

GCRC
DATA AND SAFETY MONITORING
Standard Operating Procedures And Policies

1.0 Background

In 1994, the National Institutes of Health's Office of Extramural Research established a Committee on Clinical Trial Monitoring to review the oversight and management practices of Phase III clinical trials. One of the outcomes of this review was a strong recommendation that "all studies, even those that pose little likelihood of harm, should consider an external monitoring body."

In 1998, NIH issued the "NIH Policy for Data and Safety monitoring," describing its monitoring requirements for clinical studies.

More recently, the Office of Inspector General of the Department of Health and Human Services issued "Protecting Human Research Subjects: Status of Recommendations." This report, issued in April 2000, states that "problems in gene transfer trials should be a catalyst for greater attention to be directed to ensuring human-subject protection of a broader universe of clinical trials, particularly those in which patients face significant risk." The report was followed in June 2000 by additional communications from the NIH: "Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials," "Required Education in the Protection of Human Research Participants," and "Financial Conflicts of Interest and Research Objectivity."

Beginning with the October 1, 2000 grant deadline, investigators submitting proposals to the NIH are required to include a detailed monitoring plan as part of Phase I and Phase II protocols. The monitoring plan must be submitted to the local Investigational Review Board (IRB) for review and approval before the studies begin. Consistent with that requirement, the Advisory Committee to the Director of the NCCR has recommended that all General Clinical Research Center (GCRC) protocols have a data and safety monitoring plan (DSMP) that includes periodic review and reporting as appropriate for each study.

Supporting Regulations/Policy Guidelines

45 CFR Part 46 Subpart A

NIH Policy for Data and Safety Monitoring (NIH Guide June 10, 1998).

Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multi-Center Clinical Trials (NIH Guide June 11, 1998).

2.0 Overview

In accordance with the NIH requirements, the GCRC has developed a basic Data and Safety Monitoring standard operating procedures and policies. All study principal investigators (PI) are required to adhere to the policy.

Within the GCRC, the General Clinical Research Center Advisory Committee (GCRC Advisory Committee), the Research Subject Advocates (RSAs) and the Safety Monitoring Committee (SMC) provide the infrastructure for scientific oversight and monitoring of GCRC related clinical studies. As required by the NIH, all studies conducted within the GCRC must also be approved by the Human Investigation Committee (HIC).

Ultimately it is the responsibility of the study PI to provide continual monitoring of his/her clinical trial. As part of the GCRC Data and Safety Monitoring Policy and Procedures, the SMC and the Research Subject Advocates (RSAs) aid in overseeing the safety, conduct and progress of the study.

3.0 Initial Protocol Review Process

All protocols conducted through the GCRC must incorporate, in their design, a plan for data and safety monitoring (DSMP) consistent with the potential risks and size of the trial. The plan should be submitted with the GCRC application utilizing Appendix 8 of the application template. As a part of the scientific review process, the plan will then be reviewed and approved by the GCRC Advisory Committee.

Once a study is submitted to the GCRC for initial approval, the DSMP will be reviewed first by the RSA, who will evaluate the DSMP based upon enrollment of vulnerable population and the degree of risk associated with participation in the trial. The RSA will utilize a DSMP review checklist to review the plan. If there is a need for questions and suggested improvements, the RSA will contact the Principal Investigator (PI) no later than the Friday prior to the GCRC Advisory Committee meeting in which the trial is to be reviewed. The Investigator may make the changes to the DSMP prior to the meeting. However, if the PI chooses to wait until after the GCRC Advisory Committee meeting to make changes he/she will have the comments of the entire committee and will only need to make changes once. The RSA will then submit his/her review and recommendation of risk classification and of approval to the GCRC Advisory Committee. The GCRC Advisory Committee will then vote to approve, approve with changes or reject the study.

If the DSMP is approved with changes, the PI will make the necessary changes and submit back to Lynn Simpson who will direct it to the appropriate RSA for final approval.

Exempt studies will not require GCRC Advisory Committee assessment of DSMPs.

Studies involving cancer subjects will have a previously approved data and safety monitoring plan, either at the National Cancer Institute (NCI) level or the Cancer Center Protocol Review Committee. These studies will not require GCRC Advisory Committee assessment of their plan.

