



# Faculty Development

## Promotion as a Medical Educator

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Melissa Dipetrillo, MD

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# Faculty development: Med Ed Portal Submissions

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Associate Clerkship Director Medicine 1  
Boston University School of Medicine



# Med Ed Portal

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- Online resource.
- Allows for open exchange of peer reviewed educational materials.
- Provided by AAMC.
- <https://www.mededportal.org/>



# A little about our project....

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- A Multi Modal Strategy for Teaching the Pulmonary Bedside Exam to Third Year Medicine Students.
- Melissa DiPetrillo M.D.
- Christine Phillips M.D.
- Winnie Suen M.D
- Allan Walkey M.D
- Warren Hershman M.D.



# A Multi Modal Strategy for Teaching the Pulmonary Bedside Exam to Third Year Medicine Students.

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- Case based one hour long lecture at the start of Medicine 1.
- Weekly inpatient bedside teaching with groups of 3-5 students and one faculty advisor.
- SOC's (Structured Observation Cards) for feedback review.
- Feedback forms on the case based lecture.
- Pre Post likert scale knowledge base test.
- Pre Post likert confidence based test.
- Pre test week one of the rotation during Medicine 1 orientation before the pulmonary lecture. Post tests last week (week 7 or 8) of the rotation.



# Med Ed Portal Submission

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1. Facilitators' Guide
2. Educational Work



# Facilitators' Guide

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- Learning Objectives
- Introduction: Literature review supporting why your educational work is important
- Curriculum logistics
- Pilot information
- References



# Learning Objectives

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- Clear Learning Objectives
- 3 to 4 keep concise/ brief
- Directed at the learner





# Learning Objectives

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At the end of the Medicine 1 rotation the student will be able to:

- (1) Demonstrate a complete and accurate pulmonary exam and use the exam to determine whether the patient has an underlying pulmonary condition.
- (2) Identify and interpret abnormal pulmonary exam findings and how they are associated with the pulmonary disease states: asthma, consolidation/pneumonia, pleural effusion, interstitial fibrosis and chronic obstructive pulmonary disease.
- (3) Use the tools of the history /physical exam and interpret pertinent diagnostics, in particular chest xrays and ABGs, to determine whether the patient has an underlying pulmonary condition.
- (4) Understand the definition of a likelihood ratio and develop a sense of likelihood ratios for abnormal pulmonary findings and pulmonary disease states.



# Introduction

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- Literature review that helps support why your work is important.



# Excerpt: Example

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- Third year students express lack of confidence in bedside exam skills. (Reference 6).
- Recent data regarding actual time spent teaching at the bedside during attending rounds are lacking. One study reported that less than one physical exam skill was taught per day on rounds. (Reference 15).
- There needs to be a standard, consistent approach to teach bedside skills to students. Bedside exam teaching during the inpatient medicine rotation seems to be an obvious resource to aide in student development of physical exam skills.



# Excerpt: Barriers

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- Major categories of barriers include student, teacher, patient and systems issues.
- Student issues include poor student motivation and confidence.
- Teacher concerns include environmental time constraints given their clinical duties, lack of incentive, and lack of dedicated teaching time without page interruptions or patient visitors.
- System issues include the lack of bedside teaching as the mainstay of education for third year clerks. (Reference 6).
- Patient related barriers include concerns about privacy and sharing their story in a group setting. (Reference 3).
- Studies have shown that students are not satisfied with bedside teaching rounds because of lack of individual attention provided. (Reference 4).



# Curriculum Logistics

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- Case based lecture. (In brief as this PowerPoint was submitted as our educational materials).
- Bedside teaching sessions.
- Observation cards.



# Pilot Information

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- Pre Post Testing



# Pre Post Testing

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- Advise IRB approval.
- Needed especially if you want to match students with their pre post test.
- Allows for more options with statistical analysis.



# Pre Post Testing

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- Likert scale
- Can use multiple questions and see what yields statistical significance

Example:

- Confidence in knowledge
- Confidence in ability to teach
- Confidence in ability to perform the exam





# Description of Pre Post Testing

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- Pre /Post intervention bedside skill confidence based survey.
- Pre/Post multiple choice, 6 item test that focuses on association of abnormal pulmonary exam findings with specific disease states.
- Pre tests collected during orientation week 1.
- Post tests during week 7-8 of the rotation.
- \*\*Pre / post tests were not linked on an individual student basis but rather collected per medicine block.



