DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

21 FEB 2017

MEMORANDUM FOR SGVU
ATTN: JOSHUA CALCOTE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **59th Medical Wing AAHRPP Questions of the Week** presented at/published to **59th Medical Wing Email Bulletin & 59 MDW Clinical Research Division Knowledge Exchange Website** in accordance with MDWI 41-108, has been approved and assigned local file #**17097.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]

   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers,* for additional information.

11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

    For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

    If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

    If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

    If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

    If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

    If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Calcote, Joshua - Contractor, 59 MDW/SGVU	☐ YES ☒ NO	N/A

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

N/A

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

59th Medical Wing AAHRPP Questions of the Week

7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)

☒ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)
For posting in the 59th Medical Wing Email Bulletin and on the 59 MDW Clinical Research Division Knowledge Exchange Website

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
☐ YES ☒ NO ASSIGNED FILE # _____ DATE _____

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE	
N/A	

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	15. DUTY PHONE/PAGER NUMBER
Calcote, Joshua C. - joshua.c.calcote.ctr@mail.mil	210-292-7143

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Joshua C. Calcote	Contractor	59 MDW/SGVU	
b.			
c.			
d.			
e.			

17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE	19. AUTHOR'S SIGNATURE	20. DATE
Dr. Joshua C. Calcote, Contractor		February 13, 2017

21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	22. APPROVING AUTHORITY'S SIGNATURE	23. DATE
Dr. Earl Grant, Jr., GS-14, DAF	GRANT.EARL.JR.1126544380	February 13, 2017

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED February 14, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17097
26. DATE REVIEWED February 17, 2017		27. DATE FORWARDED TO 502 ISG/JAC

28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A

29. COMMENTS ☒ APPROVED ☐ DISAPPROVED

Questionaire for periodical. approved

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	31. REVIEWER SIGNATURE	32. DATE
Kevin Kupferer/GS13/Human Research Subject Protection Expert	KUPFERER.KEVIN.R.1086667270 Digitally signed by KUPFERER.KEVIN.R.1086667270 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=KUPFERER.KEVIN.R.1086667270 Date: 2017.02.17 14:58:32 -06'00'	February 17, 2017

2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA

35. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

39. DATE RECEIVED	40. DATE FORWARDED TO 59 MDW/SGVU
February 17, 2017	February 21, 2017

41. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	43. REVIEWER SIGNATURE	44. DATE
Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	IINUMA.KEVIN.MITSUGU.1296227613 Digitally signed by IINUMA.KEVIN.MITSUGU.1296227613 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=IINUMA.KEVIN.MITSUGU.1296227613 Date: 2017.02.21 12:04:26 -06'00'	February 21, 2017

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

47. COMMENTS ☐ APPROVED ☐ DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

59th Medical Wing AAHRPP Questions of the Week

What are the three (3) main protections established by the **Common Rule** (32 CFR 219)?	Answer
What are the three (3) basic ethical principles contained in the **Belmont Report**?	Answer
How does the IRB ensure that all research is appropriately reviewed during initial review (new studies); continuing review (re-approval of existing studies), and review of modifications to research studies (amendments)? **(7 required determinations)**	Answer
When a new research study is reviewed by the IRB, how is it determined that the risks have been minimized? When a new research study is reviewed by the IRB, how is it determined that the risks are reasonable in relation to the benefits? **(Minimize Risks/Maximize Benefits)**	Answer
Does research involving children include special requirements? What does the IRB consider when reviewing research involving children? How does the IRB obtain the information it considers when reviewing research involving children? **(Research Involving Children)**	Answer
What authority has been granted to the IRB independent of institutional leadership to ensure the protection of human subjects? **(IRB Authority and Independence)**	Answer
What policies and procedures are in place to ensure financial conflicts of interest (COI) of Researchers and Research Staff do not adversely affect the protection of participants, the integrity of the research, or the credibility of the Human Research Protection Program? What are the primary components that must be addressed as part of the comprehensive COI program? **(Conflicts of Interest)**	Answer

AAHRPP Prep Question of the Week

What are the three (3) main protections established by the Common Rule (32 CFR 219)?

1. Through a system of Institutional Review Board (IRB) registration and assurances, HHS regulations require institutions to commit to compliance with human subject protections before initiating federally-funded or -conducted research involving human subjects.

   The 59th Medical Wing (59 MDW) has registered its IRB and obtained a Federal-wide Assurance (FWA). The 59 MDW applies federal regulations to **all** research conducted at the institution regardless of the funding source. As required by the Department of Defense in order to conduct research involving human subjects, the 59 MDW also maintains a DoD Assurance.

2. All human research must be reviewed and approved by the institution's IRB.

3. All participants in human research must be provided informed consent to participate or the IRB must determine that waiver of consent is appropriate. The 59 MDW IRB reviews all studies for appropriate informed consent. In some types of minimal risk research, it is possible for the IRB to waive consent, but waiver of consent is rare.

