



“A Conversation with the Department of Defense: Achieving Economies in DoD Human Research Review”

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**Under Secretary of Defense
Personnel and Readiness**

**Assistant Secretary of Defense
Special Operations and Low Intensity Conflict**



Goals

- Educate you about the evolving DoD strategies, tools, and methods to facilitate collaboration
- Encourage you to trust other DoD institutions and their IRBs to achieve economies in reviewing human subject research
- Empower you to use current tools to more efficiently develop products needed by the war fighter



Overview

- Review of basic DoD requirements
- Discuss examples of economies of IRB review in the DoD
- Identify strategies, tools, and methods to achieve those economies
- Discuss DoD harmonization initiatives in human research protections



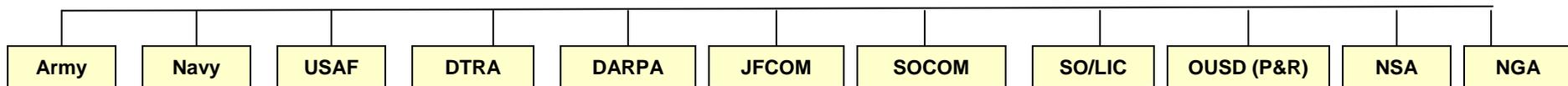
DOD Human Subjects Protection

Department of Defense (DoD)

The Common Rule - 32 CFR 219 "Protection of Human Subjects"

Director, Defense Research & Engineering (DDR&E)

DoDD 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research" applies to all DoD Components



“Each Component must have mechanisms in place to ensure that the provisions of DoDD 3216.02 are implemented.”



DoD Human Research Protection Program (HRPP) Basics

- All DoD institutions conducting human subjects research must have a DoD Assurance for their HRPPs
- All Assurances must identify responsible IRB(s)
- DoD institutions accept one another's assurances
- DoD institutions may rely on other DoD institutions' IRBs
- DoD Component-specific requirements may vary



The Problem

- Is there a way for you to conduct research involving human subjects at multiple sites and with multiple DoD and non-DoD research partners...
...and complete the research within your lifetime?



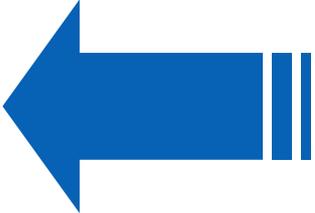
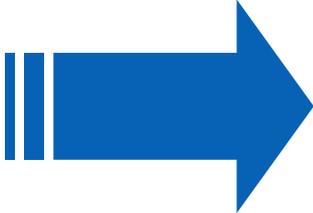
Economies in DoD IRB Review: Background

- Over the past few years, DoD Component Headquarters offices have been working with Institutions (IO, IRBs, Investigators, and other support staff) to:
 - ensure a common baseline of competent HRPPs
 - strengthen their oversight policies, procedures and practices
- This active dialogue is resulting in the ability to:
 - trust other institutions to oversee human subjects research
 - trust another DoD Component's HQ oversight program
- Over the past year, the DoD Component HQ offices have capitalized on lessons learned, enhanced transparency, and increased trust to create a set of tools that facilitates collaboration and reliance on one another



A case in point...

