

Clinical Trials

Organization: Teaching slides

Curtis L. Meinert



Clinical Trials

Organization: Teaching slides

Curtis L. Meinert

**Baltimore, Maryland
The Johns Hopkins University
School of Hygiene and Public Health
Center for Clinical Trials**



Copyright © 1999 by Curtis L. Meinert
All rights reserved

This document is protected under copyright laws and trade agreements. No part of it may be reproduced, stored in a retrieval system, or transmitted in any form or by any means electronic, mechanical, photocopying, recording, or otherwise without the express prior approval of the copyright owner.



Contents

<u>Acknowledgements</u>	vii
<u>Preface</u>	ix
<u>Introduction</u>	2
<u>Why this module?</u>	3
<u>Scenarios</u>	3
<u>About us</u>	4
<u>Things that concern us</u>	5
<u>About groups</u>	5
<u>Predictable tensions in collaborative research settings</u>	5
<u>Meeting</u>	5
<u>Types of meetings in the "trials business"</u>	6
<u>Sizing up a group</u>	6
<u>Robert's rules</u>	8
<u>Robert on rules of order</u>	9
<u>About Henry Martyn Robert</u>	9
<u>History of parliamentary law</u>	10
<u>Custom vs rule</u>	10
<u>Principle vs rule</u>	10
<u>Principles of parliamentary law</u>	11
<u>Implications underlying parliamentary law</u>	11
<u>Quorum</u>	11
<u>Terminology</u>	12
<u>Decorum</u>	12
<u>Deliberative assembly</u>	13
<u>Bylaws</u>	13
<u>Order of business</u>	14
<u>Majority</u>	14
<u>Motion</u>	14
<u>Some improper motions</u>	15
<u>Types of motions</u>	15
<u>Amendments</u>	16
<u>Tabling motions</u>	16
<u>Motion to reconsider</u>	16
<u>Duties and responsibilities of the chair</u>	17
<u>Do and do nots for chairs</u>	17
<u>Minutes</u>	18
<u>Test on Robert's rules of order</u>	19
<u>Meeting rules: Synopsis</u>	20
<u>Committee organization</u>	24
<u>Terminology of multicenter trials</u>	27
<u>Key organizational elements</u>	27
<u>Policy issues</u>	28
<u>Organizational tensions</u>	28
<u>Common points of tension in structures</u>	28

Contents

<u>General observations re organization</u>	29
<u>Factors and considerations affecting organization</u>	29
<u>How to "read" a group</u>	29
<u>Separations</u>	30
<u>Organizing principles</u>	30
<u>Pro tempore structures</u>	30
<u>Observations on organizing</u>	31
<u>Conflicts of interest</u>	31
<u>Screens and precautions against conflicts of interest</u>	32
<u>Study chair and vice-chair</u>	32
<u>Chair?</u>	32
<u>Chair types and models</u>	33
<u>Factors determining choice of chair</u>	33
<u>Chair designate in the funding proposal</u>	33
<u>Appointment considerations</u>	34
<u>Election considerations</u>	34
<u>Rotation considerations</u>	34
<u>Desired characteristics of a chair</u>	35
<u>Observations re chair</u>	35
<u>Observations re methods of selection</u>	35
<u>Vice-chair</u>	37
<u>Officers</u>	37
<u>Types of bodies</u>	38
<u>In regard to study committees</u>	38
<u>Steering committee</u>	39
<u>Issues in formulation of SC</u>	39
<u>Steering committee seating constructs</u>	40
<u>PI-based SC</u>	40
<u>Center-based SC</u>	41
<u>Function and discipline-based SC</u>	42
<u>Election-based SC</u>	43
<u>Interest-based SC</u>	43
<u>Grandfather-based SC</u>	44
<u>Mixed-mode SC constructs</u>	44
<u>SC recommended specifications</u>	45
<u>Executive committee</u>	45
<u>EC observations</u>	46
<u>EC recommended specifications</u>	46
<u>Research group</u>	46
<u>Observations re RG</u>	47
<u>RG recommendations</u>	47
<u>Treatment effects monitoring committee</u>	47
<u>Issues in creating a TEMC</u>	48
<u>Usual modes of creation for TEMCs</u>	48

Contents

<u>TEMC values</u>	48
<u>TEMC membership</u>	49
<u>TEMC procedural questions</u>	49
<u>TEMC recommendations</u>	50
<u>"Tests" of organization structure</u>	50
<u>Meeting and committee conduct and mechanics</u>	54
<u>Meeting "truisms" and "facts"</u>	55
<u>Housekeeping tasks</u>	56
<u>Mistakes concerning committees</u>	57
<u>Committee maintenance suggestions</u>	57
<u>On dealing with contentious issues</u>	57
<u>Ways to discredit oneself</u>	58
<u>How to register opposition</u>	58
<u>On large versus small groups</u>	59
<u>Political realities</u>	59
<u>Voting</u>	59
<u>Discussion procedures</u>	61
<u>About meeting times and places</u>	62
<u>Recommendations re meetings</u>	64
<u>Observations re research group and its meetings</u>	68
<u>Observations re SC and its meetings</u>	69
<u>TEMC organizational and operational mistakes</u>	70
<u>TEMC "perks"</u>	70
<u>Staff meetings</u>	72
<u>Off-site meeting locations</u>	73
<u>About meeting agendas</u>	74
<u>Adages and axioms about agendas</u>	74
<u>About conference calls</u>	75
<u>About meeting materials</u>	76
<u>About handouts at meetings</u>	76
<u>About slides (hard or electronic)</u>	77
<u>About overhead transparencies</u>	78
<u>Coping strategies</u>	78
<u>Meeting guidelines</u>	79
<u>Committee charge</u>	79
<u>Maintenance procedures</u>	79
<u>Committee rosters: Uses and issues</u>	80
<u>Centers</u>	82
<u>Center</u>	83
<u>Types of centers</u>	83
<u>Selection modes for centers</u>	84

Contents

<u>Funding modes</u>	84
<u>Center credentials and certifications</u>	84
<u>Questions</u>	85
<u>Study clinics</u>	85
<u>Coordinating center</u>	86
<u>Project Office</u>	91
<u>Central laboratories</u>	92
<u>Reading centers</u>	93
<u>References</u>	95

Generation time and date: (9:29am Monday) 4 January 1999

Acknowledgements

Thanks to Shoshana Reshef for help in compiling material for the section on Robert's rules and for reading and comments on drafts of slides.

A thank you to Susan Tonascia for her editors eye and hand and for her steady support in reading the slides in this compendium, always with good humor and always with an eye toward improvement.

Preface

To the inexperienced, *organization* is a dreary word connoting that which is not real work. It has overtones of *regimentation*, *administration*, and *management* – curse words for free spirited researchers!

Even if one admits that organizing is necessary, it remains as boring as watching paint dry. If it must be done, then let it be done by someone else. Surely not by me!

Real researchers have more important things to do. They are trained to think big thoughts and to work at the frontiers of ignorance and uncertainty. Their calling is higher. The nitty gritty of organizing can be left to others less concerned with lofty thought and effort.

For sure, researchers do not knowingly reveal their disinterest, if not disdain, for organizing, but you can see it in their faces and hear it in their voices. If you want to see faces cloud faster than the southwestern sky with an approaching twister and eyes glaze faster than a pond in a chiller from the northwest, start talking "organization" to gradual students. Quicker than a flash, you will be "alone". The silence will be deafening. You might as well be lecturing to stop signs; at least they do not yawn and read newspapers!

You will not fare much better in front of a group of investigators readying to embark on a trial. They will be obsessed with "getting started". The details of organization can wait. If you are so foolish as to raise organizational issues, you will be greeted with a polite, but impatient, silence – the kind without listening, save to hear you stop talking so the real talk can resume again before such an unfortunate and clumsy interruption. If you are too dimwitted (or blockheaded) to recognize the silence for what it is, eventually you will be brought to tow. First gently. *Oh that is an interesting (but irrelevant) point. You bring up an important point; we should take it up sometime (when we have less important things to do). Why don't you put your thoughts in a memo so we can give them due consideration (deep six them).* Later, less gently. *That is a (irrelevant) detail! We have more important issues before us now than details of organization.* Finally, with a club. *Shut the hell up!*

If you want to put someone down, characterize what they bring up as "detail". After all, detail is the hobgoblin of small minds!

To be sure organization is "detail" but so is the all of research. If you take research apart all you have is detail. Research is 99% boring tedium and 1% fun (getting started and finishing, especially if you have an "answer" the world wants).

"Organization" is easy to overlook because it is largely invisible. We recognize it when it is lacking, not because we long for it, but because we are reduced to frustration and tears by its lack. If we go to a meeting that goes off without a hitch, we take the planning and organization for granted. If nothing goes right, we blame the planners and organizers.

If Willie Sutton was a good bank robber it was because he was organized and paid attention to details. If Henry Ford succeeded it was because he was organized. If we got to the moon it was because thousands of people paid attention to millions of details. The same is true for trials. If

Preface

they succeed it is because people pay attention to thousands of "details" on all manner of things, including those of "organization".

Every trial, even the smallest of the small, requires the efforts of various people working together in a coordinated fashion – collaboration. For collaboration there must be organization and there is no organization without form and structure. Organization and structure was imposed by Ford with an assembly line. The reasons for organization and structure in trials are the same as those recognized by Ford. The chance of success (performing a quality trial) is small absent organization.

It seems obvious then, that if one wants to be a trialist, one had better know something about the art and science of organization, as applied to trials. Indeed, entering the field without such understanding is akin to a carpenter coming to a job without a hammer or saw.

Students of anything are impatient. They are more interested in doing than in learning, and more interested in practice than theory. They dislike, with passion, questions without answers and professors with more questions than answers.

So if these things are true, when does one teach students about organization of trials? Experience suggests that classroom students taking courses in clinical trials are more interested in sample size, stopping rules, and techniques for analysis than in how they should be organized. If you ride against the tide and talk about things they need to know rather than what they want to hear, they will boo you or engage in a sleep-in. Wait until they are ready? After they have been involved in a disaster or two? When they have been stuck once or twice? When a situation is hopeless? The window of opportunity is narrow. Start too soon and nothing sinks in. Start too late and the cows are out of the barn.

Gradual students, being yet young and energetic, are like Alaskan sled dogs. They want to go and they want to be the lead dog! In trials that means being at mission central – the place where trials are born, grow, and die. Where activities are directed from, where decisions are made.

Alas, they have yet to discover how much of their time will be spent following the lead dog. Also, yet to be discovered will be the amount of time that will be spent "sitting" – endless protocol meetings, meetings with investigators, meetings with study coordinators, meetings of study committees, meetings of writing committees, staff meetings, meetings with sponsors, meetings with advocacy groups, and meetings about meetings. They will ignore you (in the way children ignore parents when they forecast what lies ahead) if you tell them that they will spend 20% of their working lives in meetings. They will think their lives will be different now with "modern" communications, aseptic e-mail and the information clutter known as the internet. At last, fewer meetings and more science!

The naive think that trials come organized. They have trouble seeing how they are conceived of, how they are born. They think that the "milling around" that proceeds any organized activity is an empty meaningless activity. They have trouble believing that "organizing" can be as chaotic

Preface

and time consuming as suggested. They will have trouble knowing why one should care about such mundane matters as who sits on key committees and who votes. They will think voting is unnecessary because, surely, matters of science are settled by reason and consensus. They have trouble connecting trials and Robert's Rules of Order.

They will smile at the suggestion that science and politics are interrelated. They will scoff at the idea that science is not pure, that all science is political and that, therefore, so are trials.

This set of slides is offered to those who have come to realize the need for Robert's Rules (if for no more lofty reason than to defend against a horse's ass – a person with a briefcase full of slides over 100 miles from home – with a pension for Robert's Rule) and a wider base of understanding for models and procedures for organizing trials. It is for aspiring lead dogs. People who want to have a role in writing the tune they will march to.

It is not for those content to leave the detail and mechanics of organization to others, or for those still of the view that the detail of organization is for others. They are not yet ready (get something else to read)!

The slides are not part of any course (yet), though elements of them can be found in references 1 and 2. As with slides, they lack supporting text and are devoid of narrative (supplied when presented live). They are, however, written more densely and in table and list form to facilitate use in the silence of one's armchair.

