# INSPIRing Changes to the IRB Process: New templates and more

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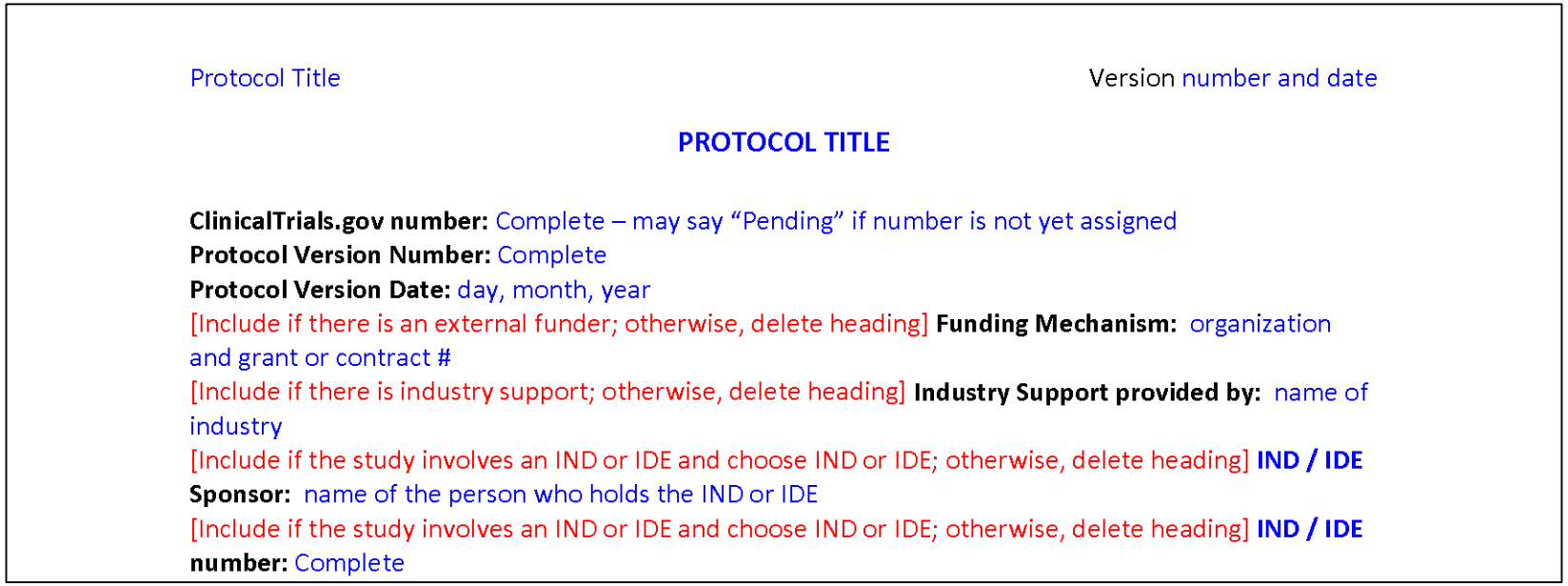
# Learning objectives

- List 3 major changes in policy effective November 1, 2016.
- Describe the process within INSPIR for including a separate protocol.
- Describe the new policy regarding limited and non-readers, including requirements in the informed consent form and when existing studies have to come into compliance.

# New Policies as of November 1 affecting only NEW submissions (1)

- Initial submissions of clinical trials that involve a drug, device, or surgical intervention must have a detailed protocol
  - Sponsor or cooperative group protocol, or
  - Local PI-written based upon template posted on our website