The DOD HIV Natural History Study

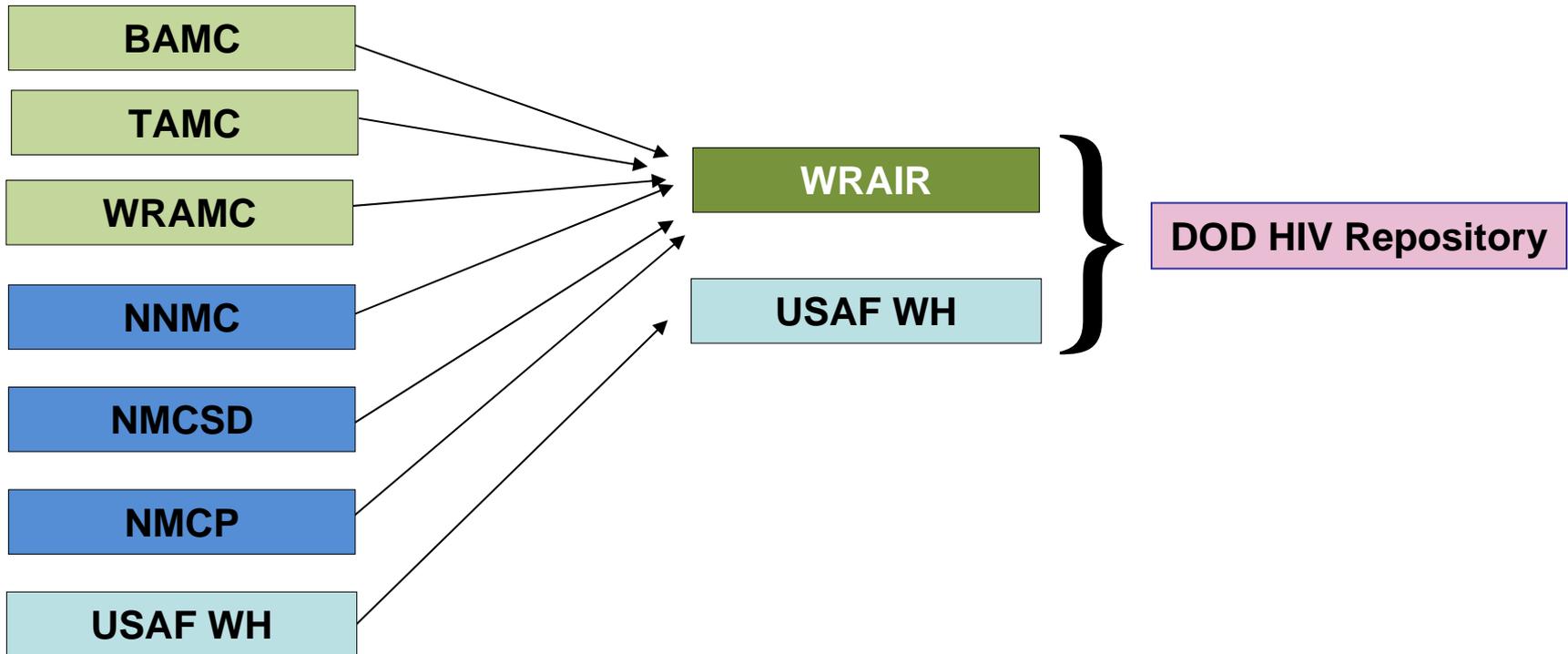
 **Then and Now** 



HIV Natural History Study

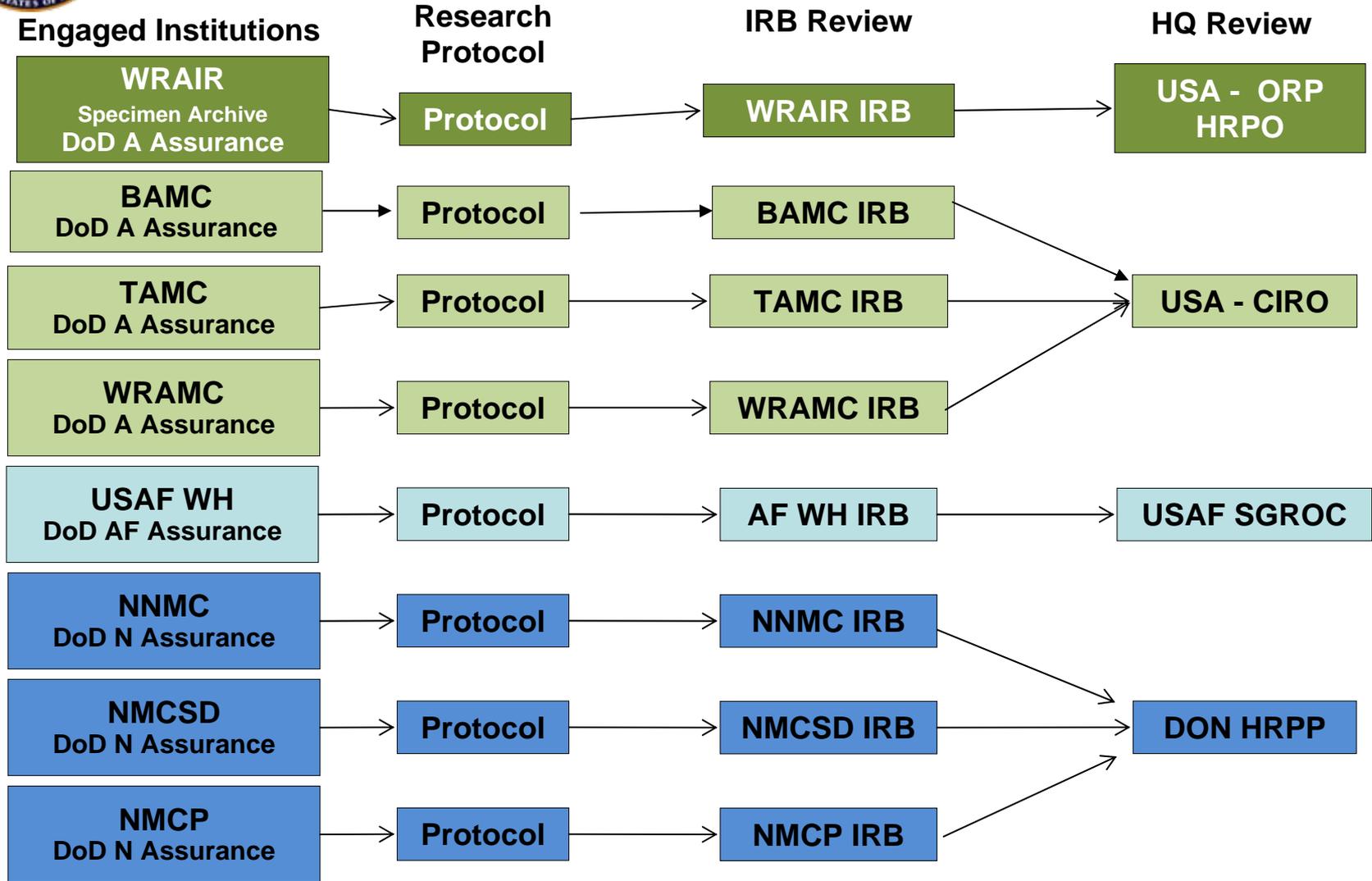
**Data and Specimen
Collection Sites
(Engaged in Research
involving Human Subjects)**

Repository Sites



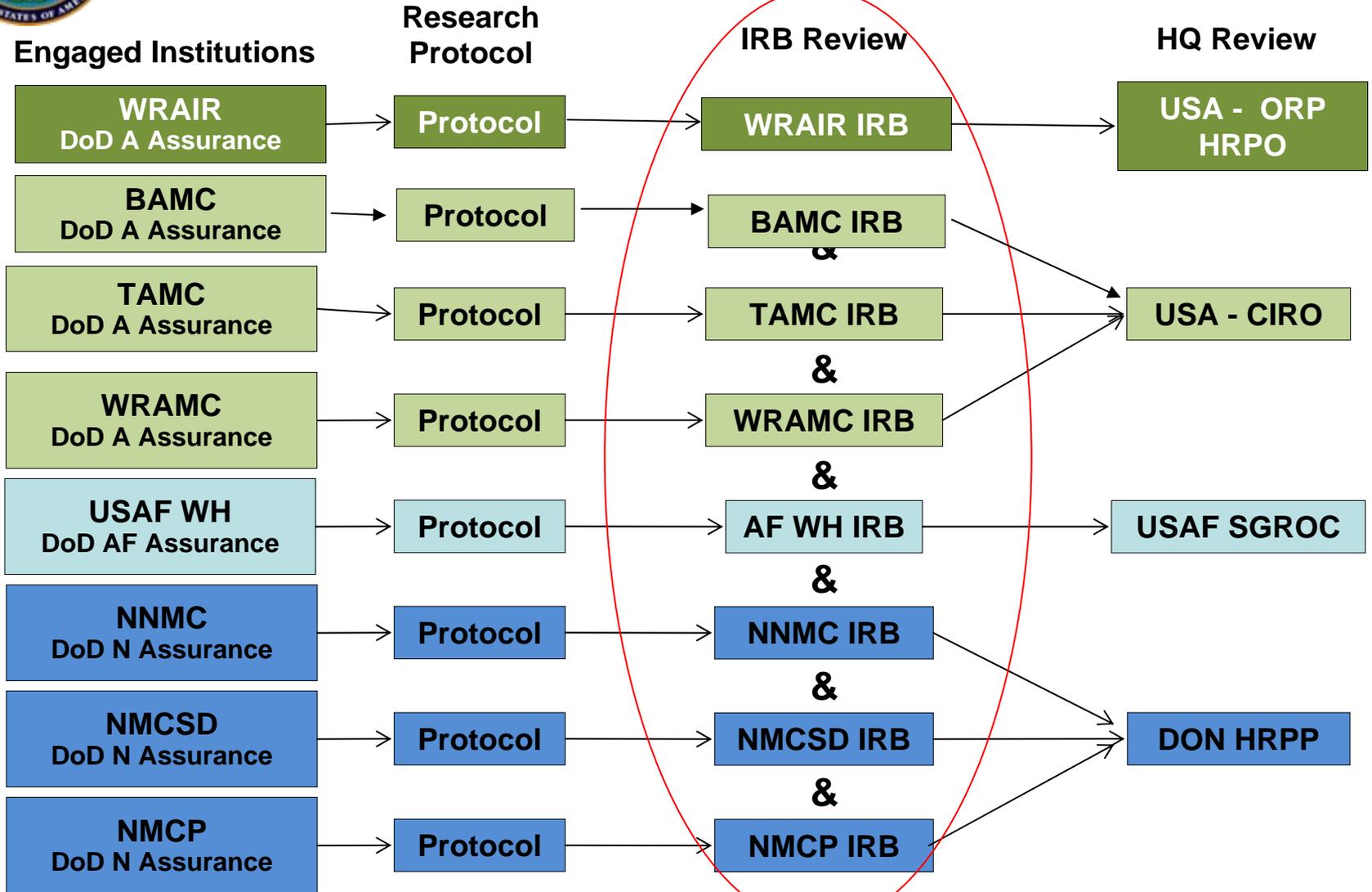


HIV Natural History Study – Specimen & Data Collection Protocol





HIV Natural History Study –Repository Use Protocol





HIV Natural History Study – Today's Repository Use Protocol Approval Process

Engaged Institutions

WRAIR
DoD A Assurance

BAMC
DoD A Assurance

TAMC
DoD A Assurance

WRAMC
DoD A Assurance

USAF WH
DoD AF Assurance

NNMC
DoD N Assurance

NMCS
DoD N Assurance

NMCP
DoD N Assurance

Agreements

IRB Review

WRAIR IRB

or

AF WH IRB

HQ Review

**USA - ORP
HRPO**

USAF SGROC



Whose IRBs Must Review?

