

THE WOMEN'S INTERAGENCY HIV STUDY

SECTION 44: ECG PROTOCOL

A. BACKGROUND

The advent of potent antiretroviral therapy (ART) has transformed the care of HIV infection, with life expectancy for people living with HIV now approaching that of the general uninfected population.¹ A counterweight to this success, however, is the finding that HIV-infected individuals receiving ART are susceptible to a range of chronic aging-related diseases.² Notable among these is atherosclerotic cardiovascular disease (CVD), which is a major factor accounting for the rise in non-AIDS mortality among people with HIV.³ Indeed, studies have shown that HIV-infected people have a 1.5-fold risk of coronary heart disease (CHD) events as compared with their HIV-uninfected counterparts.⁴

Various factors have been cited to account for increased CVD risk. These include persistent immune activation and inflammation resulting from translocation of gut bacteria following obliteration of mucosal adaptive immunity during initial HIV infection or from persistence of HIV in tissue reservoirs; associated co-infections, such as HCV, and consequent hepatic fibrosis; a high burden of behavioral and traditional atherosclerosis risk factors among HIV-infected individuals; and off-target effects of ART on metabolism and mitochondrial function.⁴ The importance of proper control of HIV to reduce clinical CHD events has been documented in various cohorts composed predominantly of men.⁴ Additional evidence for this in women has come from studies applying carotid ultrasound to measure subclinical atherosclerotic disease in the Women's Interagency HIV Study (WIHS) and the Multicenter AIDS Cohort Study (MACS), which have shown that low CD4+ T-cell count and/or increased immune activation and senescence are associated cross-sectionally with carotid atherosclerosis and carotid stiffness in HIV-infected versus HIV-uninfected individuals.⁵⁻⁷ More recently, a longitudinal evaluation in WIHS and MACS participants showed that HIV-infected individuals had a 1.6-fold greater risk of new carotid atheroma formation after adjusting for cardiometabolic factors as compared with HIV-uninfected individuals.⁸ A similar increase in risk of new carotid plaque formation was seen even among HIV-infected participants with persistent viral suppression relative to their HIV-uninfected counterparts.⁸ Notably, these heightened risks of carotid atheromatous disease were comparable in women and men, underscoring similar susceptibility in both sexes.

Apart from the impact on atherosclerosis, however, there is evidence that HIV and related factors have important effects on the myocardium.⁹ This is highlighted by the finding of marked prevalences of mild left ventricular systolic dysfunction and, especially, diastolic dysfunction by echocardiography in studies of HIV-infected individuals receiving ART.¹⁰ Such abnormalities may result from increased myocardial fibrosis or fat deposition as a result of HIV, other pathogens, associated risk factors, or ART.¹¹ In accord with these findings, the risk of incident heart failure has been documented to be higher in HIV-infected than HIV-uninfected individuals.¹² Furthermore, there are reports that HIV-infected people have an increased risk of atrial fibrillation,¹³ as well as a heightened risk of sudden cardiac death.¹⁴

In connection with dysrhythmic events in particular, mouse models have shown that HIV itself leads to prolongation of repolarization through a direct influence on K⁺ channels.¹⁵

Moreover, a variety of ART and other drugs frequently used in the context of HIV are well known to prolong the QT interval, thereby increasing the risk of torsade de pointes and sudden cardiac death.¹⁶ Such associations have been explored in several clinical reports, which have found HIV, and especially advanced or uncontrolled HIV infection, to be associated with QTc prolongation.¹⁶⁻¹⁹ Nevertheless, these reports have had limited sample size, have been uncontrolled or lacked well-matched HIV-uninfected control groups, and have had only limited characterization of HIV-related factors and therapy.

Additional information on dysrhythmia risk can be obtained from assessment of abnormal autonomic tone, as it is established that HIV's neurotropism leads it to affect the autonomic nervous system.²⁰ In fact, assessment of heart rate variability (HRV) through time-domain measures available on a 10-second ECG strip have been shown to be prognostic for mortality in non-HIV infected cohorts.^{21, 22} Analysis of such time-domain HRV measures has been applied at baseline to mostly ART-treated HIV-infected men participating in a large clinical trial, showing that non-boosted protease-inhibitor use was associated with greater HRV than non-nucleoside reverse transcriptase-inhibitor use.²⁰

While there is considerable evidence of ischemic and non-ischemic myocardial disease in connection with HIV infection, there remain gaps in understanding the extent and especially the basis for the heightened risk of dysrhythmia in people living with HIV, particularly in women. Assessment of ECG abnormalities and autonomic dysfunction in the WIHS will provide important information on the scope of electrical cardiac derangements and their determinants in this understudied population.

B. REFERENCES

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C. SPECIFIC AIMS AND HYPOTHESES

Our overarching hypothesis is that HIV infection leads to abnormal cardiac autonomic function and results in more common ECG derangements in women, and that HIV-specific factors associated with poorer control or specific medications heighten such aberrations. We will address the following specific aims:

AIM 1. To compare measures of HRV (i.e., time-domain measures) and electrical abnormalities (e.g., atrial dysrhythmias, conduction block, prolonged QTc) obtained by 12-lead surface ECG in HIV-infected and HIV-uninfected women after adjustment for behavioral and clinical risk factors.

AIM 2. To evaluate the relationship of HIV-specific factors (CD4+ T-cell count, antecedent persistent viral suppression) and medications (protease inhibitors, specific nucleoside reverse transcriptase inhibitors, antibiotics, antihistamines) with HRV and ECG abnormalities in women with HIV infection.

D. RELEVANCE TO WIHS

The proposed study addresses high-priority HIV/AIDS research areas, namely, the comorbidity of cardiovascular disease associated with long-term HIV disease and antiretroviral therapy, and the problem of health disparities in this regard. There are clear synergies, notably with ongoing echocardiography and cardiac magnetic resonance imaging in the Bronx and Brooklyn field centers of the WIHS, and the extension of echocardiography to remaining field centers. Such different cardiac assessment modalities will allow parallel investigation of electrocardiographic and cardiac structural and functional features in the WIHS cohort. In addition, the ECG abnormalities may be linked to cardiovascular events in the future, allowing assessment of their implications for cardiovascular morbidity and mortality in the cohort.

