

UM Office of Human Research Compliance Review (OHRCR)

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Director, OHRCR, OVPR
Professor, Emergency Medicine

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Who We Are

Director

- Ron Maio, D.O., M.S.
Professor, Department of Emergency
Medicine

Research Compliance Associates

- Terry VandenBosch, PhD, RN, CIP, CCRP
- Ted Hamilton, MS

In existence since 2003

OHRCR Organizational Chart

Stephen Forrest, PhD
Vice President for Research

Ronald Maio, DO, MS
Director
Office of Human Research Compliance Review

Terry VandenBosch, PhD, RN, CIP
Senior Research Compliance Associate

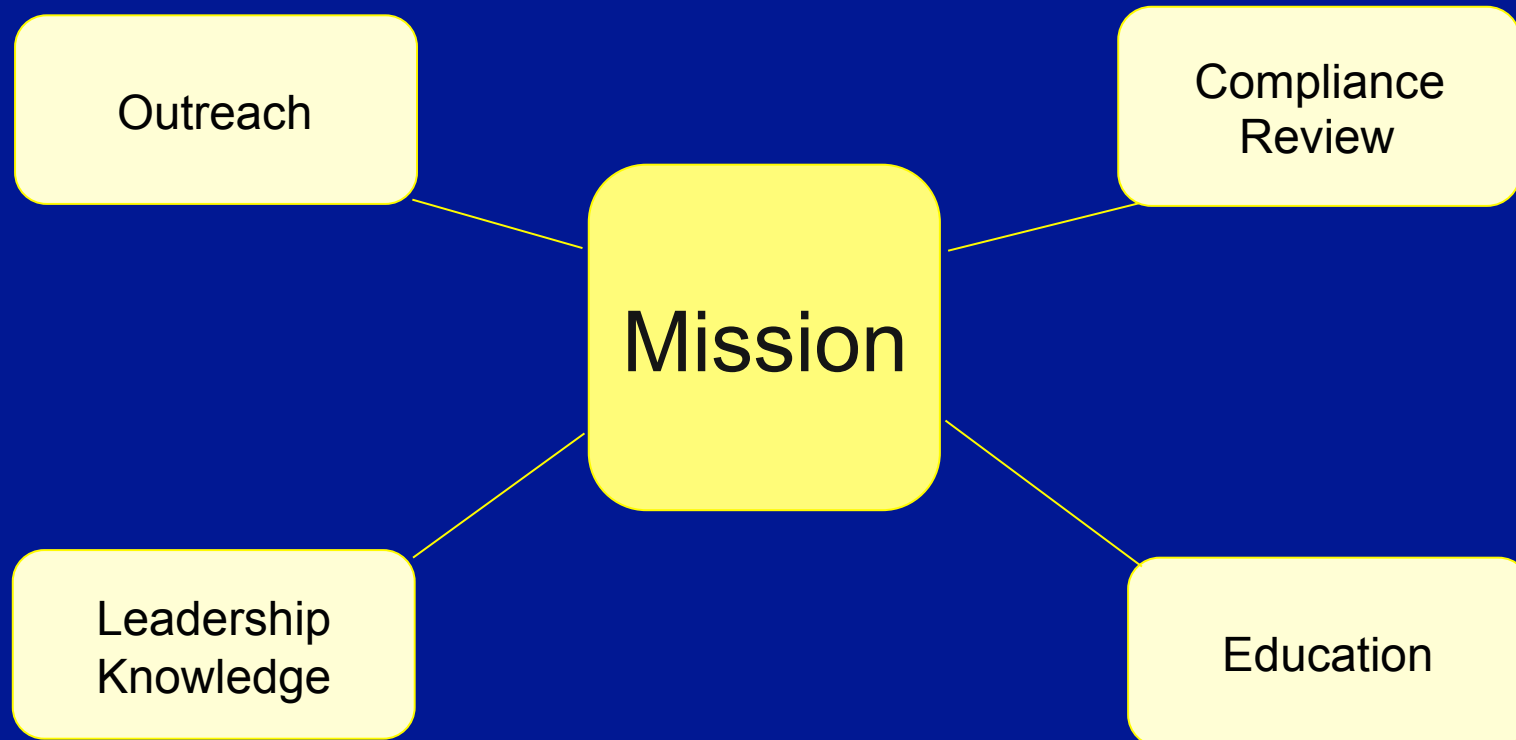
Ted Hamilton, MS
Research Compliance Associate

OHRCR Mission

“To facilitate safe, ethical, efficient and high quality human subjects research”

<http://www.research.umich.edu/ohrcr/index.html>

OHRCR Mission



What Have We Been Doing?