- Key Considerations:
 - Who is engaged in human subject research?
 - Who is NOT engaged in HSR?
 - What economies are possible?
 - Who is willing to collaborate and cooperate?
 - What agreements are needed?
 - Who has authority to enter into agreement?

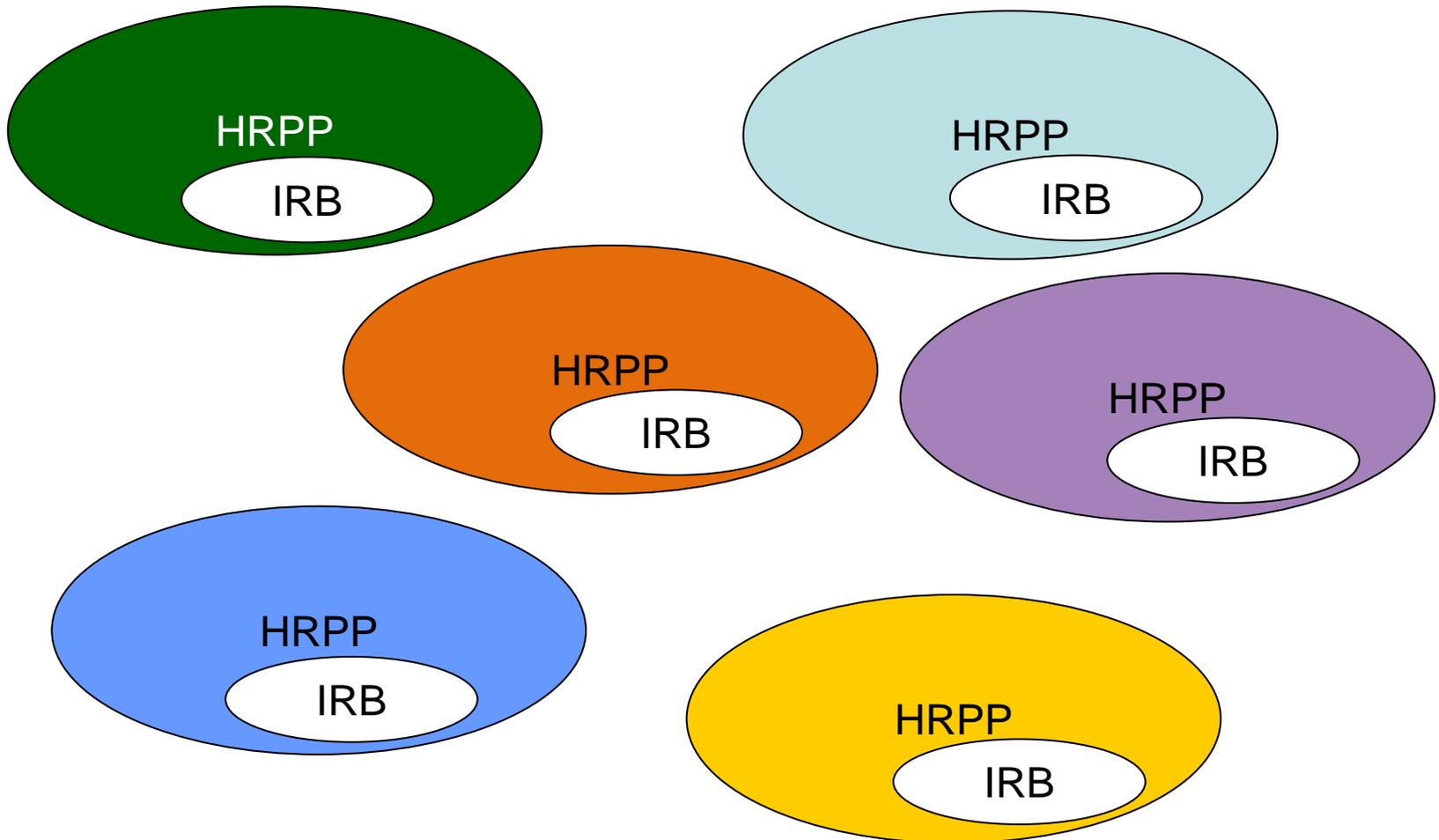


Which IRBs need NOT review?

- Institutions who are only providing sites where subjects are recruited are not engaged in HSR
(however, Commander approval required)
- Institutions who are providing funding, equipment, or de-identified existing data (a.k.a., “supporting”) are not engaged in HSR and do not need an assurance
- Institutions providing a contracted service are not engaged in HSR and do not need an assurance

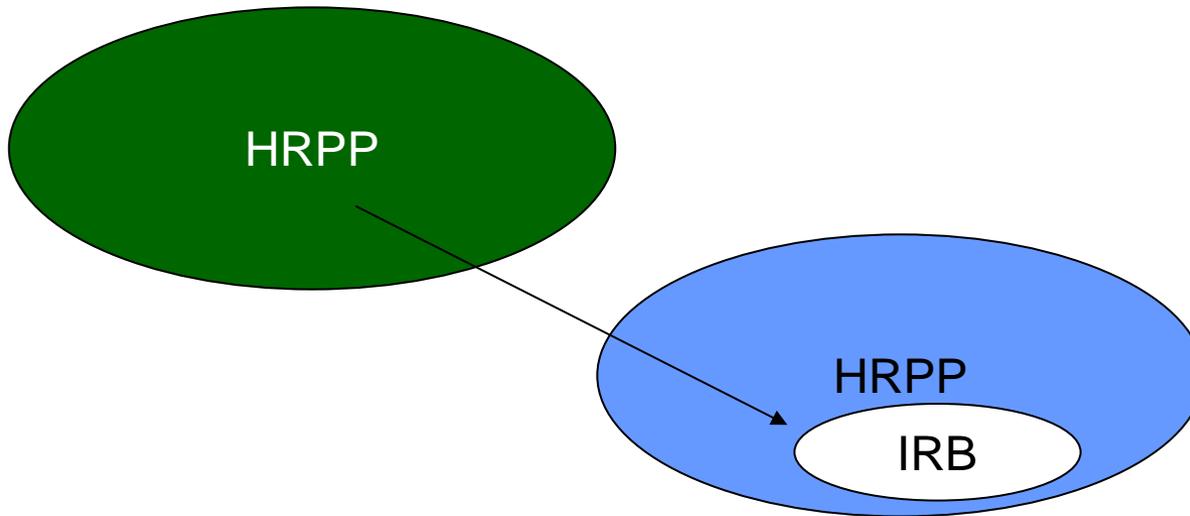


The IRB as a part of a Human Research Protection Program (HRPP)