Curtis Meinert
Towson Maryland
7 December 1998

Organization

Introduction

Introduction

<u>Why this module?</u>	3
<u>Scenarios</u>	3
<u>About us</u>	4
<u>Things that concern us</u>	5
<u>About groups</u>	5
<u>Predictable tensions in collaborative research settings</u>	5
<u>Meeting</u>	5
<u>Types of meetings in the "trials business"</u>	6
<u>Sizing up a group</u>	6

Generation time and date: (8:43am Monday) 4 January 1999

Introduction

Why this module?

- Like it or not, we can expect to spend a fair portion of time in meetings (upwards of 20% of one's working life for the career multicenter trialist!)
 - Meetings provide the essential "glue" of collaboration
 - To be effective as a collaborator, one needs to know the rules and procedures for orderly conduct of meetings
-

Scenarios

UGDP: The SC votes, 13 to 12, to stop use of tolbutamide. The minority mounts a challenge to the vote on the grounds that some persons were not authorized to vote. How would you proceed?

SOCA PDMB: The PDMB recommends stopping the MSL-109 treatment in the MACRT by a unanimous vote of those present. The chair is obliged to notify the sponsoring agency of the recommendation following the vote but refuses to do so until polling absent members (2) for their votes. Is the chair on proper ground?

HPT: You are the Director of the CC and you see a troubling pattern in blood pressure readings taken by a reader at a particular clinic. You want discussion of the generic issue of dealing with cases of suspicious data patterns before revealing particulars. The members of the SC want you to reveal the identity of the clinic and reader before discussing the generalities. You decline. A member of the group then introduces a motion intended to force identity. The motion is seconded. The vote is taken and the motion carries. What do you do?

Introduction

Scenarios

SOCA authorship: The SC has reviewed and adopted a corporate form of authorship for its primary results papers several meetings back. The first paper is so published, but the journal (unbeknownst to members of the writing committee) carries a running head in naming the 1st member of the writing committee. The person listed is a member of the SC. Some members of the SC are incensed and mount an effort to have the rules changed. If you are that member of the writing committee member and also the one who forged the policy under attack, how do you conduct yourself.

NETT: Certain members of the SC bristle under the notion that, as a member of NETT, they may not perform lung volume reduction surgery except in the trial. The sponsoring agency considers the requirement essential and the SC has, on a previous occasion, debated the issue and voted (13 to 6) to accept the principle. The issue resurfaces and there is a motion on the floor to relax the restriction. If you favor the status quo what can you do to avoid having a vote taken? If the vote is taken and the motion passes, what do you do to consolidate the group behind the vote?

Junior member of SC: The SC is constituted by center with votes for the director and deputy director. There is a contentious issue being debated and you are asked by your boss to vote in a way that is counter to your view. What do you do?

About us

Territorial
 Opinionated
 Need recognition and credit
 Preserving (sometimes)
 Rebellious (sometimes)
 Assertive (when provoked and motivated)
 Wanting to "make a difference"
 Curious
 Rational (at times)
 Irrational (at times)

Introduction

Things that concern us

- Space
 - Parking
 - Equipment
 - Money
 - Control
 - Recognition and rewards
-

About groups

Have "personalities" like people
When you have seen one group you have seen one
group
Like us they grow, mature, age, and die
Like us, they need care and nourishment to survive

Predictable tensions in collaborative research settings

- Control and direction (who is in charge)
 - How the money pie is divided
 - Rights to data and "ideas"
 - Standing
 - Recognition and credit (especially in regard to
publication)
-

Meeting

A body of persons assembled to transact business

Introduction

Types of meetings in the "trials business"

- Staff
 - Investigators
 - Steering and executive
 - Treatment-effects monitoring
 - Protocol
 - Writing
 - Other (working subgroup, performance monitoring, etc)
-

Sizing up a group

- Notice where people sit
 - Notice order of arrival; who arrives first; who last
 - Notice who sits last
 - Notice what causes a room to become silent
 - Notice where talk is directed
 - Take note of body postures and language
 - Take note of how people are addressed (informal: 1st name, shorten 1st name, nickname; formal: Dr, professor, Mr, Ms)
 - Note the presumed audience for "inside" jokes or stories
 - Take note of the way personal pronouns are used; we, us, them, I, me
 - Take note of implied reference in uses of "investigator"; "principal investigator"; researcher, scientist; note whether uses are inclusive or exclusive
-

Organization

Robert's rules

Robert's rules

<u>Robert on rules of order</u>	9
<u>About Henry Martyn Robert</u>	9
<u>History of parliamentary law</u>	10
<u>Custom vs rule</u>	10
<u>Principle vs rule</u>	10
<u>Principles of parliamentary law</u>	11
<u>Implications underlying parliamentary law</u>	11
<u>Quorum</u>	11
<u>Terminology</u>	12
<u>Decorum</u>	12
<u>Deliberative assembly</u>	13
<u>Bylaws</u>	13
<u>Order of business</u>	14
<u>Majority</u>	14
<u>Motion</u>	14
<u>Some improper motions</u>	15
<u>Types of motions</u>	15
<u>Amendments</u>	16
<u>Tabling motions</u>	16
<u>Motion to reconsider</u>	16
<u>Duties and responsibilities of the chair</u>	17
<u>Do and do nots for chairs</u>	17
<u>Minutes</u>	18
<u>Test on Robert's rules of order</u>	19
<u>Meeting rules: Synopsis</u>	20

Generation time and date: (8:44am Monday) 4 January 1999

Robert's rules

Robert on rules of order

Where there is no law but every man does what is right in his own eyes, there is the least of real liberty.
(p 14)³

... that there may be a uniformity of proceedings in business, not subject to the caprice of the chairman, or captiousness of the members (p 14)³

About Henry Martyn Robert

- Born: 2 May 1837 (Robertsville, SC); died: 11 May 1923
 - Engineer in the US military (General)
 - 1876; 1st version of rules published; by 1915 500,000 copies in circulation
 - Life effort: “assist an assembly to accomplish the work for which it was designed in the best possible manner” (p 14)³
-

Robert's rules

History of parliamentary law⁵

- 450 BC Roman Forum institutes legal code, the practice of majority vote, and shorthand for taking notes or minutes
 - 1212 AD King John signs Magna Carta, gives nobles civil rights and regularizes judicial system, thereby forming basis of English constitutional liberties
 - 1321 AD Book on parliamentary law issued in England
 - 1592 AD England, proponents of both sides of an issue given equal opportunity to speak; term *chairman* introduced
 - 1619 AD First legislative assembly in American colonies, Jamestown, Virginia
 - 1801 AD Thomas Jefferson publishes manual of parliamentary law
 - 1876 AD Henry M Robert publishes rules of parliamentary law
-

Custom vs rule

Custom: The usual way of acting in a given circumstance

Rule: Regulation governing conduct, procedure, arrangement, etc

Principle vs rule

Principle: Fundamental concept, law, doctrine, or assumption

Rule: Prescribed guide for conduct or action deriving from a principle; a regulation or bylaw governing procedure or controlling conduct

Robert's rules

Principles of parliamentary law

- The right of the majority to rule
 - The right of the minority to be heard
 - The right of the individual to participate in the decision making process
-

Implications underlying parliamentary law

- Majority rule with protection of rights of minority
 - Minority heard
 - Full and free participation of all members
-

Quorum

Definition: (1) The minimum number of officers or members (often a majority) of a body required for it to be convened for conduct of business; (2) a select group

Rationale: For proper representation of interests, knowledge, or expertise for the purpose of ensuring "balance" in deliberations and transactions

Comment: Typically set by agreement at outset or as specified in bylaws

Examples: Society for Clinical Trials by laws;⁴ IRB specification

Robert's rules

Terminology

- Assembly
 - Business: Purposeful activity
 - Chair
 - Floor
 - Majority
 - Member
 - Motion (Question)
 - Pending
 - Precedence
 - Pro tem
 - Proxy
 - Quorum
 - Session
 - Standing committee
 - Table
 - Vote
-

Decorum

- Address all remarks to the assembly
 - Speak to the issue; not to motives of proponents or opponents
 - Do not be disruptive; spurn side conversations; avoid interruptions
 - Be polite and courteous
-

Robert's rules

Deliberative assembly

Assembly: An organized group of people meeting to conduct business

Deliberative assembly: People gathered to discuss an issue of importance

Types

- Mass meeting
- Convention
- Organized society
- Legislative body
- Board or committee

Features

- Acts as an independent body
 - Every member has right to speak
 - One person one vote (ie, all persons have same weight in voting)
 - Majority rule
-

Bylaws

A set of rules created and adopted by a body for the government of its members and regulations of its affairs; includes statement of purpose of organization, qualifications for membership, duties of officers, selection of officers, quorum requirements for meetings, etc

Robert's rules

Order of business

Call to order
Approval of minutes
Approval of agenda
Report of the chair
Committee reports
Unfinished business
New business
Executive session
Adjournment

Majority

The greater part or number

Motion

Motion: A proposal for action offered by a member in a meeting

- Second required (usually)
- Can be debated
- Can be amended
- Majority vote to pass
- Can be reconsidered

Process

Member states a motion
Another seconds motion
Chair repeats motion
Chair calls for discussion
Chair puts motion to vote
Chair announces result

Robert's rules

Some improper motions

- Motion to adjourn with a motion on the floor
- Motion that conflicts with a tabled motion
- Motion that conflicts with existing bylaws
- Move to consider more than one motion at a time

Types of motions

Motion (also **main motion** or "**question**"): A formal suggestion or proposal made to an assembly; **resolution** when motion states a policy, principle, feeling, or sentiment, usually with an explanatory preamble and a series of "whereas" statements

Subsidiary motion: Motion made to aid in disposition of main motion by modification; cannot stand alone; takes priority over main motion in consideration. **Examples**: Amendments to main motion, tabling motion, motion for indefinite postponement

Incidental motion: Motion directly related to motion on floor of meeting; takes precedence over main and subsidiary motion; cannot be amended; cannot be debated (except for appeal). **Examples**: Division of a question, point of order, suspend the rules, appeal of decision of the chair

Privileged motion: Motion dealing with matter of pressing importance; highest ranking; can interrupt any business on the floor without debate or discussion. **Examples**: Adjournment, recess, question of privilege, call for order of meeting

Robert's rules

Amendments

A subsidiary motion typically intended to make a motion more specific or acceptable

Yields to:

- privileged motions
- Incidental motions
- Subsidiary motions to Limit/Extend Debate
- Previous Questions

Can be amended and reconsidered

Requires majority vote to pass

To be in order: Must pertain to motion on floor; may be friendly or hostile, but not negative; eg, may change word from "*praise*" to "*censure*", but not to "*not praise*"

Tabling motions

A motion to place a motion and all pending amendments aside with the intention of bringing them back at a later time; requires a second; not debatable; cannot be amended; requires a majority vote; may not be used to subvert or defeat a motion by disposing of it permanently

Motion to reconsider

Motion made to reconsider an action; can be made on day of an action or on the first business day following an action; needs a second, cannot be amended, is debatable, requires majority vote

Robert's rules

Duties and responsibilities of the chair

Duties

- Seeing that a quorum is present
- Opening the meeting
- Announcing the business of the assembly and the order of the agenda
- Recognizing speakers
- Stating a motion and putting it to vote
- Announcing the result of a vote
- Ensuring order and proper decorum
- Enforcing rules of debate
- Ruling on questions of order; ruling motions out of order
- Instructing as to points of order, as need be
- Authenticating the proceedings by signature
- Declaring the meeting adjourned

Responsibilities

- Set a good example
- Know rules for meetings and bylaws of the organization
- Know committee structure of the organization and membership of committees
- Follow the agenda

Do and do nots for chairs

Do

- Have a written agenda
- Call the meeting to order on time
- Entertain one piece of business at a time
- Protect the rights of the minority
- Preserve the will of the majority
- Refer to oneself in the 3rd person; as in "the chair rules"
- Maintain decorum
- Maintain a quorum
- Encourage full participation
- Be in control of oneself
- Take a vote correctly
- Use tact in enforcing rules
- Be impartial
- Say: "The motion is out of order"
- Preserve order and decorum at all times
- Insist that members follow the rules of the organization
- Step down graciously when ones term expires

Robert's rules

Do and do nots for chairs

Do not

Arrive late or ill-prepared
 Let issues become muddy
 Speak for a person
 Let a small group monopolize the debate
 Use the first person pronoun I, as in "I think"
 Allow members to become personal in debates
 Favor a minority or fraction
 Lose your temper
 Lose track of the vote
 Be pedantic about enforcing rules of order
 Try to make people bend to your will
 Say "You are out of order" when it is the motion that is out of order
 Use one's office for personal gain
 Change things because "you are in charge"