# Pre /Post Knowledge Based Test

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**(1) What pulmonary disease state is associated with increased fremitus, egophony, bronchophony and whispered pectoriloquy?**

- (a) Asthma
- (b) Consolidation/pneumonia
- (c) Pleural effusion
- (d) Chronic obstructive pulmonary disease

**(2) Which consolidation/ PNA exam finding has the highest likelihood ratio?**

- (a) Egophony
- (b) Decreased tactile fremitus
- (c) Bronchial breath sounds
- (d) Dullness to percussion



# Pre/Post Confidence Based Test

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- (1) **Estimate how many times** thus far in your medical school experience you have had the opportunity to perform a pulmonary exam on an individual/patient.

**For the remaining questions please circle the most appropriate number (1=Strongly Disagree, 5= Strongly Agree)**

- (2) I have had a lot of opportunities to practice/ perform the pulmonary exam.

1            2            3            4            5

- (3) I am confident in my ability to perform a systematic pulmonary exam.

1            2            3            4            5

- (4) I am confident in my ability to recognize an abnormal pulmonary lung sound.

1            2            3            4            5



# Feedback Form

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**For the first 3 questions, please circle the most appropriate number  
(1= Strongly Disagree ----5= Strongly Agree)**

**The content of this seminar was relevant to my learning needs**

**1            2            3            4            5**

**The format of this seminar was relevant to my learning needs**

**1            2            3            4            5**

**The instructors' presentation and facilitation enhanced my learning.**

**1            2            3            4            5**

**Please rate the value of these seminars to your learning.**

**(1=Not at all helpful----5= Extremely Valuable)**

**1            2            3            4            5**



# Some supportive data

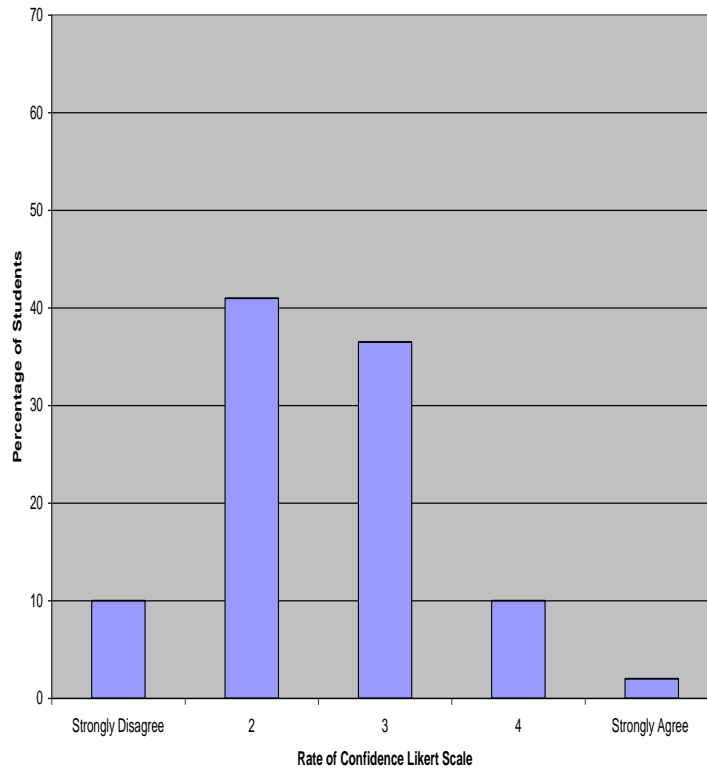
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- 118 out of 157 students answered the pre test knowledge based survey; 80/157 students answered the post test questions.
- The mean pre-and post- test scores were 48% and 75% respectively.

