13 Management tables, worksheets, and checklists

Table 13.1 Document production and distribution sites (Produce.Tab)

When: Early in the course of planning

Who: A study officer

Purpose: To identify documents needed for the trial and to specify where they are produced and where distributed from

1. Study name: _____

2. Form completed by: _____

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

Instructions

Check at left if document exists and then indicate in the check spaces at the right where the document is produced and where distributed from.

Legend

CC = coordinating center
OC = Office of study chair
S = Sponsor
Oth = Other; if checked specify site

4. Study documents	Production site				Distribution site			
	CC	CO	S	Oth	CC	CO	S	Oth
( ) Protocol	( )	( )	( )	( )	( )	( )	( )	( )
( ) Prototype consent	( )	( )	( )	( )	( )	( )	( )	( )
( ) Study handbook	( )	( )	( )	( )	( )	( )	( )	( )
( ) Study manual of operation	( )	( )	( )	( )	( )	( )	( )	( )
( ) Data collection forms	( )	( )	( )	( )	( )	( )	( )	( )
( ) Data entry manual of operations	( )	( )	( )	( )	( )	( )	( )	( )
5. Study reports								
( ) Performance monitoring reports	( )	( )	( )	( )	( )	( )	( )	( )
( ) Treatment effects monitoring reports	( )	( )	( )	( )	( )	( )	( )	( )

Table 13.1 Document production and distribution sites

	Production site				Distribution site			
	CC	CO	S	Oth	CC	CO	S	Oth
6. Other documents								
( ) Investigator's brochure	( )	( )	( )	( )	( )	( )	( )	( )
( ) Policy and procedures memoranda	( )	( )	( )	( )	( )	( )	( )	( )
( ) Data dictionaries	( )	( )	( )	( )	( )	( )	( )	( )

WS 13.1 Integrity preservation procedures (Fraud.WS)

When: Before the start of data collection

Who: Senior study personnel

Purpose: To establish procedures for ensuring integrity in the processes and procedures of the trial

Definitions

fabrication - 1. The act or process of fabricating. 2. The product of fabricating; lie; falsehood.

falsification - The deliberate act of making something false.

fraud - Broadly, deceit or trickery; specifically, a deception deliberately practiced to secure unfair or unlawful gain; an act of deceiving or misrepresenting; intentional perversion of the truth to induce another to part with something of value or to surrender a right. ***Usage note***: Avoid as an accusation, absent evidence of intent. To be fraudulent, an act has to be motivated by an intent to deceive. The element of intent is evident in the definitions of fraud, as given in the *Oxford English Dictionary*[12] and *Black's Law Dictionary*.[3] Even acts of omission can be fraudulent if intended to deceive. Oxford English Dictionary: *1. The quality or disposition of being deceitful; faithlessness, insincerity. 2. Criminal deception; the using of false representations to obtain an unjust advantage or to injure the rights or interests of another. 3. An act or instance of deception, an artifice by which the right or interest of another is injured, a dishonest trick or stratagem. 4. A method or means of defrauding or deceiving; a fraudulent contrivance; in modern colloquial use, a spurious or deceptive thing.* Black's Law Dictionary: *An intentional perversion of truth for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right. A false representation of a matter of fact, whether by words or by conduct, by false or misleading allegations, or by concealment of that which should have been disclosed, which deceives and is intended to deceive another so that he shall act upon it to his legal injury. Anything calculated to deceive, whether by a single act or combination, or by suppression of truth, or suggestion of what is false, whether it be by direct falsehood or innuendo, by speech or silence, word of mouth, or look or gesture.*

plagiarism - An act or an instance of plagiarizing; something plagiarized. ***Usage note***: Use with caution as an implied or explicit charge or accusation, especially in the absence of specific factual information supporting the charge or accusation.

scientific misconduct - 1. Willful disregard of norms and standards for conduct of research. 2. Any act or representation by a person in the conduct of research that violates accepted norms or standards for integrity. 3. Fraud, falsification, fabrication, or plagiarism in relation to the design, conduct, analysis, or reporting of research, or in relation to credentialing or documentation. 4. research misconduct

A. Identifying information

1. Study name: _____

2. Form completed by: _____

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

B. Integrity training

4. Persons exposed to integrity training
   - ( ) No integrity training planned
   - ( ) All study personnel
   - ( ) Selected personnel (check all that apply)
     - ( ) Center directors
     - ( ) Study physicians
     - ( ) Study nurses
     - ( ) Center coordinators
     - ( ) Data collectors
     - ( ) Data keyers
     - ( ) Other (specify)

       _____

5. Mode of exposure (check all that apply)
   - ( ) No integrity training planned
   - ( ) Didactic lectures and discussion
   - ( ) Case studies
   - ( ) Online course and examination
   - ( ) Other (specify)

