



(Sunday 8:21am) 8 October 2000

## Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Forms design good practice policies and procedures (GPPP)

### Definitions

**case report form (CRF)** *n* - A collection of individual **data forms** related to a person **enrolled** into a **study**, especially when arranged in order of use and completed in totality before submission to the **center** or **sponsor** responsible for receiving such forms.

**check data item** *n* - [**data form**] A **data item** (defn 1) with permissible **responses** listed, indicated by placing a mark in space next to the appropriate response.

**conditional data item** *n* - [**data form**] A **data item** (defn 1) that is completed only if certain conditions apply.

**data form walk-through** *n* - An item-by-item review of a **data form** for the purpose of spotting and correcting deficiencies prior to release for use; especially as performed in a group setting and involving persons responsible for producing or using the form.

**data item** *n* - 1. A written query or **request** for information and associated **data field** for **response** on a **data form**. 2. The response to such a query or request. 3. **data field**

**data item logic** *n* - [**data form**] **Logic** used in construction of **data items** in a **data form** for eliciting responses; **explicit data item logic**; **implicit data item logic**.

**electronic form** *n* - A **form** that is or may be displayed electronically (eg, on a **video screen**), especially one that is or may be completed using such displays and associated electronic devices. ant: **paper form**

**explicit data item logic** *n* - [**data form**] A type of **logic** in which **data items** are constructed to require **responses** even though they can be deduced from responses to preceding items or by other means, eg, an item with a **stop instruction** in the check space for *Male* in a **trial** limited to females or an item with a **goto instruction** in the *Yes* check space to direct respondents to series of data items to be completed only if the question is answered *Yes*. ant: **implicit data item logic**

Memo re Forms design good practice policies and procedures  
(Sunday 8:21am) 8 October 2000

---

**form** *n* - [ME *forme*, fr OF, fr L *forma* form, beauty] 1. A paper **document** consisting of a collection of **data items** and **data fields** in which the data items serve to characterize the type of information required and the fields represent blank spaces to be used for recording the requested information. 2. Any such arrangement, including those represented electronically on video screens. rt: **data form, data record, record, questionnaire**

**formless** *adj* - [general] Devoid of form; having no delineation or form. [**data collection**] Not involving use of **paper forms**.

formless study *n* - **paperless study** *Usage note*: Not recommended; use other terminology, such as **paperless study**, to avoid risk of being jocular or pejorative.

**forms inventory** *n* - An **inventory** of forms completed, received, or processed.

**goto data item** *n* - [**data form**] A **data item** containing a **goto instruction**. rt: **skip instruction item**

**goto instruction** *n* - [**data form**] An **instruction** directing a respondent to a particular section or **item** in a **form**. rt: **instruction box, skip instruction**

**implicit data item logic** *n* - [**data form**] A type of **logic** in which the absence of **response** is used to convey information, eg, as with a **data item** that is to be answered only if certain conditions apply in the absence of preceding items to indicate that the conditions apply. ant: **explicit data item logic**

**instruction box** *n* - [**data form**] Boxed text on a form containing **instructions**. rt: **instruction data item**

**instruction data item** *n* - [**data form**] A **data item** containing **instruction; goto instruction data item; skip instruction data item, stop instruction data item**.

**skip data item** *n* - [**data form**] A **data item** containing a **skip instruction**. rt: **goto data item, skip instruction, skip pattern**

**skip instruction** *n* - [**data form**] An **instruction** directing the respondent to skip items contained in a specified portion of a form. rt: **instruction box, goto instruction, skip pattern**

**skip pattern** *n* - [**data form**] The pattern of **skip data items** on a form. rt: **goto instruction, goto data item, skip instruction**

**P&P 1**: Construct and maintain a forms list; include all forms (even those used for management of the trial even if not intended for data entry).

Memo re Forms design good practice policies and procedures  
(Sunday 8:21am) 8 October 2000

---

**P&P 2:** Construct list to include the following:

- Form number
- Version number and date
- Name or title of form
- Purpose
- Schedule of use
- Size (eg, number of pages or number of items)
- Whether or not data entered

**P&P 3:** When deciding whether forms should be paper or electronic, regard paper as the standard; opt for electronic forms only where they can be shown to have clear advantages over paper.

**P&P 4:** If forms are to be electronic:

- Design using paper and pencil
- Produce electronic forms using paper prototypes
- Maintain paper prototypes for use when electronics fail
- Design so form, when printed from electronic version is legible and black and white photocopy robust (see P&P 5)

**P&P 5:** Construct forms to be black and white photocopy robust, ie, capable of being repeatedly photocopied from preceding photocopies without noticeable degradation in legibility. Test forms for black and white photocopy robustness prior to being placed into use; revise as necessary.

**P&P 6:** Avoid color coding as the sole means of identification of different forms or items on forms.

**Comment**

Color blindness is common, especially in males. If color coding is used for identification of paper forms, print the color of the form in a footer on the form.

**P&P 7:** Construct paper data collection forms to allow for direct data entry, ie, entry directly from the form without additional coding or transcription.

**P&P 8:** Arrange items in order of use.

**P&P 9:** Arrange items into sections.

**P&P 10:** Arrange sections in order of use; arrange to minimize interference of procedures, one with another, and to maximize patient comfort and convenience; be consistent in the ordering across visits.

**Comment**

Memo re Forms design good practice policies and procedures  
(Sunday 8:21am) 8 October 2000

---

Most of the observations and measurements made in clinical trials are settings dependent, ie, are likely to be influenced by surrounding conditions and circumstances. See *Data collection good practice policies and procedures*.

**P&P 11:** Arrange sections relating to procedures in descending order of importance in the trial.

**Comment**

The ordering is useful when clinic personnel have to ration what they do because of the condition of the patient or because the patient does not have time to sit for the entire examination.

