IRB – 04

Research Supported by the Department of Defense

Presented by

IRB Compliance Program, Human Subjects Office

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Why a New IRB?

- Department of the Navy (DoN) research previously sent to WIRB – expensive.
  - Reduce or eliminate costs to PI
  - No costs for modifications

- Keep IRB review of all DoD-supported research in-house.

- WIRB is still an option.

UI Information for PIs

Website information - http://hso.research.uiowa.edu/irb-04-department-defense

- In-depth guide
- FAQs

What is DoD-Supported Research?

- Funded by a department or agency of the Department of Defense.
- Involves cooperation, collaboration, or other type of agreement with a component of the DoD.
- Uses property, facilities, or assets of a component of the DoD.
- Subject population **intentionally** includes personnel (military and/or civilian) from a component of the DoD.

Assurances

Similar to UI PI Assurances, but with a DoD focus:

- There are separate Assurances for the Army, Navy, and the DoD
- Report significant changes & results of the CR to the DoD Human Research Protection Office (HRPO)
- Report allegations of noncompliance
- Component may have unique rules for recordkeeping, other than those required by UI or HIPAA
- DoD approval of surveys and/or interviews of DoD personnel (military or civilian)
- The Assurance is submitted with the scientific review form.

Before You Begin

– No ‘secret’ or ‘classified’ research
  - UI policy against secret research
  - Testing of chemical or biological warfare agents generally prohibited

– PI cannot be the holder of an IND or IDE (experimental drugs or devices) in DoN research.

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Before You Begin, cont'd.

– Meet requirements for additional training

– Scientific review

– Previous approval needed for surveys

People

Military Participants

- Active duty service members or reserve component members in a federal duty status, are considered to be an adults, **even if under eighteen.**

- Investigators must provide documentation of **command approval** as an attached letter of agreement, indicating that the PI has permission to conduct the research at the location.

Military Participants

Protection from Undue Influence

- Officers and senior non-commissioned officers:
  - Can't influence the decision of subordinates
  - Can't be present during recruiting

- Superior officers must be recruited in a separate session from subordinates.

- An ombudsman must be present if recruiting for greater than minimal risk studies is conducted in a group setting.

Vulnerable Populations

In addition to protected populations, such as pregnant women and neonates, the DoD may also require additional protection for:

severely ill patients
employer / employee
student / teacher
supervisor / subordinate
deployed personnel

Clinical Research Should include Women and Minorities

This requirement may be waived by the Secretary of Defense or the DoD component if the project is:

1) inappropriate with respect to the health of the subjects,

2) is inappropriate with respect to the purpose of the research, or

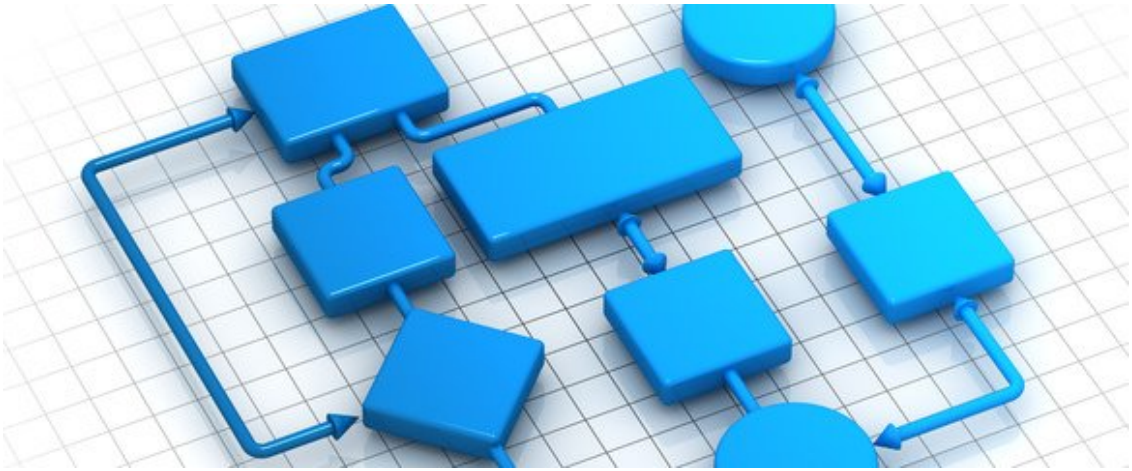
3) is inappropriate under such other circumstances as the Secretary of Defense may designate.

