

# DoD HRPP Training Day



## IO Refresher: Brushing up on HRPP Fundamentals



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# Objectives

1. Describe dimensions of the IO's role and relationship within the HRPP
2. Compare and contrast characteristics of efforts that are, and are not, human subject research
3. Distinguish and give an example of when your institution is engaged in research and when supporting research
4. Relate the various HRPP models to your institution and determine whether some might be useful to your HRPP

## Objectives:

5. Recognize the differences among federal, DoD, and your component policies and procedures vs. local implementation
6. Apply the additional, unique requirements for human research protections when you review and approve research
7. Describe strategies for on-going monitoring of your HRPP

# Take a moment to reflect: What type of IO are YOU?

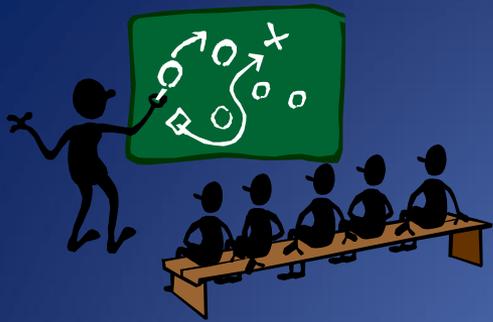
- Interested? Engaged? Supportive?
- How do you support human research protections?
- How often do you talk with the IRB Chair?  
What do you talk about?
- How many IRB members do you know?
- How do you communicate with the HRPP staff? Investigators?
- Have you talked with research subjects?





# Key Points

- **Sets the tone** for the institutional culture and how human research protections are perceived
  - Is the culture “Subject-centered” ? “Risk Avoidance”? “Pass the Washington Post test”
- You – and investigators – are the ‘face’ of the institution’s HRPP
- **Ultimately responsible** as the research approval authority – reading IRB meeting minutes is not enough



# Possible Strategies

- Phone home with IRB Chair(s)
- Drop in at an IRB Meeting as a guest
- Brown Bag Lunch with investigators
- “Walk the talk...”
- Communicate across the chain of command....
- Other...



# Who needs education and training in human research protections?

- All personnel engaged in or supporting human subject research
- Additional requirements for research with investigational drugs, devices, or biologics – FDA regulations and Good Clinical Practice (GCP)
- Responsible Conduct of Research (RCR) – mentoring, research misconduct, collaborative research, etc.





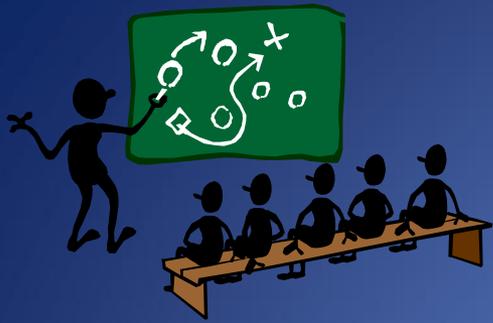
# Key Points

- Role-relevant initial and on-going training
- **Starting point** to mitigate non-compliance
- Federal, DoD, component-specific, institution-specific requirements including HIPAA, PPRA, FERPA, etc.

[Health Insurance Portability and Accountability Act of 1996 \(HIPAA\) Privacy Rule](#)

[Protection of Pupil Rights Amendment \(PPRA\)](#) Protects the rights of parents and students

[Family Educational Rights and Privacy Act \(FERPA\)](#) Protects the privacy of a student's education records



# Possible Strategies

- **Set institutional standards** – follow them
- Multiple methods – on-line, in-person, VTC
- **Embed in organizational structure** and process
  - check-in procedure
  - orientation to command or job
  - command training program
  - department/division/unit training
  - residency/fellowship training

How to determine if  
proposed work or project is  
human subject research

# Is this research?

Fede  
ral



*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

[32 CFR 219.102(d)]

# Is this research?

DoD



Research. Any systematic investigation, including research, development, testing, and evaluation (RDT&E), designed to develop or contribute to generalizable knowledge.

