GSA Webinar Series

The Multicenter AIDS Cohort Study (MACS)
Women’s Interagency HIV Study (WIHS)
Combined Cohort Study (MWCCS)

SUPPORTED BY THE GSA INNOVATION FUND: THE GENERATIVITY EFFECT

HIV and Aging: Data Access, Availability, and Research Funding Opportunities

- GSA Webinar Series
  1. The Multicenter AIDS Cohort Study (MACS)/Women’s Interagency HIV Study (WIHS) Combined Cohort Study (MWCCS)
  2. Veterans Aging Cohort Study (VACS)
  3. NIH Centers for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS)
  4. University of California, San Diego (UCSD) and Collaborating Sites Data Sources
  5. NIH National Institute on Aging (NIA) Funding Opportunities and Data Sources

Register at www.geron.org/webinars
Clarifying Questions?

- We will not be using the “raise hand” feature today
- Please use the “questions” feature accessible on the right side of your screen
- Speakers will not see questions until the end of the presentation
- If we do not get to all of the questions today, we will email responses after the webinar

Webinar Presenter

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Professor, Department of Neurology
Section for NeuroEpidemiology
State University of New York - Downstate Medical Center
Brooklyn, New York, USA

Prepared by:
MWCCS Data Analysis and Coordination Center
email: mwccs@jhu.edu
web: www.mwccs.org
Multicenter AIDS Cohort Study (MACS, 1983-2019)
Women’s Interagency HIV Study (WIHS, 1993-2019)

Study Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Grant Cycles</th>
<th>Enrollment Waves</th>
</tr>
</thead>
<tbody>
<tr>
<td>1984</td>
<td>MACS 1</td>
<td>1984-85</td>
</tr>
<tr>
<td>1989</td>
<td>MACS 2</td>
<td>1987-90</td>
</tr>
<tr>
<td>1994</td>
<td>MACS 3</td>
<td></td>
</tr>
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<td>1999</td>
<td>MACS 4</td>
<td>1995 admin censoring of some HIV-neg</td>
</tr>
<tr>
<td>2004</td>
<td>MACS 5</td>
<td>2001-3</td>
</tr>
<tr>
<td>2009</td>
<td>MACS 6</td>
<td>2010+</td>
</tr>
<tr>
<td>2014</td>
<td>MACS 7</td>
<td></td>
</tr>
<tr>
<td>2019</td>
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35 years

72nd Visit

<table>
<thead>
<tr>
<th>Year</th>
<th>Grant Cycles</th>
<th>Enrollment Waves</th>
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</thead>
<tbody>
<tr>
<td>2016</td>
<td>WIHS I</td>
<td>1994-95</td>
</tr>
<tr>
<td>2019</td>
<td>WIHS II</td>
<td>1997 WDMAC</td>
</tr>
<tr>
<td>2024</td>
<td>WIHS III</td>
<td>2002-2</td>
</tr>
<tr>
<td>2029</td>
<td>WIHS IV</td>
<td>2011-15</td>
</tr>
<tr>
<td>2034</td>
<td>WIHS V</td>
<td>2013-15</td>
</tr>
</tbody>
</table>

25 years

51st Visit

* In April 1995, 2255 HIV-negative men were administratively censored from further follow-up, per an NIH decision.

