School of Medicine

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# Industry Clinical Trials: Budgeting and Expense Management

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# The UCSF Experience

- **Industry trials represent 9.8% of awards at UCSF**
- **Clinical trials represent 17% of awards in DOM**
- **129 active clinical trials in the department, of which 90% are industry**

# UCSF Infrastructure

- **Campus and Medical Center: separate entities**
- **CAMPUS:**
  - Industry Contracts
  - Committee on Human Research (UCSF's IRB)
  - Controller's Office
- **MEDICAL CENTER:**
  - Clinical services
  - Patient billing
- **Centralized Clinical Trial Organization (CTO) does not exist**

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# Roles of the PI

- **Finalize protocol**
- **Determine standard of care (SOC) vs. non-SOC procedures/services**
- **Review / approve budget**
  - Feasibility (DOM requires ≥3% effort for PI)

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# Roles of the PI (cont'd)

- **Regulatory compliance:**
  - Amendments, modifications, renewals, extensions
- **Supervise Clinical Research Coordinator (CRC) activities**
  - Study set-up, including ZZ account
  - Proper assignment of ZZ account, V code, and QV modifier
  - Ensure invoice submission and A/R is tracked by research services analyst (RSA)
  - Campus and medical center ledger reconciliation

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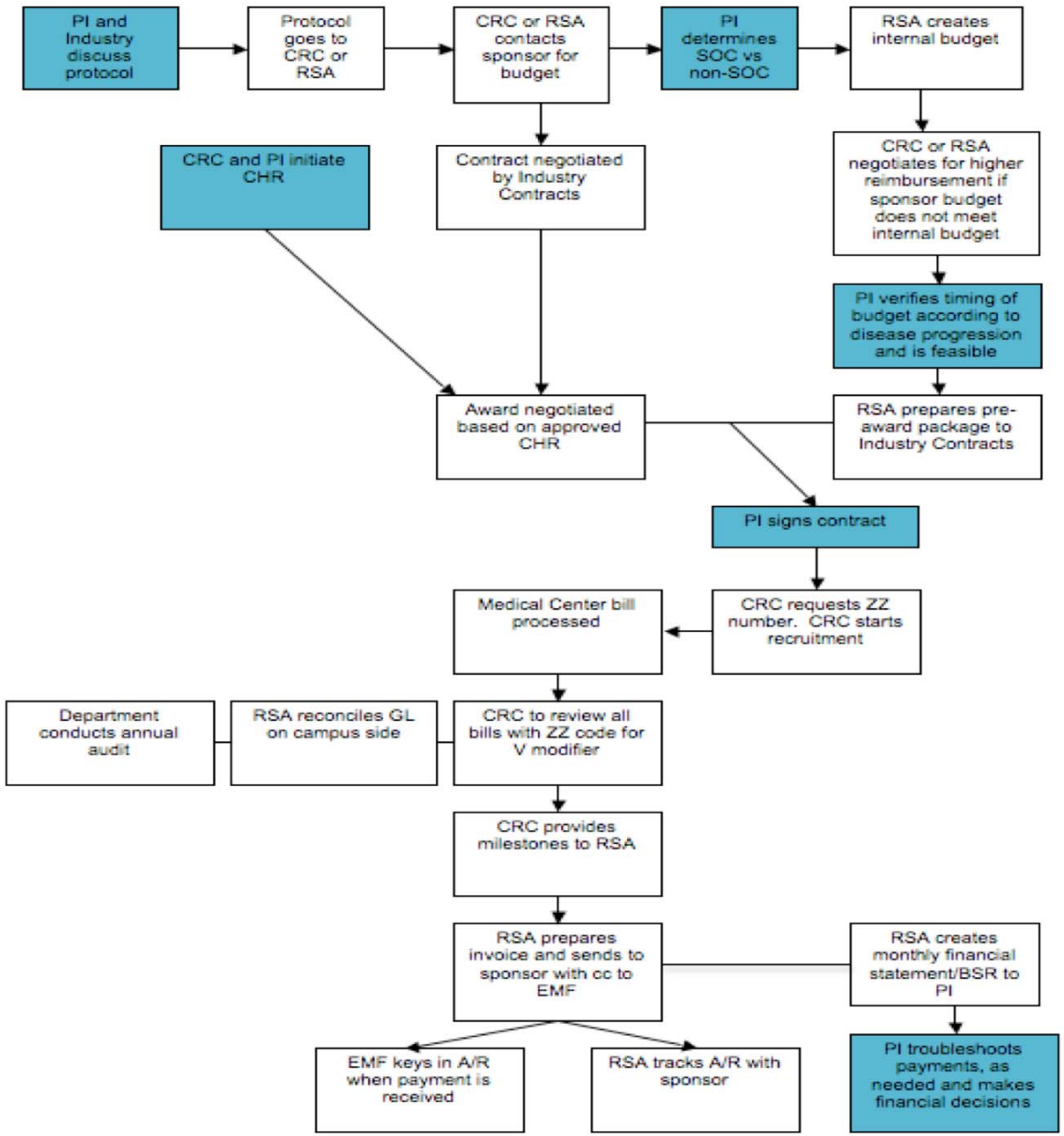