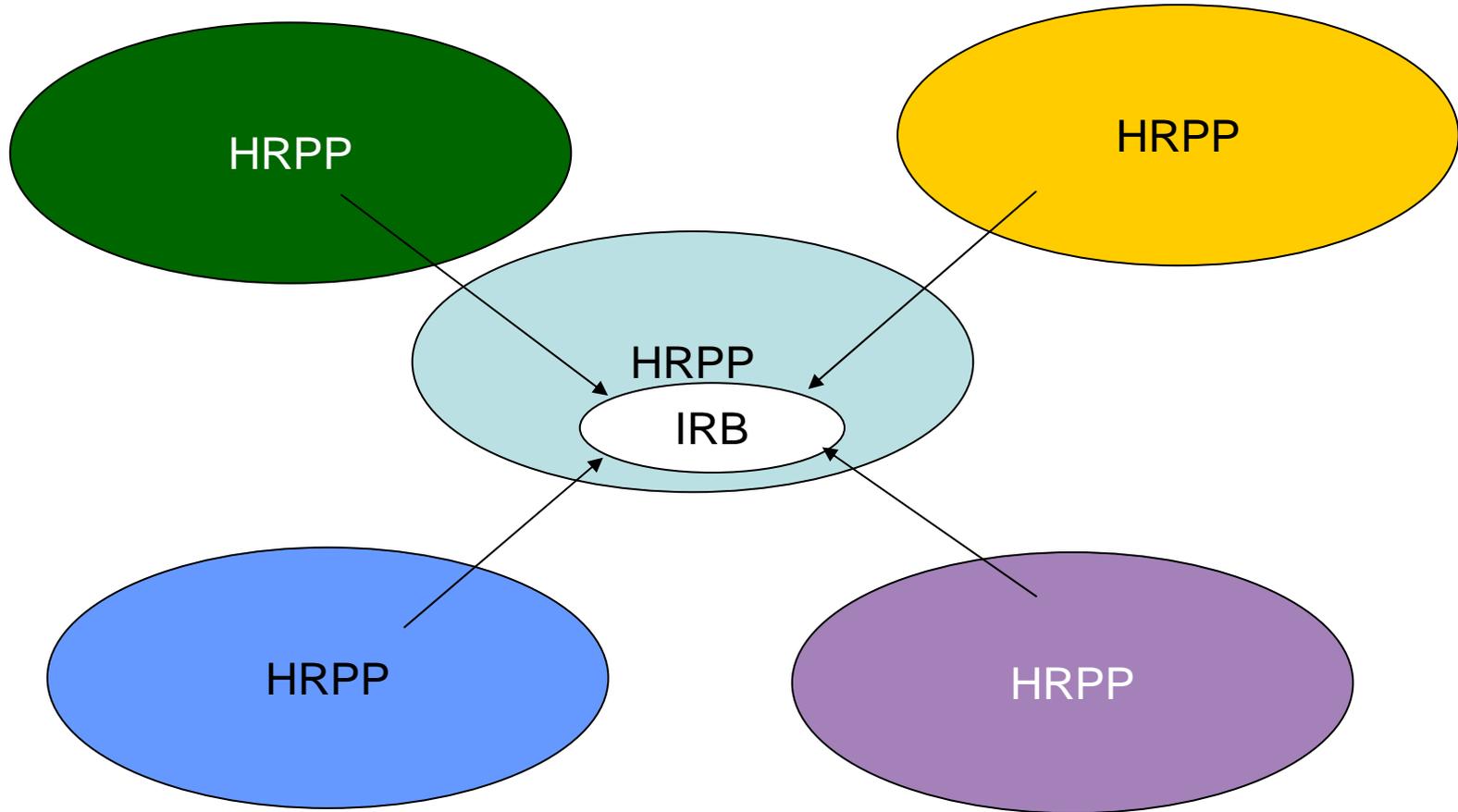


An institution and it's HRPP can rely on other than its own IRB





Multiple institutions can rely on another institution's IRB for review





DoD Economies of Review That Work

“Breacher Injury Study:
Evaluation of the Bio-Effects of
Repeated, Low-Level Blast
Exposures”



The “Breacher Study”

Engaged DoD Commands and Civilian Institutions

Naval Medical Research Center (NMRC) Silver Spring, MD

Weapons Training Battalion (WTBN) Quantico, VA

Walter Reed Army Medical Center (WRAMC) Washington, DC

US Army Aeromedical Research Laboratory (USAARL) Fort Rucker, AL

**Uniformed Services University of the Health Sciences (USU)
Bethesda, MD**

Applied Research Associates (ARA) Albuquerque, NM

University of Virginia (UVA) Charlottesville, VA

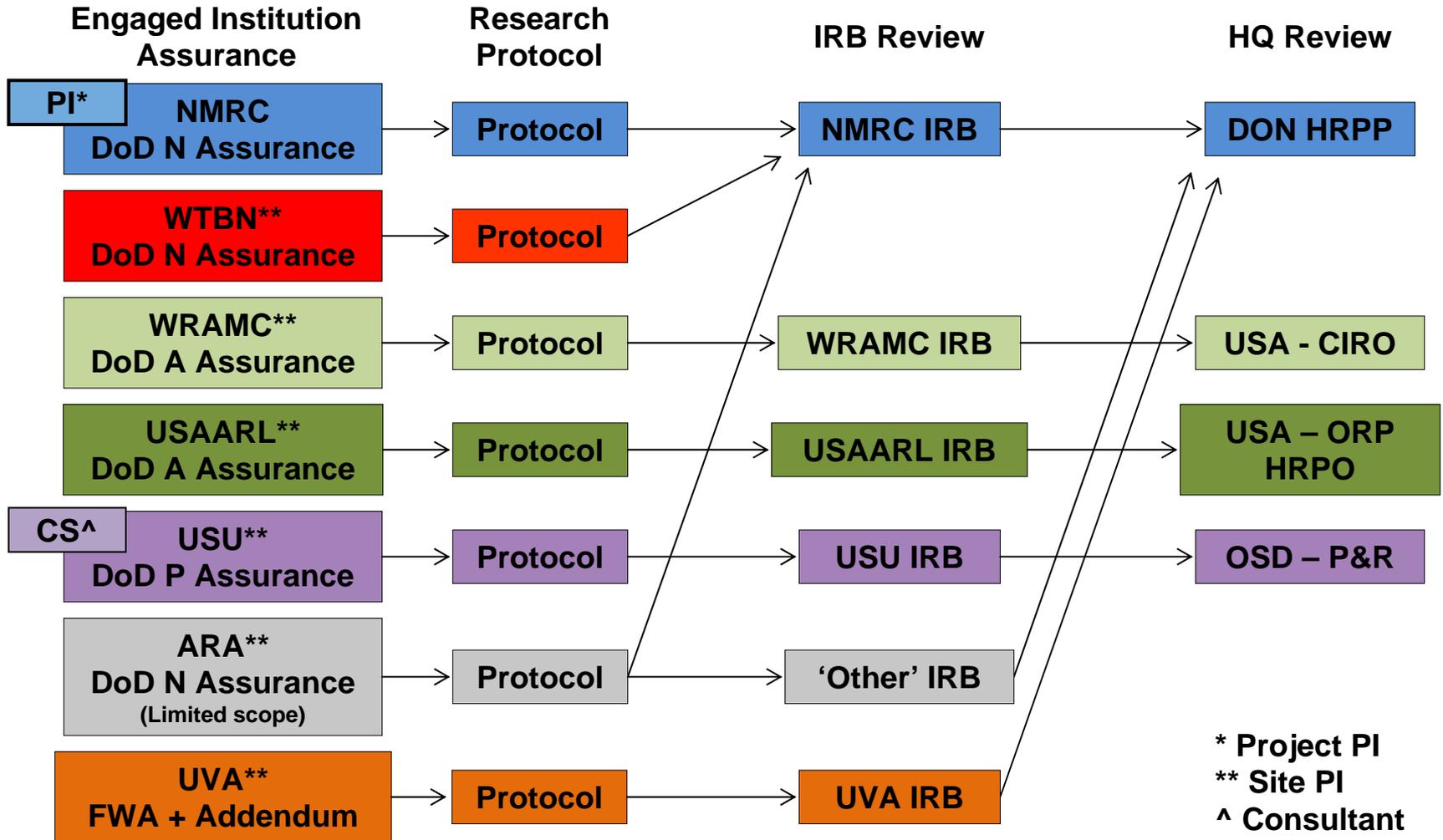


The “Breacher Study”

