# 6 Organization tables, worksheets, and checklists

**Table 6.1 Organizational elements table (Org.Tab)**

**When**: Early in the design phase of the trial during organization

**Who**: The study chair or director of the coordinating center

**Purpose**: To define and list the key organizational units in the trial; review and update over the course of the trial

Related forms: Table 6.3, Table 6.4, Table 6.5

**Definitions**

**executive committee** (EC) - A committee within some multicenter leadership structures responsible for direction of the day-to-day affairs of the study and accountable to the steering committee; usually consists of the officers of the study and others selected from the steering committee; typically headed by the chair or vice-chair of the steering committee. rt: **study officers**, **steering committee**

**key committee** - A committee essential to the operation of a trial; generally any of the following: steering committee, executive committee, study officers, treatment effects monitoring committee, advisory-review and treatment effects monitoring committee, and advisory-review committee in multicenter trials.

**research group** - The entire set of personnel involved in the conduct of a research project; in multicenter trials includes center directors and related study personnel, representatives from the sponsoring agency, and study committee members; aka: collaborative group, investigative group.

**resource center** - Any center providing expertise and support in a differentiated study structure apart from clinical centers.

**steering committee** - A committee of an organization responsible for directing or guiding the activities of that organization. In multicenter trials, the committee responsible for conduct of the trial and to which other study committees report. Usually headed by the study chair and consisting of persons designated or elected to represent study centers, disciplines, or activities. One of the key committees in multicenter structures.

**study center** - An operational unit in the structure of a study separate and distinct from other such units in the structure, responsible for performing specified functions in one or more stages of the study; e.g., a clinical center or resource center.

**study officers** - The officers of a study; typically in multicenter trials, the study chair, study vice-chair, coordinating center director, coordinating center deputy director, and project officer; one of the key committees in multicenter structures.

**support center** - Any center providing service or supply in a differentiated study structure apart from clinics and resource centers.

**Table 6.1 Organizational elements table**

## A. Identifying information

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) . . . . . __ __—__ __ __—__ __ __ __

4. Funding sources (check all that apply)
   ( ) Drug company
   ( ) NIH
   ( ) Foundation
   ( ) Private donor
   ( ) Other (specify)

   _____

## B. Centers

5. Sites where persons are enrolled and followed
   Official name to be used in study documents (check one)
   ( ) Study clinic
   ( ) Study field site
   ( ) Other (specify)

   _____

   Number of sites . . . . . _____

6. Resource centers (centers providing support or services in the study structure, apart from study clinics; check all that apply)
   ( ) Coordinating center
   ( ) Data coordinating center
   ( ) Biostatistics support center
   ( ) Data center
   ( ) Treatment coordinating center
   ( ) Central laboratory
   ( ) Reading center
   ( ) Quality control center
   ( ) Office of sponsor
   ( ) Office of the study chair

**Table 6.1 Organizational elements table**

( ) Other (specify)

_____

_____

Number of resource centers . . . . . _____

7. Support centers (any center providing service or supply in an organization structure apart from study clinics and resource centers; check all that apply)
   ( ) Central study pharmacy
   ( ) Distribution center
   ( ) Procurement center
   ( ) Procurement and distribution center
   ( ) Other (specify)

   _____

   _____

   Number of support centers . . . . . _____

8. Total number of centers (sum of totals in items 5, 6, and 7) . . . . . _____

**C. Study officers and research body** (see definitions above)

9. Study head/PI _____

10. Study officers

| | Name | Title |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |

**Table 6.1 Organizational elements table**

| | Name | Title |
|---|---|---|
| 8 | | |
| 9 | | |
| 10 | | |

11. Size of research body . . . . . _____

**D. Study committees**

12. Key committees (check all that apply)
    - ( ) Committee of study officers
    - ( ) Executive committee
    - ( ) Steering committee
    - ( ) Treatment effects monitoring committee
    - ( ) Advisory review committee
    - ( ) Other (specify)