E. OVERVIEW

The proposed study plans performance of 12-lead ECG in all active consenting participants of the WIHS (n=2355), allowing cross-sectional evaluation of the role of HIV and HIV-related factors as determinants of ECG and short-term HRV abnormalities in this cohort.

The major steps in the WIHS ECG Study research plan are as follows:

- 1) Development of protocols and procedures led by the PI, EPICARE ECG Reading Center (ERC), site PIs, and WDMAC
- 2) Submission of IRB modifications
- 3) Purchase of ECG machines
- 4) Training of site project directors and staff at a centralized reading session organized by EPICARE Reading Center
- 5) Site certification of ECG staff following successful transmission of 2 qualifying studies
- 6) Teleconference with WIHS Project Directors to review study procedures/alerts
- 7) Provision of continual feedback to ECG staff by local cardiologists and ERC
- 8) NHLBI staff will monitor project progress and research direction by attending:
 - a) Biannual WIHS EC in-person meetings
 - b) Monthly WIHS ECG Study Group conference calls, as necessary
 - c) Bi-weekly WIHS EC teleconference calls
 - d) Possible informal site visits to understand the site operations in conducting the WIHS ECG Study
 - e) Meeting with WIHS investigators at national conferences such as the annual American Heart Association Scientific Sessions and the Conference on Retroviruses and Opportunistic Infections

F. TIMELINE

The ECG study is planned for Visit 47 only (October 1, 2017 through March 31, 2018). The ECG should be performed at the core visit. In circumstances where it is impossible to do the ECG at the core visit, but the participant is willing to return for a separate visit, schedule the ECG within 4 weeks of the completed core visit.

If the site is not able to complete the ECG at the core visit or within 4 weeks of the core visit, the site should complete the ECG during the Visit 48 core visit.

G. ROLES OF ERC, WIHS SITES, WDMAC

1. EPICARE ECG READING CENTER (ERC)

Dr. Elsayed Soliman will lead the ECG Reading Center at Wake Forest (EPICARE). Dr. Soliman will assist with development of protocols and procedures at the sites; lead the centralized training session for site project directors and staff; oversee efforts to ensure successful transmission of ECG data to the ERC and the maintenance of ECG data quality; implement interpretation of ECGs using Minnesota coding and Nova coding, along with quantitative measures of ECG waveforms; conduct analyses of heart rate variability measures; and assure timely transmission of ECG data to WDMAC. EPICARE has extensive experience in the conduct and interpretation of ECGs in multi-center prospective cohort studies, and will lend its expertise to the successful execution of the proposed study.

WIHS SITES

SITE ACTIVITIES: Procedures and protocols for the local performance and interpretation of ECGs across all WIHS sites will be developed by the WIHS ECG PI, Dr. Jorge Kizer, in collaboration with Dr. Soliman, the WIHS PIs, and WDMAC. The sites will submit IRB protocols for approval; purchase ECG machines; ensure training and certification of the site project director and ECG technician; recruit and enroll participants in the ECG study; perform the 12-lead ECGs; transmit results electronically to the ERC; ensure the timely interpretation of ECGs by the site's primary or secondary cardiologist; and immediate review of ECGs by a site cardiologist, along with appropriate referrals.

12-LEAD ELECTROCARDIOGRAPHY: Standard 12-lead electrocardiography will be performed using GE MAC 3500 machines. Three successive ECGs will be obtained for each participant in order to allow calculation of short-term HRV measures. ECGs will be transmitted electronically to the ERC using virtual private networks or by analog phone line, as determined by the infrastructure of each site.

Transmission will be performed at least once or twice weekly as dictated by site workload demands. In the event of transmission difficulties, an SD card in the ECG machine will be used to backup the studies electronically. Hard copies of ECGs will be photocopied and kept as backups at each site. Machine ECGs will be deleted one day after confirmation of receipt by the ERC is obtained, to ensure that the electronic copies have been successfully stored on the ERC's servers.

LOCAL ECG INTERPRETATION: Hard copies of the ECGs will be regularly provided to the site primary or secondary cardiologist for interpretation. If there is an abnormality on any of the three ECGs, or if a discrepancy is found, all three ECGs should be provided to the site cardiologist for interpretation. If all three ECGs are normal or consistent, the site should only provide the site cardiologist with the last ECG. Cardiologists will provide their final read of the ECG by annotating their interpretation on the ECG itself. The ECGs will be interpreted as normal, non-specific findings, or abnormal ECG. Letters will be generated for mailing to participants and, if appropriate consent is given, to their physicians, indicating the ECG findings. The plan is for ECG interpretations to be completed within 7 days of the ECG performance date.

NOTE: If there are budgetary concerns at the WIHS sites regarding the cost of mailing, the site can decide not to send a "normal ECG" letter to the participant after the cardiologist has interpreted the tracing. If the site chooses not to send "normal ECG" letters and the ECG printout indicates normal findings on the day of the ECG, the site can provide the ECG printout to the participant. The site should notate "preliminary findings" on top of the ECG printout and ensure the participant understands that the findings have not been confirmed by the cardiologist. The site should inform the participant that if they do not hear from the site within 2 weeks, the participant can assume the cardiologist confirmed the normal findings.

CRITICAL ALERTS: Critical findings will be identified based on the interpretation provided on top of the ECG tracings by the ECG machine's automated algorithms. Refer to **Appendix G** for a list of critical and non-critical alert statements. Critical alerts will be identified by any result statement that includes any of the modifiers listed in **Section 1** and/or any of the statements listed in **Section 1**. ECG technicians will be instructed to

immediately contact the site cardiologist when such automated interpretations appear on the ECG.

For sites with clinicians (non-cardiologists), staff may refer certain statements that may not qualify as alerts when known to be previously present and unchanged (e.g., atrial fibrillation, prolonged QT) for immediate pre-review by the clinician before deciding to contact a site cardiologist. The clinician can decide whether such statements merit immediate referral of the ECG to cardiology (with the understanding that such referral is encouraged for all but the most clear-cut situations).

The ECG will be faxed or hand-delivered to the cardiologist, who will provide a prompt over-read, elicit further history from the participant as appropriate, and make a triaging determination. Such determination will range from dialing 911 to escorting to the Emergency Department, to expedited or routine follow-up with a physician.

Note, if any of the non-critical statements listed in **Section 2** appear with any of the modifiers listed in **Section 1**, they should be considered critical alerts and the site cardiologist should be notified immediately.

