UNIVERSITY of MARYLAND BALTIMORE

Disbursements Workshop
Payments to Research Participants

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April 24, 2019

Obligations of the Principal Investigator

- Personally conduct or supervise the Human Research.
- Protect the rights, safety and welfare of participants involved in the research.
- Conduct the human research in accordance with the relevant current protocol as approved by the IRB.
- Assure that each subject is adequately informed about all aspects of the study.
- Be open to participant's complaints or requests for information. Investigators and research staff should follow a process to respond appropriately to such complaints.

  - UMB Investigator Manual HRP 103

- UMB prohibits payments to professionals in exchange for referrals of potential subjects (“finder’s fees”) and payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments”).

  - UMB HRPP Plan HRP 101

Pre-study

- IRB submission
  - IRB approval
    - Valid informed consent document
    - Consent waiver
  - Contract/grant

Informed Consent

- Revisions to federal regulations (45 CFR 46) – Jan 21, 2019
  - Continuing review not required for minimal risk research
  - Consent will be stamped with approval date
  - No expiration date

  These revisions currently DO NOT APPLY TO FDA REGULATED RESEARCH (ex. ICDs will include an expiration date)

Consent Waiver

* The IRB can approve a consent procedure which does not include, or which alters, some or all of the required elements of informed consent.

  (see Checklist: Waiver or Alteration of the Consent Process)

  * No more than minimal risk to subjects
  * Research or demonstration project
  * Waiver or alteration does not adversely affect rights and welfare of subject
  * When appropriate, will subjects be provided with additional pertinent information

Consent Waiver (cont.)

* Also, the IRB may approve a consent procedure which waives the requirement to obtain written informed consent entirely (see Checklist: Waiver of Written Documentation of Consent Process)

Consent Waiver (cont.)

- The research presents no more than minimal risk of harm to subjects and does not involve any procedures for which written consent is normally required outside of the research context.
- The only record linking the subject and the research the consent document and the principal risk of a signed consent document the potential harm resulting from a breach of confidentiality.

Consent Waiver (cont.)

- The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure
- Written information describing the research is to be provided to the subject or the subject's legally authorized representative.
- Written information describing the research does not need to be provided to the subject or the subject's legally authorized representative.

Consent Waiver

- IRB approved script
  - Contains elements of informed consent
  - No signature required

  - In this instance, a copy of the IRB approved protocol and script may need to be provided to ensure payment to participants.

Exemptions

- Categories 1-8
- No ICD
- May request payment option

ICH GCP—Adequate Resources

2 d. The Investigator should ensure that all persons assisting with the trial are adequately informed about the protocol……. and their trial-related duties and functions.

ICH GCP

Informed Consent:

Neither the investigator, nor the trial staff, should coerce or unduly influence a subject to participate or to continue in a trial.

Informed Consent

- ICH GCP
  - The anticipated prorated payment, if any, to the subject for participating in the trial.

Payment for participation is not a study/trial benefit.

Payments to Participants

- Department of Defense
  - Employees (including temporary, part-time and intermittent appointments) may not be able to legally accept payments to participate in research.

IRB Submission

- IRB application
- Informed Consent Document
  - Required elements present (or waived)
- Script

IRB Review of Payments to Participants

- HRP 313 Worksheet
  - Provides support for the convened IRB or designated reviewer when evaluating payments to subjects or their legally authorized representatives

Worksheet UMB HRP 313

- Requirements for payments:
  - All payments are described in the protocol including:
    - Amount, method and timing of disbursement
    - Credit for payment accrues as the study progresses
    - Payment is not contingent upon completing the entire study
    - The amount of payment and the proposed method and timing of disbursement is neither coercive nor present undue influence

Worksheet UMB HRP 313 (cont.)

- Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would have otherwise withdrawn.

- All information concerning payment, including the amount and schedule of payments, is in the informed consent document (or script).

Worksheet UMB HRP 313 (cont.)

- Compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved

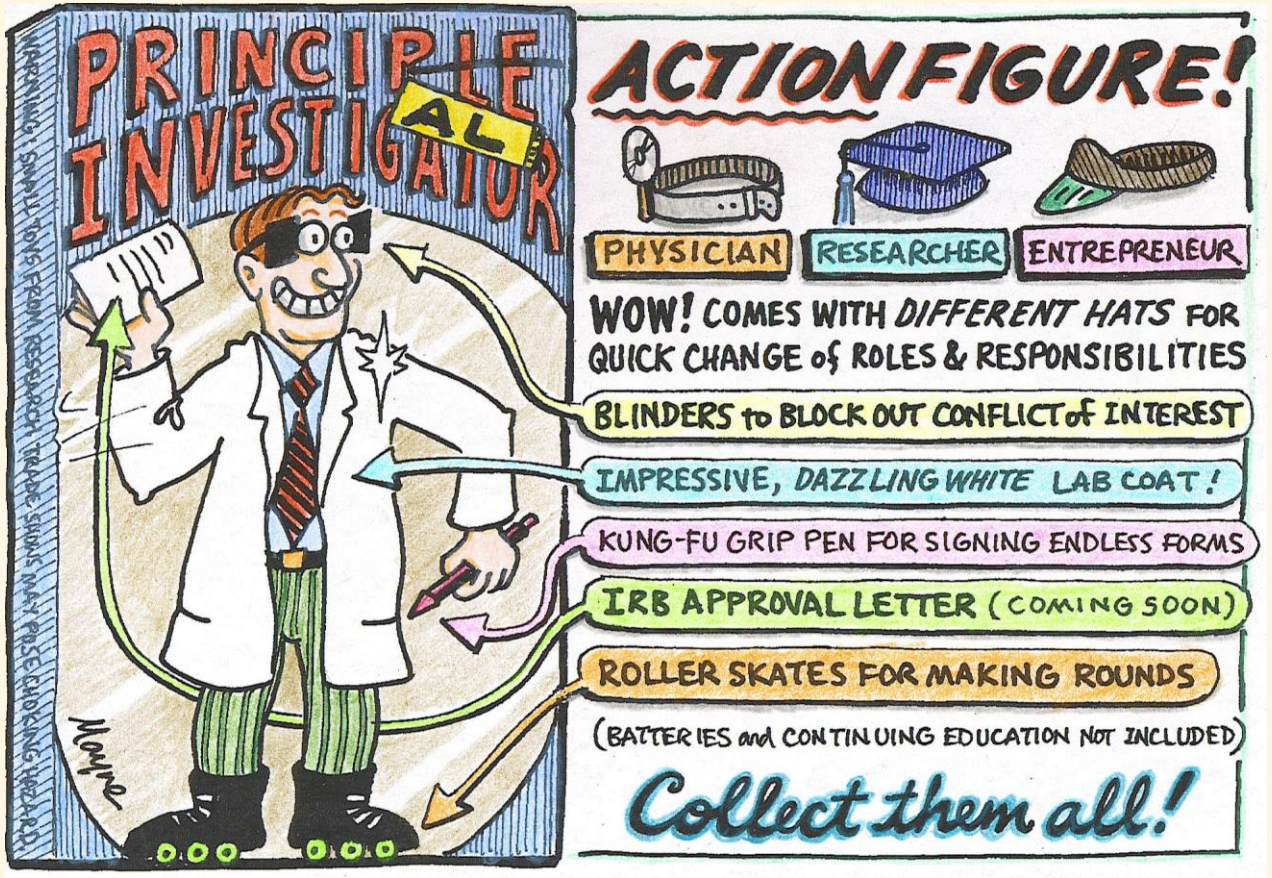
Before enrollment

- All required documents are fully executed
  - Contracts
  - Grants

  IRB approval

  - Principal Investigator should compare consent and contract or grant language to ensure consistency