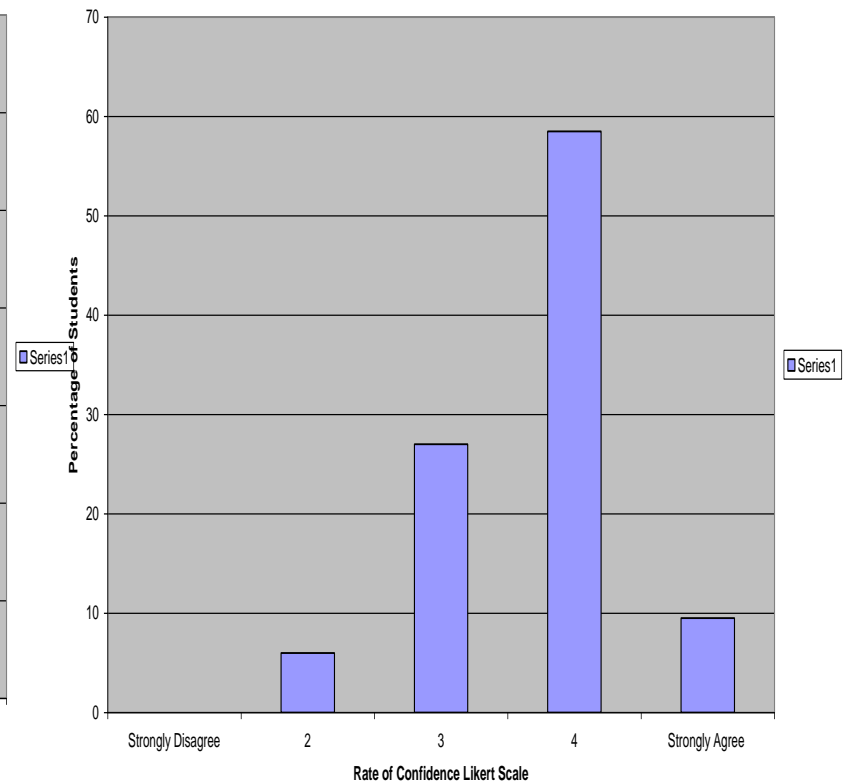
"I am confident in my ability to use the pulmonary exam to recognize the presence of an abnormal pulmonary disease state condition."

Left: Pre Test / Right: Post Test

Pre Test: Confidence in Interpreting the Pulmonary Exam



Post Test: Confidence in Interpreting the Pulmonary Exam





# Educational Material

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- Learning objectives
- 5 cases highlighting disease states: Asthma, Chronic Obstructive Pulmonary Disease, Consolidation, Pleural Effusion and Fibrosis.
- Website copy right to allow play back of abnormal pulmonary sounds during the lecture.
- Multiple choice questions reflecting the knowledge based questions on pre post test embedded in the lecture to encourage student participation.



# Lecture based PowerPoint

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- Some notations but not scripted.
- Standardize periods /bullets/font etc.
- Copy right. Email permission acceptable---very convenient!
- Before submission asked Winnie Suen M.D who had submitted to Med Ed Portal in past and Allan Walkey M.D. in pulmonary department to look over our material.





# Review Process

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- Very Helpful. Very supportive. Very enthusiastic.
- Targeted to generalized
- 3 reviewers
- Email feedback
- Resubmission by set date
- Examples:
  - Combine learning objective one and two
  - Discuss/site the following relevant article



# Why consider Med Ed Portal ?

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- More consideration now being given to Med Ed Portal in terms of promotion.
- Although looking for pattern of submissions. Single submissions likely not as helpful.
- Probably already doing something that is scholarly work and just need to tweak and submit!



# References

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1. Bates' Guide to Physical Examination & History Taking 9<sup>th</sup> Edition
2. J Gen Intern Med. 2002 August; 17(8): 647–650. doi: [10.1046/j.1525-1497.2002.10750.x](https://doi.org/10.1046/j.1525-1497.2002.10750.x)
3. The Rational Clinical Examination: Does This Patient have a Pleural Effusion? Camilla L. Wong, Jayna Holroyd-Leduc, Sharon E. Straus JAMA. 2009;301(3):309-doi:10.1001/jama.2008.937
4. The Rational Clinical Examination Does This Patient Have Clubbing? Kathryn A. Myers, MD, EdM, FRCPC; Donald R. E. Farquhar, MD, SM, FRCPC JAMA. 2001;286(3):341-347. doi: 10.1001/jama.286.3.341
5. Crackles: recording, analysis and clinical significance Eur Respir J, 1995, 8, 2139-2148 DOI: 10.1183/09031936.95.08122139
6. Steven McGee Evidence Based Physical Diagnosis 2<sup>nd</sup> Edition 2007

