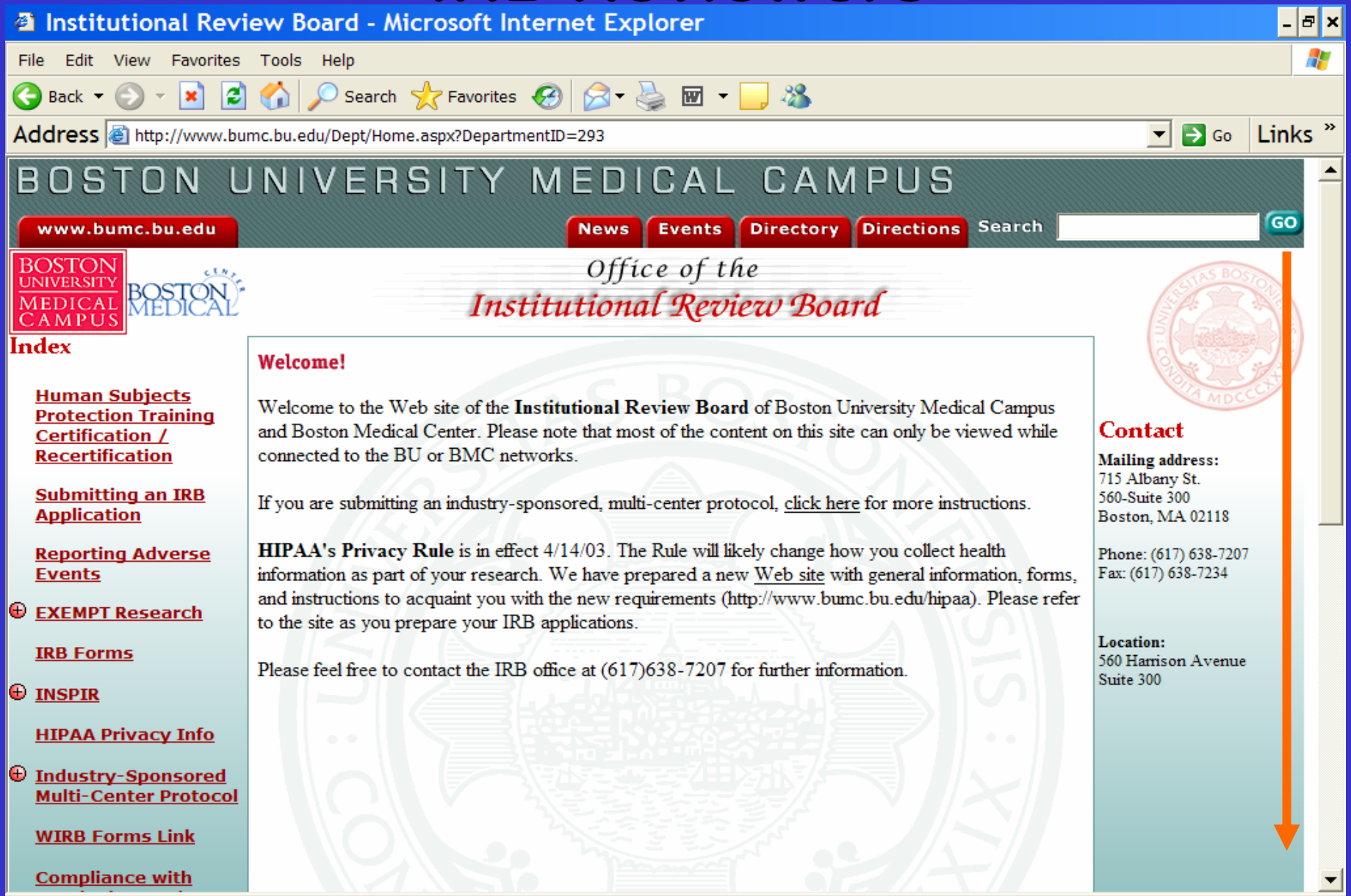