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# Compliance Policies

- **CMS National Coverage Determination.**

  Cannot bill Medicare or Medicaid for procedures or services of the research component of a trial just because CMS considers the components otherwise reimbursable when part of standard of care.

- **NIH Clinicaltrials.gov.**

  All new active Phase II to IV clinical trials registered to national database, both NIH and non-NIH funded trials.

- **Enforcement of Federal Anti-Kickback.**

  Illegal for sponsors to provide financial incentives for billing CMS for study-related procedures that should be billed to the sponsor.

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# Contract vs. Grant

- **GRANT**
  - Funds for the conduct of a project
  - Delegated authority to spend up to the award amount.
  - Award usually paid in full
- **CONTRACT**
  - Reimbursement for deliverables, services, and/or milestones achieved.
  - Payment contingent upon proof of services delineated in the agreement.
  - Rarely get full amount of the budget depending upon accrual and reimbursement schedule

# Example of Contract Reimbursement

| | | Month 1 | Month 2 | Month 3 | Month 4 | Month 5 |
|---|---|---|---|---|---|---|
| *Expenses* | | | | | | |
| IRB | | $ 2,000 | | | | |
| RX Set-up | | $ 650 | | | | |
| PI Salary | | $ 16,500 | $ 16,500 | $ 16,500 | $ 16,500 | $ 16,500 |
| CRC Salary | | $ 9,375 | $ 9,375 | $ 9,375 | $ 9,375 | $ 9,375 |
| Regulatory Salary | | $ 10,417 | $ 10,417 | $ 10,417 | $ 10,417 | $ 10,417 |
| Admin Salary | | $ 4,167 | $ 4,167 | $ 4,167 | $ 4,167 | $ 4,167 |
| **Subtotal** | | **$ 43,109** | **$ 40,459** | **$ 40,459** | **$ 40,459** | **$ 40,459** |
| *Revenue* | | # Pt | # Pt | # Pt | # Pt | # Pt |
| Visits 1&2 | $4,000 | | 10 $ 40,000 | 8 $ 32,000 | 7 $ 28,000 | 9 $ 36,000 |
| Visit 3 | $1,500 | | | | 8 $ 12,000 | 7 $ 10,500 |
| Visit 4 | $1,500 | | | | | |
| 4-monthly f/u visit | $1,500 | | | | | |
| Event/EOT visit | $2,500 | | | | | |
| F/U visit after Event/EOT visit | $1,500 | | | | | |
| EOS visit | $2,500 | | | | | |
| **Subtotal** | | **$ -** | **$ 40,000** | **$ 32,000** | **$ 40,000** | **$ 46,500** |
| **Balance** | | $ (43,109) | $ (43,109) | $ (51,568) | $ (52,027) | $ (45,986) |

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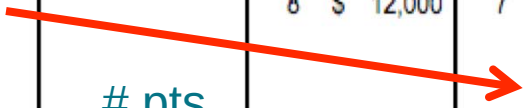

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# Pre-Clinical Trial Agreement

## Nothing ventured, nothing gained

- **Demonstrates good faith on part of sponsor**
- **Provides reimbursement for the time to establish and negotiate the protocol and/or contract**
  - PI input
  - Staff efforts
- **Insurance should the study not go forward**
  - Sponsor reneges
  - Contractual language problematic
  - Disagreement over budget

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# Start-Up Costs:

## Sponsors expect to be asked

- **Reimbursement to initiate start-up of trial that must otherwise be covered by discretionary funds or pro-fees**
- **IRB, pharmacy set-up, PI and staff personnel costs, supplies, etc.**
- **Documentation of costs should begin as soon as the Confidentiality Agreement is received.**

**RAMIFICATIONS IF NONE NEGOTIATED:**

- **Absence of start-up costs results in a deficit balance for the life of the study.**
- **Deficit balances incur negative interest.**

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# Internal vs. Sponsor Budget

