PURPOSE

Institutional Review Board (IRB) fees are charged to industry sponsored projects that are reviewed by OHSU's IRB. This procedure documents the processes that are used to identify the industry sponsored projects’ contracts that include IRB fees and the processes by which these fees are invoiced, paid and tracked by Sponsored Projects Administration (SPA).

DEFINITIONS

**Modification Form:** The IRB Modification Form is designed to summarize any proposed changes and must be submitted to the IRB with any request for protocol or forms revisions prior to the implementation of the revision.

**Jellyfish:** The Award Setup Tracking Tool that is utilized by the Research Development & Administration offices to track applications, proposals and contracts from their initiation through to account setup and notification from SPA. Link:  [http://www.ohsu.edu/research/era/jellyfish.shtml](http://www.ohsu.edu/research/era/jellyfish.shtml)

**Oracle Grants Accounting (OGA):** The official OHSU financial system utilized to track all sponsored project activity.

**Internal Billing System (IBS):** The official OHSU financial system used for inter OHSU charging. This system is used to process IRB fee transactions.

**Program Development Account (PDA):** PDA's are set up for the purpose of receiving residual balance funds from Fixed Price Agreements, which are generally industry sponsored clinical trials. These accounts are to be used to further the research mission of the university and are to be spent according to established guidelines. PDA's do not have a definable scope of work and do not involve human or animal subject expenses. These accounts are unrestricted funds that are not related to specific or Defined Research Projects.

**Initial Review Questionnaire (IRQ):** The questionnaire that collects basic logistical information about the research study, such as research staff, sponsorship, identification of data, number and ages of subjects, etc. This questionnaire provides IRB reviewers with critical information at a glance to assist the review.

**Continuing Review Questionnaire (CRQ):** The questionnaire that collects current information about the research study's activities over the past period of approval. It includes subject enrollment, adverse event, and protocol deviation information.

RESPONSIBILITIES

**Institutional Review Board (IRB):** The IRB must review and approve all OHSU research that is conducted with human subjects, regardless of funding source, to ensure the protection of the rights and welfare of all research subjects and compliance with federal and state regulations. Research activities included under the federal and state definitions include, but are not limited to, protocol-dictated interventions with human subjects; collection of tissues, blood, genetic material, or private information for current or future research use; and any chart review.
Principal Investigator (PI)s: The individual responsible for overall programmatic and managerial conduct of a sponsored project. The PI is responsible for ensuring IRB approval is obtained when required and for submitting necessary continuing reviews and modifications. The PI is responsible for providing a non sponsored account on the IRQ and CRQ. The PI is also responsible for reviewing and approving IRB fee sponsor invoices provided for concurrence by SPA, prior to the invoices being sent to the sponsors and for notifying SPA if the invoice should not be sent.

Unit/Department Staff (including Award/Project Fiscal Managers, Clinical Research Coordinators and Department Administrators): Unit/Department staff are responsible for assisting PI’s with the administrative management and oversight of their sponsored projects. For industry sponsored projects this includes responsibility for assisting the PI’s by reviewing and approving IRB fee sponsor invoices provided for concurrence by SPA, prior to the invoices being sent to the sponsors, and for notifying SPA if the invoice should not be sent.

OHSU Research Integrity Office (ORIO): ORIO is responsible for assessing the appropriate IRB fee to either the OGA project or to the department’s designated unrestricted account, as appropriate; for providing sufficient detail about the charge in IBS or providing receipts to departments; and for tracking and documenting IRB Fee revenue based on total fees processed through IBS for reporting to the executive level and CFS.

Clinical Trials Office (CTO): CTO is responsible for communicating to SPA, after execution of an industry sponsored clinical trial contract, whether invoicing for IRB fees is necessary and, if so, the amount of the initial IRB fee invoice.

Sponsored Projects Administration (SPA): SPA is responsible for receiving information from PIs, Unit/Department Staff, ORIO, and CTO related to IRB fee invoicing; processing invoices; and tracking invoice payments.