     _____

6. Will study leaders instruct study personnel in regard to (check all that apply):
   - ( ) Definition of scientific misconduct and examples thereof
   - ( ) Definitions of fraud, fabrication, and falsification and examples thereof
   - ( ) Definition of plagiarism and examples thereof
   - ( ) Consequences of misconduct to persons found guilty of misconduct
   - ( ) Consequences of misconduct to the study
   - ( ) Responsibilities of study personnel for integrity
   - ( ) Whom persons should report suspected cases of fraud to
   - ( ) How charges of misconduct are investigated and disposed of

C. Practices aimed at detecting aberrant data (check all that apply)
- ( ) Site visiting
- ( ) Data auditing
- ( ) Checking for protocol departures
- ( ) Indelible randomization audit trail
- ( ) Eligibility checks
- ( ) Performance monitoring

( ) Data analyses to identify suspicious data patterns
( ) Other (specify)

WS 13.2 Meeting planning worksheet (Meet.WS)

Use form for planning specific meetings. Indicate the meeting or group to meet item 4.

1. Study name: _____

2. Form completed by: _____

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

4. Meeting
   ( ) Research group
   ( ) Steering committee
   ( ) Study officers
   ( ) Treatment effects monitoring committee
   ( ) Working committee (specify)

   _____

   ( ) Other (specify)

   _____

5. Meeting organizer/coordinator
   ( ) Office of study chair
   ( ) Coordinating center
   ( ) Sponsor
   ( ) Other (specify)

   _____

6. Purpose of meeting

   _____

7. Day(s) of meeting
   ( ) One day
   ( ) Multiple days . . . . . Number of days ___

8. Day of week (start date for multi-day meetings)
   ( ) Monday
   ( ) Tue, Wed, or Thu
   ( ) Friday
   ( ) Sat
   ( ) Sun

9. Meeting dates
   One day meeting; date . . . . . __—___—_____

   Multi-day meeting . . . . . Start: __—___—_____ End: __—___—_____

10. Meeting time
    Start time . . . . . __:__ am/pm

    End time . . . . . __:__ am/pm

11. Expected number of people attending . . . . . Number ___

12. Travel arrangements (hotel and plane reservations)
    ( ) None necessary (local meeting)
    ( ) By persons traveling
    ( ) By meeting coordinator
    ( ) Other (specify)

    _____

13. Meeting location
    ( ) Host institution
    ( ) Airport meeting room (specify)

    _____

    ( ) Hotel

    City . . . . . _____

    Hotel name . . . . . _____

    Address . . . . . _____

    ( ) Other (specify)

    _____

14. Meeting date picked to coincide with a society meeting?
    ( ) No
    ( ) Yes (specify)

    _____

15. Meeting materials
    ( ) Distributed prior to meeting via hard copy

( ) Distributed via e-mail
( ) Distributed hard copy at meeting

WS 13.3 Conference phone meeting planning worksheet (ConfCall.WS)

Use form for planning conference calls for a group. Indicate the group meeting in item 4.

1. Study name: _____

2. Form completed by: _____

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

4. Conference call meeting
   ( ) Research group
   ( ) Steering committee
   ( ) Study officers
   ( ) Treatment effects monitoring committee
   ( ) Working committee (specify)

   _____

   ( ) Other (specify)

   _____

5. Call organizer/coordinator
   ( ) Office of study chair
   ( ) Coordinating center
   ( ) Sponsor
   ( ) Other (specify)

   _____

6. Purpose of call

   _____

7. Time of conference call
   Day of week . . . . . _____

   Time of day . . . . . __: __ am/pm

   Date . . . . . __—___—____

8. Meeting time
   Start time . . . . . __: __ am/pm

   End time . . . . . __: __ am/pm

WS 13.3 Conference call meeting worksheet

9. Number of people on the call . . . . . Number ___

10. Arrangement
    ( ) Call in (number provided by call coordinator)
    ( ) Persons called by operator
    ( ) Other (specify)

    _____

11. Call materials
    ( ) Distributed via hard copy
    ( ) Distributed via e-mail
    ( ) Distributed both hard copy and via e-mail

CL 13.1 Checklist of forms, worksheets, and checklists to be completed (Formlist.CL)

A. Identifying information

1. Study name: _____

2. Form completed by: _____

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

B. Tables to be completed

C. Worksheets to be completed

D. Checklists to be completed

CL 13.1 Checklist of forms, worksheets, and checklists to be completed

CL 13.2 Log of completed forms, worksheets, and checklists (LogList.CL)

A. Identifying information

1. Study name: _____

2. Form completed by: _____

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

B. Tables completed

C. Worksheets completed

D. Checklists completed