WIHS DATA MANAGEMENT AND ANALYSIS CENTER (WDMAC)

WDMAC will assist with the development and dissemination of the ECG performance, transfer, and data management protocols, including tracking ECG completion and receipt of data, using an interactive data management system. All protocols will be placed on the WIHS study administration website. WDMAC will also develop the codebooks for the ECG data, and programs for quality assurance. WDMAC investigators will collaborate with site and reading center investigators in the analysis of the data and disseminating results according to concepts that are approved by the WIHS Executive Committee.

Figure 1: Participating Organizations Core Roles Overview

Partner	Role in ECG
WIHS site staff	<ol style="list-style-type: none"> 1. administer ECG 2. complete ECGNOTI final disposition form (Appendix A) 3. complete ECGAER adverse event reporting form if an adverse event is observed or reported (Appendix C) 4. transmit ECG results electronically to EPICARE ECG Reading Center (daily) 5. contact local reading physician immediately in the event of an alert statement on the ECG; document Alert (use Appendix F as an example; complete ECGCA critical alert documentation form (Appendix B)) 6. send ECG hard copy results to the local reading physician for reading (frequency to be determined by site, recommended weekly for non-alert ECG) 7. prepare and mail ECG result letters to the participant and/or their physician
Local reading physician	<ol style="list-style-type: none"> 1. review ECG hard copy results (non-urgent scans) 2. review ECG urgent alerts and respond to sites before the participant leaves the clinic

	3. send results of review to site
WDMAC	1. review and run checks on the database (after first 2 weeks, monthly thereafter)
EPICARE ECG Reading Center	1. monitor data quality 2. interpret outcomes 3. send database and summary report to WDMAC (after first 2 weeks, monthly thereafter)

H. PRE-VISIT PREPARATION

1. PROGRAM ECG MACHINE FOR TRANSMISSION TO EPICARE

- See Appendix C of the ECG Assessment Manual (MOP)

2. TRAINING OF STAFF IN ECG

- Staff who did not participate in the Chicago training must be trained in person
 - Include hands on practice including applying the leads for the ECG machine
- Training videos are strongly recommended
 - ECG: <https://www.youtube.com/watch?v=SYAn8N7DZFk#action=share>

3. CERTIFICATION OF STAFF PERFORMING ECG

- Prior to administering the ECG on WIHS participants, each staff person must become certified by performing and transmitting 2 ECG sets (3 ECGs each) of sufficient quality.
 - Staff may use the same person and the same leads for the 2 certification ECGs. However, all leads must be completely removed and reapplied between the two tests (allowing ~15 minutes between the two).
- Staff should follow the instructions for data entry for the certification process (Table 3 in the ECG Assessment Manual). Site contacts will get the results of certification for their site.

4. EPICARE ACCOUNTS

- WDMAC will request EPICARE accounts for each newly certified ECG technician.
- Site must email WDMAC for additional staff accounts.
- Contact WDMAC if no EPICARE account information is received within 3 days of request.

I. ECG

1. ECG ELIGIBILITY CRITERIA

- Not recommended for participants with known adhesive allergies (latex-free).
- 8-hour fasting is recommended prior to the ECG, but not essential. Do not reschedule due to non-fasting.

2. MATERIALS AND EQUIPMENT

- ECG machine

- ECGNOTI Disposition Form (**Appendix A**)
- ECGCA Critical Alert Documentation Form (**Appendix B**)
- ECGAER Adverse Event Reporting Form (**Appendix C**)
- GE MAC 3500 Electrocardiograph with its 12-lead acquisition module
- Flexible measuring tape
- Telephone jack cable
- Scissors
- Felt tip non-toxic washable markers
- The CERC contact list (Appendix A, ECG Assessment Manual)
- Reference guides for “Patient Data Entry” (Table 2, ECG Assessment Manual)
- Reference guide for “Transmission of ECG” (Section 3.3.4, ECG Assessment Manual)
- GE MAC 3500 operation manual
- GE MAC 3500 ECG paper
- Disposable silver chloride electrodes
- Alcohol swabs and gauze pads
- Cotton surgical tape
- Examining table disposable paper

3. ECG TESTING

Site Procedure

- Ensure comfortable temperature (not too cold) in room prior to ECG.
- Perform ECG testing on participant as per detailed in the ECG Assessment Manual.
- Output an ECG hard copy of the tracing for each of the three ECGs performed.
- **Evaluate all printouts for any ECG ALERTS as defined in Appendix G.**

Storage and Transmitting of ECGs

Each center should be transmitting frequently and on a regular basis (e.g., at the end of each day) to avoid loss of electronic data. It can take about 5 minutes per ECG, or up to 15 minutes per participant. Overnight transfer is an option if you have a high volume to transfer.

Before transmitting new scans:

- Per protocol, three good quality ECGs should be saved per participant. Check to ensure that there are not extra poor-quality ECGs (e.g., flat lines). If so, delete before transmitting.
- Check to ensure that all WIHSIDs are valid.

After transmitting scans:

- Check the EPICARE website Confirmation Tab to see if your transmission has gone through. Note that the site does not update in real-time and there may be up to a 70-minute lag during regular business hours.

DELETING ECG data from the GE MAC 3500 ECG

Allow one business day after your transmission is visible on the EPICARE website before deleting the ECG(s) from the GE MAC 3500. This will allow the EPICARE's database server to be backed-up. At that point you may delete the records.

Back-up storage

If there's an error that prevents transmission, switch to a back-up SD card after 30 participants have had ECGs or after 1 week (whichever is less). Mail the SD card to EPICARE.

The GE MAC 3500 system supports only SD cards formatted for the FAT or FAT16 file systems. Recommend 256 MB or 512 MB SD cards.

ECG ALERTS

The ECG technician should refer to **Appendix G** to determine if any of the ECG statements on the ECG printout should be considered critical. If any critical alerts are identified, the ECG technician should contact the site cardiologist immediately and document on the ECGCA form.