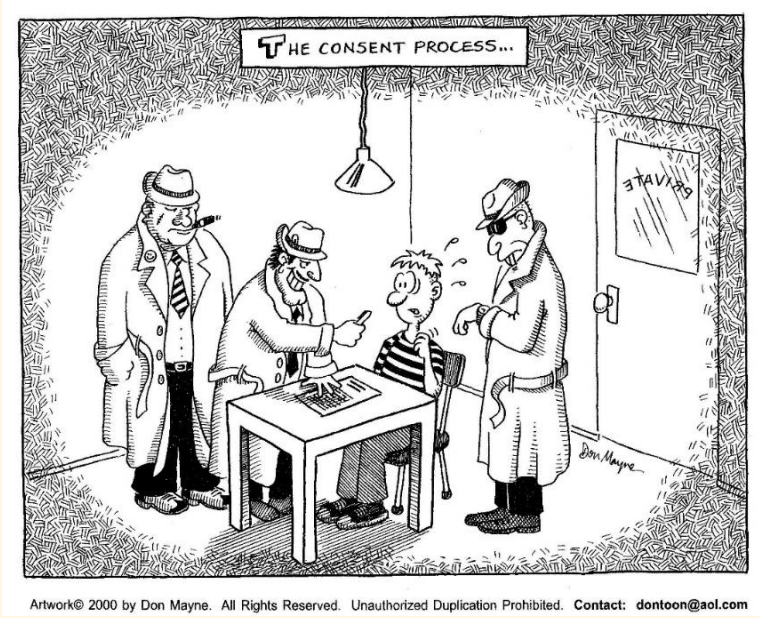
Principal Investigator



Informed Consent

- Not just a document but a process

- Review and provide adequate opportunity for participant or legally authorized representative to ask questions



Examples

Payment/Reimbursement to Participants

1 * Will participants receive payment (money, gift certificates, etc.) or reimbursement for their participation in this research?

Yes **No**

Examples (cont.)

- Informed consent document
  - Will the participant be paid for being in the study?
    - No. There will not be any payment to the participant for being in this study.

Examples (cont.)

Visit 1	$50.00
Visit 2	$50.00
Visit 3	$50.00
Visit 4	$50.00
Visit 5	$50.00
Visit 6	$50.00
Visit 7	$50.00
Visit 8	$50.00
Visit FU1	$50.00
Visit FU2	$50.00

Examples (cont.)

- **Payment/Reimbursement Detail**
  - Payment/reimbursement to participants will be for: (check all that apply):
    - *Parking*

    Total dollar value: *0*

    Describe timing and distribution plan for the payment/reimbursement (Schedule, means. etc.): *Parking vouchers will be given after completion of each research visit*

    Method of payment/reimbursement to be used : *Other: parking voucher*

Examples (cont.)

Informed consent:

- **PAYMENT TO PARTICIPANTS**
  - You will be given a parking voucher after completion of your research visits. You will not be paid for taking part in this study.

Examples (cont.)

- Payment/reimbursement to participants will be for: *Travel, Meals*
- Total dollar value of the payments/reimbursements over the duration of the study? *Approx. $22.00*
- Describe timing and distribution plan for the payment/reimbursement (schedule, means etc.)
  - *Vaccination Visit: 1000fcfa ($1.81) plus a drink and sandwich*
    Day 30: 1000fcfa ($1.81) plus a drink and sandwich
    Day of delivery: 1000fcfa ($1.81) plus 3 washcloths and soap
    6 weeks after delivery: 1000fcfa ($1.81) plus a drink and sandwich
    10 or 18 weeks after delivery (per randomized study schedule): 1000fcfa ($1.81) plus a drink and sandwich
    6 months after delivery: 1000fcfa ($1.81) plus a drink and sandwich, and soup or porridge for the baby
  - Method of payment: *Cash*

Examples (cont.)

- Informed consent document:
  - **PAYMENT TO PARTICIPANTS**
    - *Vaccination Visit: 1000fcfa ($1.81) plus a drink and sandwich*
      Day 30: 1000fcfa ($1.81) plus a drink and sandwich
      Day of delivery: 1000fcfa ($1.81) plus 3 washcloths and soap
      6 weeks after delivery: 1000fcfa ($1.81) plus a drink and sandwich
      10 or 18 weeks after delivery (per randomized study schedule): 1000fcfa ($1.81) plus a drink and sandwich
      6 months after delivery: 1000fcfa ($1.81) plus a drink and sandwich, and soup or porridge for the baby
    - Method of payment: *Cash*

Examples (cont.)

- Payment/reimbursement to participants will be for:
  - *Time and effort*
- Total dollar value of the payments/reimbursements:
  - *$50*
- Describe the timing and distribution
  - *Consented participants will be paid $30 in cash at the conclusion of their blood draw.*
    They will be paid $10 for the 30 day follow up call and $10 for the 180 day follow up call. Each of these payments will be by check.
  - Method: *Cash and check*

Examples (cont.)