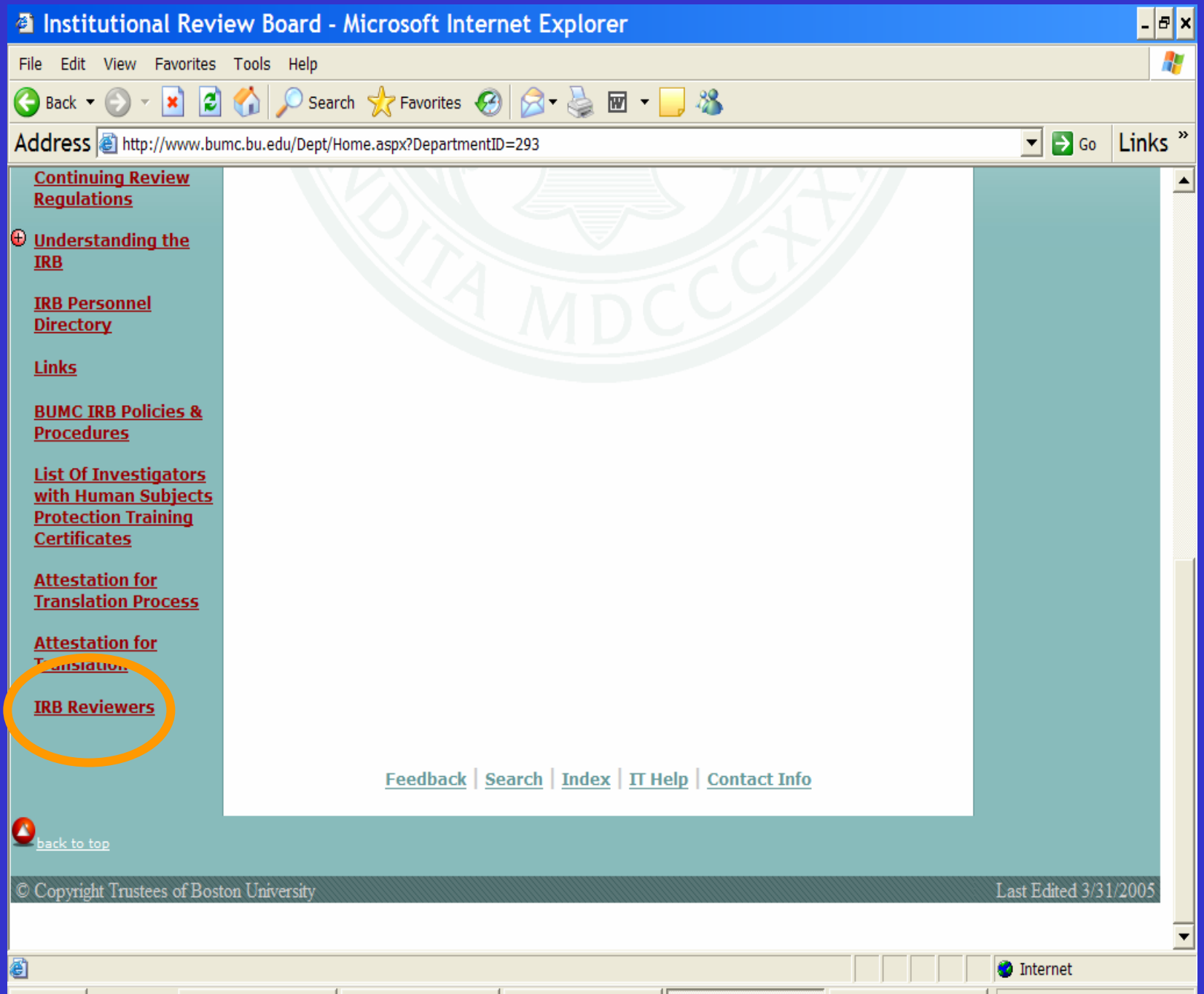
Announcements