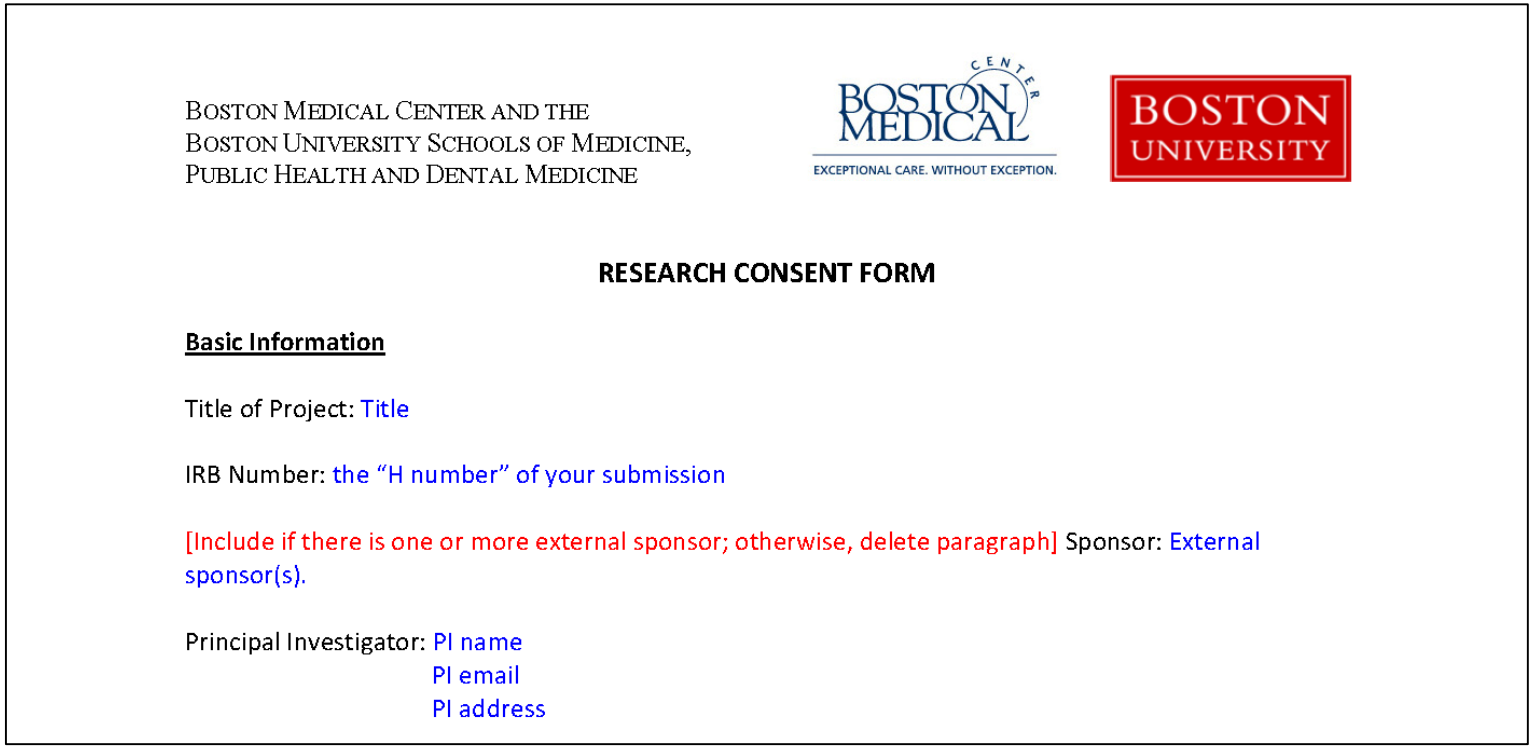
Protocol Title Version number and date

**PROTOCOL TITLE**

**ClinicalTrials.gov number:** Complete – may say "Pending" if number is not yet assigned
**Protocol Version Number:** Complete
**Protocol Version Date:** day, month, year
[Include if there is an external funder; otherwise, delete heading] **Funding Mechanism:** organization and grant or contract #
[Include if there is industry support; otherwise, delete heading] **Industry Support provided by:** name of industry
[Include if the study involves an IND or IDE and choose IND or IDE; otherwise, delete heading] **IND / IDE**
**Sponsor:** name of the person who holds the IND or IDE
[Include if the study involves an IND or IDE and choose IND or IDE; otherwise, delete heading] **IND / IDE number:** Complete

