Changes to EXEMPT Requirements

Effective  3/15/05

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Change To Exempt Requirements

• IRB has changed “required fields” in INSPIR for protocols submitted as Exempt research

• As of 3/15/05, once new research is deemed Exempt BY THE IRB continuing review is no longer needed

• If changes are made to Exempt research then a new protocol must be submitted to the IRB
No Further IRB Review Needed

Studies are Exempt from further IRB review when:

- The IRB determines that there are by definition NO HUMAN SUBJECTS.
- The IRB determines that the study does not meet the regulatory definition of RESEARCH OR
- The IRB determines that the study meets the regulatory requirements as Exempt (fits one or more Exempt categories).
**Human Subjects**

*Human subject* means a *living* individual *about whom* an investigator conducting research obtains

1. Data through intervention or interaction with the individual, OR
2. Identifiable private information

*45CFR 46.102(f)*
“A systematic investigation (including research development, testing and evaluation), designed to develop or contribute to generalizable knowledge.”

45CFR 46.102(d)
The Regulations

Exempt Studies

45CFR 46.101(b)
Studies are Exempt Unless

Human subjects can be identified

AND

Disclosure could place the subject at risk
Risks

- Physical Risks

- Other Risks
  - Criminal / civil liability
  - Damaging to financial standing, employability, or reputation
Very Important Point

Unless otherwise required... Exemption applies to research activities in which the ONLY involvement of human subjects will be in one or more of the following categories.
45 CFR 46.101 (b) (1)

- Research conducted in established educational settings
- Involving normal educational practices
  - Regular/special ed strategies
  - Effectiveness of / comparison among instructional techniques, curricula, classroom management methods
Research involving use of educational tests

Research using survey procedures, interview procedures, observation of public behavior

Except:
- If subjects can be identified directly or through identifiers linked to subjects
- Disclosure of responses could place subjects at risk (i.e. civil or criminal liability, financial standing, etc.)
- If subjects are children
45 CFR 46.101 (b) (3)

- Educational tests, survey / interview procedures, observation of public behavior not covered in #2 if:
  - Subjects are elected or appointed public officials
  - Federal statues require without exception that the Confidentiality of information will be maintained throughout the research and thereafter
45 CFR 46.101 (b) (4)

- Collection or study of **existing** data, documents, records, specimens (diagnostic/pathological)
- If sources are publicly available
- If subjects **cannot** be identified either directly or through identifiers linked to subjects
Clarification: Existing Data

Data must exist prior to the IRB submission.

Does not apply to studies where data or specimens will be collected in the future.
Subjects Can Not Be Identified

• Data collection sheets must use unique identifiers and there can be **NO MASTER CODE** list that links those identifiers back to the subjects

• Application must include information regarding
  - how the data will be collected
  - If there are any links to subjects
  - Copies of the data collection tools
45 CFR 46.101 (b) (5)

- Research and demonstration projects
- Conducted by/Approval of governmental department heads which are designed to evaluate/ examine
  - Public benefit or service programs
  - Procedures for obtaining benefits/services
  - Changes/ alternatives
  - Methods of payment
45 CFR 46.101 (b) (6)

- Taste and food quality evaluation
- Consumer acceptance
  - Wholesome foods
  - Without additives
  - Safe by FDA
  - Approved by EPA
Which Categories Most Frequently Apply to BUMC Researchers?

• Anonymous surveys (Category 2)
• Interviews (Category 2)
• Research Use of **Existing** Data (Category 4)
  - Databases
  - Chart reviews
  - Specimens
Exemptions do NOT apply to:

- Research involving
  - Pregnant women
  - Fetuses
  - Human in-vitro fertilization
  - Prisoners

- Survey/interview exemption
  - Does not apply to children

- Observation of public behavior
  - Does not apply to research with children
    (except when investigator does not participate)
More Regulations

What the Regulations Require

- Description of the Proposed Research
- Review and determination of Exempt status (not by PI alone)
- Administrative oversight - ensure research remains within the “bounds” of the Exempt category
Investigator presents the research to the IRB via INSPIR application.

Presentation includes clear documentation of how the study meets the Exempt criteria or does NOT meet the definition of human subjects research.

IRB office makes the determination of Exempt.

IRB deems the study as EXEMPT and “closes” it in INSPIR.

Annual Review not required.

Changes must be submitted to IRB as a new study—when a study is labeled Exempt in INSPIR it cannot be amended.
INSPIR Application for Exempt Studies

- Fewer data fields are required to be completed (see the instruction sheet on the IRB website for a list of the fields required in INSPIR)
- Submissions still must be signed by the department Chair
- PI must still have human subjects protection training and recertification requirements still apply
One or more HIPAA forms must be submitted in INSPIR

www.bumc.bu.edu/hipaa

Many will require a HIPAA Waiver of Authorization

No HIPAA Authorizations (because research is anonymous)

Contact Research Privacy Advocate, Ilda Montoya with questions 617-414-1347 or imontoya@bu.edu
IRB Office will

- Review the application
- Make determination regarding Exempt status (criteria met)
- Make HIPAA determination
- “Approve” it (i.e. mark it as Exempt) or return it for modifications
- Once it is deemed Exempt the system will “close” the study so no further action is required
- No renewals needed
Exempt “Approval” Letter

• Recognizes that the research is **Exempt**
  because

  1. The IRB determined that the study was Not Human Subject Research **OR**
  2. Exempt because it fits into one or more exemption categories- letter indicates which Exemption category/ categories apply

• Indicates that approval does NOT necessarily mean HIPAA is approved (HIPAA form must be signed by the IRB or Ilda and attached as External Attachment in INSPIR)

• Reminds the PI to notify IRB of any changes (Changes must be made by copying the protocol and resubmitting it to IRB as a new submission)
PI Responsibilities for Submitting an IRB Protocol as Exempt

Prior to submission make sure all of the research activities in the study

a. Fit into one or more of the Exempt categories (Section B1 of INSPIR) prior to submission*  OR

b. The study (by definition) does NOT involve human subjects research (don’t check any items in Section B1)

* Make sure that all research activities listed in Section F2 of INSPIR fall into one of the Exempt categories
PI Responsibilities

Submit to the IRB Exempt protocol PRIOR to starting the research

Verify that PI has had human subjects protection training and recertification when applicable

(www.bumc.bu.edu/irb for a listing of investigators with training certificates on file with the IRB)
Previously Submitted
“Exempt” Studies

- Must be converted to INSPIR
- IRB will review progress report
- IRB will then mark as Exempt or Not Human Subject Research and “close” if appropriate
If you have questions

Email the IRB office at

medirb@bu.edu