Investigator Training Program
09/MAR/2010
SUNY Upstate Medical University

Overall Project Management

Joseph Domachowske MD
Professor of Pediatrics,
Microbiology and Immunology
Before you start…

• Know your responsibilities as the PI
• Know what can be delegated
• Know your team
  – Strengths
  – Weaknesses
• Know where to get help
  – Institutional resources
  – Experienced colleagues
  – Study sponsor
The Local Study Team

- Principal Investigator
- Sub Investigators
- Study Coordinators
- Data Managers
- Laboratory Technician
- Research Pharmacist
Delegation of duties

• Delegation log provided by sponsor
• Overlap
  – Plan for vacations, sick time
• Cross training
  – At least two team members should know how a task is done or YOU will be doing it
    • Study software
    • Checking inventory, ordering supplies, medications
    • Shipping serum and other biologic specimens
Regular Clinical Trial Meetings

- Agenda
- Define expectations
  - Short term, long term
- Review roles and responsibilities
- Review progress of each study the team is doing
- Be sure the team knows about what’s coming next
- Answer general and specific study questions
Documentation

- Write down everything
- Save everything you write down
- File copies of all electronic communication
- Most studies now have electronic data entry
- Know which circumstances need to be reported immediately to the IRB
- Know which circumstances need to be reported immediately to the sponsor
Recruitment Strategies

• Pamphlets, brochures, billboards, radio announcements, etc
  – Must be IRB approved
• Informed consent
  – Are you interested and willing to be contacted for future studies?
Obtaining Consent

• The PROCESS is far more important than the FORM
• Delegation to the study team is appropriate
• Keep original with the subject’s study documentation. Copy to the patient, and a copy to the chart
Importance of documentation

• If its not written, it did not happen
• The sponsor generates queries
  – Memos to file are needed
  – Time consuming and largely avoidable
• Experience helps, but does not prevent problems
An Example

• Experience
  – 12 yrs clinical trial experience
  – More than 30 studies in children
  – Weekly meetings
  – Strong, experienced study team
  – We document and save everything
Informed Consent

• Study in high risk premature infants over a one year period
• Consent document was changed twice during the course of the study
• Each version of the consent must be reviewed and signed
• We were #3 in the country, #6 in the world for enrollment numbers
Study Completed

- Queries were done, study completed
- Sponsor submits BLA
- FDA performs routine audits
  - High enrolling sites are known to be selected for audits
- We were expecting an audit
- We were prepared
- Study documents were in perfect condition
FDA audit

• Auditor called to inform me he was coming the following week
• Regulatory documents and all case report forms were already organized waiting in a locked cabinet
• Audit lasted about a week
Trouble in Paradise

• Day 4 of the audit:
  – FDA auditor requests an urgent meeting with the PI (that’s me)
• There is a problem with the consent documents

• What?????
• (We are perfect. Our team is strong. What went missing? This will takes seconds to fix. He simply can’t locate something that I know is there…no worries)
Worries

- There is something wrong with consent documents for patient #54
  - Each patient had 3 separate consents.
  - The protocol was updated during the study period requiring us to obtain consent each time
  - I’ll show you the signature pages for patient #54

- The names, dates and documents are artificial but represent the experience
- Privacy laws prevent me from showing the true consents
The nature and the purpose of the above Research Study have been explained to me; I have agreed to have my child participate in the research study. I also agree that my child’s personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form. My child’s consent has not been obtained for the following reasons:

Chris Kneide
Signature of Parent/Guardian

[Signature]
Signature of Person Obtaining Consent/Authorization

[Signature]
Signature of Witness

1-1-55
Date

1-1-55
Date

1-1-55
Date
The nature and the purpose of the above Research Study have been explained to me; I have agreed to have my child participate in the research study. I also agree that my child's personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form. My child's consent has not been obtained for the following reasons:

Chris Kaudle
Signature of Parent/Guardian

Wendy Holz
Signature of Person Obtaining Consent/Authorization

[Signature of Witness]

Date

1/1/55

Date

1/1/55

Date
The nature and the purpose of the above Research Study have been explained to me; I have agreed to have my child participate in the research study. I also agree that my child’s personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form. My child’s consent has not been obtained for the following reasons:

Chris [Signature]
Signature of Parent/Guardian

Wendy [Signature]
Signature of Person Obtaining Consent/Authorization

[Signature]
Signature of Witness

1/1/55
Date

1/1/55
Date

1/1/55
Date
How is this explained?

- The auditor wants to know why the mother’s signature appears different.
- It is suggested that a forgery took place.
- I cannot explain this.
- My signature is on all three consents.
- I know the mother, I know the baby.
- What happened?
Christine and Christopher

• The parents had the same first and last name
• An astute member of the study team thought to look in the hospital chart, and found HIPPA paperwork with the father’s signature on it
• Next to his signature was a ‘relationship to patient’ line listing him as the father
• Clearly, the father brought the infant for the visit when consent 3 was signed
• We now include a line on our consent form to document ‘relationship to patient’ to avoid this problem
Documentation

• We had no documentation in our study files that the mother signed for some visits and the father for others
• The existence of a separate patient care record allowed us to quickly solve the question
• Document, document, document
Successful Clinical Trials

- Patients remain safe and informed
- PI is involved and understands the role and responsibilities
- Ongoing, regular communication between team members including formal meetings on a regular basis
- Team attends to details, is experienced, and prepared. Cross training is important.
- Careful and complete documentation is critical to success