Source: Adapted from Rozakis⁵

Minutes

A dispassionate written record of proceedings; not a vehicle for commentary; should succinctly summarize; avoid overly technical terms; should not be a transcript-like

Use proper grammar, spelling, and punctuation

Include:

Name of organization
 Date, time, place of meeting
 Type of meeting (regular, special, emergency)
 Officers present; officers absent
 Whether minutes of previous meeting read and approved

Robert's rules

Test on Robert's rules of order

- 1 A motion may not be debated without a second?
 - 2 A motion to table is not debatable?
 - 3 A motion to "call the question" (also referred to as "previous question") is not debatable?
 - 4 A motion is out of order if _____.
 - 5 If a motion to reconsider fails the matter may not be brought up again?
 - 6 A subsidiary motion is _____.
 - 7 A motion to amend takes priority over the primary motion?
 - 8 A resolution is a special kind of motion?
 - 9 The chair has the prerogative of calling the question?
 - 10 A motion to adjourn requires a simple majority to pass?
 - 11 A person may withdraw a motion after it has been seconded?
 - 12 Name the 3 principles underlying Robert's rules? (right of majority, right of minority to be heard, right of individual to participate)
 - 13 The chair votes only in the case of a tie?
 - 14 What is a quorum?
 - 15 A motion to close debate requires a 2/3 majority vote?
-

Robert's rules

Meeting rules: Synopsis (ala Robert's Rules)⁵

Quorum: Minimum number of members (set by group; usually a majority) of body required to conduct business; may entail other requirements, eg, presence of designated persons in addition to chair or acting chair

Motion (*I move that; I second the motion*)
Chair repeats motion; opens floor for discussion

Motion to call question (*I move the question be called*)
Not debatable; 2/3rds majority required for passage; question must be voted without further debate if motion passes

Motion to adjourn (*I move we adjourn*)
Not debatable; 2/3rds majority required for passage

Motion to divide a question (*I move to divide the question ...*)
To separate a question into parts to allow for separate votes; requires second; can be amended; not debatable; may not be reconsidered

Motion to reconsider (*I move that we reconsider the motion passed at our last meeting concerning ...*)
May be made on day of an action or on first day of next meeting; cannot be amended; not debatable; requires majority vote
Effect if rejected is to dispose of an issue with impunity

Motions not requiring a second

Point of order

Point of information

Verification of vote (usually by show of hands or roll call, when outcome of initial vote unclear)

Motions requiring a 2/3rds majority

Motion to end debate or to call the question

Motion to not debate a question perceived to be "off the topic" or disruptive

Motions requiring a simple majority

All seconded motions except the two above

Decorum

- Address remarks to the assembly
- Speak to the issue; not to motives of proponents or opponents; do not engage in personal attacks
- Do not be disruptive; no side conversations; no interruptions
- Be polite and courteous

Speaking

Person expresses desire to speak by raised hand, standing, or other means; speaks only when recognized

Debate on a motion

Persons wishing to speak wait to be recognized; then speak for or against the motion or addresses issues relevant to consideration of the motion

Debate continues until motion is voted; usually when debate subsides or when question is called

Amendments (*I move that the question (motion) be amended as follows ...*)

Must relate to motion on the floor; normally offered to simplify, make more explicit, change, or clarify language; or to mollify to improve chance of passage

Debatable; must be voted before disposing of the primary motion

Out of order

Adjournment with a motion on the floor
Two motions on the floor at the same time
Improper behavior of a member

Voting modes

Secret ballot

Robert's rules

Meeting rules: Synopsis

Open ballot (votes recorded on ballot then revealed)
 Show of hands
 Roll call

Order of business

Call to order
 Approval of minutes
 Approval of agenda
 Report of chair
 Report of committee
 Unfinished business
 New business
 Executive session (when indicated and appropriate)
 Adjournment

Point of order (*I rise to a point of order.*) (*Mr chair, does the motion to waive the reading of the minutes require a second?*) (*If there is no objection, I wish to read into the record the following document.*)

Does not require a second; not subject to debate, amendment, or vote; may relate to question of rules or procedures, need for information (point of information), or for reading of documents to the assemblage

Chair duties

Seeing that a quorum is present
 Opening the meeting
 Announcing the business of the assembly and the order of the agenda
 Recognizing speakers
 Stating a motion and putting it to vote
 Announcing the result of a vote
 Ensuring order and proper decorum
 Enforcing rules of debate
 Ruling on questions of order; ruling motions out of order
 Instructing as to points of order, as need be
 Authenticating the proceedings by signature
 Declaring the meeting adjourned

Chair dos and do nots

Do

Have a written agenda
 Call the meeting to order on time
 Entertain one piece of business at a time
 Protect the rights of the minority; preserve the will of the majority
 Refer to oneself in the 3rd person; as in "the chair rules"
 Maintain decorum and order
 Maintain a quorum
 Encourage participation
 Be in control of oneself
 Take votes correctly
 Be tactful
 Be impartial

Chair do nots

Arrive late or ill-prepared
 Speak for a person
 Let a small group monopolize the debate
 Use the first person pronoun I, as in "I think"
 Allow members to become personal in debates
 Favor a minority or fraction
 Lose one's temper
 Be pedantic in enforcing rules of order
 Make people bend to your will
 Saying "You are out of order" (motions are out of order)
 Use the position for gain
 Change things because one is in "charge"

Dealing with inapt or arbitrary chair

Discussion
 Points of order to remind chair of rules; appeal of ruling via motions
 Votes (no confidence or censure)
 Proceedings to remove from office

Discussion modes

By request
 By solicitation of the chair

Robert's rules**Meeting rules: Synopsis**

Round robin (everyone given an opportunity to express opinion in some predetermined order)

Organization

Committee organization

Committee organization

<u>Terminology of multicenter trials</u>	27
<u>Key organizational elements</u>	27
<u>Policy issues</u>	28
<u>Organizational tensions</u>	28
<u>Common points of tension in structures</u>	28
<u>General observations re organization</u>	29
<u>Factors and considerations affecting organization</u>	29
<u>How to "read" a group</u>	29
<u>Separations</u>	30
<u>Organizing principles</u>	30
<u>Pro tempore structures</u>	30
<u>Observations on organizing</u>	31
<u>Conflicts of interest</u>	31
<u>Screens and precautions against conflicts of interest</u>	32
<u>Study chair and vice-chair</u>	32
<u>Chair?</u>	32
<u>Chair types and models</u>	33
<u>Factors determining choice of chair</u>	33
<u>Chair designate in the funding proposal</u>	33
<u>Appointment considerations</u>	34
<u>Election considerations</u>	34
<u>Rotation considerations</u>	34
<u>Desired characteristics of a chair</u>	35
<u>Observations re chair</u>	35
<u>Observations re methods of selection</u>	35
<u>Vice-chair</u>	37
<u>Officers</u>	37
<u>Types of bodies</u>	38
<u>In regard to study committees</u>	38
<u>Steering committee</u>	39
<u>Issues in formulation of SC</u>	39
<u>Steering committee seating constructs</u>	40
<u>PI-based SC</u>	40
<u>Center-based SC</u>	41
<u>Function and discipline-based SC</u>	42
<u>Election-based SC</u>	43
<u>Interest-based SC</u>	43
<u>Grandfather-based SC</u>	44
<u>Mixed-mode SC constructs</u>	44
<u>SC recommended specifications</u>	45
<u>Executive committee</u>	45
<u>EC observations</u>	46
<u>EC recommended specifications</u>	46
<u>Research group</u>	46
<u>Observations re RG</u>	47
<u>RG recommendations</u>	47
<u>Treatment effects monitoring committee</u>	47
<u>Issues in creating a TEMC</u>	48

Contents

<u>Usual modes of creation for TEMCs</u>	48
<u>TEMC values</u>	48
<u>TEMC membership</u>	49
<u>TEMC procedural questions</u>	49
<u>TEMC recommendations</u>	50
<u>"Tests" of organization structure</u>	50

Generation time and date: (8:52am Monday) 4 January 1999

Terminology of multicenter trials

PI
Investigator
Center
 Clinics
 Resource centers
Center director
Study chair
Officer

Things to avoid

Center as a synonym for clinic
Investigator as synonym for physician investigator
PI in multicenter trials
PI to refer to directors of clinics in multicenter trials

Key organizational elements

Positions

Chair
Vice-chair
Director of coordinating center
Project officer

Bodies

Investigative group
Steering committee
Executive committee
Treatment effects monitoring committee

Committees

Policy issues

- Mechanisms for protection against conflicts of interest
 - Payments for Advisory Review and Treatment Effects Monitoring
 - Authorship and presentations procedures
 - Policies and procedures for access to study data
 - Data analysis policies and rights of individual centers
 - Training and certification procedures
 - General guidelines on employee responsibilities for protection of patient rights
 - Backup systems for data records and files
-

Organizational tensions

Who is in charge?
Who reports to whom?
Who has the final say?
Who has review authority?
Where does the power to initiate lie?
What is the order among committees?

Common points of tension in structures

- SC and EC
 - EC or SC and sponsor
 - Chair and CC Director
 - SC and TEMC
 - TEMC and sponsor
-

Committees

General observations re organization

Generally, sponsors can be expected to be more controlling when they are the initiator or when funding is via contracts with the sponsor than with grant support or when the activity is investigator initiated. The needs and requirements of sponsors are real and should not be ignored.

Organizational charts are usually out-of-date and rarely reflect the realities of a structure.

Lone Rangers and "Cowboys" regard detail regarding organization as fine print that can be ignored (until it concerns them).

Generally, the only time persons are concerned about organization is when it affects them.

Factors and considerations affecting organization

Mode of funding (grant vs contract)

Method of funding (fixed sum vs head or piecework payment)

Expectations and requirements of sponsors

Regulatory requirements

Data access and rights

Number and location of centers

Diversity of disciplines and pecking order of disciplines

Desired or required separations

How to "read" a group

- By knowing the mix of disciplines represented
 - By knowing the affiliations of its members
 - By noting where persons are seated or where they seat themselves
 - By noting where persons look when they speak
 - By body language
-

Committees

Separations

- Patient and treater
 - Treater and evaluator/observer?
 - Clinics and coordinating center?
 - Sponsor and investigators?
-

Organizing principles

- Formulate organizational structure before starting trial
 - Delineate and separate functions of key committees
 - Specify relationship of one committee to another
 - Specify committee membership and voting rules
 - Delineate disclosure requirements for protection against conflicts of interest
 - Review and revise organizational structure as trial proceeds
 - Bylaws?
-

Pro tempore structures

Structures created in an interim; usually created to dissolve when permanent structure has been created or with a sunset clause
Used when it is premature to create a permanent structure because of uncertainty as to appropriate structure or to reduce risk of mistake absent sufficient information or knowledge
Useful expedient in sponsor-initiated activities when group assembled needs time to organize

Committees

Observations on organizing

- Groups are easily bored when it comes to organization
 - Groups are impatient and tend to want to come up with something so as to "done with it"
 - One needs "tricks" and constructs to keep a group from acting too soon or precipitously
 - One can assume the researcher, inexperienced in multicenter research, to be mildly disdainful of discussion of organization because it is "administration" – a mind set not unlike that of PhD students
 - It takes months to organize from a cold start
 - The typical person will not appreciate the fine points of organization
 - Silence, when it comes to organization, should not be mistaken for acceptance
-

Conflicts of interest

Any activity, relationship, association, or position that influences or is likely to influence one's judgment, course of action, or position taken in relation to exercising some specified function or role

Types

Financial (proprietary or ownership interests, stock, stock options, future interests)

Philosophical (from having taken stands in editorials or letters in scientific journals counter to the trial or its purpose)

Emotional (eg, by being opposed to randomization or use of placebos)

Employment (consulting or retainer relationship with proprietary sponsor; being supported by a trial that you monitor)

Duty (eg, as in duty to patients vs the study protocol)

Operational (eg, having previously served as a promoter or spokesperson for a sponsor's drug)

Observations

- Credibility can be eroded by the mere perception of conflict of interest
 - Conflicts come and go
 - Life is filled with conflicts of interest
 - It is a virtual impossibility to create committees free of conflicts of interest
 - It is better to strive for a balance of conflicts than absence of conflicts when forming committees
-

Committees

Screens and precautions against conflicts of interest

Education (eg, by discussion at RG meetings)

Tests (eg, by exclusion based on information provided; signed statement, eg, as from PI prior to funding attesting to willingness to randomize)

Disclosures (eg, by establishing procedures for disclosure at annual intervals)

Reviews (eg, by systematic review of disclosure statements and action to eliminate conflicts when found)

Study chair and vice-chair

The titular head of the investigative group; typically presides over steering committee meetings and meetings of the research group

Chair?