- **Subject population**
 - Marines at WTBN, Quantico
- **Institution Roles & Responsibilities**
 - NMRC – Project PI, research interventions etc.
 - WRAMC – Neurological assessments
 - USAARL – Audiology testing and analysis
 - USU – Neurological assessments
 - ARA – Neuro-cognitive testing
 - UVA – Magnetic resonance imaging (MRI)

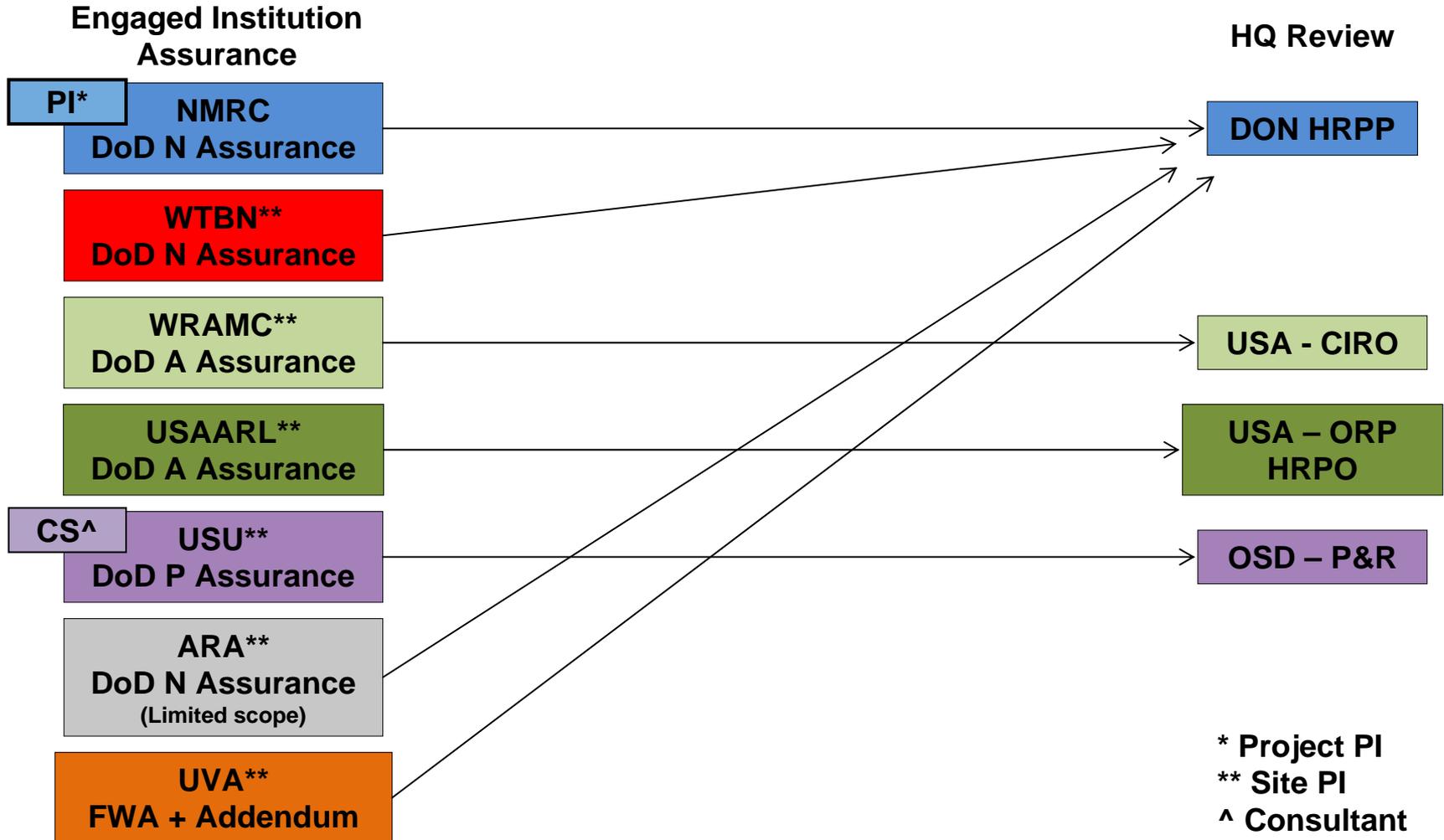