Compensation for Research Using DoD Employees

- **People:**
  - Active duty military or DoD civilian employees
  - Off duty

- **Process:**
  - Blood draw
  - Other research - as approved by the IRB. Payment from a federal contractor or non-federal source is permissible, but not directly from a federal source.

Current details are in the Guide.



Processes

Requirements for Additional Training

- The Navy requires additional certification modules offered through the CITI program.
- Other training or recertification may be necessary. Check with your DoD contact.
- Directions on accessing the CITI training will be on the website.
- Plan for it – the CITI modules will take time.

Scientific Review

Rationale: “When a **non-DoD institution** is conducting **nonexempt research** involving human subjects, the **IRB review must consider the scientific merit of the research**, as required by section 219.111 of “Title 32 Code of Federal Regulation (CFR) (the “Common Rule”).”

The Scientific Review form is attached to the Assurance.

Selected Reviewer Considerations:

- Team member **expertise**
- Valid **research hypothesis** and/or appropriate objectives
- **Study design** is likely to achieve study objectives
- Could the question be investigated **without using human subjects**?
- Is target **subject group** appropriate?
- Could **risks** be further reduced?

Reviewer Recommendations

- **Submitted** to IRB as currently written.
- **Revise** for a second review prior to submission.
- **Submit** to IRB **after revision** and **re-review.**
- **Rejected** due to lack of scientific merit.

Only submit studies that have passed scientific review.

Research Monitor

Research with greater than minimal risk requires a research monitor approved by the IRB.

- Role:
  - Subject/patient advocate, independent of the investigative team
  - Can stop research in progress and/or remove a subject from the study
  - Protects the safety and well-being of subjects until the IRB can assess the monitor's report
  - Reports observations and findings to the IRB or other designated official

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Research Monitor, cont'd.

- The PI provides the monitor's name and a summary of the monitors' duties, authorities, and responsibilities to the IRB.

- The research monitor provides documentation stating that he or she agrees to these responsibilities. The document is submitted as an attachment.

Survey Approval

Research involving surveys or interviews with DoD military or civilian personnel or their families may require DoD approval.

Check with the DoD contact for additional requirements and whether the approval is required before or after IRB review.

Collaboration

- Collaborating institutions in multi-site research must have a federalwide assurance (FWA).

- Investigators must provide documentation of IRB approval or an IRB Authorization Agreement for collaborators.

- The **roles and responsibilities** of each institution must be specified in the Agreement, along with a statement indicating that the **parties agree to comply** with any special DoD requirements.

Unique Limitations on Waivers of Informed Consent

- In addition to the Common Rule requirements for waiving consent, the IRB may waive informed consent for certain minimal risk DoD research.

- Informed Consent may be waived by the Asst. Sec. of Defense for Research and Engineering if these conditions are met:

  - The research is **necessary** to advance the development of a medical product for the Military Services.
  - The research may **directly benefit** the individual experimental subject.
  - The research is conducted **in compliance with all other applicable laws and regulations**.

Reporting

The IRB and the PI must report these events to the DoD within 30 days of the event:

- Determinations of **serious or continuing noncompliance**
- Unanticipated problems involving **risks** to subjects or others
- Study **suspensions or terminations**
- Audits, inspections, or investigations

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Reporting, cont'd.

- Results of the IRB Continuing Review

- Changes to the reviewing IRB

IRB-approved **substantive amendments to the protocol** must be reviewed and approved by the HRPO prior to implementation.

Recordkeeping

- Keep research records for the time required by UI or federal policy, usually **3-6 years**.
- DoD components may have **additional requirements**, including transferring records to the DoD component.
- A **research record should be retained at UI** unless there is an executable data usage agreement specifying otherwise.
- Retained **records shall be made accessible** for inspections and copying by authorized representatives of the DoD.

After IRB Review and Approval

- Submit application to the applicable DoD Human Research Protection Office (HRPO) for administrative review.

- HRPO may require changes to the research.

DO NOT begin research

until this review is completed.

IRB 04 Review Process

- All IRB 04 studies will have initial full board review.
  - After the initial approval, an expedited review will be considered if appropriate.

- Board meetings will be convened on an as needed basis.

Monitoring

- All DoD–supported research is monitored by the UI IRB.

- Structured visit
  - Did PI and IRB adhere to rules for DoD-supported research?
  - Were active and off-duty military personnel and civilian employees adequately protected?
  - Opportunities for education from HSO / IRB.

During the monitoring process,
the study may continue as approved.

Thank You!

For more information:

http://hso.research.uiowa.edu/irb-04-department-defense