Who?

How long?

Duties?

Committees

Chair types and models

Types

- De jure
- Appointed
- Elected

Models

- Assumed
- Rent-a-chair
- Rotating
- Ex officio

Factors determining choice of chair

- Mode of initiation (investigator initiated vs sponsor initiated)
- Source of funding (eg, industry vs NIH)
- Desire of sponsor to control or assert "ownership"
- Independence and separation

Chair designate in the funding proposal

Specified

- Implicit (assumed to be PI in RO 1 application)
- Designated (person named, eg, as in investigator initiated applications for multicenter trials; rare in RFA and RFP modes of initiation)

Not revealed (sometimes the case in NIH RFPs)

Unspecified (usually the case in RFAs)

Committees

Appointment considerations

How is a candidate identified?

Domain of choices (internal or external to the study group)?

How is a candidate screened for eligibility re conflicts of interest, integrity, and research credentials?

Who makes the appointment: Investigators or sponsor?

Advice and consent role for non-appointing authority (investigators when sponsor appoints, and sponsor when investigators appoint)?

Election considerations

Process for identification of suitable candidates

Domain of choices (Internal or external to study? Discipline? Degree?)

Type of election: By vote or acclimation?

When is an election held?

Who may vote? Absentee or proxy votes?

Open or closed vote?

Term? Term limit?

Rotation considerations

Persons eligible for rotation?

Period of service?

Order of rotation? (Lots, position, location)

Committees

Desired characteristics of a chair

Integrity
Experience
Standing
Patience
Resilience
Independence

Observations re chair

One of the most important persons in the study
A weak chair may make for a bad study
Generally, the rotating chair model leads to weak and inconsistent leadership
Inconsistency of position or philosophy can be dispiriting
A chair that does not respect or appreciate what a coordinating center does spells "T-R-O-U-B-L-E" for the coordinating center
A good chair will know how to run a meeting

Observations re methods of selection

General

Entering a study where the chair is unknown is the academic equivalent of joining a chair-less department
Investigator initiated proposals for multicenter trials are likely to be seen as "weak" when chair-less, even if details included to indicate how a chair would be selected
Vagueness of detail as to chair in RFPs means that the sponsor probably will have the final say in selecting or designating the chair

Committees

Recommendations re chair

Appointed

Investigators will find it hard to appoint when they are choosing among their own

Appointment necessary when person external to the trial desired for chair
 Advantage to appointed external chair is in independence (ie, not associated with any center in the trial); disadvantage can be in detachment

Sponsors intending to select the chair should make that intention known when soliciting applications from investigators; if the selection has been made when the RFP is released, the RFP should name the person

Appointment should be with the advice and consent of the sponsor when made by investigators and with the advice and consent of the investigators when made by the sponsor

Election

If election is used, avoid until the research group has formed and "matured" (ie, do not hold election "too soon")

Usually requires some pro tem structure until elections can be held

Ideally, pro tem chair should be person not interested in being elected chair
 Likely to produce weak leadership structure, especially in presence of short term and absence of provision for re-election

Generally best used in conjunction with specified term, with provision for re-election

"Directive" sponsor unlikely to be pleased with election as method of selection

Term can be useful expedient for "escape" from inept chair

Use election rather than arbitrary rotation

If uncertain as to long term leadership qualities of elected persons, elect for limited term

Nomination and election processes can be contentious and may result in "bruised" feelings

They can produce a feeling of "democracy" but only if the processes are "open" and all members of the research group are accorded the right of vote

Election by the executive committee is likely to be seen as a travesty

Election by the steering committee is likely to be seen as creating a "have" and "have not" investigatorship

Committees

Recommendations re chair

Rotation

Change can be refreshing, but most transitions are messy and "memory" is usually lost (ie, loss likely to be greater than gain, especially when study is short, period of rotation is short, or basis for rotation is artificial)
Usually, rotating chairs make for uncertain and weak leadership structures
Sometimes useful as an expedient to deal with an inapt de jure chair
Generally best avoided, except perhaps when planned and timed to correspond to stage of trial (eg, in transition from design and implementation to execution)

Vice-chair

A person having the duty to assume responsibility of the study chair in the absence, departure, or incapacitation of the study chair

Qualifications: Same as for chair

Selection: Usually by designation in conjunction with the chair and steering committee or executive committee

Officers

The set of persons holding elected or designated offices in a trial; in multicenter trials generally the study chair, study vice-chair and heads of key centers, such as the coordinating center and project office; may form executive committee; usually exofficio voting members of steering committee and may be exofficio members of treatment effects monitoring committee (with or without vote)

Committees

Types of bodies

Key committees

- Steering committee
- Executive committee
- Treatment effects monitoring committee

Other bodies

- Research group
 - Subcommittees
 - Ad hoc committees
 - Working groups
-

In regard to study committees

Recommendations

- Strive for a minimal number of committees
- Create only when need is apparent
- Do not create without a written charge
- Make reporting responsibility clear at creation
- Avoid overlapping responsibilities
- Except for key committees, create with sunset provision
- Strive for compactness of number per committee

Things to remember

- Every committee involves administrative overhead and requires support
 - The logistics of meeting increase with size and geographical expanse
 - A steering committee loses its ability to steer with increasing size
 - The optimal size is usually much less than the actual size
 - A committee without a charge is like a loose cannon ball on a rolling ship
-

Committees

Steering committee

A committee responsible for conduct of the trial; usually constituted to provide representation from all or selected centers in the trial

Duties: Protocol development, implementation, and maintenance; good and welfare considerations of persons studied; commissioning of subcommittees, working groups, and writing committees; performance monitoring and disciplinary actions; research agenda; review and input body for meeting agendas; policy setting in regard to authorship and presentations; reviewing authority for ancillary studies; deliberating body for proposed protocol changes

Reporting: To the research group; may also report to funding agency via chair in the case of sponsor-initiated trials

Authority: Usually final in investigator initiated, grant funded, trials; shared with sponsoring agency in sponsor initiated trials

Issues in formulation of SC

Duties?

Authorities?

Representation of investigators, centers, positions, disciplines, and functions?

Patient as a member?

Representation of advocacy or other special interest groups?

Meetings open to any member of the research group?

Public access to meetings; minutes?

Treatment effects committee representative?

Committees

Steering committee seating constructs

PI
 Clinic directors
 Center directors
 Grandfather
 Discipline
 Function
 Interest

PI-based SC

Construct: Only persons recognized or designated as a PI sit

Strengths

Intuitively appealing; easy to sell and to implement
 Avoids anxiety of sharing power with persons not having line responsibilities

Shortcomings

Tend to be elitist, especially when PI is used as synonym for physician investigator or for clinic directors
 Creates governance structure top heavy in clinical expertise and interest and impoverished regarding other kinds of PIs in multidisciplinary settings
 Emphasis on PIship may tend to disenfranchise or "cow" research group members and give little hope for proper credit for effort for young members of group
 Leads to unmanageable size when number of PIs is large

Recommendation

Generally best avoided because of shortcomings
 Do not use where number of centers is large, where only physician-investigators are considered to be PIs, or where trial involves competing medical specialties

Committees

Center-based SC

Construct: One or two members per center

Strengths

Largely the same as for PI-based representation

Common and appealing mode of formation, especially when the number of centers is modest

Shortcomings

Similar to those for PI-based to the extent that PI is used synonymously with clinic or center director

Often operational equivalent to PI-based representation, especially when voting is done in the absence of any center polling

Ill-suited for trials involving competing medical specialities (eg, surgeons and medical people in a trial of surgery vs medical treatment), especially when clinics are selected to be headed by a given speciality

Leads to unmanageable size with increasing number of centers

Voting can be divisive because representation is by center, therefore person voting has a duty to "poll" constituents before voting; failure to do so will be seen as a "slight" when person's vote is counter to majority view in center

Likely to lead to gallery seating for persons of centers not seated

Likely to lead to proxy voting or to challenges to votes when a center is not represented

Recommendation

Avoid with large number of centers and where trial involves competing specialities

Use cautiously and only when members and voting rules and procedures are spelled out in advance

Do not use if sponsor unwilling to cover cost for gallery members

Committees

Function and discipline-based SC

Construct: Formulated to include the persons from the trial with the disciplines needed for conduct of the trial and persons performing essential functions

Strengths

- Has potential for providing a discipline and function balanced body group; in that regard, better than PI- or center-based construct
- Can make for better deliberative and decision making processes because of collective understanding and knowledge
- Egalitarian; may produce more active and involved research group
- Allows for compactness of number
- Avoids implied elitism of PI-based and center-based constructs

Shortcomings

- Not usually "appealing" to PIs or center directors because of implied power sharing
- Requires thought with regard to positions and disciplines to be represented
- Requires system for nomination of representatives of positions and disciplines
- Can lead to passive members because of elections or because they felt "cowed" by more powerful members

Observations

- Difficult to move to this form of representation if once organized under PI-based or center-based construct
- Shortcomings of PI-based or center-based constructs will not be obvious at outset; lacking such insights senior investigators may be loath to embrace construct when organization is formed

Recommendation

- Preferred when number of centers is large and in discipline- or function-complex trials
- Implement at outset for reasons noted under **observations**

Committees

Election-based SC

Construct: Committee created and maintained by elections for designated terms; usually with restriction on number or types of persons or positions to be represented

Strengths

Democratic

Shortcomings

Not conventional

Can be divisive if persons are competing for nominations or seats

Not likely to provide consistent and decisive leadership

Recommendation

Generally best avoided as sole mode of formulation; may be useful in combination with other modes of representation

Interest-based SC

Construct: Members selected to represent interests of investigators, patients, sponsor, community, etc

Strengths

May have certain political appeal, especially when seats are provided for activists, community representatives, etc

May be useful in defending against criticism from the outside

Shortcomings

Difficult to identify interests to be represented

Can lead to continuing expansion of membership as new interests come forward

Individuals chosen to represent a given interest are not likely to be seen as a representative unless they themselves are elected by their constituencies

Produces a leadership group with members external to the trial; may create problems because those dictating protocol are free of responsibilities for carrying it out

Recommendations

Avoid as sole basis for representation; may be used in conjunction with other modes of representation but sparingly

Committees

Grandfather-based SC

Construct: Membership limited to persons responsible for initiation, or to persons associated with initial set of centers

Strengths

- Can provide strong and consistent leadership
- Has long-term "memory"

Shortcomings

- Tends to be seen as "Ole boys" club as trial "ages"
- May be seen as progressively elitist
- Can lose touch with rank and file in the absence of new blood
- Has many of the shortcoming of PI-based or center-based mode of representation

Recommendations

- Avoid as sole mode of formation
- May be used in conjunction with elected members (eg, as in CDP)

Mixed-mode SC constructs

Construct: Use of two or more modes for creation or maintenance

Common mixes

- Grandfathers plus elected (eg, as a means of providing wider representation when a trial is expanded)
- Center-based or PI-base representation plus appointed or elected members (eg, as "fixes" to a restive research group when the trial matures)

Committees

SC recommended specifications

Membership: ≤ 20 (ideally ≤ 15); including study officers

Mode of representation: Mixed to include representation of disciplines and skills needed for successful completion of trial

Time of creation: Within the 1st 6 months of existence

Meeting frequency: At least twice per year; more often perhaps in design and implementation phase

Meeting mode: Face-to-face or conference phone; at least 1 face-to-face meeting per year; face-to-face for serious deliberations

Quorum: At least 2 officers (chair or vice chair and at least one other officer) and a majority of members

Voting: Show of hands, roll call, or secret ballot as determined when a question is voted; no proxies; no absentee votes

Executive committee

A committee responsible for direction of the day-to-day affairs of the trial on behalf of the Steering Committee; usually composed of the officers of the trial and perhaps others selected from the Steering Committee

Duties: Organization and planning; addressing and disposing of administrative and procedural issues in accordance with established policy and procedures; agenda preparation; study administration

Reporting: To the SC

Authority: As assumed or granted by the SC

Committees

EC observations

The more compact the committee the easier to convene and to conduct business; the typical SC is too large to convene on short notice to deal with issues of immediate import

Tendency to create the EC as a miniature SC (eg, by adding subcommittee chairs or by other additions) should be resisted; generally such additions are symptomatic of an ineffective SC; they tend to reduce the power and influence of the SC

Failing an EC, some person (eg, study chair) or body (eg, the Coordinating Center) will have to assume executive functions

EC recommended specifications

Membership: Officers

Time of creation: Within the 1st 6 months of existence

Meeting frequency: At least 4 times per year and as need be; more often perhaps in design and implementation phase

Meeting mode: Primarily conference phone; face-to-face in conjunction with RG meetings

Quorum: Majority of officers

Voting: Roll call; no proxies; no absentee votes

Research group (RG)

The entire set of personnel involved in the conduct of a research project; in multicenter trials includes center directors and support staff, representatives from the sponsoring agency, and study committee members. syn: investigative team, investigative group, study group (not a recommended syn)

Duties: To execute the trial; to receive, deliberate, and act on recommendations from the SC or TEMC

Committees

Observations re RG

Often ill-defined usually because of failure to address definitional issues

May number in the hundreds for trials with large number of centers

Sponsors often reluctant to pay for meetings of the group because of size

Difficult to conduct trial without face-to-face meetings of RG

Face-to-face meetings essential for training, certification, understanding of the protocol, and for quality control and surveillance

RG recommendations

Membership: Any person associated with any center of a trial

Meeting frequency: Varied; ideally for most trials once or twice per year

Meeting mode: Face-to-face

Quorum: Chair or vice chair of SC, director or deputy director of coordinating center, and majority of centers represented by at least one person

Voting: Show of hands or secret ballot as determined when a question is voted; no proxies; no absentee votes

Treatment effects monitoring committee

A committee responsible for ongoing review of accumulating data during the trial for the purpose of determining whether a trial should continue unaltered

Committees

Issues in creating a TEMC

When to create?
 Who will appoint?
 Advice and consent rights?
 Who shall serve?
 Who has vote and who serves as nonvoting member?
 Study officers seated?
 Others to attend?
 Who covers the cost of meetings?

