

## **Service Level Understanding**

**Research Development & Administration Department:** **OHSU Research Integrity Office**

**Effective Date:** **October 1, 2006**

**Term:** One year, to be reviewed annually, review to start at least 60 days before end of term.

This Understanding identifies: baseline and optional services to be provided by the OHSU Research Integrity Office (ORIO) to the Operating Unit (OU) during the Term, performance expectations for those services, obligations of the OU in accessing those services, any costs to the OU for optional services, those persons with oversight responsibility and authority for ORIO and the OU, and contact information.

### **1. ORIO Services**

**Baseline Services of ORIO:**

See Schedule 1, Section A. ORIO will provide on-going assistance and consultation for OUs and individual investigators and their staffs. Because timely review and approval of submissions requires that investigators provide complete and correct materials, ORIO will assist investigators in creating complete and correct submissions via posted guidance and checklists, telephone consultations, and live sessions. Following committee review of protocols, investigators will be notified of the committee's decision and requirements as soon as ORIO staffing levels and workload permit, but, on average, within 5 calendar days after the review. Following receipt of the investigator's response to a review communication and submission of revised documents, a follow-up communication (final approval or request for information or further revisions) will be issued within 7 calendar days, on average.

**Optional Services of ORIO:**

See Schedule 1, Section B

**Limitations on Services of ORIO:**

ORIO services that depend upon the review of compliance committees (IRB, IACUC, IBC, CoIRC) are available and, on average, will be delivered within the stated times, so long as the committees are adequately staffed and include adequate representation among the voting members of the committees. Departments that use the services of the review committees must provide representation on the committees in the department's area of specialty or expertise or they may encounter review and approval times that exceed those posted in Schedule 1.

### **2. Operating Unit Responsibilities:**

The OU must comply with all applicable policies and laws. In addition, the OU must ensure that all investigators and study staff have completed RCR education and any other applicable training requirements, reviewed and followed posted submission guidelines, filed a current CoIR

disclosure, and have reviewed the Roles & Responsibilities in Research document. Investigators within the OU must ensure that their submissions are complete and correct. The OU must identify sufficient and appropriate members for human subjects, animal subjects, institutional biosafety, and other review committees. The performance parameters in this SLU presume that the OU will respond to review committee and ORIO communications in a timely manner. It is expected that the OU's response will be received in ORIO within 30 days of issuing the communication. OUs are expected periodically to invite ORIO representatives to regular faculty, staff, or other OU meetings so that ORIO may directly interact with investigators and their staffs.

**3. Administration of this Understanding:**

See Schedule 2

**Schedule 1 (All days are expressed as calendar days)**

**A. Baseline Services**

<b>Services</b>	<b>Availability</b>	<b>RDA Service Level</b>	<b>Responsible Party</b>
<b>HUMAN SUBJECTS RESEARCH</b>			
Initial reviews of human subjects research protocols – Full Board review	M-F, 8 AM to 5 PM	Initial study submissions will be documented in the eIRB and receive an initial assessment by ORIO staff within 5 days to determine if the submission is complete and correct. Complete & correct submissions will be placed on an agenda within 15 days of receipt of all necessary documents and information within the eIRB system.	IRB analysts, IRB chair & co-chair
Initial reviews of human subjects research protocols – Expedited review	M-F, 8 AM to 5 PM	Initial study submissions that qualify for expedited review will be documented in the eIRB and receive an initial assessment by ORIO staff within 3 days to determine if the submission is complete and correct. These protocols will be forwarded to the chair/co-chair for review. Complete & correct submissions will be reviewed within 7 days of receipt of all necessary documents and information within the eIRB system.	IRB analysts, IRB chair & co-chair
Continuing reviews of human subjects research protocols – Full Board review	M-F, 8 AM to 5 PM	Continuing reviews of approved studies must take place within 1 year of initial approval. Submissions will be documented in the eIRB and receive an initial assessment by ORIO staff within 3 days to determine if the submission is complete and correct. Complete & correct submissions will be placed on an agenda after receipt of all necessary documents and information within the eIRB system and not less than 3 weeks prior to the study's approval lapse date.	IRB analysts, IRB chair & co-chair
Continuing reviews of human subjects research protocols – Expedited	M-F, 8 AM to 5 PM	Continuing reviews of approved studies must take place within 1 year of initial approval. Submissions that qualify for expedited review will be documented in the eIRB and receive an initial assessment by ORIO staff within 3 days to	IRB analysts, IRB chair & co-chair