4. PROCEDURE FOR ROUTINE NON-ALERT RESULTS

- If NO ALERTS are seen on printout:
 - Select the third ECG to provide to the site cardiologist for interpretation (This assumes that diagnostic statements for all three ECGs are uniform, and that the third ECG is the best quality one. Otherwise, send the one of highest quality, or all three ECGs, for cardiologist interpretation.)
 - Photocopy tracing(s)
 - Place tracing(s) in designated clinic location for later delivery to local reading physician
 - File copies to keep in case of loss
- Transmit electronic data to EPICARE Reading Center for each of the three ECGs performed

At regular intervals, site will:

- Collect ECG hard copies
- Send to local reading physician for reading
- Record-keeping as per site (example: count, date sent, person sending)

Reading Physician Procedure (NOTE: Centers may tailor procedures)

- Receive regular delivery of ECG hard copies (weekly, for example)

- Handwrite any edits to the automated machine reading directly on the tracing (“Final Interpretation”)
- The site may ask the reading physician to include coding to represent the type of result letter that should be produced
 - (1) = normal (see **NOTE** on page 6)
 - (2) = non-specific findings
 - (3) = abnormality that needs further evaluation
- Final ECG interpretation confirmed by physician signature directly on the tracing
 - Suggest establishing deadlines for turnaround times by the clinicians – should aim to have a 7-day turnaround time for non-critical alerts
- Return the printout with finalized/signed ECG interpretation to the site

Site Procedure

- Receive delivery of ECG hard copies with reading physician signature
- Use Final Interpretation to produce normal, abnormal or “non-specific findings” results letter (**Appendix D**)
 - Suggest establishing deadlines, as above
 - Site may select to include more specific findings in participant results letter by using terms written on ECG tracing along with the description of these terms (see **Appendix E**: Glossary of ECG results terms)

5. PROCEDURE FOR ALERT RESULTS

- If an ALERT (as defined in **Appendix G**) is seen on printout:
 - *Stay calm and do not communicate distress to the participant. The ECG is highly sensitive and only in very rare cases will the participant require immediate medical attention.*
 - *Immediately transmit all three ECG tracings to the reading physician **while the participant is onsite**.* Options include:
 - Use phone to take pictures of tracings and printed diagnostic statement on top of the ECG printout; text or email photos
 - Fax hard copies
 - Hand carry tracings to physician
 - Contact the reading physician (by text, email, page or phone call) and receive response
 - If no response, call/page backup reading physician
 - If no response, call/page site PI
 - Document event and actions as per site protocol (i.e., save in Excel or Access) in an alert log (see an example in **Appendix F**). Save to your site

directory on the first Friday of each month with the date in the excel file, regardless if there were any alerts or not during the past month.

- Complete ECGCA Critical Alert Documentation Form (**Appendix B**)
- Transmit electronic data to EPICARE Reading Center

Reading Physician Procedure (NOTE: Centers may tailor procedures)

- Receive text, page or phone call from site
- Review ECG tracing(s) with ALERT diagnostic statement
- Communicate decision on how to proceed to the site
- Possible decisions:
 - No immediate follow-up needed
 - Site to advise participant to follow-up with personal physician in XX days
 - Site to advise participant to immediately go to hospital (ONLY if participant is in distress or recommended by reviewing physician)
 - Site to call 911 (ONLY if recommended by reviewing physician or participant otherwise in distress and in need of medical attention; do NOT call if participant is asymptomatic)
- Document the physician's recommended follow-up as per institutional protocol
- Handwrite any edits to the automated machine reading directly on the tracing ("Final Interpretation")
- The site may ask the reading physician to include coding to communicate the type of result letter to be produced
 - (1) = normal interpretation → produce *normal result* letter (see **NOTE** on page 6)
 - (2) = non-specific findings → produce *non-specific result* letter
 - (3) = abnormality that needs further evaluation → produce *abnormal result letter*
- Final ECG interpretation confirmed by physician signature directly on the tracing
 - Suggest establishing deadlines for turnaround times by the clinicians
- Return the printout with finalized/signed ECG interpretation to the site

Site Procedure

- Receive instructions from reading physician in response to ALERT Final interpretation
 - If no immediate follow-up needed, reassure participant and proceed to produce letter (see **NOTE** on page 6)
 - If reading physician advises follow-up with personal physician, inform participant and produce appropriate letter to physician

- If reading physician advises participant to immediately go to hospital, inform participant and arrange for transport to hospital; produce appropriate letter to physician [NOTE: This will be extremely unlikely]
- If reading physician advises site to call 911, then call 911 and inform participant; produce appropriate letter to physician [NOTE: This will be extremely unlikely]
- Review Final Interpretation on tracing with reading physician signature
- Produce normal, abnormal or “non-specific findings” results letter according to Final Interpretation on tracing (**Appendix D**)
 - Suggest establishing deadlines
 - Site may select to include more specific findings in participant results letter by using terms written on ECG tracing along with the description of these terms (see **Appendix E**: Glossary of ECG results terms)

Adverse Event

- Definition: An “Adverse Event” is a significant medical event which is felt to be at least possibly related to the research study.
- Fill out ECGAER Adverse Event Reporting Form (**Appendix C**) if the participant reports an adverse event while having an ECG performed.
- Note: Mild, transient skin irritation from the lead placement without development of a frank rash or hives is not considered an adverse event.
- A PDF of the form is available on the WIHS Admin website.
- If the adverse event is not readily treatable with oral Benadryl or OTC hydrocortisone 1% cream, the participant should be seen by the site clinician, with appropriate referral made for care if needed.
- Notify WDMAC of all Adverse Events.

6. DISPOSITION FORM – ECG SECTION

“ECG Disposition Form” (ECGNOTI, **Appendix A**)

- Fill in this form following ECG testing of a participant
- Indicate whether the ECG was successfully performed; and if not, what was the reason
- indicate the participant’s preference for having ECG result letters sent to herself and/or her doctor
- Collect the following additional data:
 - Fasting status
 - Electrode Location
 - If alert conditions were noted (Y/N)

- If the participant appears to be intoxicated (note: this will be defined as readily noticeable intoxication of the participant by the clinic staff)
- Enter into Apollo

**APPENDIX B: WOMEN'S INTERAGENCY HIV STUDY
FORM ECGCA: ECG CRITICAL ALERT DOCUMENTATION FORM**

INSTRUCTIONS: THE PURPOSE OF THIS FORM IS TO TRACK THE OCCURRENCE OF CRITICAL ALERTS FOR PARTICIPANTS ENROLLED IN THE ECG PROTOCOL.