Usual modes of creation for TEMCs

Recruitment and appointment of members by study leaders (common in small-scale trials and grant funded trials where sponsor operates at arm length; not recommended unless sponsor specifically declines advice and consent role)
 Recruitment and appointment of members with advice and consent of sponsor to exclude or prune list (likely in grant funded, cooperative agreements; recommended)
 Recruitment and appointment of members by sponsor after advice and consent of sponsor to exclude or prune list (likely in sponsor-initiated trials and with contract funding; recommended)
 Recruitment and appointment of members by sponsor (may be the case in high-profile government-initiated and contract funded trials; not recommended unless investigators specifically decline advice and consent role)

TEMC values

Objectivity vs competency
 Conflict of interest freedom vs balance
 Frequentist vs data speak philosophy
 Sponsor vs investigator allegiance
 Egalitarian vs parliamentary

Committees

TEMC membership

Total number of members (voting and nonvoting)
 Mix of members by discipline and speciality; medical disciplines and number from each; number and type of statisticians (external and internal)
 Number and type of study officers represented
 Skills and functions represented from the trial (treater; data analyst; reader)
 Other members (nonhealth professional; activist; patient)

TEMC procedural questions

Stopping rules? (Often imposed to preserve trial against "data dredging"; tend to be simplistic and encumbering; not recommended)
 Stopping guidelines? (Perhaps OK provided they do not come to be seen as rules)
 Adjustment of p-values for multiple looks? (OK if emphasis is on p-values and "statistical significance" provided that TEMC is not restrained from looking more than originally specified if results so require)
 Masked monitoring? (Preferred by some; seen as reducing bias and making monitoring more objective; not recommended because of effect of masking on competency of the TEMC)
 Membership to include at least one study treater? (Present day convention is to exclude to protect the study against treatment-related feedback bias and likely conflicts of conscience for a treater privy to interim results; downside is in what is lost in collective understanding of results; recommendation is to err on side of competency and include)
 Seating of advocates? (Sometimes done, usually for political reasons; OK if suitable person can be identified)
 Executive sessions? (Sometimes used when membership includes study personnel to allow voting members to deliberate and vote in the absence of nonvoting study members; not recommended)

Committees

TEMC recommendations

When to establish: On initiation of funding or soon thereafter; some IRBs unlikely to approve trial in the absence of detail regarding the general structure for monitoring

Membership: 10 - 12 members; 5 to 7 voting members plus study officers (nonvoting)

Appointing authority: Sponsor with advice and consent of SC or SC with advice and consent of sponsor

Reporting: To sponsor with assurance of timely transmission to SC, simultaneous to sponsor and SC, or to SC

Meeting frequency: Twice yearly, more often if necessary; not less than once a year

Meeting mode: Face-to-face or conference phone; face-to-face at least once a year

Meeting access: Closed (access limited to members and associated support staff)

Executive sessions (for voting members only): Not recommended

Quorum: Chair or vice chair of TEMC, majority of voting members and majority of officers

Executive sessions: Not recommended, except when deliberations concern performance of a center headed by nonvoting member

Voting: Roll call; in presence of nonvoting members; no proxies; no absentee votes

"Tests" of organization structure

When being organized

- 1 Who chooses the centers?
- 2 Who will have the last word on the treatment protocol?
- 3 Who will have the final say on the data collection protocol?
- 4 Who will chair the SC?
- 5 How will the primary results paper be authored?
- 6 Who will own the data?
- 7 Who will have access to study data?
- 8 How are members of the SC to be chosen?
- 9 Who will appoint the TEMC?
- 10 To whom will the TEMC report?
- 11 How will recommendations flow from them to investigators?

Committees

"Tests" of organization structure

After organized

- 1 How is replacement chair to be selected?
 - 2 Who is responsible for selecting a new CC Director?
 - 3 How will the primary results paper be authored?
 - 4 Who speaks for the study?
 - 5 Who "owns" the data?
 - 6 Who has access to interim treatment results?
 - 7 Does the sponsor have review over study papers?
 - 8 Who has the ultimate responsibility for firing a center?
 - 9 Who decides if a recommendation from the TEMC is implemented?
 - 10 Who will be listed in the credits for the study?
-

Organization

**Meeting and committee conduct and
mechanics**

Meeting and committee conduct and mechanics

<u>Meeting "truisms" and "facts"</u>	55
<u>Housekeeping tasks</u>	56
<u>Mistakes concerning committees</u>	57
<u>Committee maintenance suggestions</u>	57
<u>On dealing with contentious issues</u>	57
<u>Ways to discredit oneself</u>	58
<u>How to register opposition</u>	58
<u>On large versus small groups</u>	59
<u>Political realities</u>	59
<u>Voting</u>	59
<u>Discussion procedures</u>	61
<u>About meeting times and places</u>	62
<u>Recommendations re meetings</u>	64
<u>Observations re research group and its meetings</u>	68
<u>Observations re SC and its meetings</u>	69
<u>TEMC organizational and operational mistakes</u>	70
<u>TEMC "perks"</u>	70
<u>Staff meetings</u>	72
<u>Off-site meeting locations</u>	73
<u>About meeting agendas</u>	74
<u>Adages and axioms about agendas</u>	74
<u>About conference calls</u>	75
<u>About meeting materials</u>	76
<u>About handouts at meetings</u>	76
<u>About slides (hard or electronic)</u>	77
<u>About overhead transparencies</u>	78
<u>Coping strategies</u>	78
<u>Meeting guidelines</u>	79
<u>Committee charge</u>	79
<u>Maintenance procedures</u>	79
<u>Committee rosters: Uses and issues</u>	80

Generation time and date: (8:56am Monday) 4 January 1999

Meeting mechanics

Meeting "truisms" and "facts"

Talk expands to fill time

A meeting without an agenda is a waste of time

A meeting will degenerate two hours prior to the first plane reservation

The last person to arrive will be the one with the shortest distance to travel

The lights are always nowhere to be found in meeting rooms

The screen is never visible from the speakers podium

Microphones never work and when they do there is always a feedback hum

The light on the speakers podium will not work and if it does it will be powered by a 7 watt bulb (ie, if you need light, bring your own)

The last speaker in a program of speakers always ends up short on time (ie, be prepared to "cut")

The average number of tries needed to right a turned slide is 8

If you apologize for a slide you should not use it

Whatever trouble you have reading your own slides from the back of the room will be multiplied 10-fold for your audience

In slides, dark colors against a dark background are impossible to see beyond the front rows

Whatever can go wrong will when it comes to projection of slides or overheads

Those who assume that meeting places will have the software and hardware needed to project their electronic slides enjoy living life on the edge, ditto for those who come without backup slides or overheads

Empty stomachs make for bad meetings

Tired brains produce bad decisions (ie, do not make any important decisions after 6 PM)

Meeting mechanics

Meeting "facts"

People are not good at doing two things at once (ie, do not eat and meet at the same time)

People do not hear when they are talking (ie, you cannot learn anything with your mouth open)

Bad arrangements make for bad meetings

Most "meeting" rooms are not designed for meetings

Most hotel "meeting" rooms are windowless, dark, and dreary

Most meeting rooms are too hot or cold (ie, layer your clothes and bring a sweater)

Meeting rooms are rarely quiet (especially when located next to the kitchen or when separated from the annual meeting of the Rah Rah Booster Club by a scant 1" movable partition)

The hotel model for sufficient leg and elbow room is a 4 foot 2, 90 pound, person (ie, sit on the isle, in the front row, in last row, or commandeer two spaces; choose the back if prone to nodding off, doodling, or "time sharing")

Restlessness increases with crowding (ie, allow pacing room)

People, unlike mushrooms, thrive in light; they need it to reset their biological clock when from distant time zones (ie, avoid windowless meeting rooms and keep the shades open!)

Housekeeping tasks

- Creation and maintenance of committee list and roster of membership
 - Dissolving defunct or dysfunctional committees
 - Replacement of departed members or non-functioning members
 - Minute taking and keeping
 - Establishing and maintaining repository for minutes
-

Meeting mechanics

Mistakes concerning committees

- Creating absent a charge
 - Creation to allow for charge "creep"
 - Creation not providing for a vice-chair or recording secretary
 - No rules of membership or for conduct of business
 - Failure to update and revise charge or membership
 - Meeting to meet (no agenda)
 - Piggy backing (ie, to meet in conjunction with some other meeting)
 - Memory-less meetings (no minutes)
-

Committee maintenance suggestions

- Appoint or elect with attendance clauses (ie, miss 3 or more meetings and out)
 - Assign responsibility for maintaining committee and credit roster to office of the chair, CC, or PO
 - Review committee structure on annual basis
 - Assign responsibility for review to SC or EC
-

On dealing with contentious issues

When you do not have the votes

- Move for lunch or coffee break
- Move to delay vote to "sleep" on the question or for impact analysis
- Work the gallery and the halls
- Keep cool
- Stay focused
- Remain polite
- Call for a closed vote

When you have the votes

- Let the discussion run for the opposition to be heard
- Resist suggestion for tabling or for postponing vote
- Call the question (preferably by someone else)
- Be gentle
- Do not gloat

Meeting mechanics

On dealing with contentious issues

When you are uncertain

- Listen and watch
- Keep quiet
- Solicit "straw vote"
- Get a temperature reading at break

When you want to be a peace maker

- Bridge gaps by minimizing differences
 - Focus on matters in contention
 - Stay above the fray
 - Behave as a diplomat and negotiator
 - Smooth ruffled features and work to heal wounds
 - Be of good humor
-

Ways to discredit oneself

- Bad timing
 - Being wrong or ill-informed on meeting rules
 - Being pushy, personal, or sullen
 - Being "cute"
 - Running a point into the ground
 - Making frivolous motions
 - Wasting time of the group
-

How to register opposition

- By speaking against a motion
 - By voting against a motion
 - By abstention, especially if abstainers are asked to give reasons for not voting
 - By mustering sufficient votes to require a minority report
-

Meeting mechanics

On large versus small groups

- Usually more rule conscious; hence usually more "orderly" and more prone to proceeding in formal order
 - Usually more philosophical about unresolved differences, ie, usually less likely to be driven to rule by consensus
 - Usually more resilient in dealing with internal strife and in closing ranks on divisive issues
-

Political realities

- "Young" groups tend to minimize the need for meeting and voting rules (until they are faced with contentious issues)
 - Forging rules in "young" groups will be a lonely business
 - Forcing use of rules too early in the life of a group may backfire
 - Invoking rules when the group has a history of operating by consensus is likely to be seen as strange or hostile behavior
 - In groups that do not appreciate the need for rules because of an expectation that most matters can be resolved by consensus (most "academic" type researchers), it is usually best to "seed" the idea and then wait for an event to underscore the need
-

