



R&D Committee Communicator

VAMHCS

Volume I, Number I
January 2009

R&D Committee Forms and Procedures Have Changed

R&D committee procedures and forms have changed. If you have any forms please discard them. New forms are attached to this newsletter and, will soon be available for download from the Research Services website. Unfortunately, the website is not current at this time and the forms in the website are outdated.

New or revised submission forms or procedures include:

- R&D Committee Worksheet for Submitting a Human Subjects Research Project: This is a guide to help determine what forms are needed for each transaction; new, renewal, amendment, closeout; or for different types of studies; drug, devices, etc. As you go line by line through the form you will be advised on what materials are needed. Some of the materials need to be downloaded from BRAAN/CICERO including the study protocol, the investigator's brochure, the Annual Report (for continuing reviews), the HIPPA authorization form, the IRB approval letter, the VA con-

sent form (with the VA logo) and the study activity schedule which must designate research vs. clinical care. Complete **only** one worksheet for each submission and include both BRAAN and CICERO protocol numbers..

- ISO Data Security Checklist for Research Protocols: This form will be reviewed by the Information Security Officer and the Privacy Officer. Be sure to answer the questions thoughtfully. In addition describe your data security plan in section K of BRAAN/CICERO. (If you have any questions see HOT TOPICS Confidentiality and Privacy Vol. 2 No. 7 for details)
- Research Protocol Safety Survey (RPSS) or 10-0398: Human protocols may need review by the Subcommittee of Research Safety (SRS). You must complete page one and the signature page (P.5) If you marked yes to any questions ne you must complete the corresponding page. If you answered yes to IF you need to complete the "Use of Radioactive Materials" form. Do not submit the radia-



Call the R&D coordinator at 410-605-7000 ext 4528 if you have any questions about forms or submitting your protocol.

tion form if it does not apply to your study. You may be asked to answer a few questions to help determine if your study needs approval SRS

Continued on page 3

Meet the R&D Coordinator

On August 18th, 2008 the R&D committee welcomed Barbara Calabrese, RN, BA as the new R&D coordinator. Barbara comes to the VA with over 10 years of research experience having been a research nurse, research coordinator/manager at Johns Hopkins and Director of Research for a non-profit national medical organization.

"I'm looking forward to using my knowledge and skills to help VA researchers with their compliance requirements," said Ms Calabrese.

In addition to being a nurse, Ms Calabrese has a Bachelor's degree in psychology and a Masters Certificate in Adult learning. Ms Calabrese can be reached at

410-605-7000 ext 4528 or in room 3C140 (MS151). If you have any questions please feel free to contact her. Submissions of new protocols, amendments, renewals or study close outs should be sent directly to Ms Calabrese.

Inside this issue:

<i>Designating the VA as a Research site</i>	2
<i>Who to call</i>	2
<i>Research Services has Moved</i>	2
<i>Investigational Drug Agreements</i>	3
<i>Confirmation of Staff Research Training</i>	3
<i>R&D Forms and Procedures Continued</i>	3
<i>R&D Forms and Procedures Continued</i>	4

R&D Committee 2009 Meeting Schedule

- February 12
- March 12
- April 9
- May 14
- June 11

Yearly Mandatory VA Research Training

- CITI
- Good Clinical Practice
- VA Information Security 201
- VHA Cyber Security
- VA Privacy Training

New Look for the R&D Approval Letter

The R&D approval letter will now contain the date of the IRB approval in order to identify what action has been approved.

Subcommittee on Research Safety (SRS) Meeting Schedule

January 29, 2009
February 26, 2009
March 26, 2009
April 30, 2009

CICERO Update

Although CICERO is up and running at the University of Maryland it may be some time before the R&D submission process will be built into CICERO. It is hoped that this move will simplify and expedite the R&D process for the VAMHCS research community but until then investigators need to submit hard copies of their protocols to the R&D committee coordinator.

Designating the VA as a Research Site

If any of the following criteria apply to your study you must designate the VA as a site in your BRAAN/ CICERO submission and submit your protocol for R&D committee review.