REQUIREMENTS

IRB Service and Fee Assessment

- IRB performs initial, continuing, or modification review for industry funded human subjects' research protocol.

- Current IRB fees (per ORIO website, http://ozone.ohsu.edu/research/irb/irbfees.shtml) for initial, continuing, or modification are either assessed to project soon after service is provided, if project is setup in OGA, or placed onto an accounts receivable (AR) spreadsheet for further tracking.
  - ORIO tracks pending IRB fees and waits for OGA project to be established.
  - ORIO tracks status of setup via Jellyfish and/or OGA.
If, after 90 days from service date, IRB approval is imminent and it appears the account is close to being set up based on information obtained from Jellyfish, ORIO waits to post the IRB fees to the OGA project and continues to track the account status.

- Once an OGA project is established, ORIO assesses IRB fees to the OGA project via IBS. ORIO is notified of account establishment and OGA project number via the Notice of Account Setup/Revision that is sent by SPA. ORIO is copied on all notices for Industry Sponsored accounts involving human subjects.

If it does not appear that the OGA account is close to being set up after 90 days from IRB service date, ORIO assesses IRB fees to the designated unrestricted (non sponsored) department account or PDA (provided on the IRQ). Investigators are required to provide to ORIO an unrestricted department account or PDA to which IRB fees may be charged upon submission of an IRQ, CRQ, or modification. The IRB will not accept an IRQ, CRQ, or modification for industry funded human subjects’ research without this department account or PDA information.

When ORIO processes the IRB fees in IBS the following information is entered into IBS to enable SPA to process the necessary invoices and to also provide sufficient level of transaction detail to the departments:
  - Transaction Description: Old IRB #( if needed)-eIRB #, Modification #, Modification detail. For example: “8479-e1575, MR6475, Phone screen & new magazine ad.”

For PI initiated studies, the CTO contracting office will complete the PI initiated field in Jellyfish. ORIO will utilize the Notice of Account Setup/Revision provided by SPA or use the OGA system to obtain information about the estimated award total of the study. If the estimated award total of the study is $100,000 or greater, IRB fees will be processed per standard procedures. For studies that have lower than $100,000 estimated award total, IRB fees will only be assessed on a case by case basis. CTO will communicate information to SPA about whether or not an invoice should be sent to the sponsor in the same manner as other studies, via the account setup paperwork.

CTO will send an email to ORIO, including the eIRB #, when a contract is received that is determined to be for a study drug/device only and that will have no budget involved. This information will then be tracked in the AR spreadsheet by ORIO and no IRB fees will be assessed.

CTO will not mandate that IRB fees be included in every contract. When IRB fees are not included as a specific line item in the contract, CTO will document that the investigator is aware that the study account will be charged for actual IRB fees incurred regardless of the fact that the fees are not included as a separate line item in the budget. The exception to this will be for PI-initiated studies with external funding of $100,000 or less. This documentation should be included in the setup packet sent to SPA.
SPA Procedure Name:  
IRB Fee Sponsor Invoicing on Industry Projects  
Effective Date:  
5.1.07

- Information will be noted by ORIO when a department account or PDA has been charged. This information can be used if the study does end up having an OGA account setup and the IRB fee will then be adjusted by ORIO via IBS from the department account or PDA onto the OGA project for the study. ORIO will keep track of this via the AR spreadsheet and if a new account setup notice is received for a study where a department account or PDA has already been charged, ORIO will use this information to process an IBS adjustment and notify the department and SPA. This information will be maintained historically so that it can be used to assess, over a certain time period, the volume of charges needing to be directed to non sponsored accounts.

