - INSZoom visa application
- No
  - PTO Offer Letter Request

Post-doc position?
- Yes
  - RSO offer letter
- No
  - OFA offer letter

Offer Letter approved

Candidate accepts?
- Yes
  - Candidate hired
- No
  - Continue process
COMMUNICATIONS

What Our Purpose Is

City of Hope’s media relations team works with national, regional and local news media to inform the public about the institution’s medical/scientific advances, events and other notable news.

How We’re Organized

City of Hope’s Communication Department falls under the Philanthropy and External Relations Group. Investigators who have a newsworthy idea or who have been approached by the media are asked to contact the media relations office.

- Contact: Extension 68215.
- Website: [http://www.coh.org/communications/Pages/default.aspx](http://www.coh.org/communications/Pages/default.aspx)

What We Do

Activities handled by media relations include:

- Writing and distributing press materials
- Media cultivation and outreach
- Coordinating live and taped media interviews with newspapers, news wires, television, radio and Internet
- Management of campus photo and video shoots
- Fulfilling inquiries from news organizations
- Media and presentation training of faculty, other spokespeople
- Management and preparation of official statements on various topics (e.g., stem cell research at City of Hope)
- Emergency communications (internal and external)
- Media monitoring, reporting and analysis
- Production of reprints, video/audio copies of news coverage
- Contributions to various City of Hope publications

Funding for research is getting more difficult to obtain, so communicating the research done at City of Hope is important. Investigators who have news to share are asked to pass it on to the communications team. They are interested in positive stories for City of Hope internal and external publications, media outreach and social media channels.

For example, if an investigator is the first or senior author of a project that will be published, will be speaking at a conference, has won an award or has an interesting personal story or intriguing research story, the communications team would like to know about it.
EMPLOYEE HEALTH SERVICES

What Our Purpose Is

Employee Health Services (EHS) focuses on the health and safety of personnel related to the work environment.

How We’re Organized

Employee Health Services (EHS) is under Human Resources (HR).

EHS Office and Clinic

- **Location**: Modular 90
- **Hours**: Monday – Friday 6:30 a.m. - 5:00 p.m.

Walk-In TB Clinic

- **Location**: Modular 90
- **Hours**: Mon, Tue, Wed, and Fri 6:30 a.m. - 10:00 a.m.

After Hours, Weekends and Holidays

- **Location**: The Evaluation Treatment Center located in Brawerman 1A provides first aid for injured personnel.

Website: [http://www.coh.org/hr/ehs/Pages/default.aspx](http://www.coh.org/hr/ehs/Pages/default.aspx)

What We Do

Initial and Ongoing Health Screening

A brief physical examination, evaluation of immunization status and tuberculosis (TB) screening is required before beginning work. An annual update consisting of a health questionnaire is required for all personnel.

Immunization and Surveillance

All personnel whose workspace is located in a building that renders clinical services or who work in the Animal Resource Center facility are required to maintain compliance with the City of Hope Immunization Policy:

- Tuberculosis (TB) Surveillance Program – negative test of chest x-ray annually
- Rubella (Measles) – evidence of vaccination or blood test proof of immunity
- Mumps – evidence of vaccination or blood test proof of immunity
- Rubella – evidence of vaccination or blood test proof of immunity
• Varicella (Chickenpox) – evidence of vaccination, blood test proof of immunity or diagnosis or history of varicella or herpes-zoster disease documented by a health care provider
• Tetanus, diphtheria and pertussis (TDAP) vaccine – current vaccine every ten years
• Influenza – vaccine is offered as available
• Meningococcal - personnel with anatomic or functional asplenia, persistent complement component deficiencies or HIV infection should be vaccinated.
• Hepatitis B – Vaccine is offered to all personnel as indentified in the City of Hope Blood Borne Pathogen Exposure Plan in the Infection Control Manual - evidence of vaccination or blood test proof of immunity

Individuals, who choose not to be vaccinated against measles (rubeola), mumps, rubella, varicella, Tdap, or meningococcal must sign the corresponding waiver forms. Non-immune personnel who are occupationally exposed to a vaccine-preventable disease may be furloughed off work during the period of communicability with pay. Other immunizations may be offered to personnel by EHS which are not required under the City of Hope Immunization Program. A Tetanus diphtheria (Td) vaccine is offered to staff that sustain a work-related laceration or puncture wound.

Work Related Injury or Illness

Any health issue that occurs on the job should be reported as it occurs. EHS will assess the problem, provide first aid and determine if further treatment is needed.