- Informed consent document
  - PAYMENT TO PARTICIPANTS:
    - Upon completing the blood draw, you will be paid $30 in cash for your time. You will be asked to sign a document acknowledging your receipt of payment. After the successful completion of the 30 day and 180 day follow up calls you will be paid $10 for each call via check sent to your home.

Examples (cont.)

- External IRB is the IRB of record.
- External IRB application (CICERO) does not require specific breakdown of payments to participants.
- External IRB may not have provided final approved informed consent document.

Examples (cont.)

- Informed consent (draft)
  - You will be reimbursed for reasonable out of pocket expenses including travel and parking.
  - You will be paid for the study visits you complete according to the following schedule:
    - $xx.00 each for Visit (Screening, Baseline, Day 1, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28, Week 32, Week 36, Week 40, Week 44, Week 48, Week 52, Week 56, Week 60, Week 64 and Safety F/U visit). If you do not complete the study, for any reason, you will be paid for each study visit you do complete according to the schedule above.

Examples (cont.)

- Regardless of whether UMB or another IRB is the IRB of record, it is the Principal Investigator’s responsibility to ensure consistency in language between the final IRB approved informed consent document and contract or grant language

Examples (cont.)

- Exemptions
  - IRB review and determination
  - Continuing review not required; progress reports not required.
  - On-line surveys
  - Approved to enroll 500
  - Email provided
  - Everyone entered into a raffle who completes
  - 30/500 will be chosen to receive $100 gift card

Examples (cont.)

- Payment/reimbursement:
  - *Time and effort*
- Total dollar value:
  - *$100/each for 30 participant*

*Timing and distribution: *Raffle prizes (each valued $100) will be given to 30 randomly selected survey participants among those who agree to be included in the pull and submit e-mail address. The research team will randomly select 30 survey participants and provide an incentive of $100 (gift certificate) to each participant.*

*Method: *gift certificate/gift card*

- An eMessage containing a brief invitation message and an anonymous link to the online survey will be sent to eligible patients by the consultant of this study. Invited patients can go to the online survey website by clicking on the link within the eMessage. The first page of the survey will contain a welcome message along with the survey purpose and estimated time for taking the survey. In the second page, the information form, which is similar to a study consent form, will appear. The information form explains the purpose of this study, confidentiality protection, potential risks and benefits, and right not to participate. At the bottom of the information form, there will be two options. If patients are interested in participating, they will click “Yes, I want to participate” and will complete the survey questionnaire. If patients are not interested, they will click “No, I do not want to participate” and will be routed to the end message of the survey. The contact information for help desk will be provided to patients, so that they can ask any questions about the survey. Patients' survey participation will be anonymous and voluntary. Upon review of the information, if the patient agrees to participate by clicking the “Yes, I want to participate” button, the survey will open.

Documentation

- Regardless of payment method approved by IRB, the Principal Investigator should maintain adequate documentation of disbursement of payments to research participants.
  - Log
  - Per study visit/interaction
  - Participant/LAR should sign that a payment was received

Reportable New Information

- Failure to follow the protocol due to the action or inaction of the investigator or research staff
- Complaint of a study subject that cannot be resolved by the research team
- PI to report within 5 business days of becoming aware

- UMB Reportable New Information Bulletin and HRP SOP 024

- Questions?

- UMB Human Research Protections Office
  – 410-706-5037

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  Director
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UNIVERSITY of MARYLAND BALTIMORE