Voting

Secret ballot

Recommendations: Elections and for issues where anonymity is desirable, eg, on contentious issues related to matters of personal choice or philosophy

Open ballot (ie, written ballot, but vote and person revealed in counting)

Recommendations: On issues where voting should be without knowledge of other votes, but where there is a need to know how persons voted, eg, on issues where positions or views need to be discussed in order to take a proper action

Meeting mechanics

Voting procedures and issues

Show of hands

Recommendations: Default mode

Voice (aye and nay)

Recommendations: On routine mechanical and procedural matters (such as approval of minutes)

Roll call (according to some order)

Recommendations: On issues of import and where position of persons should be revealed

"Straw vote"

Recommendations: Sometimes used in small groups in formulating issues and in gauging the sense of a group; generally not helpful

Issues

- Who is allowed to vote?
- Are there conditions where proxy votes are allowed?
- Are there conditions where absentee votes are allowed?
- Mode of dealing with challenges to votes
- Things requiring 2/3rd majority vote

Facts and observations

- The method of voting can influence outcome
 - If one wants an accurate reading of the position of a group, positions have to be registered before they are revealed
 - Method of voting can be used as parliamentary maneuver
 - Persons in a center voting in opposition to the position of the center director may not endear themselves to the director
 - Usually "straw votes" are as time consuming and emotion laden as "real" votes
-

Meeting mechanics

Discussion procedures

Free for all (persons speak when they want and without permission)

Observations

- Disorderly, characterized by cross-talking, rump conversations, and interruptions; leads to disjointed discussion
- Usually the result of a weak chair or chair emotionally involved in the issue being debated
- Often self correcting when the emotions have drained or when group becomes frustrated with process

Fixes

- Remind chair of duty
- Rise to point of order
- Ask persons to address the issue on the floor
- Suspend the meeting
- Move to adjourn or for a change of location
- See to it that side talkers are seated apart

Round robin (all persons are given their say in some order, sometimes with two or more iterations)

Observations

- Good approach on contentious issues or where debate is likely to be spirited
- Can degrade to "free for all" if chair does not impose time limits or allows people to ramble
- Not useful where majority of members are reluctant to speak

Suggestions

- Make certain that the chair keeps speakers focused
- Enforce imposed time limits on speakers

Solicited (speakers solicited by chair)

Observations

- Useful if used fairly and without intent to tilt arguments for or against issue
- Useful when there is an ominous silence indicative of unspoken issues or of a "silent" minority

Suggestions

- Rise to a point of order if chair is unfair in solicitations
- Call the question if solicitations are being done to prolong discussion

Meeting mechanics

Discussion procedures

By being recognized

Observations

- Usual approach
- Will degrade to "free for all" with weak or biased chair
- Not useful where majority of members are reluctant to speak, or when a few do most of the talking

Suggestions

- Rise to a point of order if chair recognizes only certain people
 - Remind chair of need for persons to be recognized before they may speak
-

About meeting times and places

Time

- Schedule for convenience
- Avoid changing meeting dates because someone cannot attend
- Stick to announced times
- Start on time

Observations

- The difference between 7:30AM and 8:30AM start is more than an hour
- Invariably, the person for whom a meeting date is changed is the one absent from the meeting
- It is not efficient to choose meeting dates during a meeting
- The further in advance dates are selected the easier it is to book a group
- Most people need a day of rest (ie, weekend meetings make for 7-day work weeks)

Meeting mechanics

Meeting time

Place

- Choose for convenience and ease of access
- Avoid last minute site changes, especially when travel is involved
- Whatever the place, the room must be large enough to comfortably accommodate the group (ie, room for all to sit with room to spare)

Observations

- A bad place makes for a bad meeting
 - All rooms shrink in size with length of meeting
 - Serene pastoral settings are better than hotels for workshop type deliberations
 - In regard to travel: Most people schedule to minimize time away from home, ie, they arrive just in time and leave for the airport before the last word is spoken
 - Ambience has an effect
-

Meeting mechanics

Recommendations re meetings

Research group

Frequency: At least once a year; semiannual for groups involving different medical specialities for administration of treatment, for trials involving long-term treatment (to wage the battle for adherence), for trials involving complex treatment or data collection protocols, and for multistudy research groups

Mode: Face-to-face

Site options: On premise of a study center, meeting or conference center, or hotel with meeting facility; same vs different sites over life of trial

Observations

- Rotation of hosting duties may result in varied and spotty meeting facilities; likelihood can be reduced by central authority to guide and direct
- Rotation of meeting sites among cities housing study centers serves to "equalize" the burden of travel over the life of the trial; may also have the advantage of allowing persons to visit the site
- Standard location over the life of project has the advantage of familiarity and efficiency; disadvantage is eventual weariness and inequity in distribution of travel burden and expense
- Generally best to avoid scheduling in conjunction with some other meeting (people tire of being away from home for extended periods of time; meetings are tiring; competing priorities)

Duration: 1 to 3 days depending on need

Time of week: Tuesdays, Wednesdays, and Thursdays preferred (especially when travel is involved)

Start and adjourn times: Normal working hours

Recommendations

- Avoid on premise site for groups of 30 or more (unless equipped with meetings facilities and services)
- Avoid remote conference facilities
- Choose hotels with conference facilities for groups of ≥ 60
- Avoid evening meetings, except perhaps for routine considerations and housekeeping
- Choose convenient start and end times; choose to minimize overnight stays when travel is involved; when possible choose a start time consistent with "commuting"

Meeting mechanics

Meeting place

Steering committee

Frequency: At least semiannual; more frequent in the beginning phase and during closeout and paper writing

Mode: Face-to-face and conference phone

- Use face-to-face for serious deliberative processes and for topics likely to generate spirited discussion
- Limit conference phone to briefing and updating and for deliberations of noncontentious issues and for simple decision-making; voting should be limited and should be by roll call when done

Site: On premise of a center site or hotel with meeting facility (**Observations** similar to those for Research Group) or office or home via phone

Duration: Face-to-face: 1 to 1.5 days depending on need; Conference phone: 1 to 2 hours

Time of week: Face-to-face: Tuesdays, Wednesdays, and Thursdays preferred when out-of-town travel involved; Conference phone: Any day; preferably not Saturday or Sunday

Start and adjournment times: Normal working hours at meeting site or conference call host

Recommendations

Face-to-face

- When possible arrange in conjunction with meetings of Research Group
- Avoid ad hoc, last minute, meetings (usually poorly attended, disorganized, chaotic, and unproductive)
- Usually best in meeting room organized for conference seating
- Avoid evening meetings for serious deliberations or decision making
- Choose convenient start and end times and stick to them; choose to minimize overnight stays when travel is involved; when possible choose a start time consistent with "commuting"

Conference call

- Use primarily for updating (not well suited to deliberative discussion or for topics likely to generate spirited debate for groups numbering 6 or more)
- Choose a start time consistent with time zones represented by members
- Avoid cell phone connections (because of lack of privacy, fidelity, and background noises)
- Limit use of speaker phone except for connections involving several people assembled in a common area

Meeting mechanics

Meeting place

Executive committee

Frequency: At least 4 times per year; often monthly

Mode: Conference phone and face-to-face; use conference phone for most regular meetings

Site: Conference phone or location of SC or RG meeting

Duration: Conference phone: 1 to 2 hours; 2 to 4 hours when face-to-face

Time of week: Conference phone: Any day; Saturdays or Sundays only when necessary; Face-to-face: Before SC or RG meeting

Start and adjournment times: For conference phone: Fixed time (eg, 1st Wednesday of each month; 1:00 to 2:00 PM EDT)

Recommendations

Conference call

- Choose a start time consistent with time zones represented by members
- Avoid cell phone connections (because of lack of privacy, fidelity, and background noises)
- Limit use of speaker phone except for connections involving several people assembled in a common area

Face-to-face

- Default to face-to-face for complicated deliberations
- Avoid evening meetings for serious deliberations or decision making
- Choose convenient start and end times and stick to them; choose to minimize overnight stays when travel is involved; when possible choose a start time consistent with "commuting"

Meeting mechanics

Meeting place

Treatment effects monitoring committee

Frequency: At least 1 meeting per year; 2 or more times for trials with high activity rates in regard to enrollment or event rates; at least 1 face-to-face meeting per year

Mode: Face-to-face or conference phone

- Default should be face-to-face
- Conference phone should be limited to briefing and updating; usually not well-suited to deliberations involving formulation of a recommendation to stop or alter a trial

Site: On premise of a data coordinating center, chair of study, or hotel meeting room or conference phone

Duration: Face-to-face: 0.5 to 1 day depending on need; Conference phone: 1 to 2 hours

Time of week: Face-to-face: Tuesdays, Wednesdays, and Thursdays preferred when out-of-town travel involved; Conference phone: Any weekday; Saturday or Sunday only in case of crisis

Start and adjournment times: Normal working hours at meeting site or conference call host

Recommendations

Face-to-face

- Best in meeting room organized for conference seating
- Avoid evening meetings
- Choose convenient start and end times; choose to minimize overnight stays when travel is involved; when possible choose a start time consistent with "commuting"

Conference call

- Use primarily for updating (not well suited for generation of recommendations to stop or alter a trial)
 - Choose a start time consistent with time zones represented by members
 - Avoid cell phone connections (because of lack of privacy, fidelity, and background noises)
 - Limit use of speaker phone except for connections involving several people assembled in a common area
-

Meeting mechanics

Observations re research group and its meetings

Purposes and functions

- Education and certification
- Continuing education and recertification
- Discussion of duties and responsibilities to patient in regard to consent, maintenance of consent, treatment, and care
- Discussion of need for integrity and of consequences of malfeasant acts
- Discussion of quality assurance procedures and review of performance data
- Receive, review, and approve study protocol and related procedures
- Receive, deliberate, and act on recommendations from the SC or TEMC

Reality

- The notion that trials can be run by "PIs" is widespread, especially among "PIs"!
- One can expect the notion that "PIs" share power with the rank and file to be resisted
- Most "PIs" are uninterested or unwilling to admit an interest in matters of organization because it smacks of "administration" and "bureaucracy"
- The notion that part of the governance of a trial should be vested in a duly constituted research group usually is not recognized when the trial is organized
- Often funding agencies are stingy with funding for meetings of the research group and leadership personnel are likely to be members of the "PI" school of thought
- Review groups and funding agencies are prone to see travel for meetings of the research group as a frill
- Members of the SC will be reluctant to share power with the research group
- Even when established and functioning, there will be erosion of its role by reducing frequency of meetings or by limiting the number who may attend
- In most cases, running a trial without meetings of the research group is the operational equivalent of making furniture without glue

Strategies

- Build funding into budget requests and writes strong defense
 - Start discussions re governance from day 1 and keep the issue on the agenda of early meetings
 - If there is resistance, persist and try other tacks
 - Behave like a camel upon entering a tent; poke the nose in and in comes the rest of the camel
 - Use the training and certification meeting as a platform for a more lasting structure
-

Meeting mechanics

Observations re SC and its meetings

Purposes and functions

- Provides leadership and direction
- Receives and reviews proposals for change
- Reviews and approves the protocol and related procedures
- Disciplines and acts to preserve the integrity of the trial and the group
- Addresses good and welfare issues

Reality

- Usually the most appealing (and least threatening) mode of construction is to provide a seat for center directors (PIs)
- As a rule, groups do not give up power gracefully or without resistance
(Translation: If the SC is formed along the line of one member per center, the "PI" model, it will be difficult to convert to a representative form of membership if the number of centers increases to an unwieldy number)
- SC formulated along center lines or under the PI model will be top heavy in some disciplines and areas and impoverished in others
- Most SC are organized without thought as to the future (ie, are decidedly non-robust)
- Persons seated from the CC will be a small fraction of the total membership, regardless of mode of construction
- The CC has to maneuver if it is to keep from being voted down on matters of policy or procedure

Strategies (from the perspective of a coordinating center)

- Insist on parity in rights and membership with other centers and disciplines
 - Object politely but consistently to any written or spoken statements implying that the label of investigator or PI is reserved for clinician investigators
 - Work to organize along line other than center
 - Work with the chair to avoid votes that have the effect of "instructing" the CC to perform according to the will of the SC
 - Express displeasure, privately or publicly, with votes having the effect of "instruction" or of committing the CC to work
 - Enlist the help of friends to get the chair to rule motions of instruction out of order
-

Meeting mechanics

TEMC organizational and operational mistakes

- Piggy back meetings
 - Distracting or additional functions
 - Being too directive in regard to conduct of the trial
 - Behaving as a protocol or steering committee
-