A1. PARTICIPANT ID |_|_|-|_|_|_|-|_|_|_|_|_|-|_|_|

A2. FORM VERSION: **01 / 30 / 18**

A3. FORM COMPLETED BY: |_|_|_|_|_|

A4. ECG DATE: |_|_|_|_| / |_|_|_|_| / |_|_|_|_|
 M D Y

A5. NATURE OF CRITICAL ALERT:

	<u>YES</u>	<u>NO</u>
HEART RATE < 40 BPM.....	1	2
HEART RATE ≥ 120 BPM.....	1	2
VENTRICULAR TACHYCARDIA.....	1	2
ATRIAL FIBRILLATION OR FLUTTER.....	1	2
COMPLETE ATRIOVENTRICULAR BLOCK/THIRD DEGREE HEART BLOCK/COMPLETE HEART BLOCK.....	1	2
WOLFF-PARKINSON-WHITE SYNDROME.....	1	2
ACUTE MYOCARDIAL ISCHEMIA.....	1	2
ACUTE MYOCARDIAL INFARCTION/INJURY.....	1	2
PROLONGED CORRECTED QT INTERVAL (QTc ≥ 500 MS).....	1	2
OTHER ALERT 1.....	1	2
SPECIFY OTHER ALERT 1: _____		
OTHER ALERT 2.....	1	2
SPECIFY OTHER ALERT 2: _____		
OTHER ALERT 3.....	1	2
SPECIFY OTHER ALERT 3: _____		
OTHER ALERT 4.....	1	2
SPECIFY OTHER ALERT 4: _____		
OTHER ALERT 5.....	1	2
SPECIFY OTHER ALERT 5: _____		

A6. PHYSICIAN ALERTED: _____

A7. PHYSICIAN DECISION: _____

A8. PARTICIPANT ACTIONS: _____

WIHSID

A9. OTHER COMMENTS: _____

PROMPT: THIS FORM WILL NOT BE DATA ENTERED.

A9. DID THE EVENT RESOLVE?

- YES.....1
- NO2 (A10)

A. IF YES, DATE OF RESOLUTION: |__|__| / |__|__| / |__|__|
M D Y

B. HOW DID IT RESOLVE (E.G., TREATED, RESOLVED ON ITS OWN, ETC.):

A10. WAS THIS EVENT ANTICIPATED (LISTED IN THE CONSENT FORM RISK SECTION)?

- YES.....1
- NO2 (A11)

A. IF ANTICIPATED, WAS THE EVENT ANY OF THE FOLLOWING?

- RASH.....1
- HIVES.....2

A11. IS IT MORE LIKELY THAN NOT THAT THIS PROBLEM/EVENT WAS RELATED TO RESEARCH PROCEDURES OR INTERVENTIONS?

- YES.....1
- NO2 (A12)

A. IF YES, CHOOSE THE STRENGTH OF ATTRIBUTION TO THE STUDY.

- NOT RELATED1
- PROBABLY NOT
- RELATED2
- POSSIBLY RELATED3
- PROBABLY RELATED ...4
- DEFINITELY RELATED..5

WIHSID

A12. ALL UNANTICIPATED ADVERSE EVENTS SHOULD BE REPORTED TO YOUR LOCAL IRB. WAS THIS EVENT REPORTED TO YOUR LOCAL IRB?

YES.....1

NO2

PROMPT: IF THE UNANTICIPATED ADVERSE EVENT HAS NOT YET BEEN REPORTED TO YOUR LOCAL IRB, NOTIFY WDMAC WHEN IT HAS BEEN REPORTED.

PROMPT: THIS FORM WILL NOT BE DATA ENTERED.

APPENDIX D: ECG RESULT LETTER TEMPLATES
NORMAL RESULTS – DETAILED VERSION



(This document can be used as a guide – each site may wish to individualize.)

Date

Dear xxxxx :

Thank you for your participation in the Women's Interagency HIV Study (WIHS). This letter provides you with the results of your 12-lead resting electrocardiogram (EKG). **We did not detect any concerning abnormalities on your EKG.** {We have sent the detailed report to your doctor. You can review the details with your doctor **[ONLY IF REQUESTED BY PARTICIPANT]**}

It is recommended that everyone strive to lead a heart-healthy lifestyle and reduce any risk factors for heart disease, such as high cholesterol, high blood pressure, diabetes, cigarette smoking, or others. Please note that these studies were performed as part of a research study and may not be the same as tests done as part of a patient's medical care. Please contact the { SHARE } office at {xxx xxx-xxxx} if you, or your doctor, have any questions about this report.

Thank you.

Sincerely,

APPENDIX D: ECG RESULT LETTER TEMPLATES
NORMAL RESULTS – SIMPLE VERSION



(This document can be used as a guide – each site may wish to individualize.)

Date

Dear xxxxx :

Thank you for your participation in the WIHS. This letter provides you with the results of your 12-lead electrocardiogram (EKG). **Your EKG was normal.** {We have sent the detailed report to your doctor. You can review the details with your doctor **[ONLY IF REQUESTED BY PARTICIPANT]]**}

Please note that these studies were performed as part of a research study and may not be the same as tests done as part of a patient's medical care. Please contact the { SHARE } office at {xxx xxx-xxxx} if you, or your doctor, have any questions about this report.

Thank you.

Sincerely,

APPENDIX D: ECG RESULT LETTER TEMPLATES
NON-SPECIFIC RESULTS – SIMPLE VERSION



(This document can be used as a guide – each site may wish to individualize.)

Date

Dear xxxxx :

Thank you for your participation in the WIHS study. This letter provides you with the results of your 12-lead electrocardiogram (EKG). **Your EKG showed results that need further interpretation.**

We have sent the report to your doctor. These findings may or may not be new. They may or may not cause any symptoms. Please review the details with your doctor, particularly if you are having palpitations, fainting, light-headedness, chest discomfort, or shortness of breath.

Please note that these studies were performed as part of a research study and may not be the same as tests done as part of a patient's medical care. Please contact {xxx} at {xxx xxx-xxxx} if you, or your doctor, have any questions about this report.

Thank you.

Sincerely,

APPENDIX D: ECG RESULT LETTER TEMPLATES
ABNORMAL RESULTS – DETAILED VERSION



(This document can be used as a guide – each site may wish to individualize.)