review		determine if the submission is complete and correct. Complete & correct submissions will be reviewed within 7 days of receipt of all necessary documents and information within the eIRB system.	
PRAF reviews of human subjects research protocols – Full Board review	M-F, 8 AM to 5 PM	Changes to approved studies and to approved study documents, including new sources of funding, must receive prospective review and approval by the IRB. PRAFs that require FB review will be documented in the eIRB and receive an initial assessment by ORIO staff within 3 days to determine if the submission is complete and correct. Complete & correct submissions will be placed on an agenda within 15 days of receipt of all necessary documents and information within the eIRB system.	IRB analysts, IRB chair & co-chair
PRAF reviews of human subjects research protocols – Expedited review	M-F, 8 AM to 5 PM	Changes to approved studies and to approved study documents, including new sources of funding, must receive prospective review and approval by the IRB. PRAFs that qualify for expedited review will be documented in the eIRB and receive an initial assessment by ORIO staff within 3 days to determine if the submission is complete and correct. Complete & correct submissions will be reviewed within 7 days of receipt of all necessary documents and information within the eIRB system.	IRB analysts, IRB chair & co-chair
Adverse Event reviews for human subjects research protocols – Full Board review	M-F, 8 AM to 5 PM	Serious adverse events must be reported to the IRB for review and appropriate follow-up. AEs that require FB review will be documented in the eIRB, triaged, and placed on an agenda for FB review within 10 days of receipt of all necessary documents and information within the eIRB system.	IRB analysts, IRB chair & co-chair
Adverse Event reviews for human subjects research protocols – Expedited review	M-F, 8 AM to 5 PM	Serious adverse events must be reported to the IRB for review and appropriate follow-up. AEs that qualify for expedited review will be documented in the eIRB, triaged, and forwarded to the chair/co-chair for review within 7 days of receipt of all necessary documents and information within the eIRB system.	IRB analysts, IRB chair & co-chair
Protocol Deviation reviews – Expedited review of minor PDs in human subjects protocol	M-F, 8 AM to 5 PM	Any deviation from the IRB approved protocol must be reported to the IRB for review and appropriate follow-up. This includes any failure to use currently approved documents. PDs that qualify for expedited review will be documented in the eIRB, triaged, and forwarded to the chair/co-chair for review within 7 days of receipt of all necessary documents and information within the eIRB system.	IRB analysts, IRB chair & co-chair
Protocol Deviation reviews – Hearing convened for major PDs in human subjects protocol	M-F, 8 AM to 5 PM	Any deviation from the IRB approved protocol must be reported to the IRB for review and appropriate follow-up. PDs that place human subjects at significantly increased risk or that are continual will be documented in the eIRB, triaged, and forwarded to the chair/co-chair for review within 7 days. A determination that the PD is major will necessitate a hearing. This will be scheduled and conducted according to the Protocol Deviation policy.	IRB analysts, IRB chair & co-chair
Review and approval for	24/7, use is	FDA regulations permit the treatment use of a test article in an emergency where	IRB chair & co-chair, ORIO

emergency use of a test article (drug or device)	reported to next scheduled FB meeting	no other alternatives are available. The IRB administrative staff may provide permission for such use and report it at the next assembled FB meeting. Same day approval is available when all pertinent information and documentation are available.	director & associate director
<b>VERTIBRATE ANIMAL SUBJECT RESEARCH</b>			
Initial reviews of animal subjects research protocols – Full Board review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
Initial reviews of animal subjects research protocols – Expedited review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
Continuing reviews of animal subjects research protocols – Full Board review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
Continuing reviews of animal subjects research protocols – Expedited review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
PRAF reviews of animal subjects research protocols – Full Board review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
PRAF reviews of animal subjects research protocols – Expedited review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
Adverse Event reviews for animal subjects research protocols – Full Board review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
Adverse Event reviews for animal subjects research protocols – Expedited review	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager

Protocol Deviation reviews – Expedited review of minor PDs in animal subjects protocol	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
Protocol Deviation reviews – Hearing convened for major PDs in animal subjects protocol	M-F, 8:30 AM to 5:30 PM	TBD Pending Staffing Changes	IACUC chairs & manager
<b>CONFLICT OF INTEREST IN RESEARCH</b>			
Conflict of Interest in Research disclosure review – Full Committee	M-F, 8 AM to 5 PM	Investigators and study staff must complete and file a CoIR disclosure no less frequently than annually. ORIO will send annual reminders in advance of the submission deadline and process and track responses. Complete and correct disclosures requiring full committee review will be placed on an agenda within 30 days of receipt of completed documentation within the CoIR manager’s office. Review communications will be sent as soon as staffing levels permit, but, on average, within 2 days of the committee’s determination.	CoIRC chair & co-chair & CoIRC
Conflict of Interest in Research disclosure review – Expedited	M-F, 8 AM to 5 PM	Investigators and study staff must complete and file a CoIR disclosure no less frequently than annually. ORIO will send annual reminders in advance of the submission deadline and process and track responses. Expedited disclosures will be reviewed within 14 days of receipt of completed documentation within the CoIR manager’s office. Review communications will be sent as soon as staffing levels permit, but, on average, within 14 days of the expedited review.	CoIRC chair & co-chair
<b>INSTITUTIONAL BIOSAFETY, rDNA, GENE TRANSFER STUDIES</b>			
Infectious agent and rDNA protocol initial review	M-F, 8 AM to 5 PM	Use of infectious agents or recombinant DNA (rDNA) technology for research requires Institutional Biosafety Committee (IBC) review and approval or designation of exemption. Complete & correct submissions that are not exempt will be placed on an agenda within 4 weeks of receipt of all necessary documents and information within the rDNA manager’s office. Review communications will be sent as soon as staffing levels permit, but, on average, within 21 days of the committee’s determination. For rDNA projects exempt from review, exempt determinations will be issued within 7 days of receipt of all necessary documents and information within the rDNA manager’s office.	ORIO IBC manager & IBC
Continuing reviews of Infectious agent and rDNA protocols - Full Board review	M-F, 8 AM to 5 PM	Continuing review of some infectious agent or recombinant DNA projects (e.g., human gene transfer studies) must take place within 1 year of initial approval. Complete & correct submissions for studies requiring full board annual review will be placed on an agenda within 30 days of receipt of all necessary	ORIO IBC manager & IBC

		documents and information within the rDNA manager's office. Review communications will be sent as soon as staffing levels permit, but, on average, within 21 days of the committee's determination.	
Continuing reviews of Infectious agent and rDNA protocols – Expedited review	M-F, 8 AM to 5 PM	Continuing review of some infectious agent or recombinant DNA projects (e.g., human gene transfer studies) must take place within 1 year of initial approval. Continuing review submissions for those studies qualifying for expedited annual review will be reviewed by the IBC manager, Biosafety Officer(s), and the IBC chair if needed. Complete & correct submissions will be reviewed within 14 days of receipt of all necessary documents and information within the rDNA manager's office. Review communications will be sent as soon as staffing levels permit, but, on average, within 14 days of the expedited review.	ORIO IBC manager & IBC
Infectious agent and rDNA protocol modifications -Full board review	M-F, 8 AM to 5 PM	Changes to approved IBC registrations must receive prospective review and approval by the IBC. Complete & correct submissions that require full IBC review will be placed on an agenda within 30 days of receipt of all necessary documents and information within the rDNA manager's office. Review communications will be sent as soon as staffing levels permit, but, on average, within 21 days of the committee's determination.	ORIO IBC manager & IBC
Infectious agent and rDNA protocol modifications -Expedited review	M-F, 8 AM to 5 PM	Changes to approved IBC registrations must receive prospective review and approval by the IBC. Modifications that qualify for expedited review will be reviewed by the IBC manager, Biosafety Officer(s), and the IBC chair if needed. Complete & correct submissions will be reviewed within 14 days of receipt of all necessary documents and information within the rDNA manager's office. Review communications will be sent as soon as staffing levels permit, but, on average, within 14 days of the expedited review.	ORIO IBC manager & IBC
Adverse Event reviews for human gene transfer studies – Full Board review	M-F, 8 AM to 5 PM	Serious adverse events for human gene transfer studies must be reported to the IBC for review and appropriate follow-up as outlined at: <a href="http://www.ohsu.edu/research/rda/ibc/ae_requirements.shtml">http://www.ohsu.edu/research/rda/ibc/ae_requirements.shtml</a> For adverse events requiring full committee review, complete & correct submissions will be placed on an agenda within 4 weeks of receipt of all necessary documents and information within the rDNA manager's office. Review communications will be sent as soon as staffing levels permit, but, on average, within 21 days of the committee's determination.	ORIO IBC manager & IBC
Adverse Event reviews for human gene transfer studies – Expedited review	M-F, 8 AM to 5 PM	Serious adverse events for human gene transfer studies must be reported to the IBC for review and appropriate follow-up as outlined at: <a href="http://www.ohsu.edu/research/rda/ibc/ae_requirements.shtml">http://www.ohsu.edu/research/rda/ibc/ae_requirements.shtml</a> Adverse events that qualify for expedited review will be reviewed by the IBC manager and designated IBC reviewer. Complete & correct submissions will be	ORIO IBC manager & IBC