Research Review Process – ‘Before’ Economies



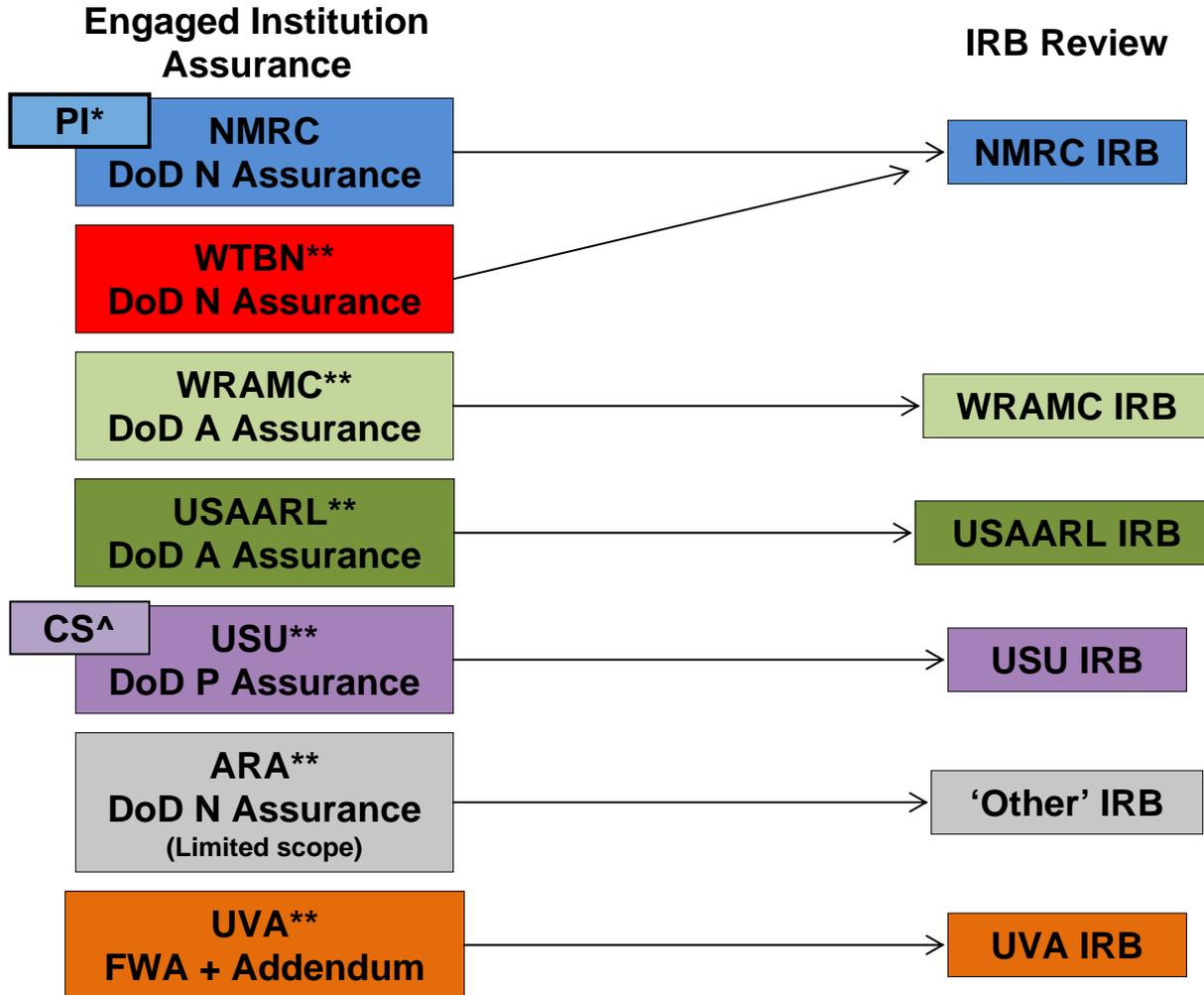


Research Review Process – HQ Review – ‘Before’ Economies





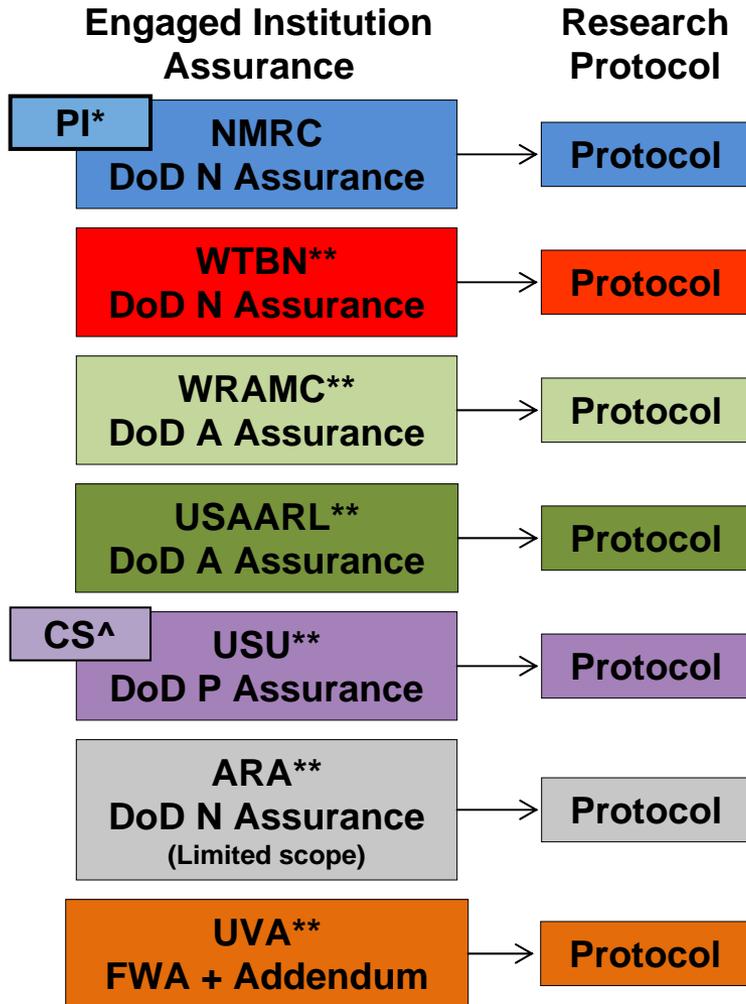
Research Review Process – IRB Review – ‘Before’ Economies



* Project PI
** Site PI
^ Consultant



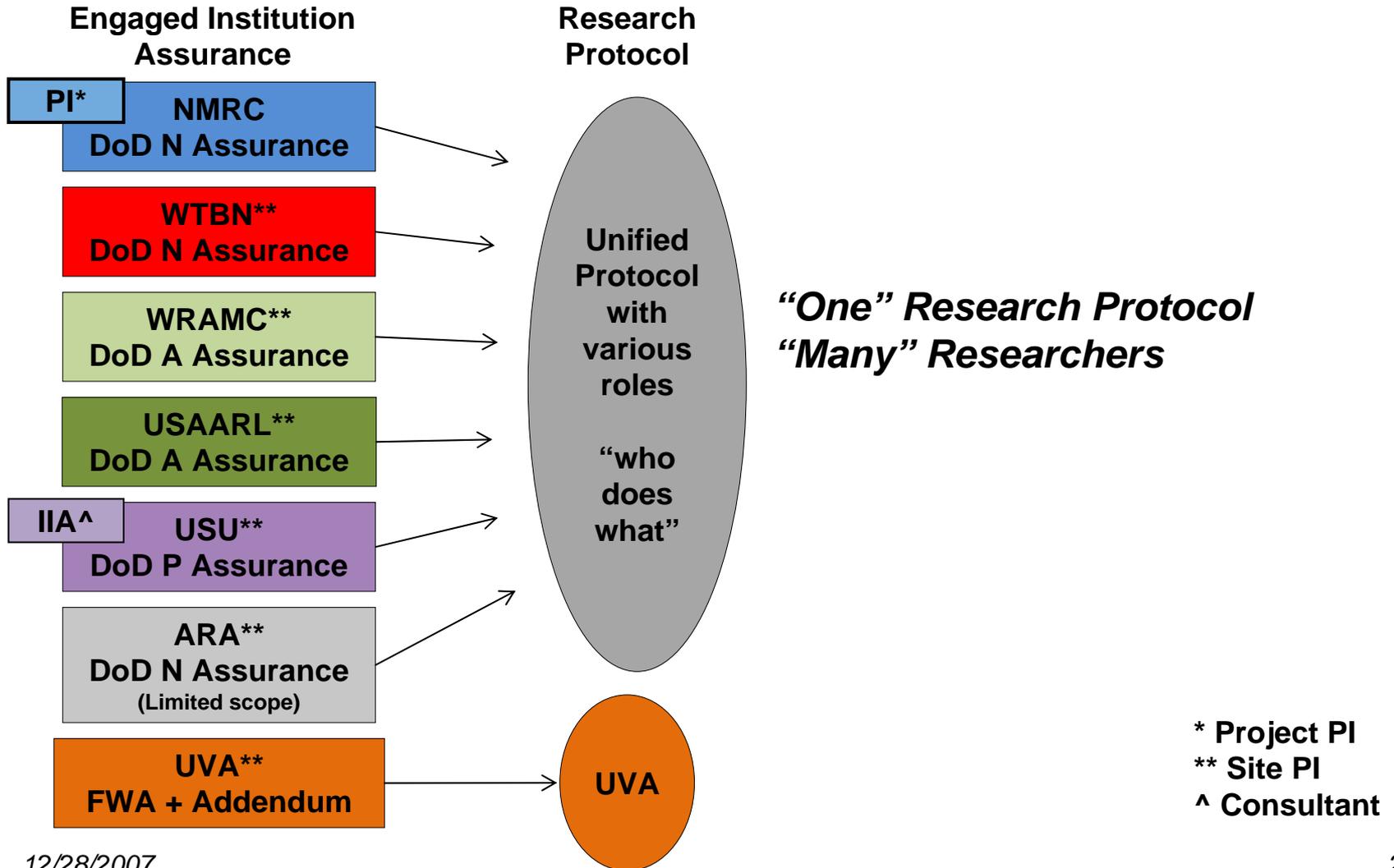
Research Review Process – Research Protocol – ‘Before’ Economies