3.1 Risk Classification

The required elements of a Data and Safety Monitoring Plan for a study are dependent on the magnitude of risk to which research subjects are exposed. The following basic

guidelines will be used by the RSA/GCRC Advisory Committee to help determine the level of risk:

Minimal Risk

- Study is eligible for expedited HIC review

Moderate Risk

- Low risk intervention in a population at risk for serious clinical events based on underlying disease
- Intervention of undefined risk or intervention with low frequency of serious adverse events
- An approved drug with a well-known adverse event profile, and includes physiologic measurements that carry little risk to the participant.

High Risk

- Intervention associated with risk of serious adverse events at high or uncertain frequency
- Experimental therapies will be administered including all new drug INDs or investigational device exemption
- Study involves population with very high risk of serious adverse clinical events based on underlying disease or in whom assessment of treatment associated adverse events may be difficult
- Gene transfer study

4.0 Data and Safety Monitoring Plan Requirements

A DSMP template is provided as an appendix to the GCRC submission form. The template will help investigators address all of the aspects listed below:

- Description of anticipated adverse events
- Adverse event grading and attribution
- Plans for reporting adverse events
- Description of the data to be captured and the forms to be used, and how those will be used to assure safety
- Description of who will be performing the safety reviews
- Description of safety monitoring to include who will provide oversight for the monitoring plan, how often they will meet, how often they will report results, and what information will be reviewed.

Guidelines for each of these elements are discussed in the rest of this document.

4.1 Data and Safety Monitoring Plan requirements for Studies open to enrollment prior to August 2003 without DSMPs.

The requirement for an approved GCRC Advisory Committee, DSMP for all GCRC protocols will be mandatory beginning with the June 2003 submissions. For those

protocols open prior to August 2003 a DSMP will be completed prior to the HIC annual renewal. HIC annual continuation notices will be sent to the PI of the protocol 2 months prior to the HIC meeting in which the study will be reviewed. For GCRC studies needing an updated DSMP, the RSA will send out a notice **12 weeks** prior to the protocol's annual renewal date. The PI will complete the DSMP template and submit to the RSA/GCRC Advisory Committee within 2 weeks of notification. The plan will be placed on the next available GCRC Advisory Committee review meeting agenda. The RSA assigned will utilize a DSMP review checklist to review the plan. . If there is a need for questions and suggested improvements, the RSA will contact the Principal Investigator (PI) no later than the Friday prior to the GCRC Advisory Committee meeting in which the trial is to be reviewed. The Investigator may make the changes to the DSMP prior to the meeting. However, if the PI chooses to wait until after the GCRC Advisory Committee meeting to make changes he/she will have the comments of the entire committee and will only need to make changes once. The RSA will then submit his/her review and recommendation of risk classification and of approval to the GCRC Advisory Committee. The GCRC Advisory Committee will then vote to approve or disapprove the plan.

If the DSMP is approved with changes, the PI will make the necessary changes and submit back to Lynn Simpson who will direct it to the appropriate RSA for final approval.

Once the GCRC Advisory Committee has approved the study, it can then be submitted to the HIC for annual continuation review.

4.2 Adverse Event Reporting Guidelines

4.2.1 Definition of serious adverse event:

A serious adverse event is defined as an undesirable sign, symptom, or medical condition which is fatal, is life-threatening, results in persistent or significant disability/incapacity, requires or prolongs hospitalization, constitutes a congenital anomaly or birth defect, or an important medical event when, based upon appropriate medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent one of the above outcomes. All serious adverse events should be reported to the HIC, RSA and to appropriate sponsors within 24 hours of notification of event. (See the HIC SOPs for further guidance on SAE reporting.)

4.2.2 Definition of adverse event:

An adverse experience (AE) is any unwanted physical, psychological, or behavioral effect experienced by a patient or healthy volunteer, during or subsequent to administration of a drug/procedure for treatment or clinical investigation, regardless of whether it is considered related or not.