Hazardous Chemical Exposure

Personnel are referred to EHS for evaluation, treatment and possible referral when they:

• Exhibit signs or experience symptoms associated with exposure to a hazardous chemical in the laboratory
• Are exposed routinely above the action level or, in the absence of an action level, above the Permissible Exposure Limit (PEL) for an OSHA regulated substance for which there is exposure monitoring or medical surveillance requirements
• When a spill, leak, explosion, or other accident occurs in the work area that results in a potential significant exposure to a hazardous chemical

If EHS is closed, staff is seen at the Evaluation and Treatment Center (ETC), a 24-hour, 7-day per week urgent care clinic on the campus grounds. For more serious injuries beyond the scope of care
provided at EHS or ETC, an industrial clinic is available for staff to receive complete care. In emergent situations 911 is called.

City of Hope provides the physician doing the medical evaluation or consultation with the following required information:

- The identity of the hazardous chemical,
- Conditions under which the exposure occurred and
- A description of the signs and symptoms experienced by the worker.

This is accomplished through information provided in the Supervisor’s Report of Injury and additional correspondence provided by the Occupational Safety and Health Department (OSHD).

City of Hope obtains the following required information from the physician after medical evaluation or consultation:

- Any written opinion for a recommended follow-up examination, medical exam and the attendant test results
- Any detected medical conditions of the personnel that might pose increased risk
- A statement that the personnel was informed of the medical examination/consultation results

City of Hope maintains for each personnel an accurate record of exposure monitoring results and any medical consultation and examinations, including tests or physician medical opinions. Such records must be kept, transferred and made available in accordance with OSHA’s rule governing access to personnel exposure and medical records (29 CFR 1910.1020).

**TRAVEL**

Egencia Corporate Travel (through Expedia) is City of Hope’s exclusive travel management provider for all business related travel including air, hotel, and rental car services for corporate travel. Travel must be in the most economical and appropriate manner to meet the business objectives of City of Hope. This includes the selection and use of City of Hope-preferred vendors. Air travel arrangements, hotels and car rentals are to be made through the City of Hope Authorized Travel Agency. Any exception to the following criteria will be identified for management’s consideration during the online pre-trip approval process. All travel requests made through Egencia Corporate Travel will be sent to the individual at City of Hope authorized to approve the individual’s travel.

City of Hope personnel and their eligible dependents may utilize the corporate travel program and negotiated rates for personal travel. Personal travel requires a personal credit card payment at the time of booking travel arrangement.

See the Intranet Travel site for current Travel Policies and Procedures, User Access Manuals and Expedia Online User Manual.
CLOSING A LABORATORY

There are several steps and activities that are required when a person’s employment with City of Hope/Beckman Research Institute ends. Some of the items described are done by the departing personnel and other tasks are accomplished for his/her administrator. All the applicable items must be properly completed prior to withdrawal from active employment status. A checklist is provided to use as a reference when departing from the City of Hope/Beckman Research Institute.

This section is under development.
ACKNOWLEDGEMENTS

The Basic Research Handbook is the collective work of a diverse team of colleagues committed to making the handbook user-friendly and responsive to the needs of investigators and their staff.

The BRH Working Group developed the format and provided most of the sections. The members are Jocelyn Cumming, Business Director for Virology and Molecular & Cellular Biology, Nancy Debrettsion, Manager in the Office of Laboratory Research Subjects Protection, Rick Gulizia, Director of the Office of Laboratory Research Subjects Protection, Janet Mendoza, Time and Effort Administrator in the Office of Sponsored Research, Chuck Pickering, Director of Safety and Occupational Health and Chief Safety Officer for the City of Hope, Frances Solano, Director of the Office of Sponsored Research, and Noe Gonzales, Manager of Research Facilities and Emergency Planning. Nancy Jenkins and Amy Stillings, who are no longer at City of Hope, contributed to early drafts of the handbook.

The following individuals also wrote sections or provided valuable information: Ileana Abich, Academic Personnel Program Manager, Janet Crum, former Director of Library Services, Mindy Dunkle, Contract Management Systems Administrator, Kenneth Golding, Animal Resources Center Manager, Sharon Gonzalez, Human Resources Coordinator, Kimberly Hosozawa, Creative Services Operations Manager, Christine Hui, IRB Operations Director, Cathreen Johnson, Employee Health Nurse Practitioner, Stacy Kimmel, Director of Creative Services, Shella Sarino-Gaor, Lead for Immigration Services and Fausto Velasco, Facilities and Logistics Support Hub Consultant.

Creative Services and the Office of Technology Licensing provided photos and other images. Kristen Santoni of Creative Services and Samuel Debrettsion, as a volunteer, consulted on the layout.

The following individuals reviewed the completed draft and recommended changes to the current version: Ileana Abich, Jonathan Espenschied, Director of Graduate Medical Education and Clinical Training, and Jeremy Jones, Assistant Professor in Molecular Pharmacology.
The Basic Research Handbook is intended to keep pace with changes in research at City of Hope and in the needs of the research community.

If you have any comments, corrections and/or suggestions for additions and improvements, please take a moment to e-mail feedback to Nancy Debretsion at ndebretsion@COH.Org.

Your input will help keep this handbook useful.