## Website resources:

7. Arcot J. Chandrasekhar, MD, FRCP, FACP, FCCP  
[www.meddean.luc.edu/lumen/meded/medicine/.../cxr/cxr\\_f.htm](http://www.meddean.luc.edu/lumen/meded/medicine/.../cxr/cxr_f.htm)
8. A Practical Guide to Clinical Medicine Charlie Goldberg, M.D., UCSD School of Medicine and VA Medical Center, San Diego, CA
9. [www.stethographics.com/main/physiology\\_Is\\_introduction.html](http://www.stethographics.com/main/physiology_Is_introduction.html)
10. [www.cvmb.colostate.edu/clinsci/callan/breath\\_sounds.htm](http://www.cvmb.colostate.edu/clinsci/callan/breath_sounds.htm)
11. Accuracy of Hisotry, Wheezing abd Forced Expiratry Time in the Diagnosis of Chronic Obstructive Oulmonary Disease. Sharon E. Straus et al JGIM:2002:17:684-688
12. The accuracy of patient history, wheezing, and laryngeal measurements in diagnosing obstructive airway disease. CARE-COAD1 Group. Clinical Assessment of the Reliability of the Examination-Chronic Obstructive Airways Disease. Sharon E. Straus et al. JAMA:200:14: 1853-7



# Faculty Development: Educational Workshops

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**Craig Noronha, MD**  
**Assistant Professor of Medicine**  
**Associate Program Director**  
**Internal Medicine Residency Program**  
**Boston University School of Medicine**



# What is a Workshop

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A set of activities designed to promote learning, discussion, and feedback about a topic or event

Seminar emphasizing free discussion, exchange of ideas, and demonstration of methods of practical application of skills and principles



# Where?

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## **Local, Regional, and National Meetings**

Local- John McCahan Educational day

Regional- SGIM/ACP

National- SGIM, Academic alliance for internal medicine, AAMC



# Why Do Workshops

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# Why Do Workshops

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- The particular subject is important to you
- Get to know people outside of BMC/BUSM
- It can be a stepping stone to other scholarly work
- Promotion





# Benefits

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Way to take local work and disseminate it regionally/nationally

Collaboration with other experts in your area of interest from around the country

Develop a national reputation



# Promotion

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Teaching

Teaching Evaluations

Could be considered scholarly work

Peer review process and evaluation process



# Workshop vs Publication

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Little up-front work, 2 hours to formulate a workshop overview/abstract

Once accepted, development takes about 20-30 hours of time, split amongst multiple participants (usually 3-5)



# Workshop vs Publication

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Often less data needed than for a publication

Works in progress with preliminary data

Depending on the topic- NO DATA  
Required



# Why do people go to Workshops?

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# Why do people go to Workshops?

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They want interactive and high yield subjects that they are interested in

Job Requirement

You can ask questions vs large group lectures

Networking



# What do the conference organizers want?

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Consider hot topics, flavor of the month, conference themes

Examples:

Value Based Care

Apps/HIT/social media

NAS: Milestones and Evaluation

Wellness

Medical Home



# What to present

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## **Clinical area of interest**

- management of abnormal pap tests, how to perform a procedure (joint injection)

## **Resident/med student related**

- behavioral-based interviewing, dealing with the problem learner, 3+1 scheduling, teaching physical exam skills

## **Methods**

- designing a curriculum, research methods in medical education research

## **Professional development**

- how to be an effective mentor/mentee, work life balance,

## **How you do it**

- Use of Apps in education, Resident patient hand offs,





# Examples of Workshops

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- ***Teaching Clinical Reasoning (Warren Hershman)***
- ***Guidance for Personal Letters of Recommendations***
- ***Breaking Away from the Inpatient to Care for the Real Patient***
- ***Urine drug testing in primary care settings: Practical considerations for clinicians and educators (Jane Liebschutz)***



# Who to work with

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Within institution others with similar interests or areas of expertise

\*\*Consider including those at different stages of their careers

Fellows, senior educators, new hires, chief residents\*\*

Multi-institutional

- Colleagues you have worked with before
- National experts in given area
- Interest group or other subgroup of a national association in your field
- List serve connections
- People you meet at other workshops



# Structure

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## **Didactic component**

- Powerpoint slides vs. handouts vs. both
- Give participants basic information about topic

## **Interactive component- MOST IMPORTANT**

- Case-based format
- Small group discussions
- Learning or skills stations
- Facilitated question/answer sessions



# Time Breakdown

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Didactic 20%

Interactive 60%

Questions and Answers 15%

Evaluations 5%



# Abstract Submission

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Consult the submission guidelines

Include background information of why topic is important to prospective audience

Tell them what to expect: what will happen

Tell them what they will take away- Deliverables- handouts, post-workshop emails, Flash drives



# Learning Objectives

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Summarize what the participant will be able to do after attending the workshop.