Date

Dear xxxxx :

Thank you for your participation in the Women's Interagency HIV Study (WIHS). This letter provides you with the results of your 12-lead resting electrocardiogram (EKG). The EKG showed that you had:

{Insert the appropriate option from below:

- 1) Extra heart beats from the upper chambers of your heart for 3 or more consecutive beats
 - 2) Extra heart beats from the lower chambers of your heart for 3 or more consecutive beats
 - 3) Abnormal heart conduction (right bundle branch block, left bundle branch block)
 - 4) Heart beats from a pacemaker
 - 5) Slow heart conduction
 - 6) Non-specific abnormalities (use this for nonspecific ST and T wave changes, first degree AVB, LVH, left axis deviation).
- }

{We have sent the report to your doctor. These findings may or may not be new. They may or may not cause any symptoms. Please review the details with your doctor, particularly if you are having palpitations, fainting, light-headedness, chest discomfort, or shortness of breath. [ONLY IF REQUESTED BY PARTICIPANT]}

It is recommended that everyone strive to lead a heart-healthy lifestyle and reduce any risk factors for heart disease, such as high cholesterol, high blood pressure, diabetes, cigarette smoking, or others. Please note that these studies were performed as part of a research study and may not be the same as tests done as part of a patient's medical care. Please contact {LOCAL CARDIOLOGIST READER} at {xxx xxx-xxxx} if you, or your doctor, have any questions about this report.

Thank you.

Sincerely,

APPENDIX D: ECG RESULT LETTER TEMPLATES
ABNORMAL RESULTS – SIMPLE VERSION



(This document can be used as a guide – each site may wish to individualize.)

Date

Dear xxxxx :

Thank you for your participation in the WIHS. This letter provides you with the results of the 12-lead electrocardiogram (EKG). **The EKG showed that you had abnormalities that you should discuss further with your doctor.**

We have sent the report to your doctor. These findings may or may not be new. They may or may not cause any symptoms. Please review the details with your doctor, particularly if you are having palpitations, fainting, light-headedness, chest discomfort, or shortness of breath.

Please note that these studies were performed as part of a research study and may not be the same as tests done as part of a patient's medical care. Please contact {xxx} at {xxx xxx-xxxx} if you, or your doctor, have any questions about this report.

Thank you.

Sincerely,

APPENDIX D: ECG RESULT LETTER TEMPLATES
ALERT RESULTS



(This document can be used as a guide – each site may wish to individualize.)

Date

Dear xxxxx :

Thank you for your participation in the Women's Interagency HIV Study (WIHS). This letter provides you with the results of your 12-lead resting electrocardiogram. As we discussed on the phone, your EKG showed that you had:

{Insert the appropriate option from below:

- 1) A slow heart rate below 40 beats per minute lasting for longer than 30 seconds
 - 2) A pause in your heart beat for longer than 5 seconds
 - 3) Abnormal heart block
 - 4) Atrial fibrillation or flutter (irregular heart rhythm)
 - 5) A fast heart rhythm
 - 6) Evidence of heart muscle damage
 - 7) Evidence of heart inflammation
 - 8) Abnormal heart conduction
 - 9) Pacemaker
- }

{We have sent a copy of the report to your doctor. Please talk to your doctor about this finding as soon as possible, especially if you are having episodes of lightheadedness, fainting, palpitations, chest pain or shortness of breath **[ONLY IF REQUESTED BY PARTICIPANT]**}. It is recommended that everyone strive to lead a heart-healthy lifestyle and reduce any risk factors for heart disease, such as high cholesterol, high blood pressure, diabetes, cigarette smoking, or others.

Please note that these studies were performed as part of a research study and may not be the same as tests done as part of a patient's medical care. Please contact the { SHARE } office at {xxx xxx-xxxx} if you, or your doctor, have any questions about this report.

Thank you.

APPENDIX D: ECG RESULT LETTER TEMPLATES
PHYSICIAN LETTER –APPLICABLE TO ANY RESULT



(This document can be used as a guide – each site may wish to individualize.)

Date

Dear Physician Name:

Your patient, xxxx, is a participant in the Women's Interagency HIV Study (WIHS), a study of HIV-infected and uninfected women in 10 U.S. cities. She has requested that we send you the results of her 12-lead electrocardiogram (EKG), which was performed as part of the research study. Please see the attached letter that was sent to your patient. We are also sending you the EKG tracing and interpretation.

Please contact us at {xxx} if you have any questions about this report.

Thank you.

APPENDIX E: GLOSSARY OF ECG RESULTS TERMS

Abnormality or alert	Description
Atrial fibrillation	This is an irregular heart rhythm of the upper chambers of the heart.
Atrial flutter	This is an irregular heart rhythm of the upper chambers of the heart.
Supraventricular ectopy (SVE) / Premature atrial contractions (PACs) / Supraventricular couplets / Supraventricular triplets	These are heartbeats that come early and originate from the upper chambers of the heart.
Supraventricular tachycardia <u>XX</u> beats OR <u>xx</u> secs	This is a fast rhythm that originates from the upper chambers of the heart and lasts for xx beats (or <u>xx</u> secs).
Ventricular ectopy (VE) / Premature ventricular contractions (PVCs) / Ventricular couplets / Ventricular triplets	These are heartbeats that come early and originate from the lower chambers of the heart.
Nonsustained ventricular tachycardia <u>XX</u> beats	This is a fast rhythm that originates from the lower chambers of the heart and lasts for xx beats.
Paced beats	These are heart beats that originate from a pacemaker device rather than your heart's own pacemaker.
Wolff Parkinson White	Abnormal heart conduction
Left bundle branch block	Abnormal heart conduction
Right bundle branch block	Abnormal heart conduction
Wide QRS tachycardia ≥ 120 bpm (includes monomorphic ventricular tachycardia, polymorphic ventricular tachycardia, ventricular fibrillation) Duration <u>xx</u> beats	This is a fast rhythm that originates from the lower chambers of the heart and lasts for xx beats.
Complete heart block	This is a slow heart beat due to an interruption in the electrical pathway in the heart.
2nd degree AV block, Mobitz I (AV Wenkebach)	This is an occasional slowing of heart rate due to a drop of a beat in the lower chambers.
2 nd degree AV Block, Mobitz II	This is a slow heart beat due to an interruption in the electrical pathway in the heart.
Pause >5 seconds	There was a pause in the heart beat for 5 seconds or longer.
Bradycardia <40 bpm	This is a slower than usual heart rate that lasted more than 30 seconds.
Acute pericarditis	This is inflammation of the lining of the heart.
Injury, infarct or ischemia (acute or marked)	This is heart muscle damage.