13. Other standing committees (check all that apply)
    - ( ) Protocol committee
    - ( ) Laboratory committee
    - ( ) Publication committee
    - ( ) Analysis committee
    - ( ) Ancillary study committee
    - ( ) Natural history committee
    - ( ) Outcomes/endpoints committee
    - ( ) Other (specify)

14. Total number of committees (sum of entries in items 12 and 13) . . . . . _____

**Table 6.2 Study officers committee organization table (Officer.Tab)**

**When**: Early in the course of the trial before the start of enrollment

**Who**: Study chair or director of the coordinating center

**Purpose**: To set forth rules for designating study officers in a study structure

**Definition**

**study officers** - The officers of a study; typically in multicenter trials, the study chair, study vice-chair, coordinating center director, coordinating center deputy director, and project officer; one of the key committees in multicenter structures.

**Reminders**

- Study officers are necessary in any formalized study structure. They exist whether or not in the presence of other study committees
- They report to the steering committees in structures having steering committees
- Typically they serve in ex-officio capacities
- Not to be confused with executive committee
- Assume the need for officers committee or executive committee if any of the following apply:
  - Single center trial with multiple investigators
  - Multicenter trial
  - Constituted steering committee
- Create before or in conjunction with creation of the steering committee

**A. Identifying information**

1. Study name: _____

2. Name of group
   ( ) Study officers
   ( ) Study officers committee
   ( ) Other (specify)

   _____

3. Form completed by: _____

4. Date completed (day-month-year) . . . . . __—___—____

**B. Composition**

5. Persons designated as study officers (check all that apply)
   ( ) Study chair
   ( ) Study vice-chair
   ( ) Director of coordinating center
   ( ) Deputy director of coordinating center

**Table 6.2 Study officers committee organization table**

( ) Project officer
( ) Deputy project officer
( ) Other (specify)

_____

6. Officers

| | Name | Office |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |

**C. Meeting modes and frequency**

7. Primary meeting mode
   ( ) Face-to-face
   ( ) Conference phone
   ( ) Other (specify)

   _____

8. Number of meetings per year
   ( ) Weekly
   ( ) Monthly
   ( ) Other (specify)

   _____

**Table 6.3 Steering committee organization table (SC.Tab)**

**When**: Early in the course of the trial before the start of enrollment

**Who**: Study chair or director of the coordinating center

**Purpose**: To set forth rules for staffing and operating the study steering committee

**Definitions**

**steering committee** (SC) - A committee of an organization responsible for directing or guiding the activities of that organization. In multicenter trials, the committee responsible for conduct of the trial and to which other study committees report. Usually headed by the study chair and consisting of persons designated or elected to represent study centers, disciplines, or activities. One of the key committees in multicenter structures.

**representation construct** - Any of various constructs used for representation on the key governing bodies of multicenter studies or study networks; includes advocacy representation, aristocracy representation, center representation, discipline representation, and PI representation.

**advocacy representation construct** - A representation construct based on advocacy, e.g., one where membership on the steering committee includes persons external to the study chosen to advocate a position or to represent an interest.

**aristocracy representation construct** - [multicenter studies] A representation construct limited to founding members, e.g., one where membership on the steering committee is limited to persons responsible for getting the study funded.

**center representation construct** - A representation construct for the governing body of a multicenter trial based on center, e.g., one where membership is by center or one where voting in the governing body is by center.

**discipline representation construct** - A representation construct for steering committees in multicenter study structures based on disciplines, e.g., one where membership on the steering committee is apportioned by disciplines in the structure.

**PI representation construct** - [multicenter studies] A leadership representation construct based on PI-ship, especially one where voting membership on the steering committee is limited to PIs.