Use Blooms Taxonomy to maximize ACTION words



# Accepted vs not

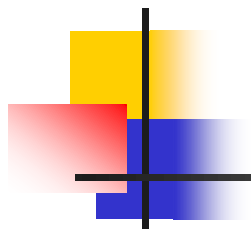
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Well written abstract?

Deliverables?

How many other submissions were similar to yours?

Did it fall within goals/themes identified by conference organizers?



**After careful review of the proposals, the APDIM Program Planning Committee decided not to accept** “Teaching residents about Professionalism in EMR use...yes that is our job to,” for inclusion in the 2014 APDIM Spring Meeting. However, APDIM encourages you to submit a workshop again in the future.

**The program planning committee had the following feedback regarding your submission:**

**Multiple submissions in this area.**

**Proposal reflects inadequate content for the time allotted to the workshop session.**





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Dear Dr. Noronha:

On behalf of the Association of Program Directors in Internal Medicine (APDIM), thank you for submitting a workshop proposal for the 2013 APDIM Spring Conference, which will take place April 28-May 2 at the Walt Disney World Dolphin in Lake Buena Vista, FL.

**After careful review of the 46 proposals, the 2013 APDIM Chief Residents Meeting Course Directors accepted** “Implementing a Curriculum—What, Where, Why, and How for Chief Residents,” for inclusion in the 2013 APDIM Chief Residents Meeting. APDIM invites you to present this workshop during Workshop Session III, which will take place Tuesday, April 30, 2013, from 2:00 p.m. to 3:30 p.m.



# We got accepted...now the real work

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## Preparation

### 1) Set deadlines

- Conference calls or meetings
- Meetings deadlines for handouts or inclusion of workshop materials IT materials

### 2) Powerpoint slides, resources, reference list, worksheets, teaching materials



# Reuse, recycle, spread the wealth

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Teaching sessions/grand rounds, noon-conference

Present at other meetings

Popular at initial meeting? Redo it next year at the same meeting

As a publication

- Descriptive piece
- Book chapter
- Systematic review
- Add data to transform it into a scientific paper

The logo consists of a vertical black line intersected by a horizontal black line. To the left of the intersection are three overlapping squares: a yellow one at the top, a red one in the middle, and a blue one at the bottom. The text 'APDIM 2012' is in a large, blue, sans-serif font to the right of the graphic.

# APDIM 2012

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## ***How to Implement an "X+1" Scheduling System in Your Residency Program***

Marc Shalaby, MD **Program director**  
Lehigh Valley Health Network  
Pennsylvania State University College of Medicine

Craig Noronha, MD  
Ryan Chippendale, MD **Geriatrics fellow**  
Boston University School of Medicine

Maria C. DeOliveira **Past BMC/BU residency administration**  
Harvard Medical School  
Beth Israel Deaconess Medical Center

# ACADEMIC INTERNAL MEDICINE INSIGHT

## AAIM IN ACTION

### Executive Vice President Update: The New Horizon

AAIM Board of Directors Executive Vice President Bergitta E. Smith, discusses the alliance's emergence as a consolidated entity with five strong, vibrant founding member organizations poised to launch new strategic initiatives in FY 2014. The merger afforded business processes improvements, stronger senior management team, opportunities for representation at the highest levels of national decision-making, and opportunities for growth and expansion of services.

## LEADERSHIP

### Speaking with Leaders:

#### AAIM Interviews John P. Fitzgibbons, MD

Insight is pleased to introduce a new feature! The interview series "Speaking with Leaders" is designed to elicit real-world lessons and advice from key leaders in academic internal medicine. The series begins with an interview with Jack Fitzgibbons, MD, a former APDIM President and a past department chair and program director.

## SCHEDULING

### How to Implement an X+1 Scheduling System in Your Residency Program

To reduce the conflict of inpatient and outpatient responsibilities, many residency programs have adopted scheduling systems that alternate blocks of inpatient time with dedicated ambulatory blocks. The most prevalent models are based on one-week ambulatory blocks, referred to as "X+1" models. This article provides practical advice on how to implement such a model, from pre-planning and buy in to implementation.