4.2.3 Adverse Event Grading/Attribution

All adverse events should be categorized or graded according to severity and then determined what relationship the event had to the study. Each protocol may have a

unique approach to grading AEs. The PI should consult the master protocol and/or the funding source for specific grading scales.

It is strongly recommended that if a protocol does not already have a specific grading scale, the World Health Organization Toxicity Criteria be used (<http://www.accessdata.fda.gov/scripts/cder/onctools/toxicity.cfm>).

An example of an attribution scale is as follows:

- Definite: AE is clearly related to the investigational agent/procedure
- Probable: AE is likely related to the investigational agent/procedure
- Possible: AE is may be related to the investigational agent/procedure
- Unlikely: AE is doubtfully related to the investigational agent/procedure
- Unrelated: AE is clearly not related to investigational agent

All studies utilizing the GCRC will report adverse events as follows:

UNEXPECTED EVENT		EXPECTED EVENT	
RATED MODERATE (GRADES 2 – 3) Attribution of Possible, Probable or Definite	RATED SEVERE (GRADE 4) Regardless of Attribution	RATED MILD OR MODERATE (GRADES 1 – 3)	RATED SEVERE GRADE 4 Regardless of Attribution
Report within 10 working days to GCRC-RSA.	Report within 10 working days to GCRC-RSA.	Adverse Event Reporting to HIC, RSA not required.	Report within 10 working days to GCRC, RSA.

Send AE reports to the GCRC RSA office:

Via messenger mail: Walt Davis, MD
Box 800758

Or electronically to Walt Davis, MD wsd3e@virginia.edu

If you have questions or need help, please contact one of the RSAs:

Phone 434-982-4311 (Karen Parks, RN)
434-924-5492 (Walt Davis, MD)

Fax 434-243-5999

Email wsd3e@virginia.edu
knp@virginia.edu

4.2.4 Adverse Event Report Form

An adverse event report form is available for download on the GCRC website or hard copies are available through the RSA or the Administrative Director. A report form should be used by study staff to keep track of adverse events throughout the protocol and as a useful tool for summarizing adverse events for the HIC annual renewal. Studies that

do not provide an adverse event report form for recording and reporting AEs are strongly encouraged to use the GCRC provided form.

4.3 Data and Safety Monitoring

The DSMP will describe the proposed plan for interim data monitoring. This plan will detail who is to be responsible for interim monitoring. (i.e. the study investigator, the SMC, a DSMB, etc.), what data will be monitored (i.e. performance and safety data only vs. efficacy data as well,) the timing of the data review (e.g., based on the number of subjects enrolled, as events occur, etc.)

The plan will specify “stopping guidelines” and other principles for the monitors to follow in their review of the interim data.

4.3.1 Data Safety and Monitoring Boards (DSMB)

A DSMB will be required for multi-center trials and all phase III clinical trials, including industry-sponsored studies. Studies that involve vulnerable populations, are blinded, are multi-institutional UVA investigator-initiated and are considered high risk may require a DSMB, depending on the nature of the study. If DSMBs are not readily apparent for a particular study, investigators are encouraged to contact the Research Subject Advocates for advice. For studies requiring a DSMB, a description of the board must be provided to the GCRC in the Data and Safety Monitoring Plan. This description should include:

- A list of the board chair and members and their qualifications
- The frequency with which the study will be evaluated
- A description of how interim efficacy analysis will be performed
- How often reports will be received from the Board.

All DSMB reports are to be forwarded to the HIC and the RSAs.

The meeting frequency of the Data and Safety Monitoring Board, its composition and its responsibilities should be tailored to the design and risks of each trial. The board should include a group of individuals with sufficient expertise to make safety decisions for the trial at hand (i.e. Clinicians, statisticians, ethicists, epidemiologists and scientists from other fields). None of the board members should be affiliated with the study.

5.0 Compliance

Compliance to GCRC clinical studies is monitored in several ways. Primary responsibility lies with the study PI. The HIC, GCRC Advisory Committee, SMC, RSAs, and external monitoring boards or agencies provide additional oversight to study compliance.