# New Policies as of November 1 affecting only NEW submissions (2)

- Initial submissions must use new consent form template
  - Sponsor-provided consent forms must use new header and have required information on the first page



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PUBLIC HEALTH AND DENTAL MEDICINE

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BOSTON UNIVERSITY

**RESEARCH CONSENT FORM**

**Basic Information**

Title of Project: Title

IRB Number: the "H number" of your submission

[Include if there is one or more external sponsor; otherwise, delete paragraph] Sponsor: External sponsor(s).

Principal Investigator: PI name
PI email
PI address

# New Policies as of November 1 affecting only NEW submissions (3)

- Study staff on all initial submissions of biomedical clinical trials must complete GCP (good clinical practice) training
  - CITI, CRRO training, or sponsor training

# New Policies as of November 1 affecting ALL submissions

- Plans for findings with potential health or reproductive importance (pertinent and/or incidental findings) must be described
- Inclusion or exclusion of limited- and non-readers must be specified
  - Default position is to include and this requires a witness line on consent form

# What in INSPIR has changed?

## Part 1: New Pathways (1)

- An abbreviated pathway when a separate detailed protocol is attached (a requirement for new biomedical clinical trials)
  - Acceptable protocols: sponsor, cooperative group, ones based upon our template or one of the NIH templates
  - NOT Acceptable: Grant application

## 8.1 Separate Protocol

Is this a new submission with a separate protocol that describes the purpose, inclusion/exclusion criteria, design/procedure, and data safety and monitoring? A separate protocol is REQUIRED for initial submissions of medical or surgical clinical trials starting on November 1, 2016. A GRANT APPLICATION IS *NOT* A PROTOCOL.

- (•) Yes
- ( ) No
- ( ) Not applicable, this submission is an amendment

**Upload here your protocol and any surveys, questionnaires, and other data collection instruments that are not included within the separate protocol.**

# What in INSPIR has changed?

## Part 1: New Pathways (2)

- Abbreviated pathway for chart reviews
  - If no external funding, exempt under equivalent protections
  - With funding and retrospective only, exempt category 4
  - With funding and includes prospective, expedited with waiver of consent.

