Research Education News

Achieving High Quality Clinical Research Seminar Series

The next seminar offered as part of the CITI seminar series will resume in September.

Education and Training Opportunities

Clinical Research Coordinator (CRC) Certification

The Office for Human Subject Protection promotes the benefits of certification. Study sites use Certification for documentation to sponsors and CROs that the site is professionally managed. To date, over 150 University of Rochester CRCs have received certification. The OHSP reimburses the examination fee for all employees that receive a passing grade on the examination. In addition, the office reimburses the employees re-certification fee every two years upon completion of continuing education time requirements. To learn more, follow this link: http://www.rochester.edu/ohsp/education/coordinators/certification.html

Good Clinical Practice (GCP) Training

The office has selected a GCP training on-line program offered through Collaborative Institutional Training Initiative (CITI Program) through the University of Miami. This course is intended for research personnel involved in conducting drug, device, or biologic studies and who would benefit from FDA--focused training. Contact bill_kelvie@urmc.rochester.edu for information on how to access the training.

OHSP List Serve

You can subscribe to the OHSP list serve and receive training and educational announcements by sending a request to:

bill_kelvie@urmc.rochester.edu

OHSP Website:

www.rochester.edu/ohsp
Good Documentation Practice (GDP) is a term the pharmaceutical industry often uses to describe best practices surrounding research documentation and its maintenance. Some GDP standards are supported by regulation (FDA) but some are policy or simply current expectation (best practices).

Below are some ideas for Good Documentation Practice:

- Ensure that your documentation meets the ALCOA standard: Attributable, Legible, Contemporaneous, Original, Accurate
- Documentation should detail the actual event. Templates are acceptable but should always be customized to represent the actual interaction with the individual subject.
- If an error does occur when documenting, single-line through it, date and initial the correction.
- Corrected or altered text should never be obscured. (i.e. No white-out or permanent stickers)
- Handwritten entries should always be in indelible ink, preferably black or blue ink.
- No spaces for handwritten entries should be left blank. If a space is not used, cross it out or mark "N/A".
- Ditto marks or continuation lines are not advised.
- A stamp in lieu of a handwritten signature is **not acceptable**. A stamp in proximity to a handwritten entry for clarification is acceptable. An example is a physician’s stamp that contains contact information placed next to his original signature.
- Critical or pivotal entries should be considered for an independent check (i.e. second person verification).
- When adding a new version to a regulatory file (e.g. newly approved amended protocol) single cross the face sheet of the previous version, write ‘superseded’ and initial and date.

### Document creation and maintenance

- When creating your source document, provide adequate space for expected handwritten entries.
- Consider password protecting online documents. This will help alleviate inadvertent or unauthorized modifications, including page deletion.
- Ensure Electronic records are located on a shared drive for team access and are routinely backed up.
- Indicate in your paper files where the electronic documents are located.
- Use Page numbering (preferably in "Page x of y" format) which allows a user or reviewer to check that there are no missing pages.
- Dates and times are often written in a variety of formats that can be confusing if read by personnel with different backgrounds. For example, a date such as "07-05-10" can have numerous meanings and therefore could be confusing and not clear. Best practices suggesting using a date with a 3-letter month, e.g. Jan 1, 2013 or 01-JAN-2013.
- Regularly review documents for breaches or errors. Adjust form template to better capture data rather than allow continued misuse.
- Retain documents for appropriate duration – as per protocol specification or policy.
- Avoid asterisks as a part of the notation of a handwritten change. When insufficient white space exists, a common practice is to use an asterisk (or other mark) near the correction, and elsewhere record the same mark and make a notation. The risk is that additional changes are made by another person who uses the same mark, and now the notation can be interpreted to apply to all changes with the mark. If an asterisk must be used, clearly include the number of changes that it applies to, such as, "* Three entries changed above due to entry errors. KMW 13-Jan-2012".
**Research Subjects Review Board News**

**Consent Issues in Research Involving Children**

*(subjects under 18 years of age)*

In all human subjects’ research, the agreement of the subject to participate is an essential protection of the rights and welfare of subjects. Minors, by definition, cannot give legal ‘consent.’ Therefore, a combination of ‘assent’ (agreement) of the minor subject and ‘permission’ of the parent or legal guardian is deemed an adequate substitute. If either the parent refuses to provide permission or the minor subject refuses to provide assent, the minor should not be enrolled.

**Waiver of Parental Permission:** The University of Rochester requires parental permission for research that involves children. There are four exceptions to this general policy which may be asked for by investigators:

1) no-risk or minimal-risk research with older adolescents (e.g., anonymous surveys in high school juniors and seniors);
2) purely observational studies (no interaction) of public behavior (e.g., classroom activities);
3) studies of existing data; and
4) research with children where New York Law expressly gives children the right to seek certain types of medical treatment without parental consent.

**Obtaining Assent:** Adequate provision must be made for soliciting the assent of children and the process must be appropriate to the study as well as the age, maturity and psychological state of the child. Information must be presented in language and format that is understandable to the child. The children should have an understanding of the research procedures and it should be clear that their participation is voluntary.

Permission of care givers and/or service providers is not sufficient to conduct research with minors. Only parents and legal guardians have that authority to provide permission. School principals, teachers, clinic personnel, etc., do not have the authority to give ‘blanket’ permission for their students/patients/clients to participate in research. They do have the authority to allow the research to be conducted in their facility, this permission should be included with the study submission. In classroom research, it must be made clear that the research is not part of the regular educational program and that the student’s grades or standing will not be affected by not participating.

**Payment:** Payment for participation must be appropriate to the subject’s age and the nature of the study. Payment (e.g., toys, coupons for food) should be given to the minor and not the parents. Parents may be reimbursed/paid for expenses, such as travel.

**Documentation:** Documentation of assent and permission depends upon the nature of the research and the maturity of the minor. For research that presents no greater than minimal risk, documentation may be waived. Usually, adolescents (age 13-17) can sign assent forms, but for younger children (ages 7-12) an assent script is usually acceptable. In most cases, documentation of parental permission (signature) should be obtained on a permission form (templates available on the OHSP website). Some research with children may require the permission of both parents. In this research, two parental signature lines would be needed on the consent form.