5.1 Investigator Responsibilities

Ultimately it is the responsibility of the study PI to provide continual monitoring of his/her trial and to ensure that the DSMP is followed. The PI is responsible for ensuring that all data required for oversight are accurately reported to the internal or external monitoring committee as required and all adverse events are reported according to protocol guidelines. Investigator responsibilities include:

- Complete DSMP

- Respond and take appropriate action to issues raised by the SMC, GCRC Advisory Committee or HIC.

5.2 Research Subject Advocates

All serious adverse events (SAE) will be reported by the study team within 24 hours of notification to one of the RSAs and the HIC. The RSA will review the SAE and make immediate recommendations to the investigator as needed. The RSA will present the recommendations at the next GCRC Advisory Committee meeting. If a SAE involved a death that was felt to be definitely related to the study, the RSA will work with the HIC to take appropriate action.

5.3 Safety Monitoring Committee (SMC)

The SMC aids in overseeing the safety and compliance of GCRC Advisory Committee approved GCRC studies. The Committee is chaired by the Research Subject Advocate (RSA) Medical Director and is comprised of a physician, GCRC nurse manager, Informatics Core Manager, GCRC administrator, Research Subject Advocate secretary, GCRC HIC coordinator, Protocol Nurse Manager, and the Research Compliance and Education Coordinator/RSA. On an every month basis the SMC reviews all adverse events that are reported to the HIC and RSAs. Study AE's are to be reported as indicated in section 4.2. This information will be retrieved for review by the RSA prior to the SMC meeting. All AEs that have occurred since the prior meeting will be reviewed. The RSA will provide the committee with a report of AEs by event, grade and frequency. In addition, descriptions of the adverse events will be summarized. The SMC will review frequencies of AE's, cumulative incidence of AEs over time as well as newly reported AE's since the prior meeting. Patterns or AEs of major concern will be flagged and reported. These patterns, as well as a summary of all SMC activities will be presented to the GCRC Advisory Committee which meets the afternoon of the SMC meeting. It is the responsibility of the GCRC Advisory Committee to review the information and determine what, if any, action should be taken. The GCRC Advisory Committee will notify the HIC and PI if immediate action is required.

At each SMC, HIC annual approvals for protocols on the GCRC occurring within the past quarter will be reviewed. During the same time interval, quality improvements issues that may have arisen during quality assurance reviews, as described in the next section, will be submitted to the SMC for review and discussion.

5.4 Quality Assurance Reviews

As part of the GCRC DSM process, quality assurance reviews will be performed. The quality assurance review is an informal, comprehensive, source document review of any GCRC trial not otherwise monitored by an external agency. The purpose of QA review is to ensure that documentation of clinical research studies is of the highest quality, verify protocol adherence, and ensure that all federal and local rules concerning clinical research are being fulfilled. Areas addressed in QA reviews include consent and regulatory procedures, eligibility criteria, treatment administration, reporting of adverse events, adherence to HIC policy, and compliance with Good Clinical Practices (GCP).

5.4.1 Selecting protocols for Quality Assurance Reviews

Protocols will be chosen through random selection utilizing the HIC and/or General Clinical Research Center (GCRC) database. For protocols to be selected at random for a quality assurance (QA) review, they will need to meet one or more of the following criteria:

- 1) Those that involve human subjects with expected enrollment of >10, currently with active approval status and not involving observational or data collection.
- 2) Those considered moderate to high degree of risk to the research subject as defined by:
 - a) Phase or nature of study (phase I, gene transfer)
 - b) Number of adverse events occurring (or potential for AEs)
 - c) Patient population to be enrolled (vulnerable subjects)
- 3) Those utilizing federal or internal funding.
- 4) Those with limited oversight or monitoring:
 - a) Principal investigator as the sole monitor
 - b) No outside Data Safety Monitoring Board (DSMB) involved
 - c) Junior investigators or inexperienced team members who may benefit from a QA review

5.4.2 Notification of review and selection of research subjects' record

A letter will be sent to the Principal Investigator (PI) notifying him/her that his/her study has been selected two to four weeks prior to review. The scope of the review and the specific areas to be reviewed will be addressed with a request for the necessary records and resources. In addition, the reviewer will request a list of all study subjects from the principal investigator/study coordinator. The list will be limited to the research participant's initials or medical history number and their date of study enrollment. From this list, the records to be reviewed will be selected by the Research & Compliance Coordinator and then made known to the PI/study coordinator.