APPENDIX F: ECG ALERT LOG EXAMPLE

ECG Alert Log - Bronx							
WIHSID	Date Alert Occurred	Alert type(s) on ECG printout	Physician alerted	Date of Physician Contact	Physician Decision	Participant Actions	Comments
51111	10/15/2016	A-Fib (new-onset)	Dr. Jorge Kizer	10/15/2016	Advise participant to go to hospital for work-up	Participant agreed to go to hospital and was taken there by friend.	Participant was hospitalized; plan to request medical records

APPENDIX G: Critical & Non-Critical Alert List

Section 1. MAJOR CATEGORIES OF CRITICAL ALERTS

1. HEART RATE < 40 BPM
2. HEART RATE > 120 BPM
3. VENTRICULAR TACHYCARDIA
4. ATRIAL FIBRILLATION OR FLUTTER
5. COMPLETE ATRIOVENTRICULAR BLOCK/THIRD DEGREE HEART BLOCK/COMPLETE HEART BLOCK
6. WOLFF-PARKINSON-WHITE SYNDROME
7. ACUTE MYOCARDIAL ISCHEMIA
8. ACUTE MYOCARDIAL INFARCTION/INJURY
9. PROLONGED CORRECTED QT INTERVAL ($QT_c \geq 500$ MS)

These will be assessed by reviewing the electronic data printed on the top of the ECG, including heart rate and QT_c , as well as output statements, specifically those listed in Section 2 below.

Section 2. CRITICAL ALERT STATEMENTS (require immediate cardiologist review, or, if appropriate, clinician review)

ANY result statement that **includes** the following modifiers:

Modifier Statements	Acronym
, possibly acute	AC
with 2nd degree AV block (Mobitz II)	MBZII
with 2nd degree AV block	SAV
with complete heart block	CHB
with fusion or intermittent ventricular pre-excitation (WPW)	ALTWPW

AND/OR ANY of the following results statements:

Result Statements	Acronym
** ACUTE MI **	ACUMI
Anterior injury pattern	AINJ
Anterolateral injury pattern	ALINJ
Atrial fibrillation	AFIB
Atrial flutter	FLUT
Consider right ventricular involvement in acute inferior infarct	CRVI
Inferior injury pattern	IINJ
Consider right ventricular involvement in acute inferior infarct	CRVI
Inferolateral injury pattern	ILINJ
Lateral injury pattern	LINJ
Marked ST abnormality, possible anterior subendocardial injury	ASBINJ
Marked ST abnormality, possible anterolateral subendocardial injury	MSTDAL
Marked ST abnormality, possible anteroseptal subendocardial injury	MSTDAS

Marked ST abnormality, possible inferior subendocardial injury	ISBINJ
Marked ST abnormality, possible inferolateral subendocardial injury	MSTDIL
Marked ST abnormality, possible lateral subendocardial injury	LSBINJ
Marked ST abnormality, possible septal subendocardial injury	SSBINJ
Marked T wave abnormality, consider anterior ischemia	MAT
Marked T wave abnormality, consider anterolateral ischemia	MALT
Marked T wave abnormality, consider inferior ischemia	MIT
Marked T wave abnormality, consider inferolateral ischemia	MILT
Marked T wave abnormality, consider lateral ischemia	MLT
Marked ST abnormality, possible anterior subendocardial injury	ASBINJ
Marked ST abnormality, possible anterolateral subendocardial injury	MSTDAL
Prolonged QT	LNGQT
Septal injury pattern	SINJ
ST depression, consider subendocardial injury or digitalis effect	STDEP
ST elevation consider anterior injury or acute infarct	AIOHAI
ST elevation consider anterolateral injury or acute infarct	ALIHAI
ST elevation consider inferior injury or acute infarct	IIOHAI
ST elevation consider inferolateral injury or acute infarct	ILIHAI
ST elevation consider lateral injury or acute infarct	LIOHAI
ST elevation, consider early repolarization, pericarditis, or injury	SERYR1
ST elevation, consider injury or variant associated with LVH	INJONV
T wave abnormality, consider anterior ischemia	AT
T wave abnormality, consider anterolateral ischemia	ALT
T wave abnormality, consider inferior ischemia	IT
T wave abnormality, consider inferolateral ischemia	ILT
T wave abnormality, consider lateral ischemia	LT
Ventricular pre-excitation, WPW pattern type A	WPWA
Ventricular fibrillation	VFIB
Ventricular tachycardia	VTACH
Ventricular pre-excitation, WPW pattern type B	WPWB
Wolffe-Parkinson-White	WPW

Section 3. NON-CRITICAL OUTPUT STATEMENTS (do **NOT** require immediate cardiologist review **unless they are displayed in conjunction with any of the modifiers outlined in Section 2)**

Result Statements	Acronym
Aberant conduction	ABCOND
Abnormal ECG	AB
Abnormal left axis deviation	ALAD
Abnormal QRS-T angle, consider primary T wave abnormality	QRST
Abnormal right axis deviation	ARAD
Abnormal right superior axis deviation	RSAD
Accelerated	ACCEL
Acute pericarditis	PCARD
, Age undetermined	AU

