Criteria For Approval

45 CFR 46.111
21 CFR 56.111

- Minimized risks
- Reasonable risk/benefit ratio
- Equitable subject selection
- Informed consent process
- Informed consent documentation
- Data monitored for safety
- Confidentiality/privacy maintained
- Vulnerable populations protected

Review Criteria

45 CFR 46.111
21 CFR 56.111

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

Beneficence

- Acts of kindness or charity that go beyond duty
- Obligations derived from beneficence
  - Do no harm
  - Prevent harm
  - Prevent evil
  - Promote good

Belmont Report

- "…complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms."

- "…the different claims covered by the principle of beneficence may come into conflict and force difficult choices."

DSMP

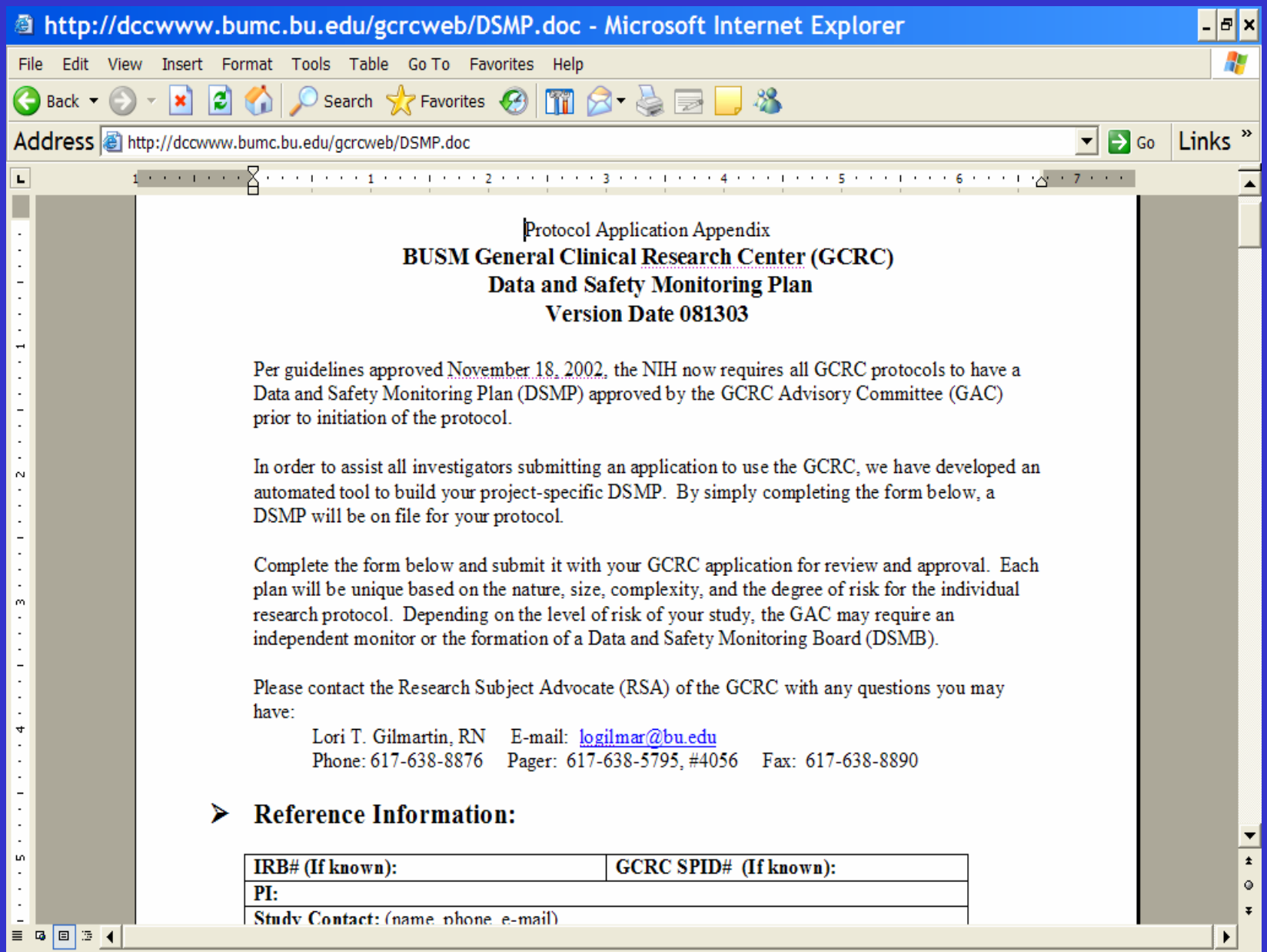
The DSMP must minimally include:

a) a description of the risks and safety assessments of the study,

b) specifics regarding who will be monitoring the data and the frequency of monitoring, and

c) a clear description of the safety findings that would cause the study to be suspended.

GCRC DSMP



Protocol Application Appendix

BUSM General Clinical Research Center (GCRC)
Data and Safety Monitoring Plan
Version Date 081303

Per guidelines approved November 18, 2002, the NIH now requires all GCRC protocols to have a Data and Safety Monitoring Plan (DSMP) approved by the GCRC Advisory Committee (GAC) prior to initiation of the protocol.

In order to assist all investigators submitting an application to use the GCRC, we have developed an automated tool to build your project-specific DSMP. By simply completing the form below, a DSMP will be on file for your protocol.

Complete the form below and submit it with your GCRC application for review and approval. Each plan will be unique based on the nature, size, complexity, and the degree of risk for the individual research protocol. Depending on the level of risk of your study, the GAC may require an independent monitor or the formation of a Data and Safety Monitoring Board (DSMB).