The scope of a review will vary according to the level of risk imposed on the research subjects. The risks will be assigned by the HIC at the time of initial review:

- 1) If the trial has been deemed minimal risk, 10- 20% of the total subject enrollment will be reviewed.
- 2) For moderate risk studies, 30% of the subjects will be reviewed.
- 3) For high risk or vulnerable populations, 50-100% of the subjects will be reviewed.

A follow-up contact will be made approximately 1 –2 weeks after the investigator is notified in writing, to answer any preliminary questions and to schedule a time to review the study documents.

5.4.3 In the QA review, the following parameters will be reviewed:

- Screening labs, safety tests, examinations, and observations
- Subject eligibility criteria
- Adherence to the protocol
- Occurrence of adverse & serious adverse events

- Adverse event reporting to sponsor, IRB, FDA, and National Institutes of Health (NIH)
- Use of stopping rules
- Report of aggregate analysis & Data and Safety Monitoring reports
- Frequency of monitoring
- Reporting mechanism of study staff to PI
- Approved protocol, amendments, and HIC correspondence
- Screening Logs
- Signed consent forms
- Regulatory binders and documentation
- Medical Records, laboratory results, &/or shadow files
- Drug or device storage, labeling and dispensing
- Case Report Forms or study worksheets

5.4.4 Documentation and Dissemination of Review Findings:

Objective findings obtained by the review process will be documented on worksheets. These findings will be measured against defined standards described in the International Conference on Harmonization Guideline on Good Clinical Practice and in the Code of Federal Regulations. A rating scale will be used to assign a criticality to the findings in the following manner:

Exceptional	Evidence of good source documentation, data quality, protocol and regulatory compliance.
Satisfactory	Few minor deviations noted. Major deviations identified during the review but have been addressed and/or corrected prior to the review.
Acceptable, needs follow up	Multiple minor deviations identified. Major deficiencies identified and not corrected and/or addressed prior to the review.
Unacceptable	Multiple minor deviations identified. Major deficiencies identified not corrected and/or addressed prior to the review.

A summary report will be given upon completion of the QA review. This report will contain the findings of the review and recommendations from the Compliance and Education Coordinator for corrective action. This report will only be shared with the PI, unless there are issues that pose significant risk to the subject, the investigator or the institution. If there is an issue deemed critical, the Compliance Coordinator may share reports of the QA review with the GCRC Director and/or the HIC as necessary. Periodically, through out the year aggregate statistical summaries of all reviews will be shared with the GCRC Advisory Committee, the Clinical Trials Office Advisory Committee, the HIC and the other administrative officials. Through constructive

feedback implementation of training programs and initiatives to improve processes and procedures may be made.

Confidentiality

In performing the study review, the Compliance and Education Coordinator will take all reasonable precautions to maintain the confidentiality of subjects' identities and sponsor's proprietary information.

All review reports will be kept confidential. Copies of review reports will be kept in a locked file cabinet in the University of Virginia Clinical Trials Office. Access will be limited to the Research Compliance Coordinator.

5.4.5 Recommendations of Protocol Termination

Grounds for suspension or termination of a protocol by the GCRC Advisory Committee include, but are not limited to, stopping rule violations or major violations in the conduct of the study that result in an unacceptable quality assurance review. PIs may appeal protocol closures to the GCRC Advisory Committee to reopen a study by submission of a corrective action plan and by attending the GCRC Advisory Committee meeting at which the plan will be reviewed and discussed.

The decision to recommend suspension or termination of a protocol is carefully considered and takes into account whether corrective actions requested at previous reviews were implemented. If the decision is made to recommend suspension or termination of a protocol, the recommendation will be made in a letter to the PI. A copy letter will be sent simultaneously to the chair of the appropriate HIC.