## LEARNING STYLES

### Bridging the Generational Chasms

In the mid-2000s, an unprecedented event occurred in US history. For the first time, four generations found themselves learning and working together in medical schools and teaching hospitals: veterans, baby boomers, generation x, and millennials. Differences among the four generations can lead to miscommunication and conflict in the perceived core principles of medicine. Understanding and respecting these differences can help bridge the gaps among the four generations.

## TECHNOLOGY

### Beyond Angry Birds: Apps in Medical Education

Despite recent data suggesting that 85% of physicians carry a "smart phone" and 50% have medical apps on their mobile devices and that 96% of medical students were using a smart phone, medical educators have been slow to integrate apps into their curricula. Why? Educators might not feel the need for more learning tools, they may not believe the tools that do exist are effective, or they might simply lack familiarity with the tools.

2

6

10

16

22

## By the Numbers

5

Number of microskills in the One Minute Preceptor Model  
Page 8

60%

Higher costs of patient care delivered in the context of medical education  
Page 13

2,000

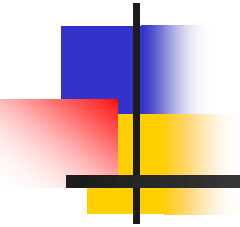
Apps available for clinician use  
Page 20

## Also in This Issue

- 4 Qualitative Research 101: Basics for Medical Educators
- 8 Effective Teaching Models in the Ambulatory Setting
- 14 Development of a Cost-Conscious Curriculum for Undergraduate Medical Education
- 20 Using Art to Teach Medical Professionalism

# Implementing a Curriculum:

What, Where, Why, and How for Chief Residents



Tuesday, April 30, 2013

Craig Noronha, MD

Jai Singh, MD

Rachel Simmons, MD

Gopal Yadavalli, MD

Boston university school of medicine



# APDIM (Association of Program Directors in Internal Medicine) Ten Tips for Workshops

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- **Workshop topics should be relevant to current concerns/needs of the membership.**
- **Be clear about what you are trying to do**
- **Identify if the workshop is designed to be didactic vs interactive**
- **Workshops should provide the opportunity for audience participation**
- **Leave ample time at the end of the workshop for questions**



# APDIM (Association of Program Directors in Internal Medicine) Ten Tips for Workshops

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- **Limit workshop presenters as necessary to streamline the workshop**
- **Anticipate where discussions can be taken off topic and plan ways to keep the group on task**
- **Keep background information/slides to a minimum**
- **Make sure the title of your workshop reflects the actual content & format of the workshop**
- **The most highly-rated APDIM workshops provide concrete “take-home” materials**





# Submitting Educational Research to the IRB

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Mary-Tara Roth, RN, MSN, MPH  
Director, Clinical Research Resources Office  
Boston University Medical Center



Supported by the BU CTSI and Office of Clinical Research (OCR)  
Serving all BUMC Clinical Researchers

## Regulatory Service and Education Program

- Consultation services
  - Study implementation
  - IRB application submission
- Tools and Resources (*web-site based*)
- Education programs for all levels of the research team
- Support for sponsor-investigators of FDA regulated research
- Quality Assurance Reviews

## Recruitment Services Program

- Consultation services
  - Study implementation
  - IRB application submission
- ReSPECT Registry
  - Community Outreach
- StudyFinder
- Resources
  - Web-based templates, tools, plans, etc.

# The 111 Criteria: Criteria for IRB Approval

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“In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied...”



21 CFR 56.111



U.S. Department of Health and Human Services  
Office for Human Research Protections

45 CFR 46.111



# The 111 Criteria

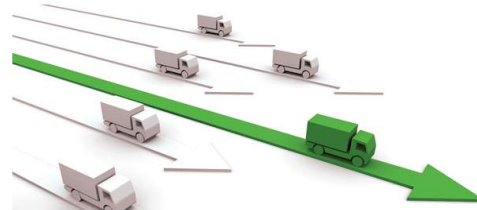
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1. Risks to subjects are minimized.
2. Risks to subjects reasonable in relation to benefits.
3. Selection of subjects is equitable.
4. Informed consent process.
5. Informed consent documentation.
6. Adequate provision for monitoring the data.
7. Provisions to protect privacy /maintain confidentiality.
8. Safeguards for vulnerable populations.