**A. Identifying information**

1. Study name: _____

2. Official name of committee
   ( ) Steering committee
   ( ) Other (specify)

   _____

3. Form completed by: _____

**Table 6.3 Steering committee organization table**

4. Date completed (day-month-year) . . . . . __—__—____

**B. Mode of representation**

5. Primary representation mode (check one)
   ( ) Advocacy representation
   ( ) Aristocracy representation
   ( ) Center representation
   ( ) Discipline representation
   ( ) PI representation
   ( ) Other (specify)

   _____

6. Secondary representation mode (check all that apply)
   ( ) No secondary representation
   ( ) Advocacy representation
   ( ) Aristocracy representation
   ( ) Center representation
   ( ) Discipline representation
   ( ) PI representation
   ( ) Other (specify)

   _____

**C. Representation definitions**

7. Advocacy representation (skip if not checked in items 5 or 6)
   ( ) Person with the disease or condition being treated
   ( ) Representative of advocacy lobbying group
   ( ) Other (specify)

   _____

8. Aristocracy representation (skip if not checked in items 5 or 6)
   ( ) Study officers
   ( ) Heads of original set of clinics
   ( ) Other (specify)

   _____

9. Center representation (skip if not checked in items 5 or 6)
   ( ) Clinical centers only
   ( ) Clinical centers and resource centers
   ( ) Other (specify)

   _____

**Table 6.3 Steering committee organization table**

10. Disciplines representation (skip if not checked in items 5 or 6)
    ( ) Person(s) responsible for treating the condition of interest
    ( ) Clinic coordinator
    ( ) Other (specify)

    _____

11. PI representation (skip if not checked in items 5 or 6)
    ( ) Heads of clinical centers only
    ( ) Heads of clinical or resource centers
    ( ) Other (specify)

    _____

**D. Chair**

12. Mode of designation
    ( ) Administrative fiat
    ( ) Appointment (specify appointing authority)

    _____

    ( ) Election (specify electing body)

    _____

    ( ) Other (specify)

    _____

13. Term of office
    ( ) Without term
    ( ) With term (specify length of term) _____
        ( ) Single nonrenewable term
        ( ) Renewable term

14. Chair name and title

    Name: _____

    Title: _____

**E. Vice chair**

15. Vice chair
    ( ) Designated
    ( ) Not designated (skip to next section)

**Table 6.3 Steering committee organization table**

16. Vice chair name and title

    Name: _____

    Title: _____

17. Mode of designation
    ( ) Administrative fiat
    ( ) Appointment (specify appointing authority)

    _____

    ( ) Election (specify electing body)

    _____

    ( ) Other (specify)

    _____

18. Term of office
    ( ) Without term
    ( ) With term (specify length of term) _____
        ( ) Single nonrenewable term
        ( ) Renewable term

**F. SC membership and composition**

19. Voting members

| | Name | Study title |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |

**Table 6.3 Steering committee organization table**

| | Name | Study title |
|---|---|---|
| 9 | | |
| 10 | | |
| 11 | | |
| 12 | | |
| 13 | | |
| 14 | | |
| 15 | | |
| 16 | | |
| 17 | | |
| 18 | | |
| 19 | | |
| 20 | | |

20. Nonvoting members

| | Name | Position |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |
| 5 | | |

21. Total number of members

Number voting . . . . . ____

Number nonvoting . . . . . ____

Total number . . . . . ____

**Table 6.3 Steering committee organization table**

22. Composition by study affiliation

Number of members from study research group . . . . . ____

Number of members not affiliated with study research group . . . . . ____

Total number . . . . . ____

23. Composition by position

Clinical center heads . . . . . ____

Resource center heads . . . . . ____

Study officers . . . . . ____

Project officers . . . . . ____

Clinic coordinators . . . . . ____

24. Composition by degree

MD . . . . . ____

PhD . . . . . ____

Other medical degrees . . . . . ____

Other research degrees . . . . . ____

25. Composition by term

Number members elected . . . . . ____

With term . . . . . ____

Without term . . . . . ____

**G. Committee rules and operating procedures**

26. Quorum requirement (check one)

( ) Majority of voting members and chair or vice chair
( ) Majority of voting members
( ) Two-thirds of voting members and chair or vice chair
( ) Two-thirds of voting members
( ) Other (specify)