- Compliance Reviews
 - Not for cause
 - Routine Research Education and Regulatory Reviews (RRERRs)
 - For Cause
- HRPP survey
- Review of Components HRPP (e.g. BEU)
- Review of IRB Demonstration Projects
- Providing feedback to HRPP
- Outreach
- Conferences/Training/Panels/Presentations

Philosophy & Personnel

- Partners not the Police
- “Public Health” approach to research compliance
 - Prevention
 - “Community” focus
 - HRPP vs. individual investigators
 - Finding solutions not assigning blame
 - Systemic changes
- Enterprise Risk Management (ERM)
 - Auditing “Public Health” approach

Focus: Compliance Reviews

For Cause

- Directed audit of investigator
- Collect data for IRB to determine serious or continuing noncompliance
- Determine the root cause of the noncompliance for investigator remediation and/or sanctions

Focus: Compliance Reviews (cont.)

Not-for-cause

- Routine or random
- Look for trends
- Change organizational culture
- Feed data to the organization for CQI
- Proactive not reactive

Our different jobs condensed

- IRB
 - What do they say they will do?
- OHRCR
 - Are they doing what they said they would do?

Routine Research Education and Regulatory Reviews (RRERs)

- Not for Cause Review
 - Post IRB-Review
 - *Not* triggered by a specific study concern
 - Pilot tested 2006-2007
 - Initiated Nov 2007
 - Approximately 130 done so far

Why

- Assist investigators
 - Identifying current or potential problems
 - Enhance understanding of principles
 - Educate about specific methods
- Identify excellent practice and areas for improvement
- Institutional verification

Who

- Who's eligible for review?
 - Human subject research
 - Reviewed and approved by UM IRB
- Who will do the review?
 - Director
 - Ron Maio, D.O., M.S.
Professor, Department of Emergency Medicine
 - Research Compliance Associates
 - Terry VandenBosch, PhD, RN, CIP, CCRP
 - Ted Hamilton, MS

How: Study Selection

- Sampling plan developed
 - Resources available
 - Areas of concern:
 - HRPP
 - Findings from For cause and Not-for-Cause reviews
 - Approved by OVPR

How: Review Process

- Two meetings
 - Meet with investigator
 - Review research records
- What will we review
 - Focus of annual review plan
 - Type of study

What Can Happen:

- Worst Case Scenario:
 - Serious/Continuing noncompliance
 - Voluntary hold on study
 - Notify IRB of record
 - Notify Research associate dean
 - Notify OVPR
 - For cause review, FDA/OHRP investigation

What Can Happen (cont):

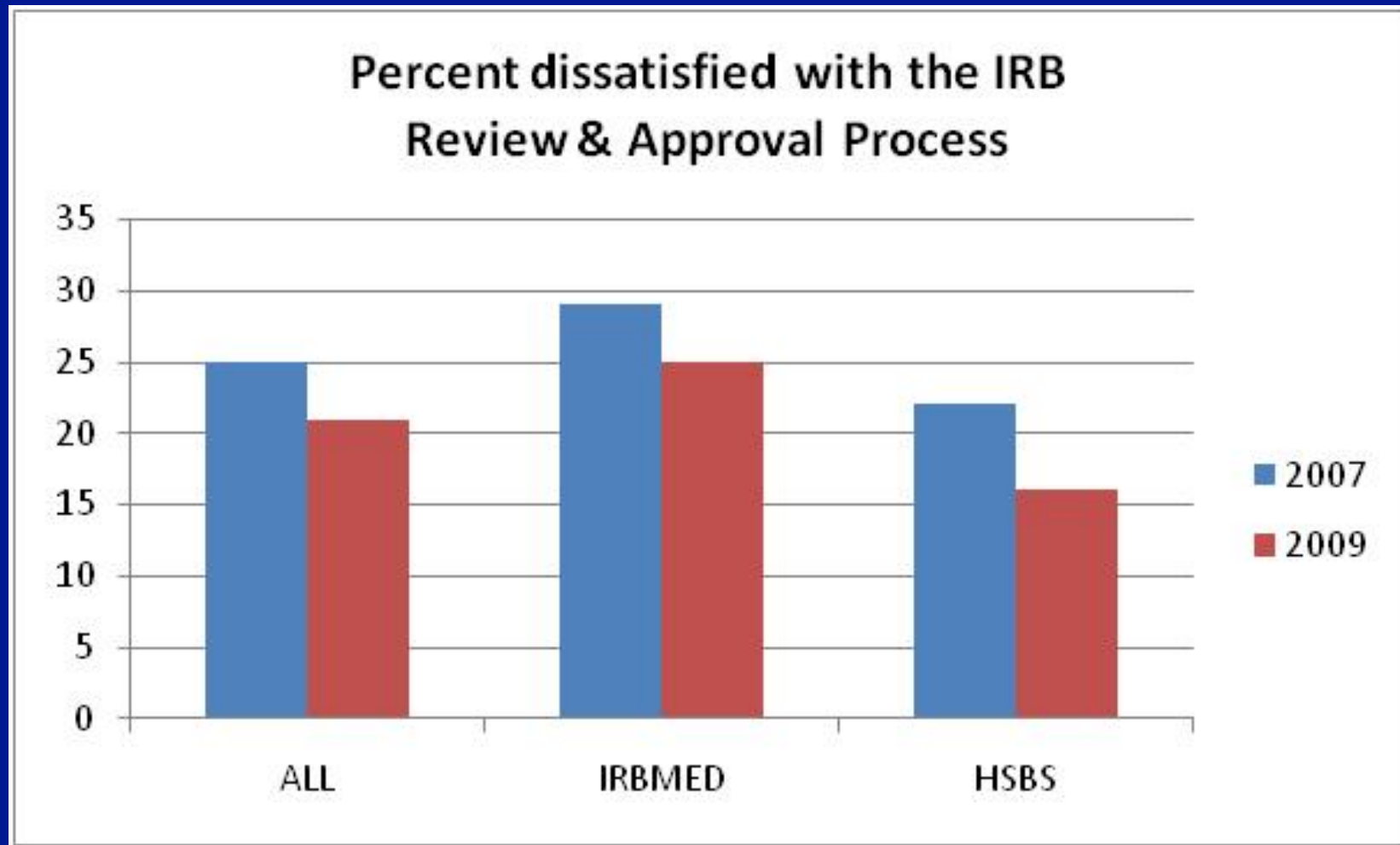
- Noncompliance/not serious:
 - Notify IRB of record
 - Notify Research associate dean
 - OHRCR follow-up on plan