Your project is a VA project if:

- It is VA funded
- Any part of the study is conducted within VAMHS, in leased VA space, or at an approved off-site location or facility
- Uses VA resources
- Recruits veterans from VAMHCS or its satellites
- Accesses VAMHCS medical records (SPRS) or databases

- Uses data from interventions or interactions with VAMHCS participants
- Uses tissue from VAMHCS participants or
- Is conducted by researchers with a VA appointments while on official VA duty.

NOTE: After receiving IRB approval and before proceeding with any VA related research activities you MUST have an R&D approval letter.

Who to Call:

For answers to your Research and Development Committee questions or to add staff to the R&D Committee Communicator email list contact:

Barbara Calabrese, RN, BA
R&D Committee
Coordinator
Room 3C 140

410-605-7000 ext 4528

Barbara.Calabrese@va.gov

For comments, complaints or suggestions regarding the Research Service or Office of Research Compliance, contact:

Jessica Mendoza, RN, BSN,
CCRC

Acting Research
Compliance Officer

Room 3A125

410-605-7000 Ext 6512

Jessica.Mendoza@va.gov

Research Services has Moved

Due to construction, the R & D staff and much of Research Services has moved. The following Research Service staff remains in 3A-125 :

Christopher Bever
David Johnson
Miriam Smyth
Shirley Rutledge
Rhonda Turner
Heather Riley

Office of Research Compliance:

Jessica Mendoza
Carol Minnich
Ronnie Dunford

The following Research Service administrative staff has moved to 3C-138:

Ann Kimball
Joanne Dailey
Holly Bowen
Cheryl Purvey

Angel Johnson

The following R&D Committee staff has moved to 3C-140:

Peggy Wess
Barbara Calabrese
R&D Committee assistant (TBA)

Investigational Drug Service Agreements

Investigational drug services agreements require a personal discussion with the Principal Investigator (PI) and the Investigational Drug Pharmacist (IDP). The purpose of this meeting is to familiarize the IDP with the level of Investigational Drug Services (IDS) involvement necessary for the study, to mutually agree on an IDS fee and to facilitate the start-up of the protocol by enabling the IDP to begin early discussions and preparations with the sponsor. When an agreement is reached the IDP and the PI will sign the Investigational Drug Service Agreement. The IDP will give the PI a copy of the signed agreement and a copy will need to be

sent to the R&D coordinator before the R&D committee can grant study approval.

This can be a length process so it is important to begin discussions with the IDP as soon as possible.

Call the IDP to arrange a meeting contact

Hai-Yan Jiang, Pharm.D.

410-605-7113

Hai-Yan.Jiang@va.gov

Confirmation of Staff Research Trainings

The R&D committee staff will no longer delay approval of a new protocol, renewal or amendment while waiting for confirmation of the study staff's research training. Only the PI's training will be checked. No approvals will be granted unless the PI's mandatory VA trainings and WOC are current. When submitting a new protocol, renewal or amendment to the R&D committee be sure to send the PI training certificates if they have been recently updated or if they have never been sent to the Research Service office.

Effect September 2008 it is the responsibility of the PI to ensure

that study staff are current with the VA research training requirements. At the time of an audit or other compliance site visit, the research staff training records will be checked. The PI is vulnerable to sanctions or corrective action if staff trainings are not current. Please note that trainings are not based on a January to January calendar year but one year from the date the last training was completed.

If interested, the R&D committee has a template available for tracking staff trainings.

Contact the R&D Committee coordinator at ext 4528 if you

have any questions or would like the training tracking template.

Contact Heather Riley at:

Extension 7131 or

Heather.Riley@va.gov

with a **list** of staff who need access to LMS. Please **do not** have each staff member call Heather individually.

R&D Committee Forms and Procedures (continued)

You will also need to attach chemical inventory and the protocol methods section.

- VA Form 10-9012: This form only applies to study drugs. If your study does not involve the use of study drugs you do not need to submit the form. Complete a 10-9012 form for EACH drug used in the study even if the drug is not investigational. The form must be typed. Informa-

tion from the 10-9012 can be pasted into your CPRS template for the Research Subject Clinical Warning section. Note: the use of investigational drugs requires a meeting with the IDP see the above news item for more information.

- The attestation forms need only be completed if the study uses investigational devices, equipment or if procedures are

performed as a part of the study. The "Attestation for the Use of Investigational Devices in the Conduct of Research" requires that the PI take responsibility for the proper management of the investigational device.