AAHRPP Prep Question of the Week

What are the three (3) basic ethical principles contained in the Belmont Report?

1. **Respect for Persons** – Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

   In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. **Beneficence** – Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm; and (2) maximize possible benefits and minimize possible harms.

   The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

3. **Justice** – Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally.

   The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Justice demands that research does not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

   Source: http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/

AAHRPP Prep Question of the Week

How does the IRB ensure that all research is appropriately reviewed during initial review (new studies), continuing review (re-approval of existing studies), and review of modifications to research studies (amendments)?

The IRB uses a systematic process to review research applications. **All reviews**, whether they are requests for new research, re-approvals, or modifications are reviewed in accordance with the following the IRB Policies:

- HRPP OI-004, *IRB Approval of Research*
- HRPP OI-005, *Initial Review of Non-Exempt Human Research*
- HRPP OI-006, *Continuing Review*
- HRPP OI-007, *Review of Research Protocol Modifications*.

Important points to remember:
In order to approve research, the IRB or Expedited Reviewer shall determine that all of the following requirements are satisfied (The Seven (7) Required Determinations):

1. Risks to subjects are minimized;
2. The risks to subjects are reasonable in relation to anticipated benefits to subjects (if any) and the importance of the knowledge that may reasonably be expected to result;
3. Selection of subjects is equitable;
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative (or altered/waived as permitted elsewhere);
5. Informed consent will be appropriately documented (or altered/waived as permitted elsewhere);
6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (when appropriate);
7. There are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data (as appropriate).

AAHRPP Prep Question of the Week

NOTE: For new studies, IRB members use "Component Analysis" to determine whether the risks are minimized and the probability and magnitude of each benefit is the greatest possible, given the research aims (maximizes benefits). See HRPP OI-005, *Initial Review of Non-Exempt Human Research*.

When a new research study is reviewed by the IRB, how is it determined that the risks have been minimized?

Determining that the risks have been minimized is one of "The Seven (7) Required Determinations" in order to approve research.

- Each research component or procedure is listed in the IRB forms, including, how often the component/procedure is performed.
- The risks and benefits for each component/procedure are also provided in the IRB forms

The risks are minimized for the study as a whole if the IRB agrees that the probability or magnitude of each component risk is the least possible for addressing the research aims and does not unnecessarily expose participants to risk. Items the IRB may consider to ensure risks are minimized:

- Are all of the reasonably expected risks listed?
- Is the study design scientifically sound and likely to answer the research questions?
- Will an alternative research design, fewer procedures, and/or an alternative population reduce the likelihood/magnitude of harm while still achieving the purpose of the study?
- Does the research maximize the use of procedures already being performed for diagnostic or treatment (non-research) purposes?
- Is the rationale for each of the research procedures acceptable?
- Will fewer participants answer the scientific question(s)?
- Are the plans for data analysis justified?
- Are members of the research team qualified to perform the research procedures?
- Are staff, facilities, etc. adequate to deal with possible harmful sequelae?

When a new research study is reviewed by the IRB, how is it determined that the risks are reasonable in relation to the benefits?

Determining that the risks to subjects are reasonable in relation to anticipated benefits to subjects (if any) and the importance of the knowledge that may reasonably be expected to result is one of "The Seven (7) Required Determinations" in order to **approve** research.

Items the IRB may consider for each of the components that **offer** the prospect of direct benefits:

- The benefit is related to the component and applicable to all subjects exposed to the component.
- The risks related to each component is reasonable in relation to the associated benefit.
- The balance of risks and benefits for the components/procedures is equivalent to that associated with accepted practice (Research Equipoise).

Items the IRB may consider for each of the components that **do not offer** a direct benefit:

- The component contributes to answering the research question(s).
- The risks are justified by the potential benefit associated with the knowledge to be gained.

AAHRPP Prep Question of the Week

Does research involving children include special requirements?
Yes, HHS regulations provides additional protections for children participating in research involving human subjects. These additional protections include:

- Requiring IRB review of some research activities involving children that would be exempt if the research subjects were adults;
- Use of parental permission and child assent instead of the procedures for obtaining informed consent used for research involving adults;
- Review by the DHHS Secretary for research that an IRB finds not approvable; and
- Additional conditions for certain research activities involving children who are wards of the State or any other agency, institution, or entity.

What does the IRB consider when reviewing research involving children?