# Types of IRB Submission/Review

- Convened Meeting (Full Board)
  - Greater than minimal risk research
- Expedited
  - 8 expedited categories
  - Minimal risk research
- Exempt or NHSR
  - Minimal risk
  - 6 categories of exemption
  - NHSR = not human subjects research
    - No research OR no human subjects





# Exempt/NHSR vs. Non-exempt

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- Reviewed by one reviewer
  - Senior IRB staff-member
- Typically shorter IRB review timeframe
- Shortened application
  - INSPIR “smart” form
- You get a “determination” vs. approval letter
- Usually limited or no consent process
- No continuing review



# BUMC IRB Panels

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- Blue: Sociobehavioral, public health, international, etc.
  - 2<sup>nd</sup> and 4<sup>th</sup> Thursdays, 12-2pm
- Green: Biomedical
  - 1<sup>st</sup> and 3<sup>rd</sup> Thursdays, 12-2pm
- Purple: Progress reports
  - 2<sup>nd</sup> and 4<sup>th</sup> Wednesdays, 9-11am
- Orange: Repositories and genetic research
  - 1<sup>st</sup> and 3<sup>rd</sup> Wednesdays, 12-2pm
- Red: expedited, exempt, NHR
  - no meetings
- WIRB: multicenter industry-sponsored studies
  - Sponsor has to agree to specific language for the Compensation section of the Consent form

# BUMC IRB Review Times

Review Time for Submissions that Reached Final Determination during February, 2014

	Number	Days from submission until final determination*	Days in IRB office*	Days in investigator's office*
New Protocols				
Full-board	4	47 (27-93)	28 (16-60)	19 (2-42)
Expedited	12	17 (1-196)	9 (1-57)	2 (0-189)
Exempt	28	6 (0-169)	6 (0-70)	0 (0-143)
Amendments				
Full-board	12	28 (7-141)	25 (7-48)	2 (0-96)
Expedited/Exempt	83	12 (0-24)	12 (0-91)	0 (0-114)

\* These columns show the median number of days (and range).

<http://www.bumc.bu.edu/irb/bumcirb/irb-review-time/>





# Determining when OHRP Regs Apply...

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1) Does the activity involve Research? (46.102(c))

If yes, then.....

2) Does the research involve Human Subjects?  
(46.102(f))

If yes, then....

3) Does the human subjects research meet criteria  
for Exempt from 45 CFR 46? (46.101(b))

Decision Trees: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>



# Definitions

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- Research (OHRP regs: 45 CFR 46.102 (d))
  - "... *a systematic investigation*, including research development, testing and evaluation, *designed to develop or contribute to generalizable knowledge.*"



# Definitions

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## Human Subject (OHRP regs: 45 CFR 46.102 (f))

- "... a **living individual** about whom an investigator (whether professional or student) conducting research obtains:
  - Data through **interventions or interactions** with the individual, or
  - **Identifiable private information.**"



# Definitions

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- **Interaction/Intervention** (45 CFR 46.102 (f))
  - Physical procedures by which data are gathered
  - Manipulations of the subject or the subject's environment for research purposes
  - Interaction includes communication or interpersonal contact between investigator and subject.



# Definitions

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- **Private information** (45 CFR 46.102 (f))
  - ... info about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
  - **Private information must be individually identifiable** i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

(\*\*See OHRP guidance on coded data/specimens, 2008:  
<http://www.hhs.gov/ohrp/policy/cdebiol.html>)



# More on Private Identifiable Information (OHRP)

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- In general ..... 3 ways by which the identities of subjects' data/specimens can be ascertained
  - **Direct identifiers:** name, medical record number, address, social security number, photographs
  - **Code linking to direct identifiers:** data/specimens assigned a study ID that can be linked to identifiers via a mastercode or key
  - **Deductive Disclosure:** no direct identifiers but identity can be reasonably ascertained from the data itself (small population or specific data elements)



# Exempt determination<sub>(45 CFR 46.101 (b))\*</sub>

1. **Normal educational practices** in established educational settings
2. Educational tests, **surveys, interviews**, or observation of public behavior -unless identified & sensitive\*\*
3. Research on elected or appointed public officials or candidates for public office
4. Research using existing data, if publicly available or recorded without identifiers (existing = at time of submission to IRB)
5. Evaluation of public benefit service programs
6. Taste and food quality eval./consumer acceptance studies