[DoDD 3216.02, Enclosure 2, item E2.1.2]

# Research is ...

“...systematic investigation...”



Research is not . . .

- Defined by type of money or label
- “Healthcare practice” – biomedical or social-behavioral - designed solely to enhance the well-being of an individual patient
- some customer satisfaction surveys\*

\*May still need Survey approval.

# Research is ...

**“... including research, development, testing, and evaluation (RDT&E)...”**

- Research and development with humans might be included
- Pilot tests and evaluations are included
  - Sample size and scope of research does not determine whether it is “research”

# Research is ...



“...designed...”

- Test hypothesis / objectives / questions
- Formal protocol / plan
- Procedures designed to reach objectives
- Use of non-research collections (e.g. employment records) may be research
  - Information collection *per se* may not be research
- Surveys with purpose to develop generalizable knowledge are research

# Research is ...

“...to develop or contribute to...”

- Preliminary or exploratory work and pilot projects are included



# Research is ...

“...generalizable knowledge...”

- Expressed in theories, principles, and statements of relationships
- Results of planned interventions, interactions, or organized processes with purpose of understanding or explaining



# Is this research involving human subjects?

Living individuals about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information

[32 CFR 219.102(f)]



# Human Subject Research is ...

“... about whom...”

- Studying people’s reactions or responses to equipment may be human subject research
  - Testing equipment *per se* is not human subject research
- Studying information about people



# Human Subject Research is ...

**“... intervention or interaction...”**

- Physical procedures to collect data
- Manipulating someone’s environment
- Communication or interpersonal contact between investigator and subject
  - Focus groups, interviews, phone conversations, email

# Human Subject Research is ...

“... identifiable private information...”

- Research with identifiable private records (e.g., school or medical records)



Human Subject Research is not

- Using identifiable public information (e.g., library research)
- Using non-identifiable private records

# Many Terms, Same Meaning



*Clinical investigation* means any experiment that involves a test article and one or more human subjects... the terms *research, clinical research, clinical study, study* and *clinical investigation* are synonymous.

# Human Subject Research or not?

- An Administrative Officer at a military command wonders if the budget process can be improved.
- She reviews the number of steps in her current process.
- She determines that two steps are not necessary and eliminates them from the process.

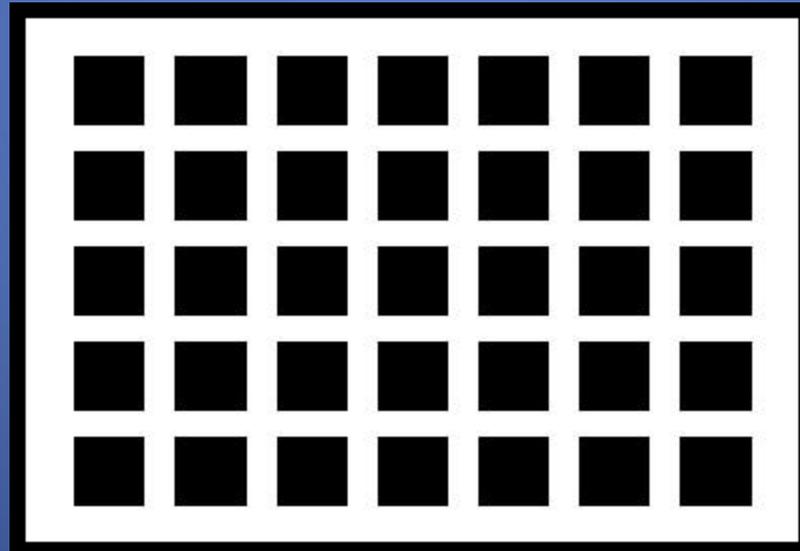
- The Administrative Officer conducts the review as described to left, and
- Sends a questionnaire to 7 other administrative officers asking them about the steps in their processes.
- She also is considering presenting the data to higher authority.