- **SPONSOR BUDGET**
  - May show which services they will pay for to derive the per patient reimbursement
  - May or may not accurately reflect the SOC and study services defined by the PI and protocol.
- **INTERNAL BUDGET**
  - Delineates all expenses (non-SOC) and items to be invoiced
  - Must be negotiated, particularly since the medical center expects to (and will be) paid
- **Discrepancy requires re-negotiation or YOU CAN REFUSE TO DO THE STUDY.**

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# Developing the Internal Budget

1. Review the protocol.
2. PI determines which / when procedures are SOC
3. PI dictates which and when are procedures non-SOC
4. Medical Center research rate for each non-SOC procedure identified
5. RSA details all expenses (salary, IRB fees, supplies, clinical costs, etc. )
6. PI review
   - Are milestones realistic given nature of disease?
   - Is accrual over-estimated?

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# Standard of Care: The Balance

- **Reasonable assessment of normal care for a patient receiving treatment**
  - Standard management
  - Accepted imaging and laboratory parameters
- **Possible research-specific procedures v. SOC**
  - Frequency of tests, visits
    - EKG's, MUGA's, etc…
- **Research-specific costs**
  - Investigational agent
  - Special or extra imaging
  - Pharmacokinetics or other unique lab tests

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# Milestones / Accrual

- **MILESTONES**
  - Benchmarks match the likely course of disease
    - e.g. realistic life expectancy, clinical outcomes
  - Minimize ability of sponsor to control milestones
    - Payable upon study closure vs. completion of CRF
    - Payable at accrual or treatment initiation
- **ACCRUAL**
  - Reimbursement for “screen failures”
  - Under rather than over-estimate patient numbers
    - Costs distributed per patient:
      - Overestimate accrual = costs not covered
      - Underestimate accrual = possible margin

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# Directs vs. F&A: "hidden costs"

- **DIRECTS**
  - Dollars that go towards the personnel and supplies for conduct of the science
- **F&A**
  - Overhead cost (charge) to the University
- **UCSF F&A negotiated rate for Industry-sponsored trials is 26% and 33% for industry-sponsored with subcontracts.**
  - THESE ARE VERY COMPETITIVE RATES!!
- **Need to add F&A to budget negotiation**

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# F&A Example

- **Internal budget**
  - $267,000 for direct costs
  - $69,420 additional in F&A ($267,000 X .26)
  - Total budget is $336,420.
- **Sponsor reimbursement = $3,150 per patient**
  - PI estimates accrual of 100.
  - $315,000 ÷ 1.26 = $250,000 in directs
  - $65,000 in F&A
  - PI actually gets $2,500 per patient.

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# Clinical Trial Risks

- **Underbudgeting will result in deficit regardless of recruitment.**
- **Important to distinguish SOC from non-SOC procedures at the time of protocol and budget development**
  - Facilitates correct billing
  - Facilitates correct language for patient financial responsibility in consent forms and other regulatory documents
  - Decreases exposure for audit

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# Post-Award Management

- Delineation of SOC vs. Non-SOC is used by CRC to correctly bill.
- Separate encounter forms at each visit, as appropriate.
- CRC must include V code and QV modifier for all SOC study procedures billed to Medicare.

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# Compassionate Use Protocols

- Agent provided free of charge
- All other components of care either SOC or unreimbursed
- Regulatory expectations similar to clinical trial in terms of reporting, etc..
- Compassionate use = clinical trial if > 1 patient treated (without funding)