		reviewed within 14 days of receipt of all necessary documents and information within the rDNA manager's office. Review communications will be sent as soon as staffing levels permit, but, on average, within 14 days of the expedited review.	
--	--	--	--

**B. Optional Services; Accessing Optional Services and Applicable Charges**

<b>Services</b>	<b>Availability</b>	<b>Service Level &amp; Charge</b>	<b>Responsible Party</b>
Protocol, study document, or other review and approval in less than stated, basic service times	M-F, 8 AM to 5 PM	Reviews performed outside of the basic schedule will be done via staff overtime. The requesting department will be charged actual costs for this overtime.	IRB chair & co-chair, ORIO Associate Director
Human subjects consent/authorization form preparation	M-F, 8 AM to 5 PM	ORIO staff will provide major consent form editing or preparation upon request. The ORIO will charge the PI's department a negotiated fee for each CF prepared. The fee will be related to the length, complexity, and number of consent and authorization forms that are needed for a particular study.	IRB chair & co-chair, ORIO Associate Director, IRB analysts

## **Schedule 2 Administration**

### **A. Oversight and Authority**

1. Oversight Responsibility: Gary T. Chiodo, DMD, FACD; appeals to Dan Dorsa, PhD
2. ORIO Department Responsibility by Subject Area:
  - i. Human Subjects: Charlotte Shupert, PhD; Susan Bankowski, MPH, JD; Kara Drolet, PhD; Susan Hickman, PhD; Katie McClure, MD
  - ii. Animal Subjects: Charlotte Shupert, PhD, Barbara Cox, PhD
  - iii. Institutional Biosafety/rDNA/Conflict of Interest in Research: Kara Drolet, PhD
3. There will be a Quality Advisory process to periodically evaluate the performance and accessing of services under this Understanding. The purposes of the QA process will be to ensure that services are being delivered per the timing set forth in this Service Level Understanding, the parties are complying with their stated responsibilities, the manner in which services are being delivered are appropriate and helpful to the OU, and areas for improvement or efficiency are identified.
  - i. The QA process will involve internal evaluation by the following:
    1. Human Subjects: Charlotte Shupert, Susan Bankowski, Kara Drolet, Susan Hickman, Katie McClure, Gary Chiodo
    2. Institutional Biosafety: Kara Drolet, Janet Billups, IBC Chair(s), Biosafety Officer(s), Gary Chiodo.
    3. Conflict of Interest in Research: CoIR committee chair(s), Janet Billups, Gary Chiodo.
  - ii. The QA process will involve external evaluation conducted by in-person, paper-based, or electronic (e.g., Zoomerang) surveys of OU leaders and users of ORIO services. Summaries of the QA survey data will be presented to OU leaders for dissemination within their OUs and to OHSU leadership.
  - iii. Any representative of an OU may bring QA or service level performance issues to the ORIO at any time. Issues should be forwarded, in writing to the ORIO Director or Associate Director.
  - iv. ORIO will document and report to OU representatives, identified trends related to best practices and areas in need of improvement for both ORIO and investigator performance.
  - v. If there is disagreement between an OU investigator and an ORIO department, appropriate representatives of the OU, the ORIO Department, and any other pertinent individuals will attempt to resolve the issue via informal processes. If informal processes are not successful in resolving the disagreement, the ORIO Director and OU leader will attempt to resolve the issue. If this process is not successful, the issue will be remanded to the VPR.