Findings

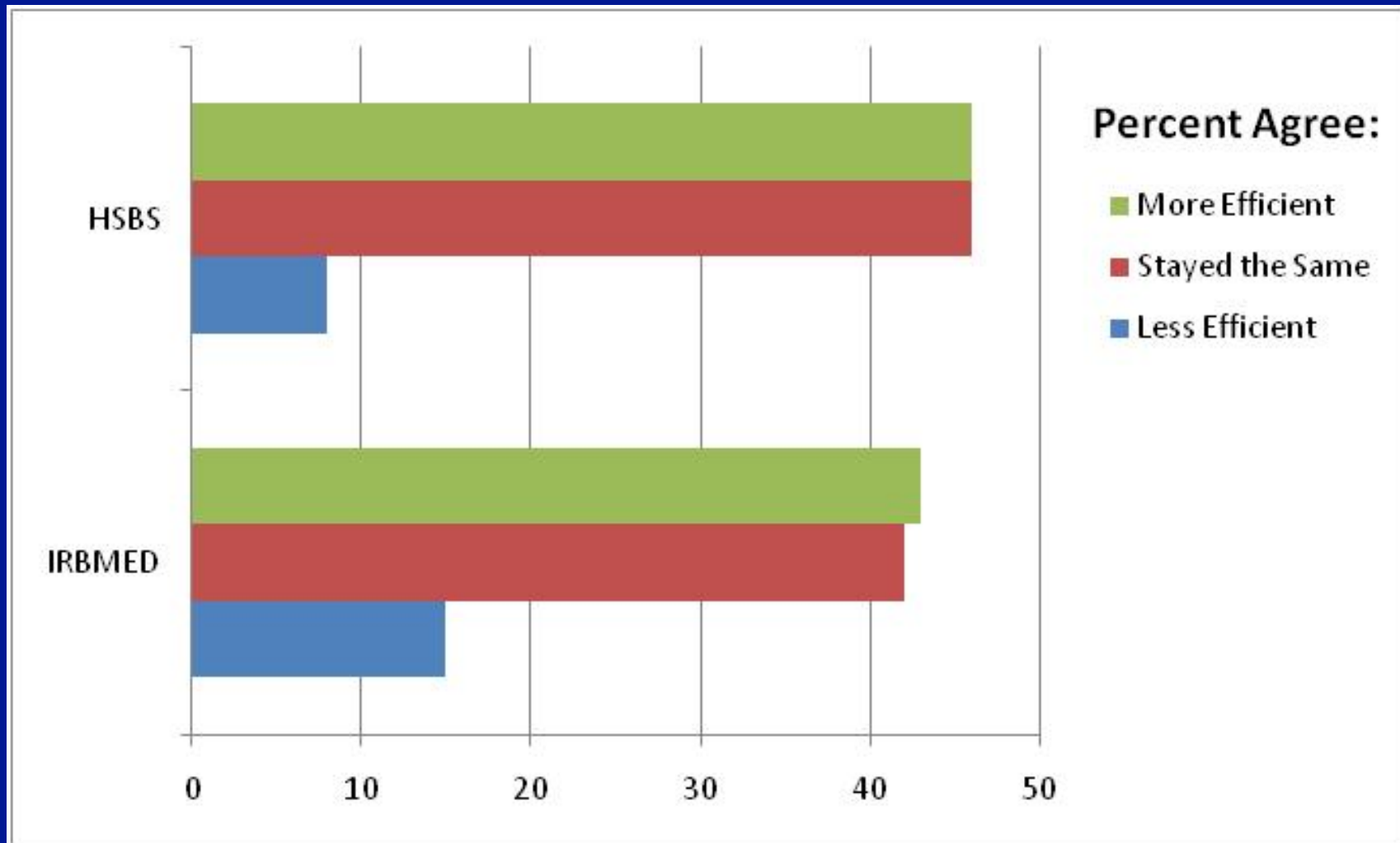
- Serious non-compliance
 - 1
- Noncompliance/ not serious
 - Approx 30% of the time
- No noncompliance but room for improvement
 - Almost all!
- Exemplary
 - 6 studies