Initial IRB Fee Sponsor Invoices:

- CTO will provide the information that should be included in the initial invoice on the setup worksheet provided to SPA. SPA will use this information to create the initial invoice, process the invoice in OGA, send the invoices to sponsors and track payments. SPA will send copies of initial invoices via email to the following individuals:
  - PI (based on PI listed in OGA)
  - Award and Project Department Fiscal Managers (based on OGA roles)
  - Department Administrators (based on OGA Org Hierarchy Contact roles)
  - Award and Project Clinical Research Coordinators (based on OGA roles)

- SPA will also use the information provided by CTO at the time of setup to track whether or not invoices should be sent to sponsors for IRB fees. If, for example, the IRB fee costs are included in the per patient payment and therefore IRB fee invoices should not be sent to sponsors, SPA will track this information in OGA in order to pull this information into the automated reporting for the IRB fee invoicing process. SPA will also track cases where invoices are to be sent to departments for notification purposes only, and invoices not sent to sponsors.

- To facilitate the transition of sponsor invoicing, SPA will run a report of all active industry sponsored projects with human subjects to verify whether or not IRB fees have been assessed historically and whether or not invoices were entered in OGA for the initial IRB Fee. This will help SPA keep track of possible projects that should not have IRB fees invoiced to the sponsor. Going forward this information will be provided to SPA by CTO at the time of account setup.

- The majority of IRB fee invoices generated will be for industry funded clinical trials; contracts for industry funded clinical trials are handled by CTO. Other pre award offices [Technology Research and Collaborations (TRC) and Research Grants and Contracts (RGC)] may manage contracts and setup processes for industry funded projects that require IRB review and therefore that may get assessed IRB fees. ORIO and SPA will interact with the appropriate pre award office regarding invoicing for IRB fees.

Continuing and Modification IRB Fee Sponsor Invoices:

- SPA will run a monthly Oracle report to determine which OGA projects have had IRB fees posted to them in the last month. This report will include the type of IRB fee being assessed (using IBS item code: initial, continuing, or modification), the fee amount, as well as the transaction description. The transaction description will include the modification detail so that this information can be added to the invoices when necessary.
Utilizing this report and also information previously received related to which studies should NOT have invoices for IRB fees generated or sent, invoices will be generated using the standard SPA clinical trial invoice template http://www.ohsu.edu/research/rda/spa/docs/invtemplate.xls and entered into OGA.

SPA will continue the practice of sending all sponsor invoices for continuing and modification IRB fees to the department for a two business day concurrence period prior to sending the invoices to sponsors and to provide departments with a copy of all invoices sent to sponsors for their projects. After the two day concurrence period, invoices will be sent to sponsors. Actions will be taken by SPA, as appropriate, when department feedback on invoice is received. Copies of continuing and modification invoices will be emailed to the following individuals for concurrence:

- PI (based on PI listed in OGA)
- Award and Project Department Fiscal Managers (based on OGA roles)
- Department Administrators (based on OGA Org Hierarchy Contact roles)
- Award and Project Clinical Research Coordinators (based on OGA roles)

**Invoice Tracking Process**

- Once invoices are processed, SPA will regularly run reports for pending charges and report on unpaid invoices to all necessary individuals and will contact sponsors directly in order to receive payment.

- When payments are received, they will be matched to the invoice and deposited to the proper account, with copies of the checks being emailed to the PI and department.

- Budget adjustments will be processed, as needed, to increase the overall clinical trial budget if the cash received is in excess of the established budget.

**Questions**

- All questions from sponsors or departments regarding invoicing to sponsors should to be routed directly to SPA.

- All questions from departments related to the IRB fee charges on their accounts should to be routed directly to ORIO.

- SPA and ORIO will collaborate and keep each other informed related to any charges that need to be reversed, invoices that should be credited, etc.

**RELATED DOCUMENTS**

- IRB Fee Policy http://ozone.ohsu.edu/research/irb/irbfees.shtml
- SPA Standard Clinical Trial Invoice Template http://www.ohsu.edu/research/rda/spa/docs/invtemplate.xls