**\*None of the categories apply to Prisoner research (Subpart C).**

**\*\* #2 does not apply to research with children except for research involving observation of public behavior when investigator(s) do not participate in the activities being observed.**



# Exempt Category 1 (Education)

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- Normal Educational Practices and Settings
  - Research in established or **commonly accepted educational settings** involving **normal educational practices**
  - Research on regular and special education instructional strategies
  - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods





# Exempt Category 1

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- What's likely not exempt
  - Radically new instructional strategies
  - Use of random assignment to different instructional methods
  - Research involving deception or withholding information
  - Use of deception in the research design
- Why?
  - Because these methods deviate from normal educational practices and could increase risk to subjects



## Exempt Category 2

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- Anonymous Educational Tests, Surveys, Interviews, or Observations of Public Behavior
  - Information obtained should be recorded in such a way that subjects cannot be identified
  - Subjects should not be placed at harm where any disclosure of responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation



## Exempt Category 2

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- What's not exempt
  - Surveys/interviews of children
  - Surveys, etc. where there are sensitive questions **and** the subject can be identified.
- Why?
  - Because this could mean greater than minimal risk to the subjects



# Exempt Categories 1 and 2

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- Attach your survey/interview and/or data collection forms
- Consent
  - Consent form does not need to include all required consent elements
  - You DO want to tell people that this is a research study and it's voluntary
  - Use the consent form builder in INSPIR and choose the exempt consent template or modify the non-exempt template as appropriate



Account: Mary-Tara Roth, RN, MSN, MPH  
Department: BU - MED - Clinical Research Resources Office  
Navigation: Home > my studies > study mgmt. > consent list

IRB Number: H-30435

Study Nickname: 30435

## Informed Consent Document

PI: Roth, Mary-Tara, RN, MSN, MPH

Study Status: **Draft**

Study Title: Sample INSPIR Protocol

Expiration Date:

\* Please select the Consent Template:

Consent Statement for Anonymous Survey/Interview Exe ▼

Provide the Consent Title if different from the template name:

\*Version Date:

\*Version Number:

.0

\* Language:

English ▼

Comments:



## Cat 2 (Survey) Consent Statement should provide the following information:

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- that this is a research study
- the purpose and what the subjects are being asked to do and approximately how long it will take
- that participation is voluntary and if they don't want to participate it will not impact their [jobs][care] in any way
- that they can choose not to answer any questions that they wish
- how their confidentiality will be protected
- payments for participation if any
- who to contact with questions about the study (must be a member of the research team)
- who to contact if they have questions about their rights as a research subject - BUMC IRB at 617-638-7207 or [medirb@bu.edu](mailto:medirb@bu.edu)



# So ... you have a research question!

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- What you need to get started:
  - If you are not faculty, get a faculty advisor experienced in clinical research
  - Decide what your role is...
    - Will you be working on somebody else's protocol as staff member?
    - Or, do you have a new research question?
  - NIH Human Subjects Protections Training on file
  - INSPIR II access
    - BU username and Kerberos password

# NIH Human Subjects Protections Training

- BU/BMC requires that researchers be “certified” in human subjects protection.

<http://www.bumc.bu.edu/ocr/certification/>

- And don't forget recertification via the Clinical Research Times if you plan to be here conducting research for > 2 years! <http://www.bu.edu/crtimes>





# INSPIR (II)



- Integrated Network for Subject Protection In Research
  - BUMC's electronic, internet-based IRB system
  - <https://inspir.bu.edu/iMedris/>
- Need user name and kerberos password
  - [bumchelp@bu.edu](mailto:bumchelp@bu.edu)
  - x8-5914
- See CRTimes Feb. 2011
- Update your **personal profile** under "My Assistant," then "My Account."
  - You just have to do this once and you can only do it yourself.
  - Degree, Specialty, Primary number, Location, Affiliation, and Other Affiliation.



## “Must reads” from CR Times

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- Preparing an IRB Application: Where do I Begin? (Nov. 2013)
- Exploring IRB Review Options for Clinical Record Review (Oct. 2013)
- Is Exempt Review Right for You? (Sept. 2013)
- Survey Says.... Exempt! (Oct. 2012)