27. Primary voting mode for protocol changes
    ( ) Secret ballot
    ( ) Roll call
    ( ) Show of hands
    ( ) Other (specify)

28. Absentee votes
    ( ) Allowed
    ( ) Not allowed

29. Proxy votes
    ( ) Allowed
    ( ) Not allowed

**H. Meeting modes and frequency**

30. Primary meeting mode
    ( ) Face-to-face
    ( ) Conference phone
    ( ) Other (specify)

31. Number of meetings per year (excluding "as necessary" meetings)
    ( ) One
    ( ) Two
    ( ) Three
    ( ) Four
    ( ) More than four; specify number . . . . . ___

**I. Sign-off approval**

32. Name of review and approving authority _____

33. Date of sign-off (day-month-year) . . . . . __ __—__ __ __—__ __ __ __

**Table 6.4 Executive committee organization table (EC.Tab)**

**When**: Early in the course of the trial before the start of enrollment

**Who**: Study chair or director of the coordinating center

**Purpose**: To set forth rules for staffing the study steering committee

**Definition**

**executive committee** (EC) - A committee within some multicenter leadership structures responsible for direction of the day-to-day affairs of the study and accountable to the steering committee; usually consists of the officers of the study and others selected from the steering committee; typically headed by the chair or vice-chair of the steering committee.

**Reminders**

- Executive committee, as used herein, is not to be confused with steering committee. In this document steering committee is regarded as the premiere leadership body. The executive committee under this nomenclature is subservient to the steering committee
- Assume the need for an executive committee if any of the following apply:
  - Multicenter trial
  - Steering committee consists of 10 or more members
  - Steering committee not constituted to deal with the executive functions of the trial
- Create before or in conjunction with creation of the steering committee

**A. Identifying information**

1. Study name: _____

2. Official name of committee being created
   ( ) Steering committee
   ( ) Other (specify)

   _____

3. Form completed by: _____

4. Date completed (day-month-year) . . . . . __—___—_____

**B. Composition**

5. Members

| | Name | Title |
|---|---|---|
| 1 | | |
| 2 | | |

**Table 6.4 Executive committee organization table**

| | Name | Title |
|---|---|---|
| 3 | | |
| 4 | | |
| 5 | | |
| 6 | | |
| 7 | | |
| 8 | | |
| 9 | | |
| 10 | | |

6. Membership

   Number voting . . . . . ____

   Number nonvoting . . . . . ____

   Total number . . . . . ____

7. Composition by study affiliation

   Number members from study research group . . . . . ____

   Number members not affiliated with study research group . . . . . ____

   Total number . . . . . ____

8. Composition by position

   Clinical center heads . . . . . ____

   Resource center heads . . . . . ____

   Study officers . . . . . ____

   Sponsor project officers . . . . . ____

   Clinic coordinators . . . . . ____

**Table 6.4 Executive committee organization table**

9. Composition by term

   With term . . . . . ____

   Without term . . . . . ____

10. Study officers seated as ex-officio members of the EC (check all that apply)
    ( ) Study chair
    ( ) Study vice-chair
    ( ) Director of coordinating center
    ( ) Deputy director of coordinating center
    ( ) Project officer
    ( ) Deputy project officer
    ( ) Other (specify)

    _____

**C. Meeting modes and frequency**

11. Primary meeting mode
    ( ) Face-to-face
    ( ) Conference phone
    ( ) Other (specify)

    _____

12. Frequency of meetings
    ( ) Weekly
    ( ) Twice monthly
    ( ) Monthly
    ( ) Other (specify)

    _____

**Table 6.5 Treatment effects monitoring committee organization table (TEMC.Tab)**

**When**: Before the start of enrollment

**Who**: Study leaders in conjunction with the study sponsors

**Purpose**: To establish the organizational structure for treatment effects monitoring

**Definition**

**treatment effects monitoring committee** (TEMC) - A standing committee in the structure of single or multicenter trials responsible for the periodic review of accumulating data for evidence of adverse or beneficial treatment effects and for making recommendations for modification of a study treatment, including termination, when appropriate. One of the key committees in the organizational structure of a multicenter trial; usually constituted such that voting privileges are restricted to members not directly involved in the execution of the trial and not associated with participating centers or sponsors of the trial. Others, such as officers of the study or other key study investigators, if included as members, usually serve without vote. Voting members are appointed by the sponsor or research group, often with the advice and consent of the other party. The committee reports to the appointing authority and usually to the other party via the appointing authority or directly. syn: data monitoring committee, data and safety monitoring committee, safety monitoring committee