MWCCS Visit Timeline: 2020-2026

<table>
<thead>
<tr>
<th>Visit Structure</th>
<th>Start of Window</th>
<th>End of Window</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 201</td>
<td>1/1/2020</td>
<td>2/28/2020</td>
</tr>
<tr>
<td>Core Window</td>
<td>1/1/2021</td>
<td>2/28/2021</td>
</tr>
<tr>
<td>Completion Window</td>
<td>3/1/2021</td>
<td>3/31/2021</td>
</tr>
<tr>
<td>Data freeze, edits, &amp; summary files</td>
<td>4/1/2021</td>
<td>4/30/2021</td>
</tr>
<tr>
<td>Visit 202</td>
<td>1/1/2022</td>
<td>2/28/2022</td>
</tr>
<tr>
<td>Core Window</td>
<td>1/1/2023</td>
<td>2/28/2023</td>
</tr>
<tr>
<td>Completion Window</td>
<td>3/1/2023</td>
<td>3/31/2023</td>
</tr>
<tr>
<td>Data freeze, edits, &amp; summary files</td>
<td>4/1/2023</td>
<td>4/30/2023</td>
</tr>
<tr>
<td>Visit 203</td>
<td>1/1/2024</td>
<td>2/28/2024</td>
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<tr>
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<td>1/1/2025</td>
<td>2/28/2025</td>
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<tr>
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<td>3/31/2025</td>
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<tr>
<td>Data freeze, edits, &amp; summary files</td>
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<td>4/30/2025</td>
</tr>
<tr>
<td>Visit 204</td>
<td>1/1/2026</td>
<td>2/28/2026</td>
</tr>
<tr>
<td>Core Window</td>
<td>1/1/2027</td>
<td>2/28/2027</td>
</tr>
<tr>
<td>Completion Window</td>
<td>3/1/2027</td>
<td>3/31/2027</td>
</tr>
<tr>
<td>Data freeze, edits, &amp; summary files</td>
<td>4/1/2027</td>
<td>4/30/2027</td>
</tr>
<tr>
<td>Visit 205</td>
<td>1/1/2028</td>
<td>2/28/2028</td>
</tr>
<tr>
<td>Core Window</td>
<td>1/1/2029</td>
<td>2/28/2029</td>
</tr>
<tr>
<td>Completion Window</td>
<td>3/1/2029</td>
<td>3/31/2029</td>
</tr>
<tr>
<td>Data freeze, edits, &amp; summary files</td>
<td>4/1/2029</td>
<td>4/30/2029</td>
</tr>
<tr>
<td>Visit 206</td>
<td>1/1/2030</td>
<td>2/28/2030</td>
</tr>
<tr>
<td>Core Window</td>
<td>1/1/2031</td>
<td>2/28/2031</td>
</tr>
<tr>
<td>Completion Window</td>
<td>3/1/2031</td>
<td>3/31/2031</td>
</tr>
<tr>
<td>Data freeze, edits, &amp; summary files</td>
<td>4/1/2031</td>
<td>4/30/2031</td>
</tr>
</tbody>
</table>
MACS/WIHS Combined Cohort Study Sites

- Johns Hopkins serves as the MWCCS Data Analysis and Coordination Center (DACC)
- 57-Member Executive Committee
- >30 Scientific & Operational Working Groups

US Map from AIDSVu with shading reflecting 2016 HIV Prevalence per 100K

Characteristics of Active* Participants

N=4,106

* MACS and WIHS Participants Who Contributed Data in the Year Prior to MWCCS
Characteristics of WIHS
(2,154 Active Participants)

**Former WIHS Cohort**

- Seroprevalent: 3677 (74%)
- Seronegative: 1305 (26%)

**AIDS**
- Active: 1726 (67%)
- Alive: 804 (47%)
- Dead: 922 (53%)

**AIDS-free**
- Active: 1951 (53%)
- Alive: 1645 (84%)
- Dead: 306 (16%)

**AIDS converter**
- Active: 28 (1%)
- Alive: 14 (50%)
- Dead: 14 (50%)

**AIDS-free converter**
- Active: 16 (0.7%)
- Alive: 10 (62%)
- Dead: 6 (38%)

**Seronegative**
- Active: 1277 (98%)
- Alive: 1146 (90%)
- Dead: 131 (10%)

Active: 4878 (65%)
Active: 1008 (65%)
Active: 6 (1.0%)
Active: 8 (0.8%)
Active: 645 (56%)

* HIV & AIDS status as of the end of visit 49 (3/31/15). Deaths via NDI (through 12/31/14 for site 4; 12/31/15 for sites 2, 3, 5; 12/31/17 for sites 1, 4, 6, 8, 9, 10, 11) and through 3/31/15 via other reports.

† Three seroconverters found at death.

Characteristics of MACS
(2,083 Active Participants)

**Former MACS Cohort**

- Seroprevalent: 3147 (65%)
- Seronegative: 1371 (27%)

**AIDS**
- Active: 1712 (67%)
- Alive: 1448 (84%)
- Dead: 264 (16%)

**AIDS-free**
- Active: 1435 (49%)
- Alive: 1224 (85%)
- Dead: 211 (15%)

**AIDS converter**
- Active: 767 (38%)
- Alive: 515 (67%)
- Dead: 252 (33%)

**AIDS-free converter**
- Active: 1011 (50%)
- Alive: 385 (38%)
- Dead: 626 (62%)

**Seronegative**
- Active: 3444 (90%)
- Alive: 1518 (44%)
- Dead: 1926 (56%)

Active: 7308
Active: 259 (0.7%)
Active: 705 (94%)
Active: 37 (5%)
Active: 304 (68%)
Active: 95 (32%)
Active: 959 (64%)
Active: 172 (13%)
Active: 79 (5%)