- The Administrative Officer conducts the review as described to left, and
- Designs a study at multiple military commands, using focus groups with administrative officers asking about their skill sets, experiences, education, to determine if they have an impact on the budget processes.
- She will present the results at a conference.

# Simple, right?

or do you see gray?

Even when you know it should be black  
and white it's not always easy to tell.



# When the Gray Began

“Research and [*practice*] may be carried on together when research is designed to evaluate [*the safety and efficacy of a therapy*]. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.”

*The Belmont Report 1979*

Place other activity in [ ]s

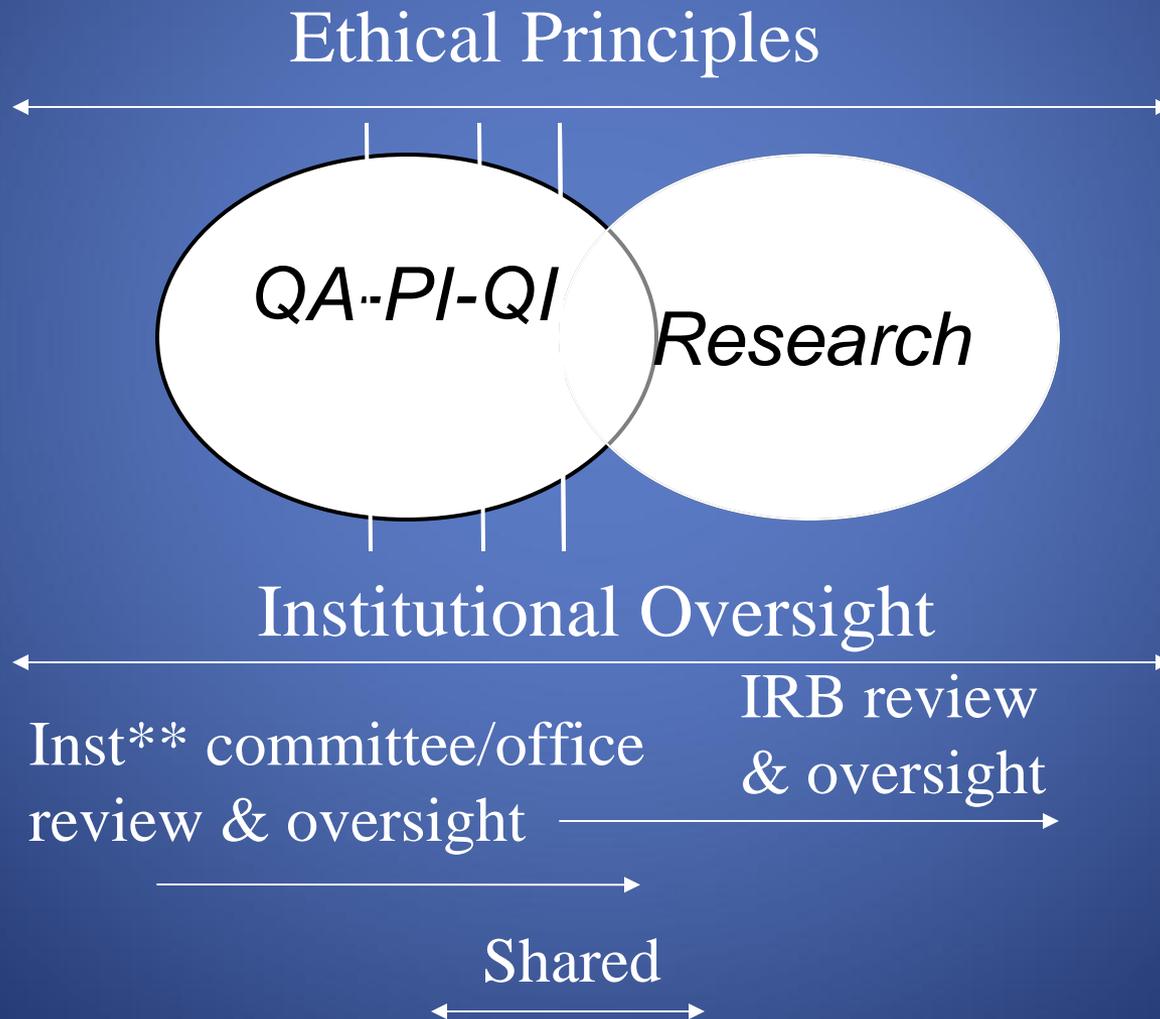
# Another Perspective...