**A. Identifying information**

1. Study name: _____

2. Official name of committee
   ( ) Data monitoring committee (DMC)
   ( ) Data and safety monitoring committee (DSMC)
   ( ) Data and safety monitoring board (DSMB)
   ( ) Treatment effects monitoring committee (TEMC)
   ( ) Other (specify)

   _____

3. Form completed by: _____

4. Date completed (day-month-year) . . . . . __—___—____

**B. Vetting and appointing authority**

5. Who vets voting members of the committee?
   ( ) Study investigators
   ( ) Study sponsor
   ( ) Jointly by study investigators and sponsor

**Table 6.5 Treatment effects monitoring committee organization table**

( ) Other (specify)

_____

6. Who writes the letter of appointment to vetted members?
   ( ) Study investigators
   ( ) Study sponsor
   ( ) Jointly by study investigators and sponsor
   ( ) Other (specify)

_____

**C. Composition**

7. Number of members?
   Number voting members . . . . . _____
   Number nonvoting members . . . . . _____
   Total number. . . . . _____

8. Credentials represented in voting members? (check all that apply)
   ( ) Experience treating the condition of interest
   ( ) Medical ethics
   ( ) Experience doing randomized trials
   ( ) Biostatistics
   ( ) Epidemiology
   ( ) Other (specify)

_____

9. TEMC chair qualifications (check all that apply)
   ( ) Experience treating the condition of interest
   ( ) Medical ethics
   ( ) Experience doing randomized trials
   ( ) Biostatistics
   ( ) Epidemiology
   ( ) Other (specify)

_____

10. Nonvoting members of the committee (check all that apply)
    ( ) Study chair/PI
    ( ) Director of coordinating center
    ( ) Study sponsor

**Table 6.5 Treatment effects monitoring committee organization table**

( ) Other (specify)

_____

11. Standing of nonvoting members relative to voting members (check all that apply)
    ( ) At parity except for voting
    ( ) Excused when results presented
    ( ) Present when results presented, but excused when votes are taken
    ( ) Other (specify)

_____

12. Quorum requirement (check one)
    ( ) Chair or vice chair of TEMC and majority of voting members
    ( ) Chair or vice chair of TEMC and majority of voting and non-voting members
    ( ) Other (specify)

_____

**D. Operations**

13. Written charge?
    ( ) No
    ( ) Yes
    If yes, written by whom?
    ( ) Study investigators
    ( ) Study sponsor
    ( ) TEMC
    ( ) Other (specify)

_____

14. Meeting frequency?
    ( ) Calendar driven
    ( ) Once yearly
    ( ) Twice yearly
    ( ) Other (specify)

_____

    ( ) Event/landmark driven
    ( ) After specified numbers of events (specify)

_____

( ) After enrollment of specified numbers of people (specify)

_____

( ) Other (specify)

_____

15. Compensation for voting members?
    ( ) No
    ( ) Yes
    If yes
    Mode of compensation
    ( ) Retainer (amount) . . . . . _____
    ( ) Per face-to-face meeting (amount) . . . . . _____
    ( ) Per conference phone meeting (amount) . . . . . _____

16. Objectivity constructs imposed
    ( ) No objectivity constructs
    ( ) Stopping rule
    ( ) Stopping guideline
    ( ) Masking
    ( ) Restrictions on number of looks to be performed
    ( ) Other (specify)