## 4.0 Review Path Determination

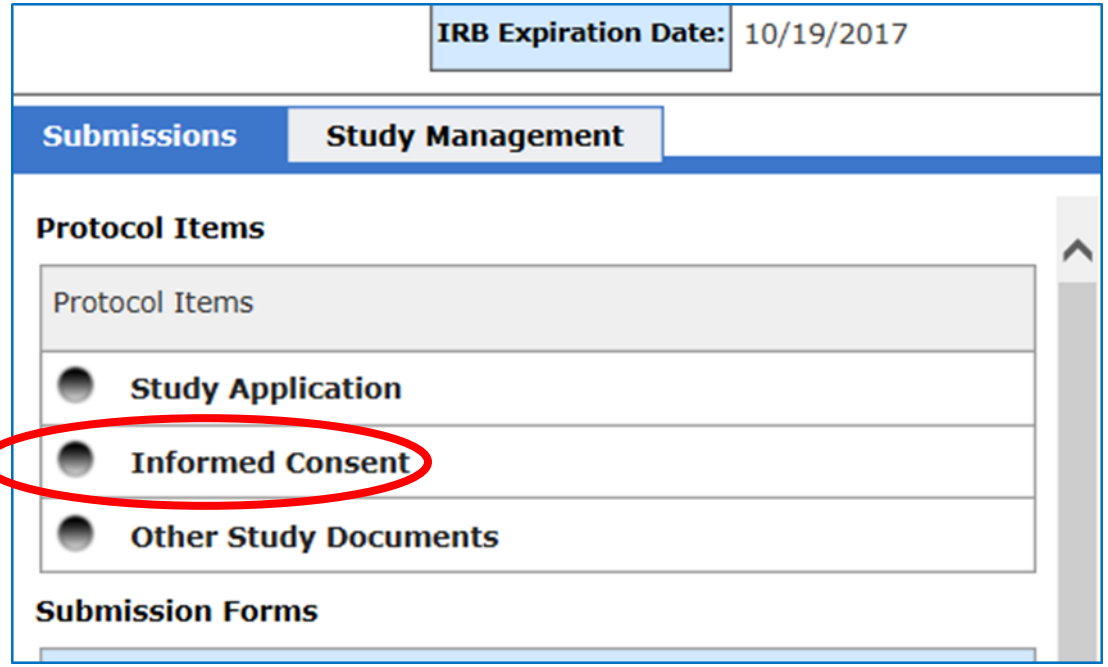
### 4.1 Review Path Determination

- ○ This project meets the regulatory definition of Not Human Subject Research (NHSR). Examples are Quality Assurance, Quality Improvement projects, or studies that involve obtaining anonymous data/tissues or coded data; or BMC/BU Medical Campus is not '"engaged" in human subjects research.
- ○ BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.
- ● The only research activities in this study involve chart reviews.
- ○ This study fits into one or more of the federal Exempt categories or the study does not have to follow federal guidelines and fits into one or more of the Equivalent Protections Exempt categories.
- ○ None of the above. This study requires Expedited review or the review of the Full Board.

# What in INSPIR has changed?

## Part 2: New Process (3)

- Short Forms
  - Investigator requests specific languages (no change)
  - IRB approves use of specific languages (no change)
  - IRB staff upload approved (stamped) short forms (with PI name, telephone number filled in) into consent form section (new)
  - IRB staff upload additional page for signatures of witness and person obtaining consent; page is signed and appended to existing English-language consent form when short form is used (new)




| | View History | Edit/ View | Title | Version | Language | UnApproved Consent | Approved Consent | Consent Outcome | Approval Date |
|---|---|---|---|---|---|---|---|---|---|
| ☐ | | | Signature page for short form *Revision modified by the IRB | | | | | | |
| | | | Adult Consent | 1.0 10/20/2016 | English | | | Approved | 10/20/2016 |
| ☐ | | | Short Form Vietnamese *Revision modified by the IRB | | | | | | |
| | | | Adult Consent | 1.0 10/20/2016 | Vietnamese | | | Approved | 10/20/2016 |
| ☐ | | | Short Form Portuguese *Revision modified by the IRB | | | | | | |
| | | | Adult Consent | 1.0 10/20/2016 | English | | | Approved | 10/20/2016 |
| ☐ | | | Short Form Hindi *Revision modified by the IRB | | | | | | |
| | | | Adult Consent | 1.0 10/20/2016 | English | | | Approved | 10/20/2016 |

# What in INSPIR has changed?

## Part 3: Modified Questions (1)

- Plan for the return of subject level findings
  - Before: Asked if study results would be returned: if no, no other questions; if yes, asked to explain how
  - Now: Asks if the study could yield findings of potential health or reproductive importance (pertinent and/or incidental findings): if no, no other questions; if yes, asked to explain plan to return or reasons not to do so.