“For those in the gray area, it is in the best interest of patients and research participants to have the organization and the IRB carefully evaluate each one [project] individually.”

DAVID L. WYNES, Ph.D.

CHAIR OF AAHRPP'S COUNCIL ON ACCREDITATION, AAHRPP  
Advance, Spring 2008

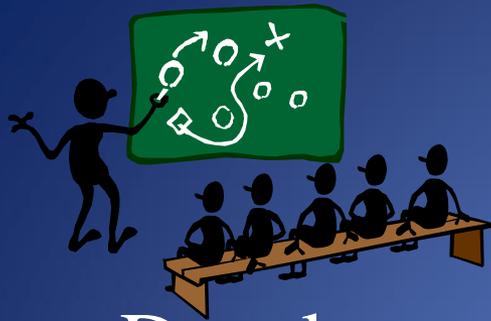
# An Institutional Approach





# Key Points

- Not every project involving people, data, records, specimens is automatically human subject research
- Some work would benefit from IRB review – esp. privacy, confidentiality, consent aspects



# Possible Strategies

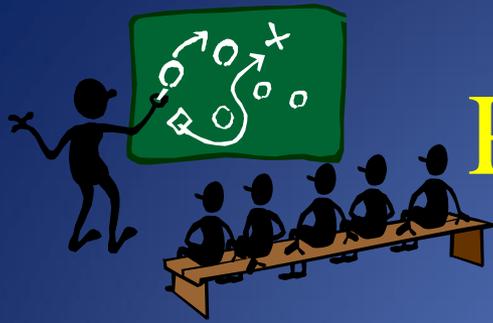
- Develop policy and procedure for the ‘shades of gray:’ who determines, criteria used, and how rationale is documented
  - Serves both investigator and institution
  - May choose to have broader – more inclusive policy
- Determine whether other projects warrant a separate review process, collaboration with the IRB, or review by the IRB

Which human subject research  
might meet exemption criteria?



# Key Points

- Fits into one or more of the six (6) defined categories
- IRB Chair or other HRPP official may conduct and document the review and recommendation
- DoD components vary in policy and practice



# Possible Strategies

- HRP staff or IRB members may review and make determination
- Implement post-approval monitoring: periodic progress report, review of amendments and unanticipated problems, and final report
- Review as minimal risk and not use exemption criteria

How to determine who is engaged  
in human subject research?

# What does it mean to be engaged in *human subject* research?

An institution is ‘engaged’ in research when employees intervene or interact with *living individuals* or obtain *individually identifiable* private information for research purposes.

(32 CFR 219.101, DoDD 3216.2, 4.4.3)

# What is required when engaged in *human subject* research?

Institutions engaged in human subject research must have an **Assurance** acceptable to Component Official and appropriate for the research being reviewed and conducted under the Assurance.

# Dimensions of Engagement

- Not engaged, but supporting in human subject research
  - Provide support to some degree
- Engaged in human subject research
  - Unilaterally (single institution, fully responsible for human research protection)
  - Collaboratively (multiple institutions/sites, all responsible to some degree)

# Institution is Not Engaged

When your institution's support limited to:

- Its staff acting as consultants, but not having access to, receiving, or possessing identifiable private information

# Institution is Not Engaged

(but involved)

Scenario:

Dr. I. M. Researcher from STATs-R-Us, an expert in analyzing data using the ‘gee whiz’ method, consults with Team Data. Dr. Researcher uses the method with already-collected database of de-identified data.



