59th Medical Wing

59 MDW Research Fundamentals Workshop

"*Human Research – Curves in the Road*"

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Agenda

PURPOSE: To introduce unique "Curves in the Road" and how to navigate them successfully in human subject research

1. Unique "Curves in the Road"
2. Navigating for Success

The views expressed are those of the presenter and do not reflect the official views or policy of the Department of Defense or its Components

Unique "Curves in the Road"

1. DHA Component Level Administrative Review (CLAR) is required for foreign research; fetal research; classified research; Large Scale Genomics Data (LSGD) research; and research requesting a waiver of 10 USC 980
   - Study must receive CLAR approval, following IRB approval, before it is implemented…expect 2-3 months delay
2. Research using single-site or multi-site administered non-validated survey tools must be submitted to the DHA Information Management Control Office (IMCO) for approval prior to use
   - Expect 2-4 weeks delay in final survey approval
3. Research using multi-collaboration sites requires each site Commander to approve implementation of the study within their institution
   - Institutional authorization can occur before or after IRB approval

Unique "Curves in the Road"

4. FDA requirements for research using investigational test articles (drugs, devices, biologics) or the off-label use of FDA-approved test articles
   - Expect 1-2 months delay in FDA approval

5. Must consider participation in drug/device intervention studies that could jeopardize the deployment of military personnel or their fitness for duty

6. Without a DHHS-approved Certificate of Confidentiality (CoC), complete anonymity and confidentiality cannot be guaranteed for Active Duty members participating in research due to self-identified concerns (e.g., via research surveys) and must be reported to leadership
   - Ilegal use of drugs, alcohol abuse, violence, sexual misconduct
   - Health issues

7. Under the new Common Rule, studies requiring Broad Consent will not be accepted by the 59 MDW IRB for review/approval

Unique "Curves in the Road"

8. All non-DoD/contract employees must be covered by a DHHS Federal-wide Assurance (FWA) or a DoD Individual Investigator Agreement (IIA) to participate on DoD research
   - Until the study is approved, recommend removing these folks from the study until they receive their assurance coverage. Then add them to the study with a protocol amendment

9. Active duty military CANNOT receive research-related compensation, unless it is for blood draws (up to $50/draw) or they are in an approved off-duty status through their Commander

10. Collaborative Research & Development Agreements (CRADAs), Intellectual Rights Agreements, Contracts, etc., can take 3-6 months to be approved
    - Research cannot begin until official approval is received

Unique **"Curves in the Road"**

11. OASD(HA) Guidance (GD-20-001) requires individuals engaged in research at OUSD(P&R) institutions to take the OUSD(P&R) CITI training when a subject's current CITI has either expired or will be expiring and needs to be renewed
    - More training modules than current CITI and very time-consuming

12. Scientific review is required for non-exempt human subject research to determine scientific merit or feasibility ***prior*** to proceeding to an Institutional Review Board for further considerations. Scientific review is conducted by a Subject Matter Expert unaffiliated with the research study or through a Scientific Review Board. Scientific reviews must be documented using Defense Health Agency (DHA) Form 201.
    - This process could take 1-2 weeks or more

Navigating for Success!!!

Warrior Medics – Mission Ready – Patient Focused

- Seek advice from faculty mentors, advisors *early* in the concept phase for protocol development
- Seek clinical research consultation through the 59 MDW Office of Clinical Research Support and support staff
- Use pre-existing templates and forms to develop the protocol
- Plan ahead for all required outside reviews and approval processes that may be required for the study (FDA, DHA, IMCO, Contracting, etc.)

Navigating for Success!!!

Warrior Medics – Mission Ready – Patient Focused

- All research proposals due 4th Monday of the month to the 59 MDW Office of Clinical Research Support for IRB processing to meet the following month's IRB meeting
  - Scheduled convened IRB meeting - 4th Tuesday of the month

- Keep the 59 MDW Office of Clinical Research Support informed of your contact info at all times (esp. during medical rotations & deployments)
  - IRB-directed changes to a research protocol; missing documentation; upcoming continuing reviews/progress reports, etc.

  - **NOTE**: failure to keep in contact may result in your protocol expiring or being withdrawn with no further action

- 59 MDW Office of Clinical Research Support:
  - Rachel Montez [Branch Chief] – (210) 292-4683
- 59 MDW Clinical Research Administrator:
  - Dr. Rocky Calcote – (210) 292-5203

Questions?

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