What constitutes a Clinical Study?

A clinical study, a clinical trial, or a clinical protocol all mean the same thing….a scientific study of how a new medicine or treatment works in people. In order to perform such research, generally a protocol is established by a researcher and submitted for funding to a granting agency or a protocol is established by a granting entity and submission is made by various researchers to participate in the protocol’s research or to expand upon the original protocol.

Research protocol submission is sent by the researcher(s) first through department administration for departmental agreement and signatures, and then on to the Office of Sponsored Projects (OSP) for institutional review, signatures, and submission to the agency.

How is a project established?

In order for research to be initiated, the following should be in order:

1) All Necessary Assurances
   - Human subjects/Human Derived Materials
   - Animals
   - Biological Agents (including DNA)
   - Radioactive Materials
   - Biohazardous Materials
   - Radioactive Materials
2) Funding for the research
3) An anticipated budget, including the criteria for charges and amounts applicable to each criteria
4) Indirect Cost (IDC) waiver if applicable (standard IDC for such studies is 30%)
5) All necessary institutional approvals are acquired
6) A fully executed agreement (i.e., both parties have signed off on and agreed to all terms outlined in the contract)

Once funding has been granted by an agency, most usually a drug company such as Merck, Pfizer, etc., and all of the above is in order, a new project can then be established in the institutional financial system by Post Award Finance (PAF). The project is set up indicating the period of performance, the title, the Principal Investigator, any required Assurances, applicable IDC, etc.
**How are funds received?**

Clinical studies generally receive funds based upon patients or markers which are reported to the agency and are then reimbursed after-the-fact based upon the budget provided at submission, or as finally agreed upon in the fully executed contract. Because funding is not guaranteed unless specified criteria are met, these projects are set up with no funds until such time as the first payment is received from the agency. Funds are only applied in a project at set up if *startup funds* have been received as indicated in the approved budget. These funds generally are requested to cover IRB costs for assurances and the acquisition of goods or the development of documents to be used in relation to the study.

Payment most often comes in the form of a check. It may come, generally, in three ways:

1) **Institutional Lockbox.** Current contracting now indicates payments to be sent to a specified *lockbox* at our institution’s bank. This lockbox was created to accept all payments against sponsored projects in our institution. Checks which arrive at the bank are imaged in *Iliad* with any accompanying documentation, and the institution is notified electronically of their arrival.

2) **Directly to the Department/PI:** In the past, contracts indicated that all such payments be sent directly to the department or PI performing the research. In this case, department administrators submit the payments and (hopefully) accompanying documentation to the Bursar’s office for deposit to the bank and bank imaging to *Iliad*.

3) **Directed to PAF from another source.** At times the payment is received directly by PAF or from an individual who does not route it through the Bursar’s Office, or via a wire transfer (very rare for clinical studies). This is becoming less common, but does still occur in relation to older projects.

PAF accesses the lockbox daily, reviewing and identifying (if possible) where each check should be applied in our financial system (i.e. which project to which each belongs). Most often a protocol is referenced on the check or, if not, hopefully there is an accompanying document referencing the protocol or the Principal Investigator involved. When no such reference can be determined, PAF will contact the agency to request information regarding the payment in order to ensure it is applied to the appropriate study. The check is then coded by PAF in the banking system program (*Iliad*) and the payment revenue is applied to the financial system itself by *Financial Administration Support* (FAS). PAF also budgets the funds from revenue for use, differentiating in the system Direct funds (funds which can be used by the department/PI) and Indirect Funds (funds agreed upon at 30% for institutional overhead—e.g. electricity, space, administration, etc.).

If, for some reason, the check cannot clearly be identified as a payment toward a specific project, or if PAF must await agency response to an inquiry, the funds are placed in the *PAF Clearing Account*. This is a “holding account” which basically allows income to be shown on institutional books, but does not have it yet ascribed to the final identified/verified project’s revenue. Once it is positively identified, PAF moves the funds to the verified project.
Likewise, any checks received outside of the Institutional Lockbox or outside of all deposits reflected in Iliad, are reviewed and coded as described above.

All clinical studies are referred to as **Cash Basis** accounts…funds are only reflected as they are actually received. Therefore, whatever is reflected as recognized revenue is what has actually been received to date.

**What can impact a clinical study?**

Issues which can impact a clinical study include:

1) The need for renewal of approvals. If approvals are not current, research should be suspended until approvals are updated.
2) Lack of income due to insufficient patients (either no patients or no patients meeting the set criteria for reimbursement).
3) Lack of a renewal contract to continue the study past a given end date as per the agreement (many are “until completion”, but some are not).
4) Termination of the contract by the agency for any stipulated reason—funds may be requested for return in such cases.
5) Departure of the Principal Investigator.
6) A serious negative outcome due to treatment received. This outcome may occur here or at another study site, thereby impacting all related studies.

**FMS Queries**
(Examples attached)

- **ARX Deposits by Chartfield**—search by **Department/Fund** (clinical studies are fund 57001)
- **ARX Deposits by Payment**—search by **check number**
- **ARX Journals to Deposit ID**—search by **ARDIR** or **ARPMT** journal reference
Payment and Deposit Research Tools

The following public queries have been developed to facilitate departmental research efforts on deposit entries of a payment or deposit to a specific chartfield.

**ARX_Deposits_By_Chartfield** - Lists all deposits made for a given period of time. Prompts are setup for user ID (% can be used as wildcard), accounting date from and to, fund and department codes.

**ARX_DEPOSITS_BY_CHARTFIELD** - DEPOSIT BY DEPT

Enter User ID: %

From Accounting Dt: 05/01/2006

To Accounting Dt: 05/31/2006

Fund: 33039

DeptID: 25280001

View All

Posted will only show an amount here if an actual invoice was created for billing. If number different from Amount column, payment was a mixture of non-invoiced and invoiced billings.

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**ARX_Deposits_By_Payment**: Lists all deposits referencing a specific payment ID number (check number). Query prompts you for the check number and returns results as below:

**ARX_DEPOSITS_BY_PYMT - DEPOSITS WITH JOURNAL REFERENCE**

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**ARX Journals to Deposit ID:** If you are reviewing your general ledger and see an ARDIR or ARPMT journal reference and need additional information to reconcile this is the query for you. The query prompts for the journal reference number and will provide you with ALL information referenced on the journal—not just the line amount you may be looking for.

**ARX JOURNALS_TO_DEPOSIT_ID - DEPOSIT BY ARDIR & ARPMT**

| Journal ID: | ARDIR36105 |

Download results in: Excel Spreadsheet  CSV Text File  (306 kb)

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