STATs-R-Us is NOT engaged.

# Institution is Not Engaged

(but involved)

When your institution's involvement is limited to:

- informing prospective subjects about availability of research
- providing subjects written information
- providing investigator's contact information
- obtaining & documenting permission for investigator to contact
- permitting use of facilities for research interventions or interactions

# Institution is Not Engaged

(but involved)

## Scenario:

Loud-n-Proud Research, Inc. wants to survey Fort Bliss commissary customers about attitudes and beliefs regarding media coverage of the war...



Fort Bliss is NOT engaged.

# Institution is only involved, but . . .

- Savvy CO / IO:
  - Verifies Assurance
  - Verifies IRB approval
  - Documents institution's role and responsibility
  - Adds conditions, if appropriate



# Institution is Engaged (in research)

When institution's staff:

- intervene with living individuals by manipulating the environment for research purposes

# Institution is Engaged (in research)

## Scenario:

Air Force research lab staff is testing a new hearing device to measure effects of background noise on performance of logistics tasks by varying the background noise and complexity of the tasks.



AF lab is engaged.

# Institution is Engaged (in research)

When institution's staff:

- obtain, receive, or possess individually identifiable private information (directly or indirectly through coding systems) for research purposes

# Institution is Engaged (in research)

## Scenario:

Army investigators from Fort G.I. Joe receive individuals' records from training commands to study job performance and retention of specialized ratings.



Fort G.I. Joe is engaged.

# Institution is not Engaged (in research)

When institution:

- receives direct DoD support  
(funds, resources, materiel, etc.)  
and research activities are done  
elsewhere (in-house or under contract)
- For DoD – funding alone does not constitute  
engagement (different than HHS-OHRP)



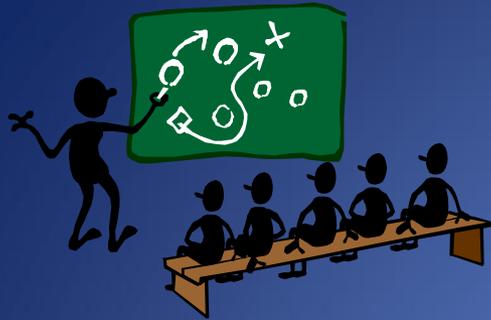
# Each Institution Must Determine

- What is institution and staff role in the research?
  - People, resources, \$\$\$, other support
- What are institutional responsibilities?
  - Design & conduct, analysis
  - Getting consent (or waiver)
  - Interventions



# Key Points

- **Know** whether you are engaged or supporting
- Engagement requires Assurance, HRPP, IRB review
- **Engagement means responsibility and accountability**
- Need process to determine whether supporting (not engaged) and document type of support and verification of human research protections
- **Some responsibilities can be divided & delegated**  
-some cannot be delegated



# Possible Strategies

- Look for economies while maintaining HRP standards
- Disengage (support only) when possible – may increase protection
- When in doubt.. call

Questions? Comments?



What type of Assurance and HRPP  
are needed?

How many IRBs must review  
HSR?

# Current Federal Assurance + Additional DoD Oversight

- **Accepts** the basic principles and procedures of the current federally-approved assurance
- **Close cooperation** with the DoD Component sponsor to ensure research is being approved and conducted in accordance with DoD policies and procedures

## DoD Addendum to Federalwide Assurance (FWA)

- Supplements the institution's FWA
- Establishes accountability to DoD
- Outlines DoD-unique requirements for research involving human subjects
- Designates reviewing IRB(s)
- Outlines component-specific requirements
- Effective as long as FWA in force

# Agreement for IRB Review

- Affirms **institutional** responsibility for overseeing conduct of research with human subjects
- Establishes scope of agreement – one, all, or some research protocols
- Designates “reviewing IRB(s)” - external
- Effective time period