- Please submit bills for broadband access to Donna Abbadessa in a timely manner (at least quarterly).

- New approach to Board education

www.bumc.bu.edu/irb
IRB Reviewers

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Criteria For Approval

45 CFR 46.111
25 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

- (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Sound Research Design

- Qualified investigator(s)
- Scientific value- the “so what” question
- Scientific validity
  - Design
  - Analysis
  - Sample size
  - Correct control group

Emanuel et al. JAMA 2000

Requirement	Explanation	Justifying Ethical Values	Expertise for Evaluation
Social or scientific value	Evaluation of a treatment, intervention, or theory that will improve health and well-being or increase knowledge	Scarce resources and nonexploitation	Scientific knowledge; citizen's understanding of social priorities
Scientific validity	Use of accepted scientific principles and methods, including statistical techniques, to produce reliable and valid data	Scarce resources and nonexploitation	Scientific and statistical knowledge; knowledge of condition and population to assess feasibility
Fair subject selection	Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research and the rich and socially powerful not favored for potentially beneficial research	Justice	Scientific knowledge; ethical and legal knowledge
Favorable risk-benefit ratio	Minimization of risks; enhancement of potential benefits; risks to the subject are proportionate to the benefits to the subject and society	Nonmaleficence, beneficence, and nonexploitation	Scientific knowledge; citizen's understanding of social values
Independent review	Review of the design of the research trial, its proposed subject population, and risk-benefit ratio by individuals unaffiliated with the research	Public accountability; minimizing influence of potential conflicts of interest	Intellectual, financial, and otherwise independent researchers; scientific and ethical knowledge
Informed consent	Provision of information to subjects about purpose of the research, its procedures, potential risks, benefits, and alternatives, so that the individual understands this information and can make a voluntary decision whether to enroll and continue to participate	Respect for subject autonomy	Scientific knowledge; ethical and legal knowledge
Respect for potential and enrolled subjects	Respect for subjects by (1) permitting withdrawal from the research; (2) protecting privacy through confidentiality; (3) informing subjects of newly discovered risks or benefits; (4) informing subjects of results of clinical research; (5) maintaining welfare of subjects	Respect for subject autonomy and welfare	Scientific knowledge; ethical and legal knowledge; knowledge of particular subject population

*Ethical requirements are listed in chronological order from conception of research to its formulation and implementation.

Where to Look in INSPIR

- Section C: Summary
- Section D: Background; study question
- Section F: Design
- Section G: Statistical Issues
- Attachments:
  - Sponsor's protocol
  - Grant
  - Investigator's brochure

3. Is there any conflict of interest for the PI or other study personnel?	☐	☐	☐
Comments:			
SECTION D: BACKGROUND/RATIONALE/PURPOSE	**YES**	**NO**	**N/A**
1. Is there suitable justification for a study involving humans?	☐	☐	☐
2. Is the research problem/hypothesis adequately stated?	☐	☐	☐
3. Are the specific aims of the research and how these will contribute to scientific/medical knowledge adequately described?	☐	☐	☐
Comments:			
SECTION E: PROTOCOL RISKS/SUBJECTS	**YES**	**NO**	**N/A**
1. Is this research more than minimal risk? **Risk:** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." **Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.	☐	☐	☐
2. Is the subject population appropriate for the research?	☐	☐	☐
3. If only English-speaking subjects are to be recruited, has an adequate justification been provided?	☐	☐	☐

Do Not Unnecessarily Expose Subjects to Risk

- Eligibility Criteria
- Withholding of known effective treatment

Where to Look in INSPIR

- Section E: Protocol Risk/ Subjects
- Section F1: Inclusion/Exclusion
- Section H: Risks

Use Clinical Procedures or Data

- whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes

- NB: If study includes interventions that have risks (i.e. use of FDA approved drugs and devices, xrays, etc.) even if they are used in standard of care, if they are part of the RESEARCH INTERVENTIONS, then the study is not < minimal risk.

Where to Look in INSPIR

- What is standard of care?
- What procedures are already being performed on the subjects for diagnostic or treatment purposes?

- Should be in Sections D and/or F

Next?

- Send suggestions for topics to Sue Fish or Mary Banks