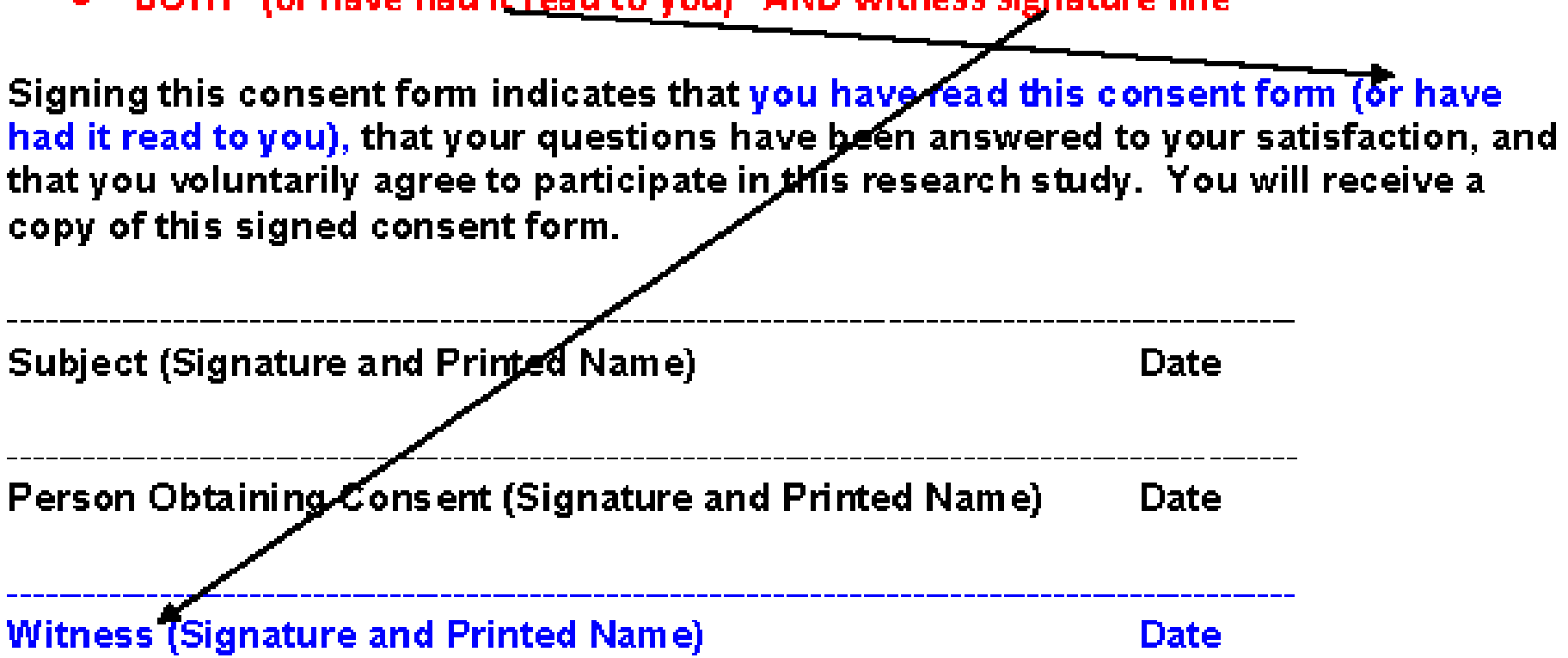
# What in INSPIR has changed?

## Part 3: Modified Questions (2)

- Inclusion of limited- and non-readers
  - Before: Limited- and non-readers were one of a dozen special populations, no directions for witness signatures in consent form
  - Now: Specific question about limited- and non-readers; if no, justify exclusion; if yes, consent form must include "(or has been read to me)" and place for witness signature.

A. Limited- and non-readers INCLUDED

- BOTH "(or have had it read to you)" AND witness signature line



Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

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Subject (Signature and Printed Name) Date

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Person Obtaining Consent (Signature and Printed Name) Date

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Witness (Signature and Printed Name) Date

# What in INSPIR has changed?

## Part 3: Modified Questions (3)

- Screening processes
  - Before: Screening questions only had to be answered if sensitive identifiable information was being kept or clinical procedures just for screening.
  - Now: Screening questions (including provisions for "abbreviated consent") must be answered if screening involves any interaction with potential subjects.