**Institution – not reviewing IRB – is responsible**

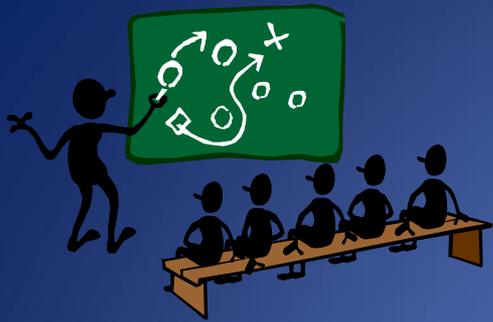
# Individual Investigator Agreement (IIA)

- Affirms investigator responsibility to institution
- Establishes scope of agreement – specific research protocol(s) for the investigator
- Affirms institutional oversight of investigator and research itself
- Effective time period



## Key Points

- **Trust, but verify** - Coast IRB
- Rely on other DoD IRBs – think DoD-wide, not just within your component
- Currently, DoD cannot rely on non-DoD IRBs
- **Engaged institution is still accountable**
- If engaged in HHS-supported research also must have Federalwide Assurance (FWA)
- Be realistic.....



# Possible Strategies

- Be open to and support ‘out of the box’ thinking – Is there a box?
- Empower the HRPP professionals to be creative
- Use Agreements for IRB review – all research, reciprocal on a protocol-by-protocol basis, protocol-specific,
- Encourage upfront discussion and ‘road maps’



# Requirements for Supporting Research

# Defense Federal Acquisition Regulation Supplement (DFARS) - 29 July 2009

- Addresses requirements for the ethical treatment of human subjects involved in research
- Informs contractors of their responsibilities for compliance (Common Rule, DoD, and FDA)
- Establishes the Human Research Protection Official (HRPO) within DoD Components

[www.acq.osd.mil/dpap/dars/dfars/changenotice/2009/20090729/E9-17949.htm](http://www.acq.osd.mil/dpap/dars/dfars/changenotice/2009/20090729/E9-17949.htm)

Before initiating research, PI/institution must be notified by the DoD Component HRPO that it accepts:

- Assurance
- IRB approval, or
- Exemption determination
  - Category & rationale
  - HRPO has final judgment
- Human research protections (protocol)

# Research \*\*\*Sponsors may:

Award a contract for proposals lacking definite plans for involvement of human subjects and for research without the intention of involving human subjects

However, institutions must meet requirements for human research protection prior to involving human subjects

[32 CFR 219.118 and 32 CFR 219.119]

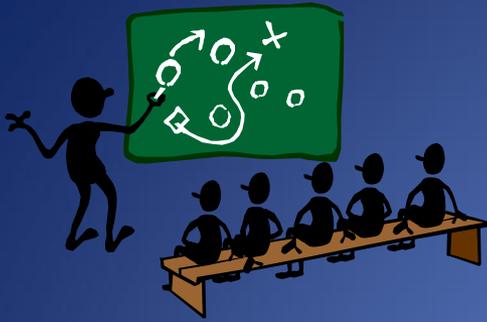
# Does institution practice reflect your policies and procedures (and do the P&P reflect your practice)?

- Federal regulations - Minimum standards.
- DoD requirements
- Component requirements
- FDA requirements
- Other collaborators or sponsors requirements
- State laws
- Institutional Requirements



# Key Points

- Say it once
- Do what you say, say what you do – “walk the talk”
- Define and describe roles and responsibilities – “who does what; when, where, why, and how”
- Use the flexibility allowed
- Avoid non-compliance with your policies and procedures
- Be aware of ‘mission creep’



# Possible Strategies

- **Define roles and responsibilities**— “who does what” in policy (Directive, regulations, instruction – formal)
- Describe the “...when, where, why, and how” in SOPs – flexible, update as needed
- Don’t reinvent the wheel - Use current models and adjust
- Develop policy with input from all users
- Think beyond your institution and your component
- Look backward and look forward to evaluate

Questions? Comments?





