**PHOENIX VA HEALTH CARE SYSTEM (644)**

**R&D COMMITTEE AGENDA**

**<enter date>**

1. **Attendees and Voting Status**

Chair: xxxx, MD, Medicine Rep, Voting Member

Vice Chair: xxxx, MD, Medicine Rep, Voting Member

xxxx, MD, Medicine Rep, Voting Member

xxxx, SRS Chair, Scientific Rep, Voting Member

xxxx, MD, Mental Health Rep, Voting Member

xxxx, MD, Surgery Rep, Voting Member

xxxx, MD, IRB Chair, Medicine Rep, Voting Member

xxxx, PharmD, Pharmacy Rep, Interim Voting Member

xxxx, DO, Mental Health Rep, Voting Member

Staff: xxxx, MD, ACOS/Research, Executive Secretary, Ex-Officio

xxxx, R&DC Coordinator

xxxx, Acting Foundation Executive Director

xxxx, MD, Chief of Staff, Ex-Officio

xxxx, PhD, Deputy ACOS/Research, Ex-Officio

xxxx, PhD, Human Research Protection Program Officer

xxxx, RN, Research Compliance Officer, Consultant

xxxx, Interim Medical Center Director, Ex-Officio

xxxx, AO/Research, Ex-Officio

1. **Call to Order/Review of Ethics Statement:**

VHA Handbook 1004.07, Financial Relationships Between VHA Health Care Professionals and Industry, dated October 21, 2009 requires members to be asked whether they have any real or potential conflicts of interest that may arise as a result of discussion of agenda items.

1. **Approval of Minutes:** (vote required)

R&DC Minutes for <enter date>

1. **Review Subcommittee Minutes:** (no vote required)
   * 1. IRB Minutes for <enter date>
     2. IRB Expedited Reviews Report for <enter month/year>
     3. SRS Minutes for <enter date>
     4. IACUC Minutes <if applicable> for <enter date>
     5. IBC Minutes <if applicable> for <enter date>
     6. CIRB Meeting Minutes for <enter date>

<if applicable and list any references made to Phoenix in the Minutes and Expedited Review Report>:

* + 1. CIRB Expedited Actions for <enter date>

<if applicable and list any references made to Phoenix>.

* + 1. Amendment to Final CIRB Minutes for <enter date>

<if applicable and list any references made to Phoenix>.

1. **Updates from Subcommittees:**  (no vote required)
2. Subcommittee Decisions Memo - <enter date>

This is the list of decisions by the IRB, CIRB, SRS, IACUC and IBC subcommittees for reviewing new, continuing, and closure research projects for the month of <enter month/year>.

1. IRB Chair Report
2. SRS Chair Report
3. **QA-Compliance: POC: RCO** (no vote required unless oversight action needed)
4. Consent and Regulatory Audit Report - <enter date>
5. Consent and Regulatory Audit Report for AoU Study - <enter date>
6. Consent and Regulatory Audit Report for CIRB Studies - <enter date>
7. Consent and Regulatory Audit Report for MVP – <enter date>
8. RCO Compliance Measures Report for <enter date>
9. **New Protocols:** (vote required)
10. <enter study name> (enter study #)

1. Principal Investigator:

2. Primary Reviewer:

3. Protocol Objective:

4. Sponsor:

5. Note:

1. **Designated Review Approvals** (no vote required)

<enter study name> (enter study #)

**A. Initial review**

1. Principal Investigator:

2. Designated Reviewer:

3. Protocol Objective:

4. Sponsor:

5. Review Results:

6. Notes:

7. Information Only

**B. Continuing review**

1. Principal Investigator:

2. Designated Reviewer:

3. Protocol Objective:

4. Sponsor:

5. Review Results:

6. Notes:

7. Information Only

1. **Continuing Reviews:** (vote required)
2. <enter study name> (enter study #)

1. Principal Investigator:

2. Protocol Objective:

3. Sponsor:

4. Note:

1. **Closures:** (vote required by local policy)

1. <enter study name> (enter study #)

1. Principal Investigator:

2. Funding:

3. Note:

1. **Old / Unfinished Business:**
2. **New Business / Open Discussion:**
3. **Research Programmatic Updates:** (no vote required)
4. There are <enter #> active studies that have received the Notice to Proceed (NTP). <if applicable>…The studies below require the PO final review and signature before the NTP can be initiated. [FY20 Active Research Studies](file:///C:\Users\VHAPHOHatchR\Desktop\FY2020%20Active%20Research%20Studies%20-%20Shortcut.lnk). **POC: AO**
5. The following studies were approved by R&DC pending contingencies on <enter date>:
6. <enter study name> (enter study #)

Note:

Update:

1. RDC Final Approval:

enter study name> (enter study #)

Updates: (e.g. date of final approval)

1. <enter any new Leadership Report or ORO cases>. <ex: ORO Case xxxx (xxxx) – Local SAE>

**POC: DACOS**

1. Update on programmatic topics, items on strategic planning, etc.

**POC: ACOS**

1. Update on financial status (general and for individual studies at risk) **POC: xxxx**
2. **Education:**

1. **Announcements:**
2. **Next Meeting:**

Wednesday, <enter date> at 12:30 PM in Building 21, Conference Room 108

1. **Adjournment:**