_____

17. TEMC reporting structure
    ( ) From TEMC chair to study chair/study PI
    ( ) From TEMC chair to study sponsor and from study sponsor to study chair/study PI
    ( ) From TEMC chair simultaneous to study chair/study PI and study sponsor
    ( ) Other (specify)

_____

18. Treatment effects monitoring reports prepared by (check one):
    ( ) Coordinating center/data center
    ( ) Study sponsor
    ( ) Contract research organization
    ( ) Other (specify)

_____

**E. Sign-off approval**

**Table 6.5 Treatment effects monitoring committee organization table**

19. Name of review and approving authority: _____

20. Date of sign-off (day-month-year) . . . . . __ __—__ __ __—__ __ __ __

**Table 6.6 Considerations leading to a separate ARC and TEMC or combined ARTEMC (TEM&ARC.Tab)**

**When**: Early in planning, prior to decisions on approach to treatment effects monitoring

**Who**: Study officers

**Purpose**: To decide whether to create an advisory review committee independent of the treatment effects monitoring committee

**Definitions**

**advisory-review** - Of or relating to providing advice and review; in relation to trials primarily in relation to the design and operation of the trial for the benefit of study investigators and sponsors and offered by persons or a committee independent of the investigators and sponsor.

**advisory-review committee** (ARC) - [trials] A committee in the organizational structure of a trial responsible for reviewing the design and operations of the trial for the purpose of advising investigators related to the trial; voting members usually not involved in the execution of the trial or associated with any of the participating centers or sponsor of the trial. Selected investigators from the trial may serve as nonvoting members. A committee in the organizational structure of some multicenter treatment trials with method of appointment and route of reporting similar to that described for treatment effects monitoring committee. aka: advisory board, advisory committee, policy-advisory board, policy-advisory committee, policy board, policy committee.

**advisory-review and treatment effects monitoring committee** (ARTEMC) - A committee that performs the functions of both an advisory-review committee and treatment effects monitoring committee.

**treatment effects monitoring committee** (TEMC) - [trials] A standing committee in the structure of single or multicenter trials responsible for the periodic review of accumulating data for evidence of adverse or beneficial treatment effects and for making recommendations for modification of a study treatment, including termination, when appropriate. One of the key committees in the organizational structure of a multicenter trial; usually constituted such that voting privileges are restricted to members not directly involved in the execution of the trial and not associated with participating centers or sponsors of the trial.

**Considerations for separate ARC and TEMC**

- When treatment monitoring activities require frequent meetings and where each meeting requires a half day or more to carry out the necessary data reviews
- When the TEMC meets other general analysis needs of the study (e.g., is responsible for developing analytic approaches for dealing with special analytic problems)
- When the meeting schedule for review is different than that for treatment effects monitoring
- When the trial is investigator-initiated and grant-supported
- When the sponsor and/or investigators desire separate committees

**Table 6.6 Separate ARC and TEMC vs combined ARTEMC**

**Considerations for combined ARTEMC**

- When the time required for treatment monitoring is not great relative to the time required to perform more general advisory and review functions
- When there is little or no need for advice or guidance concerning the analysis procedures used for assessing treatment effects
- When the trial is sponsor-initiated
- When the sponsor and/or investigators desire a single combined committee

**A. Identifying information**

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) . . . . . __—__—____

**B. Advisory review functions**

4. Desired investigator advisory-review functions (check all that apply)
   ( ) None
   ( ) Review of the study protocol
   ( ) Approval of the study protocol
   ( ) Review to provide go ahead for initiation of enrollment
   ( ) Review of major protocol changes before implementation
   ( ) Review of changes in sample size requirements
   ( ) Review of proposal to change the primary outcome measure
   ( ) Review of revision of the timetable for the trial
   ( ) Review of ancillary study proposals
   ( ) Review of uses of banked specimens
   ( ) Review of study publications
   ( ) Other (specify)