BREAK

# IO: What to know before you say GO!



# Caution! Additional curves in the road ahead. ..

1. Research that must have higher level of approval

2. Research with children and students. Consider state laws

3. Research greater than minimal risk requires a Medical/Research Monitor

4. Provisions for research-related injury for non-DoD subjects



5. Safeguards for research with international populations

6. Limitations on consent by legally authorized representatives

7. Limitations on exceptions from informed consent for emergency medicine research

(e.g., 10 USC 980, 45 CFR 46, and 21 CFR 50)



8. Prohibition of research with prisoners of war (POW)

9. Review of surveys within DoD

10. FDA requirements for research using investigational test articles (drugs, devices, and biologics)

11. Financial and other conflicts of interest



## 12. *Active Duty Personnel and others*

- Additional protections for military research subjects to minimize undue influence
- Limitations on compensation
- Participation in drug studies (prescription or non) can jeopardize the deployability of certain personnel

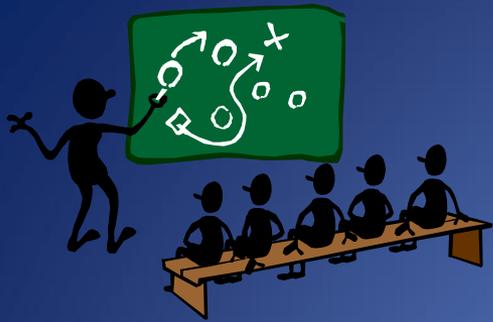
## 12. *Active Duty Personnel and others*

- Personal conduct standards and security clearance requirements for DoD personnel
- Duty to Report, e.g., substance abuse, violence, sexual conduct
- Duty to Warn, e.g., health issues
- Because unique population and demographics, anonymity/confidentiality cannot always be afforded



# Key Points

- Approval authority for new and continuing research
- Know the extent of your authority
  - Cannot override IRB's disapproval
  - Add more protections or safeguards
  - Suspend (stop) research
  - Place limitations or conditions on research
  - Refer for higher level of review



# Possible Strategies

- Keep an eye towards unique requirements or other issues when reviewing research protocol summary and the substance of IRB meeting minutes
- IRB Chair or HRPP staff can highlight the unique requirements
- Consider impact on institution (mission-related, financial, legal, public relations, etc.)
- Decide whether to implement the research

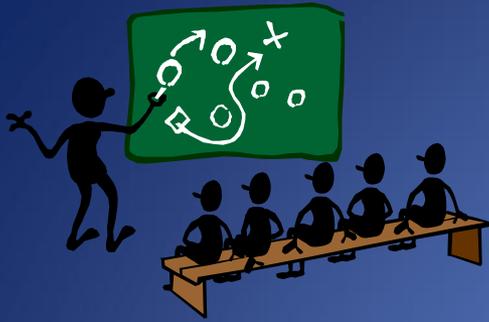
# Supporting and monitoring the IRB and HRPP

- Respect IRB's autonomy in review and recommendations
- Reporting structure – IRB has direct line to IO
- Process for selecting and appointing IRB Chair and members
- Sufficient staff and resources to support IRB and HRPP

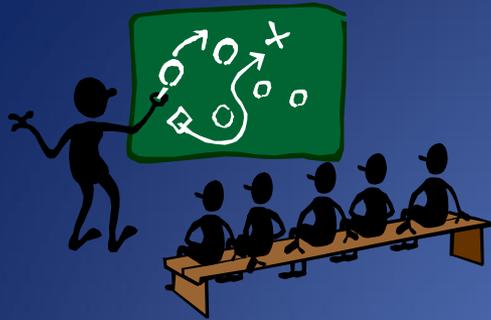


# Key Points

- **Reevaluate** periodically resources for IRB and HRPP
- Consider training, protected time, research support staff for investigator
- Support on-going training, networking or IRB and HRPP staff
- **Evolutionary process**