, and consecutive	CSEC
and	AND
Anterior infarct	AMI
Anterior leads	ANT
Anterolateral infarct	ALMI
Anterolateral leads	ANTLAT
Anteroseptal infarct	ASMI
Anteroseptal leads	ANTSEP
Anteroseptal injury pattern	ASINJ
(Atrial rate=)	ARAT
Atrial tachycardia	ATAC
AV sequential or dual chamber electronic pacemaker	AVPCK
Biatrial enlargement	BAE
*** Bifascicular block***	BIFB
Biventricular hypertrophy	BIVH
Blocked	BLKED
Borderline ECG	BORDE
Borderline	BO
Cannot rule out	CRO
Clockwise rotation of the heart, may invalidate criteria for ventricular hypertrophy	CWRT
Coarse	CRS
Counterclockwise rotation of the heart, may invalidate criteria for v. hypertrophy	CCWRT
Deep Q wave in lead V6,	QV6
Demand pacemaker; interpretation is based on intrinsic rhythm	DPCK
Dextrocardia	DXTRO
Early repolarization	REPOL
Electronic atrial pacemaker	APCK
Electronic ventricular pacemaker	PCK
Fusion complexes	FUS
In a pattern of bigeminy	BIGEM
Incomplete left bundle branch block	ILBBB
Incomplete right bundle branch block	IRBBB
Increased R/S ratio in V1, consider early transition or posterior infarct	QESPMI
Idioventricular rhythm	IVR
Indeterminate axis	INDAX
Inferior infarct	IMI
Inferior leads	INF
Inferior-posterior infarct	IPMI
Inferolateral leads	IFLAT
Inferoposterior leads	INFPOS
Irregular	IRR
Junctional bradycardia	JUNBRAD

Junctional rhythm	JUNCTR
Junctional ST depression, probably abnormal	JST
Junctional ST depression, probably normal	JSTN
Large	LARG
Lateral infarct	LMI
Lateral leads	LAT
Left anterior fascicular block	AFB
Left atrial bradycardia	LABRAD
Left atrial enlargement	LAE
Left atrial rhythm	LAR
Left atrial tachycardia	LATACH
Left axis deviation	LAD3
Left bundle branch block	LBBB
Left posterior fascicular block	PFB
Left ventricular hypertrophy	LVH2
Leftward axis	LAD
** Less than 4 QRS complexes detected, no interpretation possible **	ANLERR3
Low right atrial bradycardia	RABRAD
Low right atrial rhythm	RAR
Low right atrial tachycardia	RATACH
Low voltage QRS	LOWV
Marked sinus bradycardia	MSBRAD
(masked by fascicular block?)	MAFB
, maybe secondary to QRS abnormality	SNDQA
** Memory allocation failure, no ECG interpretation possible **	ANLERR1
Minimal voltage criteria for LVH, may be normal variant	QRSV
Moderate voltage criteria for LVH, may be normal variant	LVH3
Moderate	MOD
Narrow QRS tachycardia	NQTACH
(No P- waves found)	NOPF
** No QRS complexes found, no ECG analysis possible **	ANLERR2
Nonspecific intraventricular block	IVCB
Nonspecific intraventricular conduction delay	IVCD
Nonspecific ST abnormality	NST
Nonspecific ST and T wave abnormality	NSTT
Nonspecific T wave abnormality	NT
Normal ECG	NML
Normal sinus rhythm	NSR
Northwest axis	NWA
or	OR
or digitalis effect	ODIG
Otherwise normal ECG	ABR
*** Pediatric ECG analysis ***	PEDANL
, plus right ventricular enlargement	RVE+
*** Poor data quality, interpretation may be adversely affected	QCERR

Possible	PO
Posterior infarct	POSTMI
Posterior leads	POS
premature atrial complexes	PAC
premature ectopic complexes	PEC
premature junctional complexes	PJC
premature supraventricular complexes	PSVC
premature ventricular and fusion complexes	PVCF
premature ventricular complexes	PVC
, probably digitalis effect	PDIG
Prominent lateral voltage	PLV
Prominent mid-precordial voltage,	PMDPV
Prominent posterior voltage	PPV
Pulmonary disease pattern	PULD
*** QRS contour suggests infarct size is probably	MISIZ
Right atrial enlargement	RAE
Right axis deviation	RAD4
Right bundle branch block -or-right ventricular hypertrophy	RBBRVH
Right bundle branch block	RBBB
Right superior axis deviation	RAD5
Right ventricular hypertrophy	RVH
Rightward axis	RAD
RSR' or QR pattern in V1 suggests right ventricular conduction delay	RSR
S1-S2-S3 pattern, consider pulmonary disease, RVH, or normal variant	S1S2S3
Septal infarct	SMI
Septal leads	SEP
Sinus/Atrial capture	CAPUR
Sinus bradycardia	SBRAD
Sinus rhythm	SRTH
Sinus tachycardia	STACH
Small	SMA
ST &	ST&
ST abnormality and	STABAND
ST abnormality, possible digitalis effect	STDIG
ST depression in	STDPIN
ST elevation in	STELIN
ST elevation, probably due to early repolarization	SERYR2
Statement not found	SNF
Supraventricular tachycardia	SVT
*** Suspect arm lead reversal, interpretation assumes no reversal	ARM
Undetermined rhythm	UR
Unusual P axis and short PR, probable junctional bradycardia	JBRAD

Unusual P axis and short PR, probable junctional rhythm	JR
Unusual P axis and short PR, probable junctional tachycardia	JTACH
Unusual P axis, possible ectopic atrial bradycardia	EABRAD
Unusual P axis, possible ectopic atrial rhythm	EAR
Unusual P axis, possible ectopic atrial tachycardia	EATACH
T wave inversion in	TINVIN
very large	VLAR
very small	VSMA
Voltage criteria for left ventricular hypertrophy	LVH
with	WITH
wide QRS rhythm	WQR
wide QRS tachycardia	WQTACH
with 1st degree AV block	FAV
with 2:1 AV conduction	W2T1
with 2nd degree AV block (Mobitz I)	MBZI
with 2nd degree SA block (Mobitz I)	SABI
with 2nd degree SA block (Mobitz II)	SABII
with 3:1 AV conduction	W3T1
with 4:1 AV conduction	W4T1
with 5:1 AV conduction	W5T1
with a competing junctional pacemaker	CJP
with AV dissociation	AVDIS
with frequent	FREQ
with junctional escape complexes	JESC
with marked sinus arrhythmia	MSAR
with occasional	OCC
with premature aberantly conducted complexes	ABER
, with posterior extension	PXT
with QRS widening and repolarization abnormality	QRSW-2ST
with QRS widening	QRSW
with rapid ventricular response	RVR
with retrograde conduction	RETC
with repolarization abnormality	2ST
with right ventricular involvement	RVI
with short PR	SPR
with sinus arrhythmia	SAR
with sinus pause	PAUSE
with slow ventricular response	SVR
with strain pattern	WSTR
with undetermined rhythm irregularity	IRREG
with variable AV block	VAVB
with ventricular escape complexes	VESC