# What in INSPIR has changed?

## Part 4: Previously Optional Questions, Now Required

- Four questions were optional when first introduced, now are required
  - PI confirming human subjects training and filing Conflict of Interest forms
  - Privacy protections
  - PI confirming no recruitment incentives
  - Whether a repository stores genetic information

# What in INSPIR has changed?

## Part 5: Lower-Impact Changes

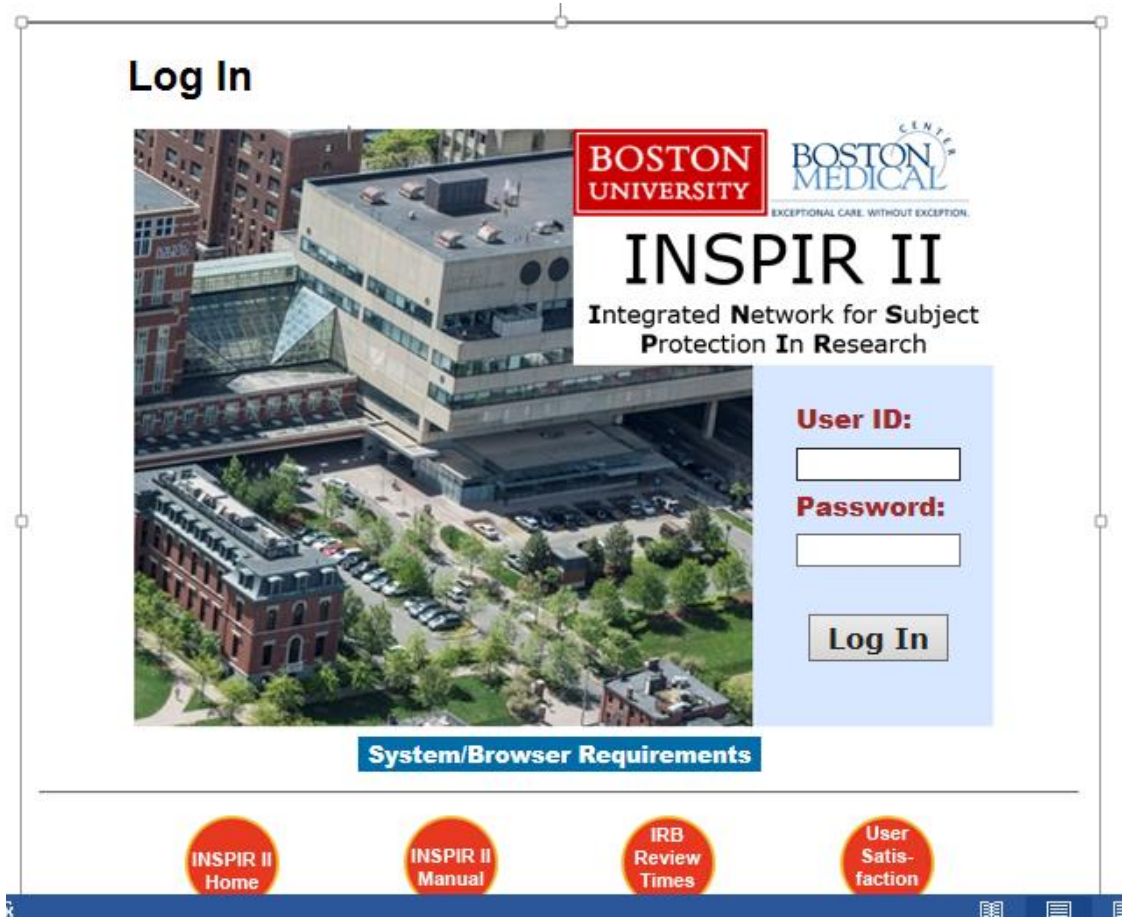
- Exempt submissions must provide a lay summary
- Cede requests have new questions about local policies
- Drug and device studies have new and reworded questions
- Not Human Subjects Research submissions answer whether the study meets the definition of “research”
- Studies recruiting from Community Health Centers have specific guidance

# More Information

*Clinical Research Times*

An Online Resource for Clinical Researchers Provided by the Office of Clinical Research

# How you will recognize the new INSPIR



# Thank you!