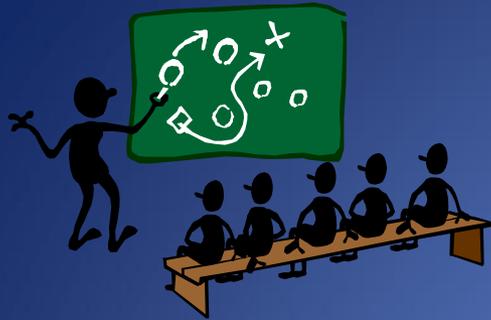
# Quality Assurance and Quality Improvement for HRPP



# Possible Strategies

## **Institutional level:**

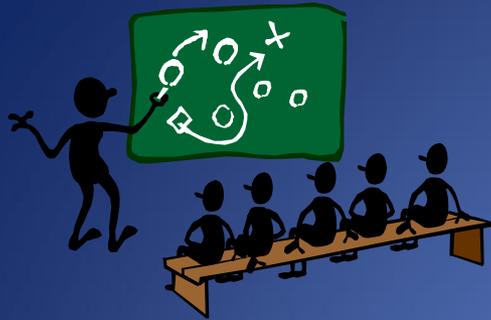
- Review and update policy periodically and as needed
- \*Review OHRP determination letters and FDA Warning Letters – does anything apply to your institution?
- Review OHRP and FDA guidance: does anything apply to your institution?



# Possible Strategies

## **IRB level:**

- Conduct targeted evaluation of IRB function through objective assessment of a topic or function
- Review certain exemption determinations to verify if ‘correct’
- Review research with active duty, children, investigational drugs, devices, biologics etc.
- Observe an IRB meeting



# Possible Strategies

## Investigator level:

- Discussions with investigators
- Directed review/audit with selected investigators
- Compare investigator and IRB records
- Audit consent documents
- Observe consent process or research

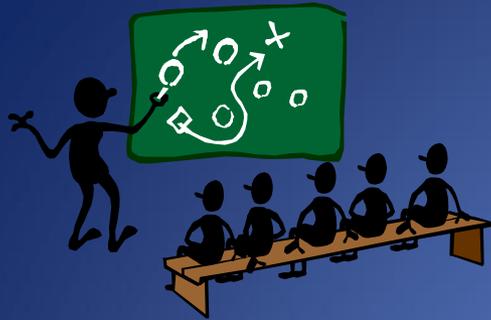
# Expect the unexpected

- Unanticipated problems with research protocols, the IRB, or other aspects of the HRPP
- Things will happen



# Key Points

- **Be prepared** with a fair process for handling triage/preliminary inquiry, formal investigation, and appeals
- **Differentiate** between non-compliance with human research protections and other things (research misconduct, conflict of interest, financial issues etc.) – there may be overlap
- **Involve the ‘right’ people for the job**



# Possible Strategies

- Initial triage/preliminary inquiry by small number of experienced people: IRB Chair, HRP Professional, non-involved subject matter expert, Quality Assurance (QA), Risk Management etc.
- Continuity between inquiry and investigation
- Use current structures or committee, if possible

Questions? Comments?



# Summary – The IO Top Ten



1. Set the tone for the institutional culture
2. Support role-relevant initial and on-going training
3. Develop SOP for determinations of what is not human subject research
4. Develop SOP for research that meets exemption criteria
5. Share and delegate responsibilities, when appropriate in collaborative research efforts

# Summary – The IO Top Ten



6. Use economies for review while maintaining research protection standards
7. Define and describe roles and responsibilities – “who does what; when, where, why, and how” and use the flexibility allowed
8. Keep an eye towards unique requirements or other issues when reviewing research protocol summary and the substance of IRB meeting minutes
9. Reevaluate periodically resources – QA-QI for HRPP
10. Prepare for the unexpected

**Which way is your institution going?**



**Open for questions**

**In appreciation to all DoD investigators,  
IRB members, and staff...**



**... for protection of human subjects  
in research efforts.**

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