Please contact the Research Subject Advocate (RSA) of the GCRC with any questions you may have:

Lori T. Gilmartin, RN E-mail: logilmar@bu.edu
Phone: 617-638-8876 Pager: 617-638-5795, #4056 Fax: 617-638-8890

➢ Reference Information:

IRB# (If known):	GCRC SPID# (If known):
PI:	
Study Contact: (name, phone, e-mail)	

IRB Review of DSMP

- Who is performing safety monitoring?
  - PI
  - Other research staff
  - Independent monitor
- What is being assessed?
- How is assessment performed?
- How often is assessment performed?
- How and when will safety issues lead to suspension or termination of the study?

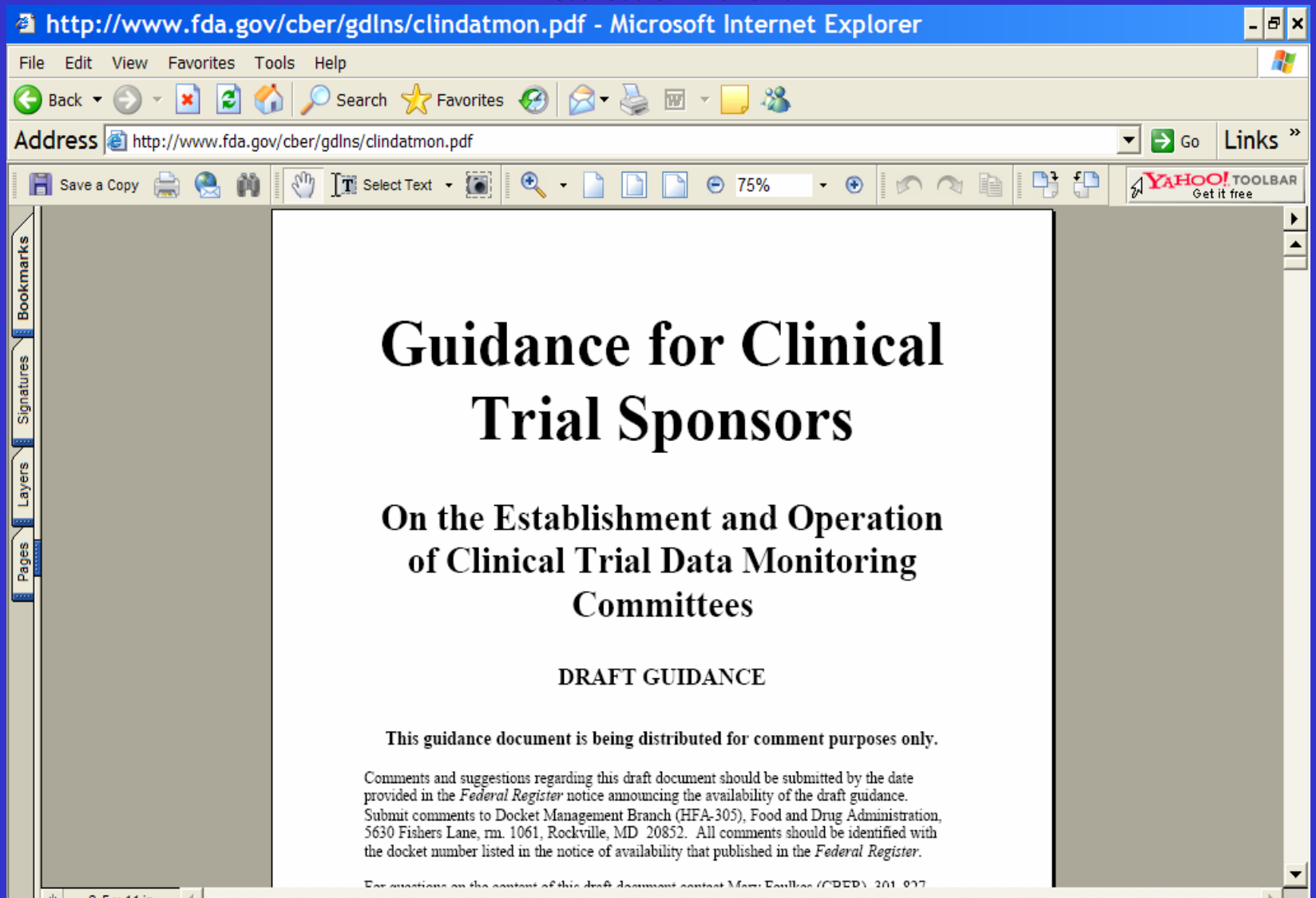
DSMB

- Independent
- Committee
- SOPs
- Safety monitoring
- Interim analysis
- Sample size assumptions

DMC Guidance

www.fda.gov/cber/gdlns/clindatmon.pdf

draft 2001



INSPIR Section H: Potential Risks/Discomforts

- List the possibilities for risk or harm to the subjects as a result of their participation in the research, including discomforts, hazards, or inconveniences to the subject. Whenever possible, include for each:
  - Probability of occurrence
  - Magnitude
  - Duration

Types (Domains) of Harm in Research

Physical

Psychological

Social

Economic

Legal

INSPIR Section H: Potential Risks/Discomforts

- Indicate what measures will be taken to prevent or to minimize the effects of hazards, discomforts or inconveniences. Include a detailed description of your Data Safety Monitoring Plan (DSMP). The DSMP must minimally include a) a description of the risks and safety assessments of the study, b) specifics regarding who will be monitoring the data and the frequency of monitoring, and c) a clear description of the safety findings that would cause the study to be suspended.