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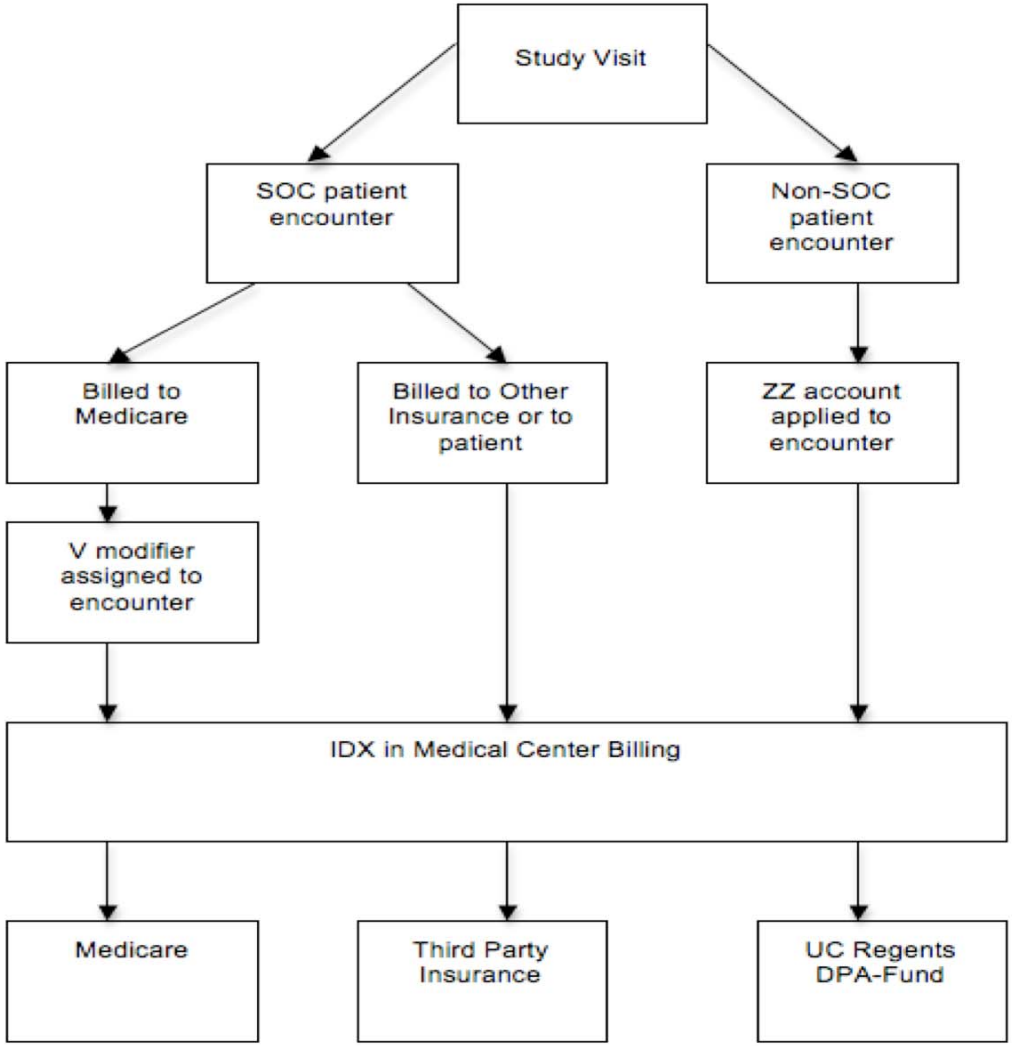
# Flow of ZZ Account



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# Challenges at UCSF

- Electronic medical record system does not exist
- Centralized database of study subjects does not exist
- Decentralized invoicing
- Decentralized tracking of A/R
- Manual system of reconciliation
- Reimbursement lag on expenses
- Negative interest

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# Recent Progress and Achievements

- Implementation of iMedRIS for IRB review, approval, and document management
- Newly appointed Assistant Vice Chancellor of Research (was the Director of Industry Contracts)
- Portion of Medical Center charge master interfaces with OnCore
- Clinical trials infrastructure is major component of the Campus' recently completed Research Administration Systems Strategic Plan

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# Resources

- **Department of Medicine**
  - Suzanne Sutton, ssutton@medicine.ucsf.edu (415) 502-4896
  - Beth Davis, bdavis@medicine.ucsf.edu (415) 502-3176
  - Joseph Wilson, jwilson@medicine.ucsf.edu (415) 514-1120
- **Industry Contracts, Office of Sponsored Research**
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  - Irene Shin, JD, irene.shin@ucsf.edu (415) 514-8920
  - Sophia Chang, JD, sophia.chang@ucsf.edu (415) 514-6204
  - Kent Iwamiya , kent.iwamiya@ucsf.edu (415) 353-4445
  - Mora Mattingly, mora.mattingly@ucsf.edu (415) 353-4695
  - Brenda Hefti, PhD, JD, brenda.hefti@ucsf.edu (415) 514-8074
  - Susan Shih, PhD, susan.shih@ucsf.edu (415) 514-8985

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# Resources (continued)

- **Committee on Human Research**
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  - Richard M. Wagner, richard.wagner@ucsf.edu (415) 476-117
  - Lisa Denney, lisa.denney@ucsf.edu (415) 514-2152
  - Michael Thomas, michael.thomas@ucsf.edu (415) 476-9837
- **Medical Center Billing**
  - Tim Arnold, tim.arnold@ucsfmedctr.org (415) 353-3885
  - Derek Howes, derek.howes@ucsfmedtcr.org (415) 353-3716
  - Liza Shapiro, (415) 353-7617 (ZZ number)