

Department of Medicine
Clinical Research Coordinator Monthly Meeting
March 27, 2007 – 2:00-3:00, Parnassus S170

Present: Michele Carter, Fred Fishman, Irina Gorodetskaya, Emily Little, Jenny Spede, Suzanne Sutton

Guests: Andrew Boulter, Kathleen McGinley

**Office of Sponsored Research's (OSR's) Contracting Process: Industry Contracts
(presented by Kathleen McGinley)**

Kathleen McGinley, an Industry Contracts Officer from the Office of Sponsored Research, outlined the process that OSR follows when dealing with Industry Contracts, explaining the realistic timeline and common pitfalls that may occur.

Industry Contracting Process, step-by-step

1. Principal Investigator (PI) and Sponsor organization find a shared interest, agree on a project, and hash out the science protocol that will be followed throughout.
2. Research Service Analyst (RSA) notifies the appropriate Industry Contracts Officer.
3. PIs Department uploads the OSR Form and necessary documents into the Research Administration System (RAS)-PeopleSoft database. *Note:* work *cannot* begin on the contracting process until all of the documents are received, the OSR form is signed and uploaded, and OSR has a hard copy of the Budget.
4. RSA sends the original signed OSR Approval Form and 700U (with the 700U Supplement if it is a Clinical Study) to the Industry Contracts Unit.
5. Industry Contracts Unit sends the original copy of the 700U to the Conflicts of Interest Committee.
6. PIs Department obtains Institutional Review Board (IRB)/Committee on Animal Research approval (CAR) and sends Committee on Human Research (CHR) approval application to OSR. *Note:* RSAs/Pis should get their application to CHR as soon as possible, as processing time at this stage is a common cause of delay, which may result in the loss of a trial.
7. Negotiation begins between OSR and the Sponsor on the legal terms of the contract. The length of time that this process takes fluctuates, as it depends primarily on often unknown terms and variables. *Note:* International sponsor organizations are often more difficult to negotiate with in a quick and timely manner due to differing practices outside of the U.S. – keep this in mind and plan accordingly.
8. RSA and PI negotiate the Budget Payment terms. *Note:* Be sure that the phrase “Final Payment on Acceptance” is never used, as this can have a significant, detrimental effect on the project. The phrase “*Final Receipt on Acceptance*” should be used instead.
9. Contract is cleared by the Conflict of Interest Committee.

10. Originals are sent to the Sponsor and to the Industry Contracts Unit; it is then uploaded by the Contracts & Grants RAS team into the PeopleSoft database and the Award Synopsis is created.
11. The Award Synopsis is sent to Extramural Funds (EMF); the PI and EMF set up and authorize the fund.

In total, the Review process itself combined with the travel time taken to send out the necessary paperwork can easily take up to two months. If you would like to help speed up this process make sure that everything is submitted as soon as possible, and that OSR has all of the paperwork that they will need before they need/request it.

Facilities and Administrative (F&A) Rates

If a clinical study is not FDA sponsored, it is not considered to be a Clinical Trial, but is instead considered to be Sponsored Research.

Material Transfer Agreement (MTA)

When OSR is in possession of a Master Agreement or a recent agreement with the same sponsor, or an agreement between the sponsor and another UC this processing of an MTA is extremely quick.

If there is a hold-up with an MTA, OSR suggests that PIs contact their scientific colleague working with the sponsor to instigate a quick turnaround in the sponsor's legal department.
Note: This is especially advisable with International and European companies.

Miscellaneous

Once a project is approved, uploaded into RAS, and sent to EMF, the PI and RSA should contact *EMF* with any questions/concerns, as OSR no longer has the relevant information.

When changes in the projects case a modification of the contract in a Clinical Trial, OSR issues an amendment. This should not interrupt or compromise the access to the Budget, and it is not necessary for the trial to be interrupted. While these Amendments are usually very cut-and-dry and do have a long processing time, the PI and RSA should make sure that the Amendment is processed in advance of the Trial's end date; if this does not occur, a new Contract will have to be created, which will necessarily halt/delay the scientific progress...

When there is a **protocol** change, CHR approval is necessary, and work/research may need to halt (this is determined on a case-by-case basis.)

OSR's Contracting Process: Contracts and Grants (presented by Andrew Boulter)

Andrew Boulter, a Contracts and Grants Officer with the Office of Sponsored Research, outlined the process that OSR follows when dealing with Non-Industry Contracts.

Breakdown of the Separation of responsibilities with Contracts and Grants (C&G)

Note: Contracts and Grants deals with everything that is *not* Industry-related**

Federal funding is separated as follows:

Federal Contracts → Andrew Boulter's group

Cooperative Agreements → Debbie Caulfield's group

Subcontracts → Andrew Boulter's group

F&A Rates

Non-Industry agreements do not have the same F&A Rates as Industry agreements do.

Federal Rates are negotiated by Campus and the Federal Government.

Budget

When C&G looks at the Budget, they are mainly looking to confirm the following:

1. The contract is for a Clinical Trial (FDA Phase I-IV), or an ancillary of a Clinical Trial. If this is not the case, then it is likely to be Clinical Research.
2. Will the Clinical Trial take place On-Campus or Off-Campus? If it will take place Off-Campus, then the budget will need to take the necessary rental fees into consideration.
3. The Cost Accounting Standards are being met.

Miscellaneous

Much of the work that Contracts and Grants does is dealing with Federal Agencies.

When an Request for Proposal (RFP) is issued, it lays out what the Government wants to see. It is then read by C&G, who create a proposal, which is submitted 6-9 months prior to the creation of an award. In this way, the Budget is created with an eye to the future.

RFPs are extremely dense and time consuming for C&G to deal with (about 80 pgs. of complicated, intricately-worded obligations.) RSA/PI team should get in touch with C&G as soon as possible when they are dealing with Federal Contracts, as C&G will help to narrow down what the RSA/PI team will need to deal with themselves, helping to narrow-down their workload.

In terms of Human Subject Approval, Clinical Trials do not require this before the C&G Proposal is submitted. This may be done in the 6-9 months prior to the creation of the award.

The proposal is sent by C&G to the Government; the Government returns it with questions which usually have to do with the *technical* (science) and *business* (money) end. When the Government requests certain expenses/aspects of the proposal be removed, C&G must justify why it needs to stay, but does not necessarily need to remove these items from the Proposal.

If the Government has agreed to C&G's requests, there will be a short turnaround time (about 2 weeks) once the award comes in.

NIH and CDC are agencies which are traditionally difficult to deal with and tend to require a lengthy negotiation period.

Publication and Intellectual Property restrictions levied by the sponsor agency are often hidden in the proposal by complex language, and are taken extremely seriously by C&G – such restrictions will usually mean that the proposal cannot be accepted by C&G in the current form, and will have to be renegotiated. Such restrictions can have serious legal ramifications for both UCSF and the PI in the future. Because of the tendency for such clauses to be hidden within the contract, each contract must be read carefully and thoroughly in its entirety by both OSR and C&G. The through reading alone is time-intensive, and any clauses with issues will required C&G to re-work and/or re-write the clauses that are at issue, send the proposal back to the sponsor for them to re-negotiate and send back to C&G (etc.), until everyone is satisfied.

The next CRC Meeting is scheduled for Tuesday, April 24th, 2007 from 2:00-3:00 PM in room LHTS 430F