



Food and Drug Administration
Rockville, MD 20857

February 1999

Dear Colleague:

**SUBJECT: 1998 Update of INFORMATION SHEETS: GUIDANCE FOR
INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS**

In 1984, the Office of Health Affairs published a series of Information Sheets to help IRBs carry out their responsibilities for protection of human research subjects. These were revised extensively in 1989 and in 1995.

The 1998 Information Sheets represents an update of the 1995 document rather than a complete revision. For example, the offices and telephone numbers to contact for information have been updated. The table of contents has been reorganized to include individual sections of many of the Information Sheets. Many of the individual information sheets have been edited for ease of readability. Specific updates include:

- The "Frequently Asked Questions" section has been reorganized and expanded to incorporate additional established guidance.
- The Information Sheet, "A Guide to Informed Consent Documents" has been reorganized and now includes the information formerly contained in the Information Sheet, "Informed Consent and the Clinical Investigator."
- Appendix H: "A Self-Evaluation Checklist for IRBs" has been revised to include references to the regulations and to include when the item is required by the regulations.
- Appendix K has been added to include a list of World Wide Web sites that may be of interest to IRBs and clinical investigators.

As you know, this is an evolving field with continual changes in regulations and guidance. No written document can be entirely current for long. For example, on November 9, 1998, FDA published in the *Federal Register* concurrently with OPRR a new Expedited Review List. Because the updated Information Sheets would be in press for several months, a decision was made to distribute it when it became available and to notify the human subject protection community when the new Expedited Review List was issued. The *Federal Register* publication, including the FDA preamble, was published on pages 60353-60356 of the November 9, 1998 *Federal Register* and is

available on the World Wide Web at <http://www.fda.gov/ohrms/dockets/98fr/110998b.txt>. I am enclosing a copy of this *Federal Register* notice as a replacement for Appendix D in the Information Sheet booklet.

We are attaching to this letter an Addendum that lists a number of modifications to the publication. A comprehensive review and revision of the Information Sheets is planned to begin in the near future. We hope that you will keep this Addendum with the document. **(NOTE: The modifications listed in the Addendum have been included in the online version of the Information Sheets.)**

The Information Sheets can be found on the FDA Office of Health Affairs (OHA) website. Changes to regulations and guidances (including the [FDA Information Sheets](#)) applicable to clinical investigators and IRBs will be posted on the [OHA home page](#) as they become available.

We hope that you find this update helpful, and that the Information Sheets continue to be a valuable resource to you in carrying out your responsibilities for protecting human subjects who participate in clinical research. We invite you to provide any suggestions you may have for improvements or additions which would make future revisions of the Information Sheets more useful to you. Please send any comments to: Paul W. Goebel, Jr., Associate Director for Human Subject Protection (HFY-20), Office of Health Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (telephone 301-827-1685, facsimile 301-443-0232, e-mail: pgoebel@oc.fda.gov).

Sincerely,

/s/

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

Enclosures