



(Wednesday 7:51am) 27 September 2000

Memorandum

To: Center for Clinical Trials faculty and staff

Fr: Curt Meinert

Re: Public access good practice policies and procedures (GPPP)

Definitions

end of trial *n* - 1. The **point** at which **treatment** is stopped or changed for a person. 2. **close of trial**

close of trial *n* - 1. The **point** at which **treatment** (as dictated under the **treatment protocol**), **scheduled followup**, and **data collection** end — typically marked by completion of the **close-out stage** of the **trial**. 2. The point at which treatment is stopped or suspended in a trial (not recommended usage); **treatment cessation** (defn 2); **treatment termination** (defn 2). 3. The point at which all activities related to the trial, including **data analysis**, end — typically marked by completion of the **termination stage** of the trial. 4. Termination of the **enrollment phase**. 5. Termination of funding for the trial. 6. **end of trial** *Usage note*: Phrase subject to ambiguities, especially in settings in which **study treatments** are administered only once on **enrollment** or shortly thereafter and in which those so enrolled and treated are then simply followed for **outcomes** of interest. In one sense, in this setting, the trial is ended as soon as the last person enrolled has been treated, even though **followup** may continue for years thereafter. Usage should be restricted to settings in which all patient-related activities are terminated, including **scheduled followup visits** and related data collection. Avoid use in settings in which only specific activities or functions are terminated, such as enrollment but not followup; be specific in such settings about what has ended and what continues.

public archive *n* - A place, such as a library, where **documents** are stored for **access** and use by the general public or members of a defined class of people (eg, students and faculty of a school in regard to use of its library). syn: **public repository** *Usage note*: See **public repository** for note.

public domain *n* - Documents, products, or processes available for use or appropriation by the general public by virtue of the absence of copyright, patent, or other protections. rt: **public use**

privileged access *n* - Access granted because of **privilege** due to standing or position. rt: **privileged use, restricted access**

privileged use *n* - Use granted because of **privilege** due to standing or position. rt: **privileged access, restricted use**

public use *adj* - Of, related to, or concerned with use by the general public.

public use *n* - Use open to the general public. rt: **unrestricted use**

public use dataset *n* - 1. A **dataset** residing in a **public repository**. 2. A dataset residing at a Federal, State, County, or City agency that is available for use by the public.

public repository *n* - A **repository** open to use by the **public** at large or to members of a defined class (eg, students and faculty of a school in regard to use of its library). In regard to such a repository for **datasets**: One in which access to datasets is provided to the public at large or to members of a defined class without regard to privilege, position, rank, or motive of the requesting party. syn: **public archive** *Usage note*: In regard to datasets, a repository is not public if the datasets it holds remain under the control of the investigators or research organization responsible for collection of the **data** or if those investigators or that organization retain the right to decide whether a request is granted. See **repository** for additional comments.

restricted access *n* - **Access** that is limited; access open only to specified individuals or groups, eg, as with access to **treatment results** during conduct of the **trial** to the **treatment effects monitoring committee** only. ant: **unrestricted access** rt: **restricted use**

restricted use *n* - Use limited by condition or restriction, eg, use of unpublished **study data** granted a **sponsor** for the purpose of meeting **regulatory requirements**. ant: **unrestricted use** rt: **privileged use, restricted access**

unrestricted access *n* - **Access** not limited by condition or restriction; access granted without regard to privilege, standing, or position; eg, as in regard to information in the **public domain**. ant: **restricted access** rt: **unrestricted use**

unrestricted use *n* - Use not limited by condition or restriction. ant: **restricted use** rt: **public use, unrestricted access**

P&P 1: Establish methods and procedures for dealing with requests for information concerning the trial during the design phase; establish in conjunction with the SC; review and modify as the trial proceeds.

P&P 2: Opt for policy in which information is made available except when doing so:

- Compromises rights of patients
- Involves use of resources needed for conduct of the trial
- Compromises or violates investigators' right of primacy

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- Involves data not yet analyzed or published
- Involves release of draft study documents

P&P 3: Establish policy in conjunction with the funding agency.

Comment

The emphasis should be on *in conjunction with* in contrast to *dictated by*.

P&P 4: Regard the study protocol and consent forms as available for release when the trial is opened for enrollment.

P&P 5: Consider data collection forms and related procedures and policy handbooks and manuals to be available for release when approved for use in the trial.

P&P 6: In writing policy, avoid imposing restrictions on access in the absence of legitimate reasons for doing so (see P&P 2).

P&P 7: Classify the following as to level of access; list nature of restriction if access is restricted.

- Minutes of meetings
- Performance monitoring reports
- Site visit reports
- Enrollment data
- Baseline data
- Treatment effects monitoring reports
- Interim treatment results
- Conflict of interest disclosures
- Investigators brochure
- IRB submissions and approvals
- Funding application

P&P 8: List documents regarded as being in the public domain (hence available without restriction) and when so regarded.

P&P 9: Establish policy and procedures aimed at ensuring access to finished data of the trial by deposit of datasets in public archives.

P&P 10: In establishing policy pursuant to P&P 9, opt in favor of deposit of datasets in relation to published papers, even if the plan is to deposit the finished dataset at the "end of trial".

P&P 11: If the entire finished dataset is to be deposited at the "end of trial" (see defn above), define "end" relative to when the last person was seen, relative to when results were published, or when funding terminates.

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Comment

The tendency of investigators is to procrastinate on defining "end" or to hedge its meaning.

P&P 12: Avoid "end of trial" methods of deposit as the sole means of deposit if archiving is not part of the work scope of the trial or is not covered in funding awards.

Comment

One obvious difficulty with policies built on a single deposit at the "end of study" is that the "end" can come in unexpected ways, some of which make deposit unlikely. Unless support is provided for deposit, personnel, when the "end" comes, will be more interested in finding new work than in archiving data for deposit.

P&P 13: Designate a spokesperson for the study and inform all study personnel as to who that person.

P&P 14: Establish methods and procedures for dealing with requests for information from news media; instruct study personnel as to methods and procedures for dealing with such requests.

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