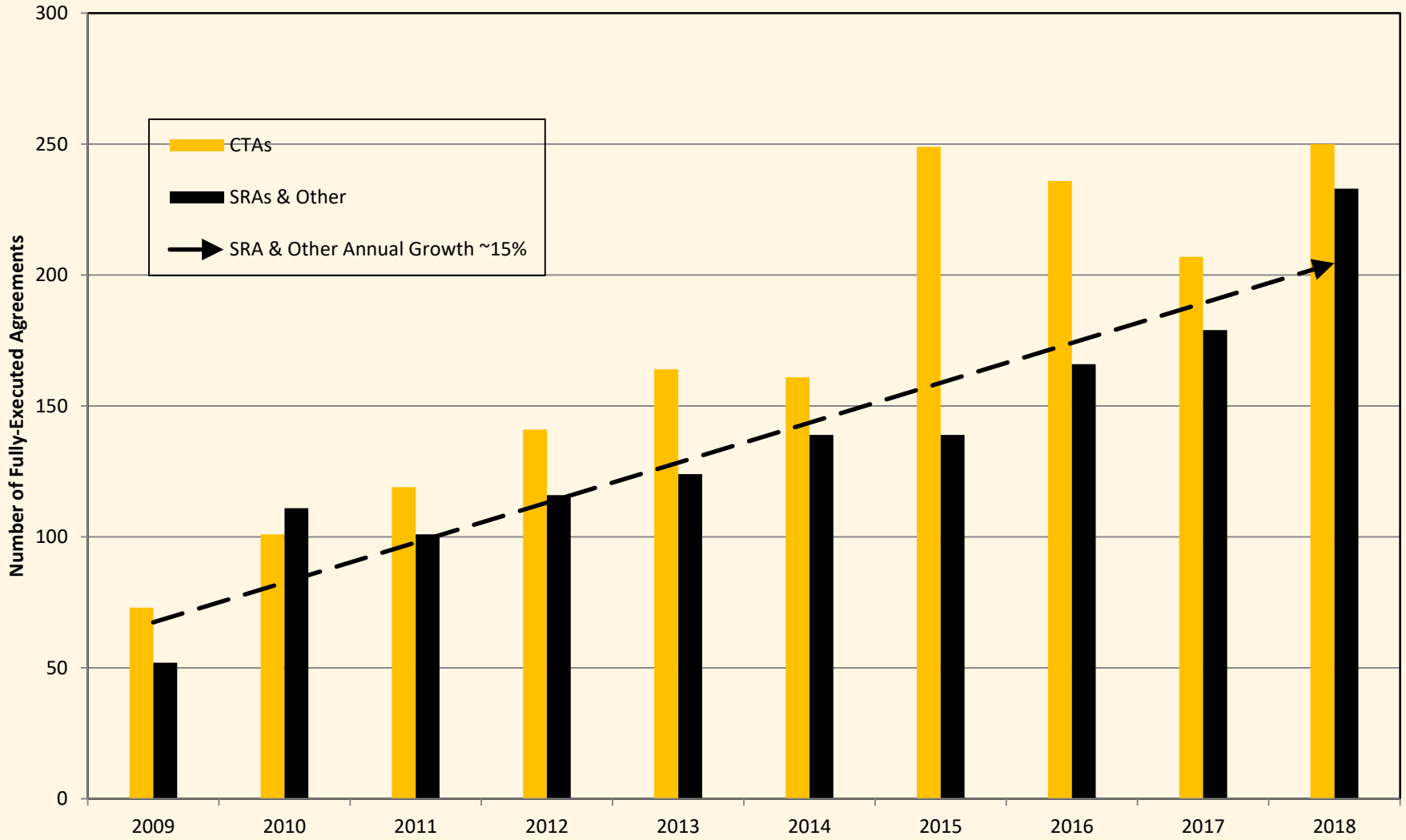
CCT's Role In Corporate-Sponsored Clinical Trials