Investigator Survey

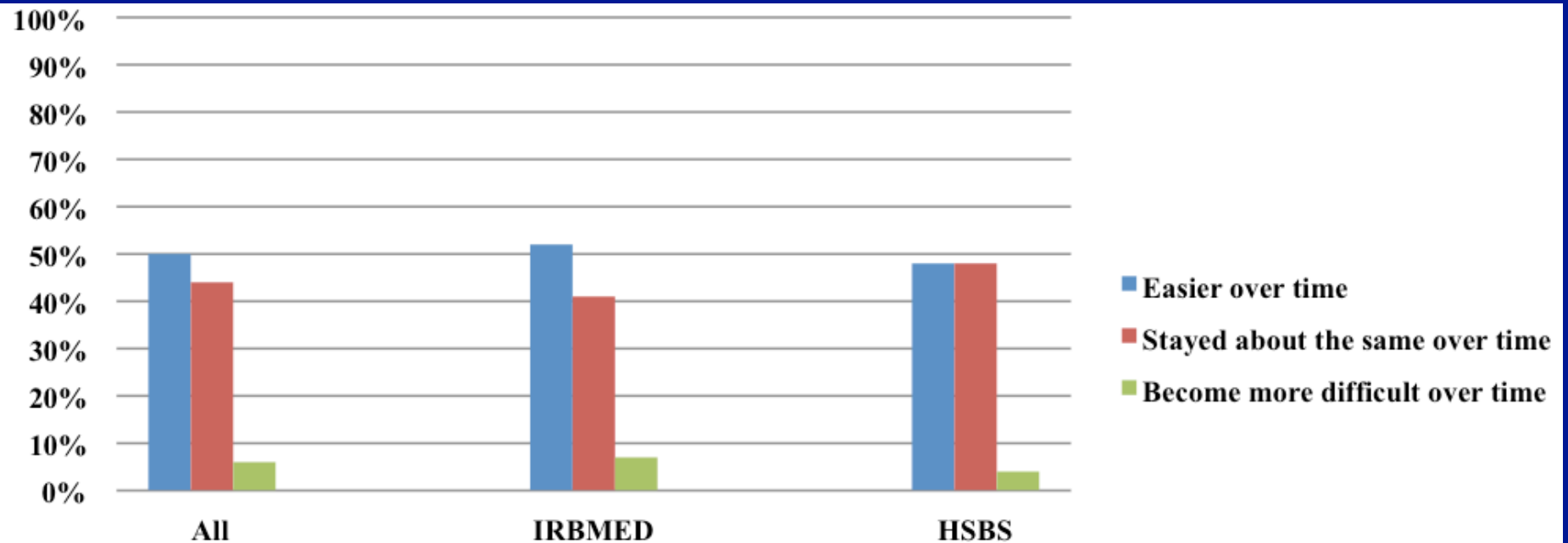
Dissatisfied with Review & Approval Process



Review & Approval Process Change Over Time



Usability of eResearch Over Time



Usability of eResearch Over Time (Among Investigators who Prepared at Least 2 eResearch Applications)

Compliance Review



Compliance Review



OHRCR: Partners not the Police