- The risks of the research are no more than minimal.
- The risks of the research are more than minimal, but the intervention or procedure holds out the prospect of direct benefit for the child or a monitoring procedure contributes to the child's well-being.
- The risks of the research are more than minimal, but the risk is justified by the anticipated benefit to the child.
- The risks of the research are more than minimal, but the relation of the anticipated benefit to the risk is at least as favorable to the child as that presented by available alternative approaches.
- The risks of the research are more than minimal, and the intervention or procedure does not hold out the prospect of direct benefit for the child, but the risk represents a minor increase over minimal risk.
- The risks of the research are more than minimal, and the intervention or procedure does not hold out the prospect of direct benefit for the child, but the intervention or procedure presents experiences to children that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.
- The risks of the research are more than minimal, and the intervention or procedure does not hold out the prospect of direct benefit for the child, but the intervention or procedure is likely to yield generalizable knowledge about the child's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition in children.

How does the IRB obtain the information it considers when reviewing research involving children?
The IRB requires the H23 Template – Research Involving Children to be submitted. The information about risks and benefits are detailed in this form.

AAHRPP Prep Question of the Week

What authority has been granted to the IRB independent of institutional leadership to ensure the protection of human subjects?

See HRPP OI-001, *Institutional Review Board*.

- To approve, require modifications to secure approval, or disapprove all human research activities overseen or conducted by the institution.
- To suspend or terminate IRB approval of human research not being conducted in accordance with the IRB's requirements or that had been associated with unexpected serious harm to participants.
- To observe, or have a third party observe, the consent process and the conduct of the research.
- To investigate allegations of non-compliance with institutional policies or research regulations for the protection of human subjects and reports of unanticipated problems.

  In cases where corrective actions are needed for non-compliance or unanticipated problems, the IRB may take appropriate actions, to include, but not limited to: requiring modifications, determining data collected cannot be used for publication, suspending or terminating approval, requiring additional education, disqualifying investigators from conducting research involving human subjects at the institution, and recommending to the institution's administration that further administrative action be taken.

Important points to remember:

- Officials of the institution, including the Institutional Official (IO) and Authorized IO (AIO), may NOT allow any human research to be conducted at the institution without the prior approval of the IRB.
- The IO, Maj Gen Bart O. Iddins, 59th Medical Wing (59 MDW) Commander, and/or the AIO, Dr. Debra M. Niemeyer, 59 MDW Chief Scientist, has the authority to NOT allow the conduct of a human research protocol at the institution even if it has been approved by the IRB.
- The institution does not tolerate attempts to unduly influence members of the IRB regarding the approval of research involving human subjects. Discoveries of suspected undue influence should be reported to the Clinical Research Administrator (Dr. Rocky Calcote) immediately.

AAHRPP Prep Question of the Week

What policies and procedures are in place to ensure financial conflicts of interest (COI) of Researchers and Research Staff do not adversely affect the protection of participants, the integrity of the research, or the credibility of the Human Research Protection Program?

- 59 MDWI 40-404, *Managing Conflict of Interest in Research*

What are the components that must be addressed as part of the comprehensive COI program?

- Disclosure of financial interests.
- Evaluation of disclosed financial interests for financial conflicts of interest.
- Management of financial conflicts of interest.
- Monitoring and enforcement of policies, reporting, and education.

Important points to remember:

- The policy applies broadly to research performed at the institution, regardless of funding source.
- All **Covered Individuals** must file and update financial disclosure statements. A "Covered Individual" is an individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research.
- A disclosure statement must include information regarding **Covered Family Members**. "Covered family members" include: a spouse, a dependent child or stepchild, other persons financially dependent on the covered individual, and persons with whom the covered individual has joint financial interests.
- The threshold for reporting financial interests is **$5,000**, received in the preceding 12 months from an entity, when aggregated.
- Reimbursed or sponsored **travel** in the preceding 12 months must be disclosed if the aggregated value of all payments from the sponsor/organizer exceeds $5,000.
- COI training must be completed before engaging in research and at least once every **four** years thereafter.
- The 59 MDW Form 14, *Financial Conflict of Interest Disclosure* must be submitted to the COI Manager (usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil) annually and when a new financial interest that requires disclosure is acquired.
- The **COI Manager** reviews each financial interest disclosure statement to determine if a significant financial interest (the financial interest appears to be affected by the research) could directly and significantly affect the design, conduct, or reporting of the research. Possibly conflicting disclosures are sent to the **Scientific Ethics Subcommittee (SES)** for determination.
- If a financial conflict of interest is determined, a **management plan** is developed to govern that conflict of interest. The management plan ensures the COI will not adversely affect the protection of participants or the integrity of the research.
- The day-to-day activities of COI policy compliance, including compliance monitoring for implemented management plans, is handled by the COI Manager.
- Neither the institution nor a covered individual may expend research funds unless the COI Manager or SES have determined that no COI exists or that any COI is manageable in accordance with the terms of a management plan that has been adopted and implemented.
- Research on human subjects by anyone holding a Significant Financial Interest will not be permitted without a compelling reason and an appropriate management plan approved by the IRB. The **IRB has the final authority** to determine whether the research in which the researcher has a COI and the management plan of that conflict, if any, allow the research to be approved.