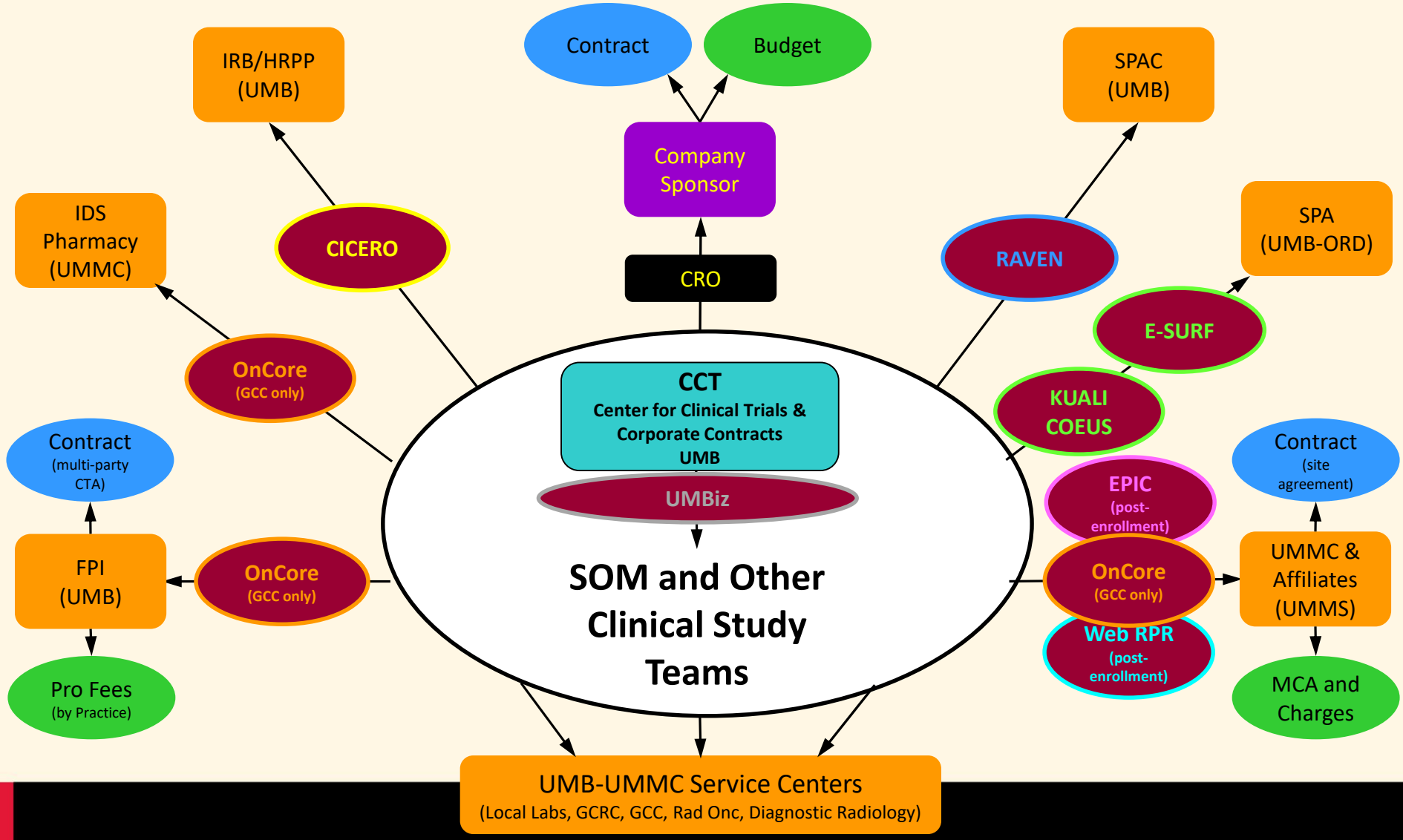
The Center for Clinical Trials & Corporate Contracts (CCT)

April 24, 2019

CCT's Role is Limited to Corporate-Sponsored Research and Related Agreements:

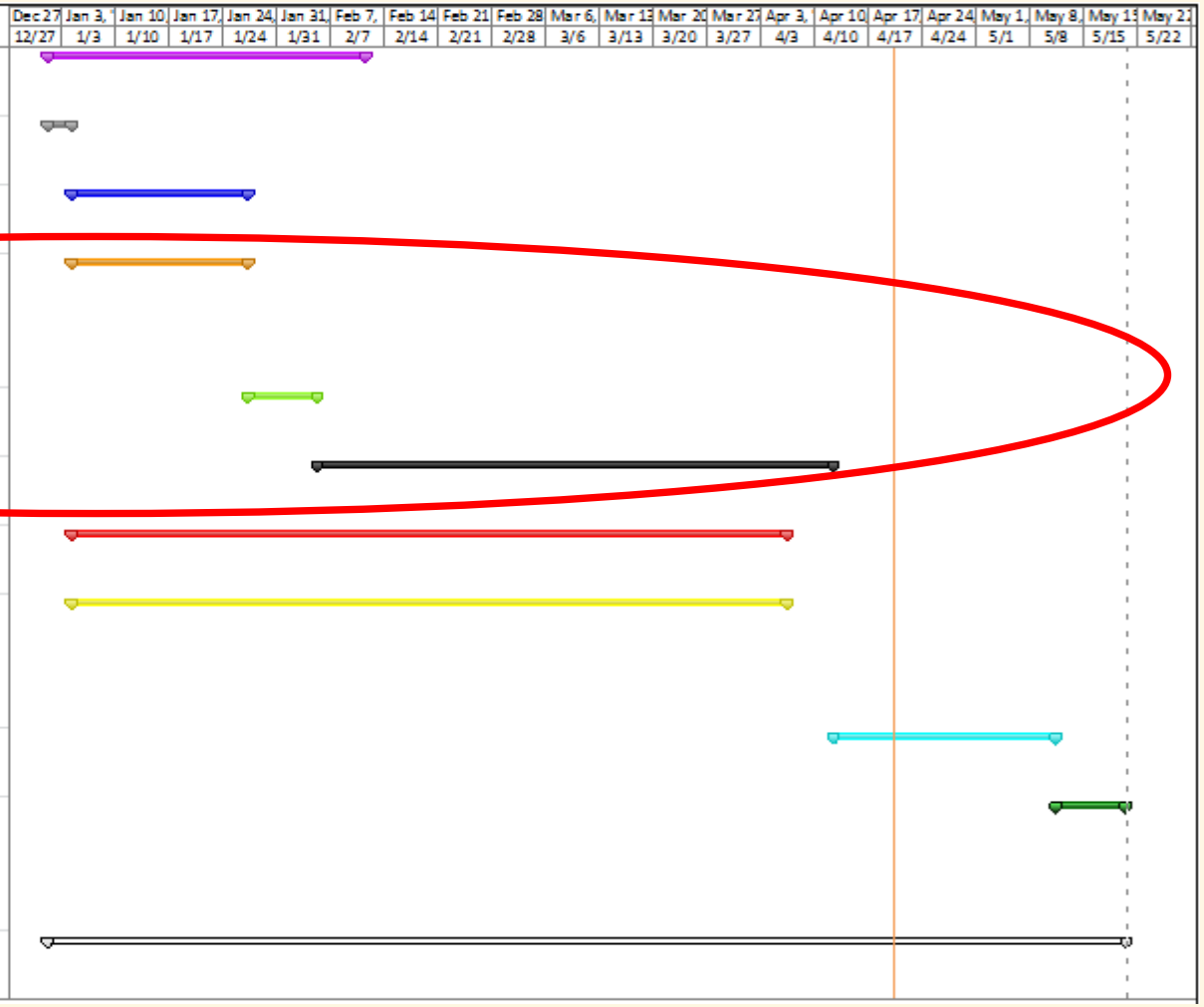
- Sponsored Research Agreements (SRAs)
- Clinical Trial Agreements (CTAs)
- Research Services Agreements (RSAs)
- Collaboration Agreements
- Unfunded Agreements:
  - Confidentiality Agreements (CDAs)
  - Data Use Agreements (DUAs)
  - Material Transfer Agreements (MTAs)
- Cost Estimates (Pricing) for Federal and Non-Profit-Funded Clinical Trials


300
250
200
150
100
50
0
Number of Fully-Executed Agreements
CTAs
SRAs & Other
SRA & Other Annual Growth ~15%
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018



"Ancillary Services"

ID	Task Name	Duration
1	IRB Submission & Approval	30 days
8	**Clinical Trial Request & Triage**	**1.4 days**
11	**MCA Development**	**16.8 days**
16	**Pre-Budget Information Acquisition/Validation**	**16.8 days**
28	**Internal Budget Development**	**7 days**
36	**External Budget Negotiation**	**47.5 days**
39	**Contract (CTA) Negotiation (2-Party CTA)**	**67.2 days**
43	**Site Agreement/Faculty Use Agreement Negotiation [2-Party CTAs Only]**	**67.2 days**
47	Contract (CTA) Execution (2-Party CTA)	21 days
54	**Contract (CTA) Routing and Project ID Setup via KUALI COEUS**	**7 days**
59	Total Project	101 days



Clinical Trials Project Management (Pre-Award)
Detailed Gantt Chart