   _____

5. Desired sponsor advisory and review functions (check all that apply)
   ( ) None
   ( ) Review and approval of the study protocol before implementation of enrollment
   ( ) Review of major protocol changes before implementation
   ( ) Review of change in sample size requirements
   ( ) Review of proposal to change the primary outcome measure
   ( ) Review of revision of the timetable for the trial
   ( ) Review of recommendations to add clinical centers
   ( ) Review of performance of clinical and resource centers
   ( ) Review of recommendations to terminate funding for centers not performing adequately

( ) Review of study publications
( ) Other (specify)

## WS 6.1 Research group organization worksheet (RG.WS)

**When**: The trial is being organized

**Who**: A study officer

**Purpose**: To set forth principles of composition of the research group

**Definition**

**research group** - The entire set of personnel involved in the conduct of a research project; in multicenter trials, includes center directors and related study personnel, representatives from the sponsoring agency, and study committee members; aka collaborative group, investigative group, study group.

### A. Identifying information

1. Study name: _____

2. Official name of research group
   ( ) Research Group
   ( ) Collaborative Group
   ( ) Study Group
   ( ) Other (specify)

   _____

3. Form completed by: _____

4. Date completed (day-month-year) . . . . . __—___—____

### B. Composition

5. Basis for membership (check all that apply)
   ( ) Certified by the coordinating center to perform specified study functions
   ( ) Receives salary support from the study
   ( ) Listed as members by center directors
   ( ) Involved as an author on a study publication
   ( ) Other (specify)

   _____

6. Are members listed in a directory?
   ( ) Yes
   ( ) No (explain)

   _____

7. Who maintains the directory?
   ( ) Coordinating center
   ( ) Office of the study chair
   ( ) Study sponsor
   ( ) Other (specify)

   _____

8. Does the directory listing include past members of the research group
   ( ) Yes
   ( ) No

9. Who has access to the directory? (check one)
   ( ) Anyone receiving a printed copy of the directory
   ( ) Anyone with access to the password-protected study website
   ( ) Open; posted to a public website
   ( ) Other (specify)

   _____

**C. Modes of communications and meetings**

10. Principal modes of communications with the research group: (check one)
    ( ) E-mail
    ( ) Letter
    ( ) Telephone
    ( ) Conference telephone (specify frequency)
        ( ) As needed
        ( ) Weekly
        ( ) Monthly
        ( ) Other (specify) _____
    ( ) Face-to-face meetings (specify frequency)
        ( ) As needed
        ( ) Twice yearly
        ( ) Once yearly
        ( ) Other (specify) _____

## WS 6.2 Committee organization and meeting rules worksheet (MeetRule.WS)

**When**: In conjunction with creation of a key committee

**Who**: The chair or vice chair of the committee

**Purpose**: To put forth basic organization and operating rules for the committee

### A. Identifying information

1. Study name: _____

2. Form completed by: _____

3. Committee to which form pertains (check one)
   ( ) Steering committee
   ( ) Executive committee
   ( ) Study officers committee
   ( ) Treatments effects monitoring committee
   ( ) Other (specify)

   _____

4. Date (day-month-year) . . . . . __—___—____

### B. Chair and vice-chair

5. Chair

   Name: _____

   Method of selection
   ( ) Appointment
   ( ) Election
   ( ) Fiat
   ( ) Other (specify)

   _____

   Term
   ( ) Without term
   ( ) With term (specify term)

   _____

   ( ) Renewable
   ( ) Not renewable

6. Vice chair

   Name: _____

   Method of selection
   - ( ) Appointment
   - ( ) Election
   - ( ) Fiat
   - ( ) Other (specify)

     _____

   Term
   - ( ) Without term
   - ( ) With term (specify term)

     _____

     - ( ) Renewable
     - ( ) Not renewable

**C. Membership**

7. Mode of designation
   - ( ) By appointment (specify appointing authority)

     _____

   - ( ) By election (specify electing body)

     _____

   - ( ) By virtue of positions in study (specify positions)

     _____

   - ( ) Other (specify)