TEMC "perks"

Pay

No pay: Usual case for small-scale single center trials and for nonvoting members of TEMC for multicenter trials

Honorarium: Nonstudy members paid modest honorarium per meeting (eg, \$300 per meeting); usually nothing for conference phone meetings

Fee: Nonstudy members paid sum commensurate with time spent for meeting and "homework"(eg, perhaps \$1,000 per meeting, maybe "1st class" airfare)

Retainer: Nonstudy members paid a retainer by sponsor to cover activities for life of trial or for a designated time period (eg, \$5,000 per year regardless of number of meetings)

Observation

- NIH operates under the honorarium mode of funding; industry operates under the fee or retainer system
- One does not serve for the money
- Fees or retainers, seen as exorbitant, have the potential of tainting the treatment effects monitoring process, especially if persons are seen as being reluctant to recommend stopping because of fees or retainers lost
- It is foolish to believe that a person will give freely of his or her time for years simply for the "honor" of serving

Meeting mechanics

Payments for TEMC members

Travel

- Necessary for some except where all members are from the same locale
- Usually expenses paid by appointing authority
- Usual policy: Sardine class airfare, per diem living expenses or expense reimbursement for the day of meeting; may be one night lodging when there is no "Red eye"
- Arrange meetings to avoid travel on weekend or on heavy travel days
- Arrange start and end time of meeting for convenience of travelers and to allow persons to minimize time away from home

Observation

- Travel is often seen as a "perk" (especially by those who do not travel)
- Travel arrangements allowing for travel of one's spouse will be seen as perk

Meeting site

Site of coordinating center
 Site of sponsor
 Site of a society meeting
 Piggy back on another meeting
 Hotel
 Resort

Observation

- CC site has advantage of access to support personnel and added study information when needed
 - Meetings at the site of sponsor may blur lines of separation of sponsorship and investigatorship; not recommended
 - Strategically located hotel has advantage of minimizing total travel time for the group, but may cause everyone to travel; airport hotels, while dreary, are convenient
 - Site of a society meeting OK only if majority of TEMC members plan to attend society meeting (unlikely because of heterogeneity of group)
 - Piggy backing usually not a good idea (because people cannot do two things at the same time)
 - Resort settings, even if convenient, are likely to be seen by the public as junket travel, especially if travel includes one's spouse
-

Meeting mechanics

Staff meetings (CC perspective)

Purpose: Training and indoctrination, direction and coordination of work effort, interaction and communication among work subgroups, planning, development and implementation of procedures, testing of procedures, quality control, monitoring

Frequency: At least monthly

Mode: Face-to-face

Site: Convenient location at work site

Duration: 1 to 3 hours

Time of week: Any workday; preferably the same day (eg, every Tuesday; 8:30 - 10:30)

Do

- Have a written agenda
 - Start and end on time
 - Keep written notes
 - Maintain a running list of *to do assignments*
 - Review status of *to do assignments* as part of each meeting
 - Designate a person to run the meeting and a second in line to convene the group in the absence of that person
 - Avoid endless discussion on matters of detail
 - Keep order
-

Meeting mechanics

Off-site meeting locations

Location

City of a participating center
 On premises of a participating center
 Airport hotel
 Popular vacation city
 Resort
 Conference site

Observations/recommendations

- Most people leave as soon as a meeting ends (25% before)
 - Shopping for airlines (ie, last minute ticket changes to get home 2 hours sooner) is better at hubs
 - People are like rats: They hate being stuck (ie, stay away from cities served by a single feeder line)
 - People are like chickens: They are not easily herded (ie, stay away from sites where one has to schedule departure by booking with Kamikaze Limousine Service)
 - Airport hotel: When you have seen one you have seen them all; OK for one day meeting with majority flying in and out same day
 - Popular vacation cities: Difficult to find rooms at the last minute; hotels more expensive; smaller rooms per unit dollar (and less light)
 - Generally best to steer clear of on premise meetings, except, perhaps, for small groups (catering usually nonexistent or poor and meeting arrangement and facilities cave man style)
 - Fancy resorts: Expensive, distracting, and politically risky except, perhaps, when in conjunction with another meeting
 - Conference site located in serene spot: Frustrating for 1 day meetings (all that green grass and no time to enjoy it); OK for meetings of several days; potentially great for small groups involved in deliberative or creative process
-

Meeting mechanics

About meeting agendas

- Essential
- The larger the group the greater the need and the greater the lead time
- Stay short on allotment of time to difficult or open-ended topics
- Agenda should include date, time, and place of meeting

Observations

- People lose things (have extra copies of the agenda for distribution at a meeting when mailed in advance of meeting)
 - People don't read (announce from the podium things people need to know)
 - People can't find their room in the dark (post signs, spread crumbs, and post sentries to direct people to their particular meeting room for large multi-room meetings)
 - People will ignore times in agenda if they are not followed or if they are unrealistic
 - Print the agenda in large enough font to be readable in dark rooms and by old eyes
-

Adages and axioms about agendas

- You can't get anything done if you don't have anything to do
 - You can't learn anything with your mouth open
 - You don't think right on an empty stomach
 - The likelihood of making a bad decision increases exponentially with each passing minute after 6PM
-

Meeting mechanics

About conference calls

- Arranged vs announced: Arrange date and time if attendance is important; announce date and time with large groups (15 or more)
- Connected vs call-in: Better attendance with connected; easier to be "late" with call-in; call-in less expensive than connected; less labor intensive to organize
- Conference phone call best for "show and tell"; not well suited to thoughtful interactive processes needed for deliberative or creative processes (especially when number is 6 or more)

Observations

- Silence is golden when on hold (ie, steer clear of vendors with piped in noise while on hold with connected calls)
 - Piped in music: Fills the office with vapid nothingness when hold on speaker phone for "time sharing"
 - Recorded timed messages (eg, AT&T "Please continue to hold, your call will start momentarily"): Like waiting for your upstairs neighbor to drop the other shoe!
 - People are more polite (unlike when enclosed in a steel shell on the road) when on the phone (ie, less walk-ons)
 - Good for unobserved doodling and for making obscene gestures in response to irritating comments
-

Meeting mechanics

About meeting materials

- Label and date (headers and footers every page)
- Assemble and bind (staple, perfect binding, O rings, bull clips, or loose leaf binder)
- Number pages (continuous single numbering scheme by far superior to any other form)
- Margins: Top and bottom (sufficient for binding with print-less gutters)
- Reproduction robust

Observations

- Documents come apart (and are taken apart); all the Kings men and all the Kings horses cannot put them together again when unlabeled and unnumbered
 - Stay away from meetings with a lot of handouts (sign of poor planning and lousy logistical support)
 - There is no convenient way to get people to focus on a particular page in a handout when distributed loose leaf with pages unnumbered
 - Paper clips make better tie clasps than "binders" for paper
-

About handouts at meetings

Avoid by planning and preparation of a meeting package; if handouts necessary:

- Title
 - Label as to source
 - Date
 - Number pages
 - Secure with staples
-

Meeting mechanics

About slides (hard or electronic)

- If you have to apologize for a slide don't use it
- Stay away from gimmicks and special effects (unless you are going into the entertainment business)
- Avoid multiple projections except where comparison is necessary (ophthalmologists take note!)
- Color slides are pretty but often hard to read (ie, presentations are not light shows, go to Las Vegas if you long for light shows)
- Produce slides to be reproduction robust (ie, do not use color alone to label)
- Avoid turns (ie, mix of landscape and portrait)
- Check equipment and slides before going "live"
- Practice recovery routines

Observations

- Old fashioned black on white provides maximum contrast and most ambient light
 - The darker the room, the greater the doze index
 - Assume the worst and you will not be disappointed when you go live (ie, do not assume the presence of projection equipment or that it works; do not assume you will be able to see what you are projecting from the podium; do not assume light at the podium will work or be adequate)
 - A disaster in the making: A loaded slide carousel without a retaining ring
 - A mess: Dropped slides; unnumbered and unlabeled as to orientation
 - An impossibility: Getting someone to reorient an upside down slide
 - An un-doable job: Removing a jammed slide (it usually takes 5 people and 10 minutes before they resign in failure)
 - Entertainment: Watching someone move the mouse on a screen while trying to project high tech slides
 - A fool: One who goes half way around the world with only an electronic file of slides
-

Meeting mechanics

About overhead transparencies

- Good for small meetings
- Shortest lead time to production
- Blank transparency and grease pencil is a good substitute for those tiny flip charts sitting on easels and "markers" provided by hotels
- Same rules and reminders regarding readability, facilities, and the like

Observations

- People make better doors than windows and so do projectors (ie, when you stand beside your slides someone cannot see)
 - Take transparencies or slides for backup of electronic slides
 - Overheads usually suggestive of more informality than when slides are used
 - Easier to skip around with transparencies than with slides (random access)
-

Coping strategies

Incompetent chair

- Replace or "retire"
- Rotating chair
- Promote the vice-chair

Arbitrary chair

- Insist on rules of order
- Arrange a coup
- Replace or retire

Bad meeting

- Leave
- Bide your time (it will pass)
- Take a walk
- Learn lesson and fix to prevent

Bad meeting facility

- Move
 - Don't go back
 - Complain
 - Don't pay
-

Meeting mechanics

Meeting guidelines

- Start on time; end on time
 - Insist on order (one person talking at a time; no rump conversations; no commotion in the back of the room)
 - Arrange so everyone has line of sight to chair (without need for binoculars or leaning)
 - Avoid tier seating (haves and have not's)
-

Committee charge

- Create and review a written charge before commissioning
 - Be explicit on who committee reports to
 - Specify members or criteria for membership and conditions for maintaining membership (attendance clause)
 - Specify chair or method of selection
 - Specify rapporteur
 - When in doubt create with sunset provision or option for renewal
 - Designate the official custodian and repository for minutes
-

Maintenance procedures

- Review and revise charge and membership as necessary and periodically
 - Decommission as necessary (ie, those where work is finished, useless committees, and where the sun has set)
 - Remove dead wood (members who never attend)
 - Maintain roster, dates of comings and of goings of members
-

Meeting mechanics

Committee rosters: Uses and issues

Uses

- Maintenance and housekeeping in regard to committee
- Study directories
- Listing in publications and other study documents

Issues

- Who maintains and updates rosters? (Usually the CC or Office of the Chair)
- Should listings be designed to provide listing of past members and time of membership? (Good idea for key committees; information may be of historical value; also useful for crediting past members in publications)
- Should listing include degrees of listed persons? (May be informative if accurate; difficult to maintain; hard to decide where to cut line on degrees that are listed)
- Should listing include institutional affiliation of person listed? (Recommended)
- Should listing include study title? (Recommended)

Observations

- All persons, big or little, are interested in receiving their due credit
 - It takes a considerable amount of discipline to maintain accurate and up-to-date rosters in large-scale activities
 - You cannot rely on center directors to review and update their rosters
 - You should not publish a roster without re-checking accuracy and completeness
 - Inevitably you will learn of mistakes made when the list is published
-

Organization

Centers

Centers

<u>Center</u>	83
<u>Types of centers</u>	83
<u>Selection modes for centers</u>	84
<u>Funding modes</u>	84
<u>Center credentials and certifications</u>	84
<u>Questions</u>	85
<u>Study clinics</u>	85
<u>Coordinating center</u>	86
<u>Project Office</u>	91
<u>Central laboratories</u>	92
<u>Reading centers</u>	93

Generation time and date: (8:57am Monday) 4 January 1999

Center

An operational unit in the structure of a trial, separate and distinct from other such units in the structure, responsible for performing specified functions in one or more stages of the trial; eg, a clinical center or resource center.¹

Types of centers

Clinic

- Affiliate
- Associate
- Field
- Lead
- Parent
- Satellite
- Sister

Resource

- Analysis center
- Biostatistical center
- Central laboratory (CL)
- Chair's office (CO)
- Clinical coordinating center (CCC)
- Coordinating center (CC)
- Data center
- Data coordinating center (DCC)
- Project office (PO)
- Quality control center
- Reading center (RC)
- Treatment coordinating center (TCC)
- Statistical center

Support

- Procurement and distribution center
- Arrangements
- Meeting support

Centers

Selection modes for centers

Self-selected (eg, as in investigator-initiated proposals)
Invitation via RFA or RFP
Fiat

Funding modes

NIH grant (RO 1; U 10)
Unrestricted gift (rare)
Contract (direct or indirect); cost reimbursement or
fixed sum
Fee-for-service
Piece or per unit payments

Center credentials and certifications

Space
Environment
Resources
IRB (local MPA preferred over central commercial)
Qualified, "clean" (re absence of disqualifying conflicts of interest and
record of debarment) personnel
Previous experience
Departmental and institutional interest and support
Willingness to accept and work within a group environment

Centers

Questions

- What constitutes a center?
 - Are all centers equal? What is the standing of the coordinating center relative to clinics? Other resource centers?
 - When is a center a center? When is a center no more? (answers have operational importance when representation on SC is along center lines)
 - What are the rights and responsibilities of centers?
 - Is the project office to be granted center standing?
 - How are centers to be listed in credit rosters? Should the list include past centers? Should the list include clinics that did not recruit any patients to the trial?
 - What are the procedures for dropping or adding a center?
-

Study clinics

study clinic *n* - A clinic responsible for the recruitment, enrollment, followup, or treatment of patients and related examinations and data collection procedures, as required in a specified trial.