* Project PI
** Site PI
^ Consultant

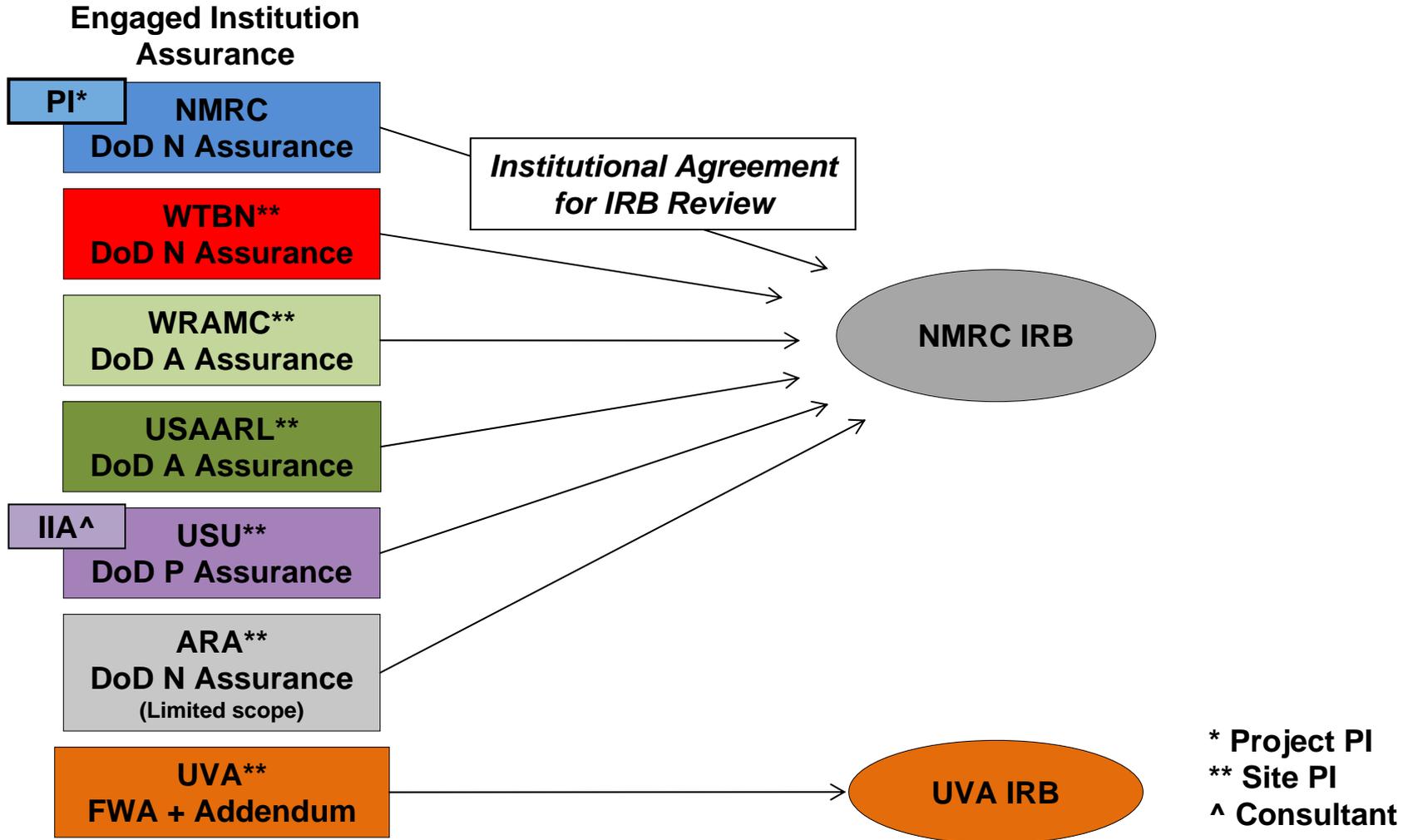


Research Review Process – Research Protocol - ‘After’ Economies



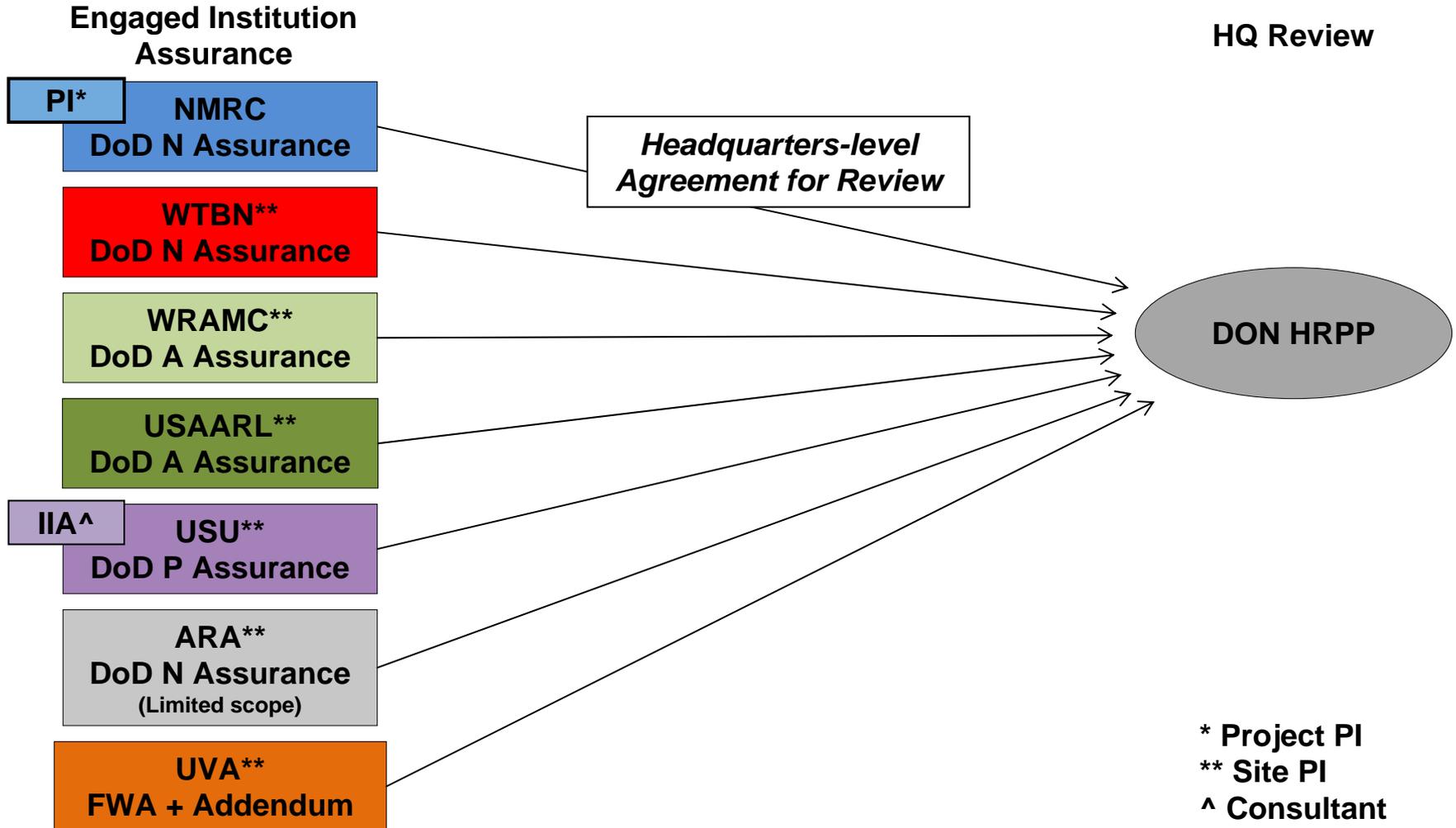


Research Review Process – IRB Review - ‘After’ Economies



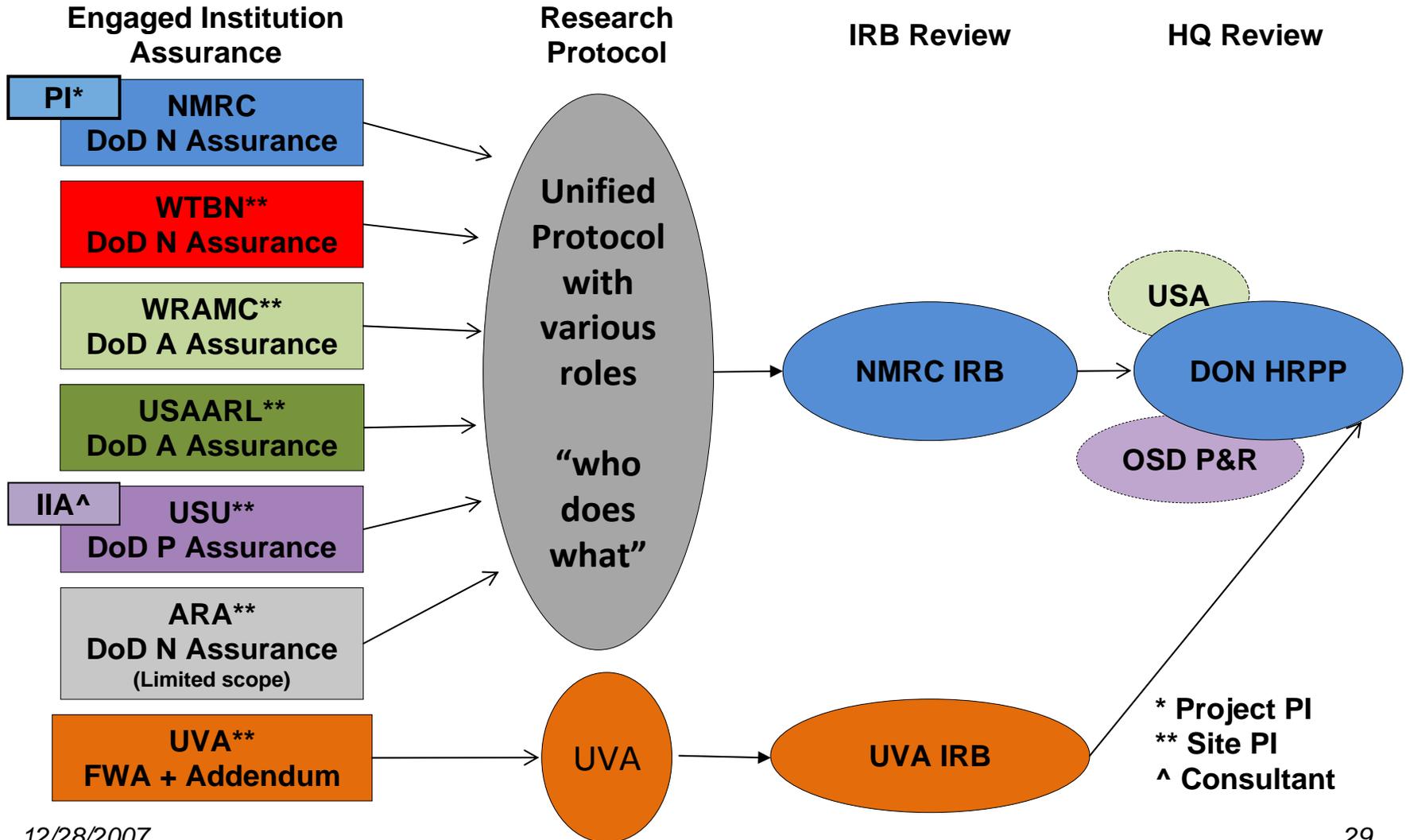


Research Review Process – HQ Review - ‘After’ Economies





Research Review Process – ‘After’ Economies





“Breacher Study” HRPP Tool Box

- **Assurance**
 - **DoD Assurance for DoD institutions**
 - **DoD N Assurance for NON-DoD institution**
 - Applied Research Associates (ARA)
 - Limited to ‘Breacher Study’
 - **DoD Addendum to Federalwide Assurance (FWA)**
 - University of Virginia (UVA)
 - All DON-supported research with human subjects
 - **Individual Investigator Agreement (IIA)**
 - Consultant at Uniformed Services University (USU)



“Breacher Study” HRPP Tool Box

- **Agreements**

- **DoD Institutional Agreement for IRB Review**

- Six party agreement among DoD commands and civilian partner with reliance on NMRC IRB

- **Headquarter-level Review Agreement**

- Four-party agreement among DON HRPP, Army’s CIRO and ORP HRPO, and OSD-P&R



Other DoD Models

- **Infectious Disease Cooperative Research Program (ID CRP)**
 - Centralized, program-specific IRB review for multi-centered research protocols
- **Multi National Corps – IRAQ (MNC – Iraq)**
 - Designated state-side IRB review for in-theater research covered by MNC –I Assurance



DoD Institutional Agreement for IRB Review: Key Elements

- Affirms institutional responsibility for overseeing conduct of research with human subjects
- Establishes scope of agreement – one, all, or some research protocols
- Assigns responsibility for IRB review
- Effective time period



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



DoD Addendum to Federal Wide Assurance (FWA)

- Supplements the institution's FWA
- Establishes accountability to DoD
- Outlines DoD-unique requirements for research involving human subjects
- Assigns responsibility for IRB Review
- Outlines component-specific requirements
- Effective as long as FWA in force



Summary

- Education, trust, and empowerment move us from yesterday's hair ball to today's streamlined review of research involving human subjects
- Education helps you indentify institutions engages in research, those institutions supporting research, and those not engaged in research
- Trust allows you to accept another Component's determinations about the roles of each collaborator; exemption determinations, IRB review, and Component HQ oversight
- Empowerment allows you to avoid duplication of effort without compromising compliance with human research protection requirements



For the times they are a-changin'

Rules of the past...

Rules of today...

Rules of the future...

...stay tuned!