The "Attestation for the Use of Equipment in the Conduct of a Research Study" requires the PI to take responsibility for the proper use of ANY equipment used for research purposes even

What to submit to the R&D Committee?

- **New protocols**
- **IRB Continuing Renewals**

This will take the place of the R&D Annual Updates

- **All Protocol Amendments**

Some amendments may be processed through an administrative review or just be acknowledged, only the R&D Committee chair and staff can make this decision.

- **Study closures**

Did you Know?

You have **10 working days following IRB approval** to submit your renewal or amendment. Failure to do so can result in suspension of the study. See new procedures article.



VAMHCS

Baltimore Veterans Medical Center
10 N. Greene St
Baltimore, MD

Phone: 410-605-7000 ext 4528
Fax: 410-605-7992
E-mail: Barbara.Calabrese@va.gov

<http://www.maryland.research.va.gov/>

**Access to R&D
forms will soon
be coming to the
web!**

What Research Clinic will be used for this protocol?

NEW CLINIC NAME

BT CARDIOLOGY RESEARCH
BT DEPLETED URANIUM RESEARCH
BT DERMATOLOGY RESEARCH
BT DIABETES RESEARCH
BT ENDOCRINOLOGY RESEARCH
BT EPIDEMIOLOGY RESEARCH
BT GASTROENTEROLOGY RESEARCH
BT GRECC RESEARCH
BT GYNECOLOGY RESEARCH
BT HYPERTENSION RESEARCH
BT INFECTIOUS DISEASE RESEARCH
BT MEDICINE RESEARCH
BT MENTAL HEALTH RESEARCH
BT MIRECC RESEARCH
BT NEPHROLOGY RESEARCH
BT NEUROLOGY RESEARCH
BT NURSING RESEARCH
BT ONCOLOGY RESEARCH
BT OPHTHALMOLOGY RESEARCH
BT ORTHOPEDICS RESEARCH
BT OTOLARYNGOLOGY RESEARCH
BT PHARMACY RESEARCH
BT PHYSICAL THERAPY RESEARCH
BT PULMONARY RESEARCH
BT RADIATION ONCOLOGY RESEARCH
BT RADIOLOGY RESEARCH
BT REHABILITATION RESEARCH
BT RHEUMATOLOGY RESEARCH
BT SURGERY RESEARCH
BT UROLOGY RESEARCH

NEW ABBREVIATION

CARD
DU
DERM
DIAB
ENDOCRIN
EPI
GI
GRECC
GYN
BP
ID
MED
MH
MIRECC
NEPH
NEURO
NURS
ONC
EYE
ORTHO
ENT
PHARM
PT
PULM
RAD ONC
RAD
REHAB
RHEUM
SURG
UROL

R&D Committee Forms and Procedures (continued)

if the equipment itself is not investigational.

The "Attestation for the Performance of Procedures in the Conduct of a Research Study" requires the PI to take responsibility for research related procedures performed by him or herself or his or her research staff. This includes procedures performed solely for research purposes even if the procedure is not itself investigational.

- Outpatient Clinic Study visit notes need to be tagged to a Research Clinic in CPRS. See above for a list of research clinics in order to answer the question on the worksheet
- Clinical Trials Data Sheet
- Page 18 This form is used

to register PIs and the study in the VA automated protocol management system, ePromise. Failure to complete the form will delay study approval.

- Closeout requirements: PI's must notify the R&D committee when they close a study. Complete the R&D Committee Worksheet and attach the necessary forms before sending to the R&D office.
- VAMHCS research may continue without interruption while awaiting R&D renewal and R&D approval for amendments (under the new amendment) as long as the renewal or amendment has been submitted within ten (10) working days of the IRB approval. Amendments or renewals submitted after the ten

working day rule place the study at risk of suspension.

- Other changes include:
- The PI has 90 days to resolve any R&D contingencies otherwise the study risks being suspended.
- Although a the R&D needs to be notified of all amendments some do not need to be approved and will only receive an acknowledgement letter. Acknowledgement and approval letters should be kept in the study regulatory binder.
- The PI is responsible for uploading the R&D approval or acknowledgement letters into BRAAN/ CICERO



WOC questions contact Teia Fenwick at ext 7130