Selection

- Evidence of experience and personality suitable to multidisciplinary, shared activities
- Evidence of ability to recruit; ability to follow a protocol
- Availability of experienced clinic coordinator
- Staff: Availability? Backup of key positions?
- Look in the closets before you buy, if there are skeletons they are often found there

Observations re selection

- CVs of center director only of modest value in making informed selections; CVs fat with single-authored papers may indicate a personality not suited to collaborative research
- Be wary of estimates of patient load absent hard data (most people are unrealistically naive as to the effort and difficulty involved in recruitment)
- Learn to distinguish between smooth talk from informed talk
- Learn to differentiate between a BSer and a realistic (realistic will have lower estimates of their ability to recruit than a BSers but they will deliver and a BSer will not)
- Even the most experienced make bad picks

Centers

Clinics

Adding a clinic

- Ability to add depends on level and mode of funding
- There is a non-trivial front-end cost in bring on a new center
- It may be more cost efficient to extend the period of recruitment than to add new clinics
- The later one adds (clinics) the smaller the return (ie, it takes time for a clinic to come online and up to speed)
- The Addition will not be well received if it reduces funding for existing clinics

Dropping a clinic

- Urge resignation (resignation is easier and less confrontational than dismissal)
 - Create due process procedures for taking actions against a clinic
 - Decision should be a corporate one and should be coordinated with funding agency
 - There is a built in reluctance to drop because it is an admission of failure or defeat
 - The CC is often the heavy in drops because of performance; being a heavy can be lonely
 - Ensure the well-being and safety of patients
 - Make provisions for orderly drop where possible, including completion of outstanding data requests
-

Coordinating center

coordinating center (CC) *n* - 1. A center in the structure of a multicenter study that is responsible for receiving, editing, processing, analyzing, and storing study data and for coordination of activities required for execution of the study. 2. A center having general responsibilities for coordination of activities required for execution of a study, without responsibilities for coordination of data collection. rt: biostatistical center, data center, data coordinating center, statistical center, treatment coordinating center

Centers

Coordinating center

Application for CC

Do not apply if:

- Sponsor is not receptive
- Funding is known to be inadequate
- Level of funding is not indicated (for RFPs)
- Sponsor is naive as to CC costs
- Sponsor's view of what is needed is markedly different from yours
- You see yourself as a trialist-investigator and the sponsor wants a servant-service center
- You are a hard head and the sponsor wants someone more malleable
- You are resistant to direction by sponsors
- There is a personality mismatch with sponsor
- Likely to be "wired"

Be wary if:

- Standing of CC not at parity with other centers
- CC is administratively subservient to a clinical center
- If funds for CC subsumed in someone else budget
- Mode of funding for CC is different than for other centers (especially if contract for CC and grant for clinics)
- Funding is indirect, eg, via another center
- Other people control your budget
- There are too many people who want to "help"
- CC is dumping ground for unpleasant or routine housekeeping or administrative tasks
- CC is required to report to sponsor more frequently than other centers

Centers

Coordinating center

Observations and realities in applying

- The nature of the competition for grant funding is different than for contract funding; competition in grant funding is against all other investigators; competition in contract funding is against other investigators competing to do a particular thing
- The closed nature of contract funding means that those who compete can be subjected to charges of "restraint of trade" or "price fixing" if they discuss details of an application with other would-be competitors
- Do not assume *Apply and they will review it*
- Be wary of the margin and font police!
- Usually, the more detailed an RFP, the greater the likelihood of investigators being seen as the "labor force" by the sponsor
- Some people are better suited to contract funding than others
- Zebras do not change their stripes
- Money is money, but it is not all the same
- There is a difference between contract and grant funded activities!
- The mentality of the academic researcher (fierce independence, survive by one's own, publish or perish, lose your funding and die) is not a virtue when sponsors want to direct
- Painting by the numbers is no fun once you have had a canvas and a brush

RFPs for CCs

Be suspicious of genuineness of request if:

- Lead time unrealistically short
- Request contains strange restrictions (eg, CC must be within 100 miles of sponsor; may indicate attempt to "wire")
- A commitment to fund is lacking

Be wary of chances for success if:

- Experience is lacking in subject matter area
- RFP is released for routine re-competition and existing group and CC plan to compete
- Budget is far in excess of that expected

Be wary if:

- RFP is for a "takeover"
- Existing CC is being "fired"
- Need for CC an after thought (unlikely to ever achieve parity of relationship; usually an indicator of naivety or of desire for a "Mikie type" center)

Centers

Coordinating center

Review of application

- Know how sponsor will review; keep in mind when preparing application
- For NIH unsolicited grant submissions: Try to determine if review will be done by a standing study section or a special ad hoc group
- For NIH unsolicited "big ticket" grant applications: Do not submit without communication or coordination to ensure assignment to the proper institute
- Nature of review process and feedback is different for grants and contracts; no "pink sheet" for contract proposals
- Site visits unlikely; reverse site visit, maybe

Negotiation/best and final

NIH grants

- Opportunity for negotiation limited, especially in RO 1 submissions
- Generally, project officer reluctant to "override" recommendations of review group
- Cuts generally not negotiable; strategies include:
 - Walk
 - Absorb cut; argue for restoration later (cuts sometimes restored near end of fiscal year if agency has unspent monies), or submit a request for supplemental funding later on
 - Offer to redo budget (so cuts can be made selectively)

NIH RFPs

- Notification of being in "competitive range" is no cause for celebration (it simply means you made the 1st cut); likewise with requests for "best and finals"
- Best and finals: On a short time fuse, often nit picky, often time consuming, and only rewarding some of the time
- Strategies with regard to cuts:
 - Walk
 - Counter with reductions in work scope, especially when funding is via cost reimbursement contract
 - Absorb cut and wait for a better day or more opportune time for restoration
- If you are not selected, do not expect to know why

Centers

Coordinating center

NIH award

- Do not expect your institution to allow you to spend before the "award statement" is received and the necessary clearances are in hand (including IRB approval)
- Award statement is not a check (ie, no money flow with an award statement; no assurance that you will be able to spend to the bottom line dollar amount in the statement)
- A contract is not a contract until it is signed by the responsible administrative official of your institution
- Be aware, that as an investigator, you have no standing in the contracting process
- Be aware that, unless you are proactive, your administration can sign contracts committing you to a work scope you have not been party to!

NIH renewal/re-competition

- Know the difference between renewal and re-competition
- NIH grant awards: Usually for multiple years but never for more than 5 years; awards on a year-by-year basis; hence a 5 yr award requires 4 "renewals"
- "Re-competition" is undertaken in an effort to sustain funding beyond the scheduled sunset on funding; not to be confused with renewal; renewal is "easy" re-competition is energy consuming and nerve racking
- The grant funded investigator has to start the process of re-applying at least 1 year before scheduled sunset to have hope of continuous funding
- Re-competition for contract funding will be orchestrated by the sponsor
- Contract funded activity that is expiring in which sponsor lacks a desire to continue funding might be sustained by grant funding
- There is no assurance of success in re-competitions

Replacement of director

- In cases of retirement, illness, or departure: Usually awardee institution nominates a replacement; sponsor reviews and approves
- In case of misconduct: All bets off; institution may try to retain activity with new director
- In case of poor performance: New director may help if poor performance due to director, otherwise just moving the deck chairs on the Titanic

Replacement of CC

- Consequences and impact likely to be less if planned and ordered than when forced or unplanned
- Firing not a good risk factor for survival of study
- Best when ordered with overlap of funding for transition

Centers

Coordinating center

Takeover

- Always difficult, decidedly unpleasant when hostile (eg, when new kid wins re-competition from existing center)
 - Expect difficulties in study due to delays, backlogs, and inactivity
 - Center taking over starts out behind 8 ball and will be there for months to come
-

Project Office

project office (PO) *n* - 1. In the parlance of the NIH grants and contracts, the office located in the sponsoring agency within the NIH, usually staffed with one or more individuals trained in research or medicine, responsible for dealing with technical, scientific, and programmatic aspects of a research project funded by grant or contract; medical liaison office. 2. program office

Observations

- Tends to be more passive in grant funded research than in contract funded; more active in U 10 grant funding than in RO 1 funding
 - Proceed by assuming an active role
 - Can be trouble if relationship sours
-

Centers

Central laboratories

central laboratory (CL) *n* - 1. A study center in the structure of a multicenter study, such as a multicenter trial, responsible for performing specified tests on specimens collected by participating field centers or clinical centers from people enrolled or considered for enrollment into the study; as distinct from local laboratory. 2. A facility within an institution, such as a hospital, responsible for performing a variety of tests or analyses, as ordered by and received from staff of the various departments or units of the institution having access to its services. rt: local laboratory

Issues and considerations

- Is the trouble worth the cost?
- Are the determinations needed for eligibility or for patient care?
- Why a central lab? Cost savings? Standardization? Convenience?
- What kind of lab? Commercial? Academic?
- Method of funding?
- Batched or real-time determinations? If batched, how?

Observations

- The logistics of storage, transport, and data transmission are major
 - Be wary of use of central laboratories for determinations in the critical path of eligibility determination and patient care
 - The need for standardization to reduce variation (by having one lab as opposed to local labs) is overrated in trials
 - The variation from lab to lab (absent a central lab) is serious only if it is marked and differential by treatment group
 - Systems of batching to allow one to perform all determinations on a person reduces the utility of the determinations for monitoring
 - Squirrelling (ie, batch to the end of the trial) makes use unlikely and renders sample useless for monitoring
-

Centers

Reading centers

reading center (RC) *n* - 1. A center responsible for interpreting and codifying information from a specified set of materials, records, or documents (eg, ECGs, fundus photographs, chest x-rays, biopsy or autopsy specimens, death certificates). 2. Such a center in a multicenter study.

Issues and considerations (largely similar to those for central laboratories)

- Adjudicated readings?
- Readings fed back to clinic?
- Readings to be used in treatment process?
- Batched or real-time readings?

Observations (largely similar to those for central laboratories)

- Need for adjudicated readings is overrated; important in natural history studies, less important in trials
 - Processes for adjudication are complicated and increase time to availability of information
 - Stay clear of adjudication for eligibility readings; rely on local readings
 - Tend toward local readings if you want to mimic usual practice
 - Usually best to isolate readers at a central facility from role in treatment decisions
-

References

- 1 **Meinert CL:** *Clinical Trials Dictionary: Terminology and Usage Recommendations*. The Johns Hopkins Center for Clinical Trials, Baltimore, **1996**. (Meinert, 1996)
 xi, 83
 - 2 **Meinert CL:** *Design and conduct of clinical trials: Course slides (3rd ed)*. The Johns Hopkins Center for Clinical Trials, Baltimore, **1998**. (Meinert, 1998)
 xi
 - 3 **Patnode D:** *Robert's Rules of Order*. Barbour & Company, Inc, Uhrichsvile, Ohio, **1989**. (Patnode, 1989)
 9
 - 4 **Society for Clinical Trials, Inc:** By-laws. Controlled Clinical Trials 1:83 - 88, **1980**. (Society for Clinical, 1980)
 11
 - 5 **Rozakis L:** *Merriam-Webster's Rules of Order*. Merriam-Webster, Inc, Springfield, Mass, **1994**. (Rozakis, 1994)
 10, 18, 20
-

Index

center	
central laboratory (CL)	92
coordinating center (CC)	86
project office (PO)	91
reading center (RC)	93
clinic	
study clinic	85
coordinating center	
coordinating center (CC)	86
Meinert CL	95
National Institutes of Health (NIH)	91
office/officer	
project office (PO)	91
study	
study clinic	85

Last page

Clinical Trials

Organization: Teaching slides