     _____

8. Members

   _____ Voting members

   _____ Nonvoting members

   _____ Total number

9. Terms
   ( ) Without term
   ( ) With term (specify)

_____

**D. Rules and meeting procedures**

10. Quorum requirement (specify)

_____

11. Primary mode of voting
    ( ) Ballot
    ( ) Show of hands
    ( ) E-mail
    ( ) Other (specify)

_____

12. Voting rules
    Absentee votes
    ( ) Allowed
    ( ) Not allowed
    Proxy votes
    ( ) Allowed
    ( ) Not allowed

13. Primary meeting mode
    ( ) Face-to-face
    ( ) Conference phone
    ( ) Other (specify)

_____

14. Rules of order
    ( ) Robert's
    ( ) Other (specify)

_____

**E. Housekeeping**

15. Rapporteur _____

16. Location of repository of minutes

## WS 6.3 Credits and acknowledgments worksheet (Credit.WS)

**When**: Early in the course of the trial

**Who**: A person designated by the study chair; typically a person located in the office of the study chair/PI or in the study coordinating center

**Purpose**: To establish and maintain a list of credits and acknowledgments for use in study documents and publications

**Definitions**

**acknowledgment** - A written expression of such appreciation or thanks, e.g., as appearing in a published manuscript.

**study credit roster** - A list or roll of names of persons, institutions, businesses, agencies, or organizations having some role, function, or association with a study; such a list as appearing at the end of a study manuscript.

**full study credit roster** - A roster of all study centers and all members of the research group, past and present; such a list of current centers and current members of the research group.

**partial study credit roster** - A credit roster of selected study centers or of selected members of the research group.

**study directory** - A directory of centers and personnel involved in a study; such a directory maintained over the life of a study.

**Reminders**

- The credit and acknowledgment list in a publication will be incomplete without efforts to maintain the list as the study proceeds
- A full study credit roster can always be abridged but the reverse is not possible
- Ninety percent of the effort in credit rosters is in maintaining them

**A. Identifying information**

1. Study name: _____

2. Form completed by: _____

3. Date completed (day-month-year) . . . . . __—___—_____

**B. Study directory**

4. Content of basic study directory (check all that apply)
   - ( ) Present and past participating clinics
   - ( ) Present and past participating resource centers
   - ( ) Present and past study personnel by center
   - ( ) Subdirectories of personnel by study function
   - ( ) Study committees and composition

( ) Other (specify)

_____

5. Form of study directory (check one)
   ( ) Electronic
   ( ) Paper
   ( ) Both

**C. Credit formats and rosters**

6. Centers listing
   ( ) Differentiated, e.g., list of clinical centers and locations followed by list of resource centers and their respective locations
   ( ) Undifferentiated, e.g., alphabetic listing of centers without indication as to whether a clinic or resource center
   ( ) Other (specify)

   _____

7. Personnel listing
   ( ) Differentiated, e.g., list of clinical centers and locations followed by list of resource centers and their respective locations
   ( ) Undifferentiated, e.g., alphabetic listing of centers without indication as to whether a clinic or resource center
   ( ) Other (specify)

   _____

8. Committee listing
   ( ) Current membership
   ( ) Present and past members
   ( ) Other (specify)

   _____

9. Does the study maintain a cumulative credit roster of all members of the research group from beginning to present? (recommended)
   ( ) No
   ( ) Yes

   If yes
   Who is responsible for maintaining the roster?

   _____

10. Does the study maintain an abbreviated study credit roster? (recommended)
    ( ) No
    ( ) Yes

    If yes
    Who is responsible for maintaining it?

    _____

**D. Acknowledgments list**

11. Does the study maintain an acknowledgment list? (recommended)
    ( ) No
    ( ) Yes

    If yes
    Who is responsible for maintaining the list?

    _____

12. Contents of the acknowledgment list (check all that apply)
    ( ) Sponsoring agency
    ( ) Funding sources; including grant and contract numbers in the case of NIH funding
    ( ) Drug suppliers
    ( ) Suppliers of study equipment
    ( ) Other (specify)

    _____

    _____