Appendix I

General Clinical Research Center University of Virginia School of Medicine

Data and Safety Monitoring Plan Review

Title of Project	
Principal Investigator	
GCRC#	
HIC #	
Reviewer(s)	
Date of Review	
Funding Source	

Study Design

Study Phase: I Physiology Site: Single
 II Outcome Multi
 III Other - specify
 IV _____

Blinded: No Controls: None, open-label
 Yes, single blinded Placebo-controlled
 Yes, double blinded Active control

UVA Cancer Center Study?: Yes No

Internal DSMC?: Yes No

External DSMB/DSMC?: Yes No

Subject Vulnerability Assessment

- | | |
|---------------------------------------------------------|-----------------------------------------------------------------------|
| <input type="checkbox"/> Minors under age 18 | <input type="checkbox"/> Pregnant women |
| <input type="checkbox"/> Cognitive impairment | <input type="checkbox"/> Rare disease |
| <input type="checkbox"/> Terminal illness | <input type="checkbox"/> Prisoners |
| <input type="checkbox"/> Language barrier | <input type="checkbox"/> Physical impairment |
| <input type="checkbox"/> Sensitive information recorded | <input type="checkbox"/> Psychological risk |
| <input type="checkbox"/> Progressive disease | <input type="checkbox"/> Fluctuating or unpredictable clinical status |
| <input type="checkbox"/> Other – specify: | |

Risk Assessment

Minimal Risk

- Study is eligible for exemption from HIC review
 - Study is eligible for expedited HIC review
 - Research on drug(s) for which IND not required
 - Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
 - Prospective collection of biological material or specimens for research purposes only and by non-invasive means
 - Collection of data through non-invasive means
 - Other – describe:
-

Moderate Risk

- Low risk intervention in a population at risk for serious clinical events based on underlying disease
 - Intervention of undefined risk or intervention with low frequency of serious adverse events
 - Low risk study in vulnerable population
 - Other – describe:
-

High Risk

- Intervention associated with risk of serious adverse events at high or uncertain frequency
 - Study involves population with very high risk of serious adverse clinical events based on underlying disease or in whom assessment of treatment-associated adverse events may be difficult
 - Gene transfer study
 - Phase III comparative clinical investigation
 - Other – describe:
-

Adverse Event Reporting Comments	Yes	No	N/A
Is the study definition of an “adverse event” included in the plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the definition of a “serious” adverse event included in the plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan describe what events will be Reported to the HIC in an expedited manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan describe what events will be reported to external entities (such as sponsor, study medical monitor, DMC, FDA, NIH, etc.) in an expedited manner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, does the plan indicate which entities will be notified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan indicate the time frame for expedited reporting?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan include how adverse events will be captured? (report by subject, physical examination, laboratory reports, medical records, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan indicate what information regarding the adverse event will be collected? (onset date, duration, severity, relationship to the investigational agent, action taken with investigational agent, outcome.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Safety Monitoring

Does the plan indicate who is responsible for the overall safety monitoring of the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan include rules for stopping the investigational agent in an individual subject for safety concerns?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan include a review of the safety data in aggregate form?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan indicate who will conduct the review?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the plan specify the safety information that will be reviewed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If there is an external data and safety monitoring entity (DSMB, DSMC, etc.), does the plan specify membership of the entity, schedule of meetings, as well as content, frequency, and distribution list for reports?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RSA Recommendation: _____ **Approve DSMP**
_____ **Approve DSMP with modifications**
_____ **Do not approve DSMP**

Appendix II

GCRC Data and Safety Monitoring Committee

- | | | |
|----|--------------------------|------------------------------------------------------------|
| 1. | Dr. Walt Davis | wsd3e@virginia.edu |
| 2. | Ms. Sandra Ware-Jackson | msj@virginia.edu |
| 3. | Ms. Helena Estes-Johnson | hve5r@virginia.edu |
| 4. | Ms. Karen Parks | knp@virginia.edu |
| 5. | Mr. Martin Phillips | mtp0f@virginia.edu |
| 6. | Ms. Lynn Simpson | lss2f@virginia.edu |
| 7. | Ms. Pam Sprouse | pfs2h@virginia.edu |
| 8. | Dr. Mary Lee Vance | mlv@virginia.edu |
| 9. | Ms. Charlotte G. Bailey | cb3t@virginia.edu |

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