**P&P 12:** Construct paper forms to include keying codes.

**P&P 13:** Identify items on forms completed by clinic personnel that are to be *asked as written* or *shown as written*.

**P&P 14:** Establish templates for paper forms; specify the following:

- Right and left margins (left hand margin should not be less than 1"; right hand margin should not be less than 0.75")
- Top and bottom margin (top margin should not be less than 1"; bottom margin should not be less than 0.5")
- Font type (serif type font such as Times Roman)
- Font size (not less than 11 point)
- Page layout (full page or columns)
- Default page orientation (portrait)
- Headers and footers (see P&P 15)

**P&P 15:** Construct headers and footers of the 1st page of each paper form to include:

- Name and acronym of trial
- Name of form
- Form number
- Version number and date
- Whether form is intended for data entry

Construct headers and footers of continuation pages to include:

- Acronym of trial
- Short form name
- Form number
- Version number and date
- For data collection forms, Id number of person being observed
- Whether form is intended for data entry
- Page number

Memo re Forms design good practice policies and procedures  
(Sunday 8:21am) 8 October 2000

---

**P&P 16:** Design data collections forms to include fields for recording:

- Visit identifier and number
- Time and data of visit
- Name of responsible study physician for the visit and signature block
- Name and certification number of person responsible for review of completed data form

**P&P 17:** Establish conventions for:

- Numbering forms
- Numbering sections on forms (Roman or Arabic; Recommendation: Arabic)
- Numbering items on forms (Arabic; continuous (non-nested) from beginning to end of form)
- Numbering of pages in a form (Arabic; continuous from beginning to end of form; eg, 4 of 7, 4 of 7 pages, or page 4 of 7 pages; recommended format: x of n); display in upper or lower right hand corner
- Capitalization (Minimize unnecessary use)
- All capital letters (use sparingly; reduces readability)
- Boldface (use sparingly)
- Italics (use sparingly; reduces readability)
- Underlining (use sparingly; reduces readability)

**P&P 18:** Establish print and display conventions for instructional material included on data collection forms; maintain consistency across forms.

**P&P 19:** Head each form with boxed text indicating:

- Purpose of the form
- Use
- When and were completed
- Who is to complete form

**P&P 20:** Provide instruction boxes as needed throughout forms.

**P&P 21:** Establish format for item types; maintain consistency across forms and over the course of the trial.

**P&P 22:** In regard to item formats, establish the following:

- Arrangement of the various component parts of the different item types
- Layout for check items (Recommended: horizontal for yes-no and similar 2 or 3 category check items; vertical for all others)
- Check space type, eg, box, (), or []
- Check space area; approximately 0.25 x 0.25 inches)
- Check space color and shading (Recommendation: white, no shading)
- Check space separations (Recommendations: Vertical: at least 0.5 lines; Horizontal: at least 3/8 inch)

Memo re Forms design good practice policies and procedures  
(Sunday 8:21am) 8 October 2000

---

- Check space location (Recommendation: Right flushed when following text, otherwise left aligned)
- Location of check category (Recommendation: In or immediately below the check area, eg, ( y ) ( n ) or ( \_ y ) ( \_ n ) for yes-no type items)
- Order of response options (eg, for yes-no items, always *yes* followed by *no*)
- Consistent spacing within and between items
- Consistent skip instructions and skip patterns
- Method for indicating field size for numeric or character information (Recommendation: Line segments of 3/16 inch with a space separating segments)
- Location and space for write-in responses

**P&P 23:** Avoid horizontal layouts in which spacing is likely to result in recording errors, eg, as with Yes( )No( )Unk( ); the likelihood is that some respondents will check *Yes* when they meant to check *No*.

**P&P 24:** Establish date and time formats; maintain consistency across forms (Recommendations: 12 hour am-pm clock for time; day, month (3 letter alphabetic), year (4 digits) for date)

**P&P 25:** The page orientation of all data collection forms should be the same, preferably portrait.

**P&P 26:** Construct for independent completion.

**Comment**

To comply with this P&P it is necessary to avoid constructions involving linked forms.

**P&P 27:** Construct to be able to open and close a form in the same session of use and independent of other forms.

**Comment**

Avoid constructions in which forms are linked (P&P 26).

**P&P 28:** Construct with "stand-alone" logic, ie, logic contained on the form without reference to other forms.

**P&P 29:** Construct using explicit data item logic.

**Comment**

Use of construction techniques in which the absence of response is used to convey information is undesirable because of uncertainty as to whether the absence of response is appropriate or due to oversight.

**P&P 30:** Construct so that key identifying information, such as Id number, name code, and visit number are located in the same relative position on all data collection forms.

Memo re Forms design good practice policies and procedures  
(Sunday 8:21am) 8 October 2000

---

**P&P 31:** Provide space in the upper right corner on all pages of every data collection form for clinic personnel to write or stamp information used in filing and retrieving forms, such as Id number and visit number.

**P&P 32:** Perform walkthroughs of forms before being placed in use.

**P&P 33:** Test forms prior to use.

**P&P 34:** In regard to production, opt in favor of just in time (JIT) systems of production; preferably systems in which forms are printed or made from photocopy masters at clinics as needed.

**Comment**

Printing large quantities of forms in advance of use is risky, especially early in a trial, because of changes to forms.

**P&P 35:** Opt in favor of photocopying for copies of completed forms; be skeptical of NCR (no carbon required) multipart forms for reasons implied in P&P 34.

**P&P 36:** Steer clear of forms packets (packets containing all forms needed for enrollment and followup of a person) prepared in advance of the trial or when a person is enrolled.

**Comment**

See P&P 34.