* HIV & AIDS status as of the end of visit 69 (3/31/15). Deaths through 3/31/15.
** Seroconverters include 123 (of 767) who were HIV+ at entry, but with known date of seroconversion.
Age Distribution of Active* MWCCS Participants

* Active = All participants who contributed data at Visit 48 or 49 for WIHS; 69 or 70 for MACS

MACS and WIHS Demographics

<table>
<thead>
<tr>
<th></th>
<th>Former MACS Men</th>
<th>Former WIHS Women</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PLWH N=1,024</td>
<td>HIV- N=915</td>
</tr>
<tr>
<td>Median Age (IQR)</td>
<td>58 (50, 64)</td>
<td>63 (57, 70)</td>
</tr>
<tr>
<td>Race/Ethnicity (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black/African American</td>
<td>27%</td>
<td>17%</td>
</tr>
<tr>
<td>Hispanic/Latino, any race</td>
<td>16%</td>
<td>7%</td>
</tr>
<tr>
<td>White</td>
<td>53%</td>
<td>73%</td>
</tr>
<tr>
<td>Multiple Races/Other</td>
<td>4%</td>
<td>7%</td>
</tr>
<tr>
<td>Median (mean) Follow-up Time, years</td>
<td>16.7 (21.5)</td>
<td>34.0 (27.9)</td>
</tr>
</tbody>
</table>

MACS and WIHS Combined Cohort Study
# MACS and WIHS Chronic Disease Indicators

<table>
<thead>
<tr>
<th></th>
<th>MACS PLWH N=1,024</th>
<th>MACS HIV- N=915</th>
<th>WIHS PLWH N=1,516</th>
<th>WIHS HIV- N=651</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Smoking (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>22%</td>
<td>14%</td>
<td>34%</td>
<td>43%</td>
</tr>
<tr>
<td>Former</td>
<td>47%</td>
<td>53%</td>
<td>32%</td>
<td>30%</td>
</tr>
<tr>
<td><strong>BMI Median (IQR)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% BMI &gt;30 [&gt;40]</td>
<td>26 (24, 30)</td>
<td>27 (24, 30)</td>
<td>31 (26, 37)</td>
<td>32 (27, 38)</td>
</tr>
<tr>
<td>% BMI &gt;30 [&gt;40]</td>
<td>23% [2%]</td>
<td>26% [3%]</td>
<td>54% [18%]</td>
<td>58% [18%]</td>
</tr>
<tr>
<td><strong>Hypertension (SBP≥140, DBP≥90, meds)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>50%</td>
<td>55%</td>
<td>53%</td>
<td>53%</td>
</tr>
<tr>
<td><strong>Diabetes (HbA1C≥6.5%, FG≥126, meds)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>16%</td>
<td>13%</td>
<td>25%</td>
<td>25%</td>
</tr>
<tr>
<td><strong>Dyslipidemia (LDL&gt;130, HDL&lt;40)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>34%</td>
<td>28%</td>
<td>36%</td>
<td>32%</td>
</tr>
<tr>
<td><strong>Chronic Kidney Disease</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CKD-Epi eGFR &lt;60 [&lt;30]</td>
<td>14% [1%]</td>
<td>8% [0.1%]</td>
<td>15% [2%]</td>
<td>7% [2%]</td>
</tr>
<tr>
<td>% with Confirmed Cancers (% AIDS Defining Event)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11% (4%)</td>
<td>8%</td>
<td>6% (1%)</td>
<td>4%</td>
</tr>
</tbody>
</table>

---

**WIHS Prevalence of the Frailty Phenotype WIHS by HIV Status and Age in 2015-2017 (n=1,404)**

Overall Frailty Prevalence:

- HIV+ 10%; HIV- 15%

Fatukasi TV et al., AIDS. 2019.
Frailty Phenotype in MACS: 2007-2011

Overall Frailty Visits:
HIV+: 12% HIV-:9%

MACS and WIHS
Antiretroviral Medication Exposure*

<table>
<thead>
<tr>
<th></th>
<th>Former MACS Men</th>
<th>Former WIHS Women</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PLWH N=1024</td>
<td>PLWH N=1,516</td>
</tr>
<tr>
<td>% Currently on Any Therapy</td>
<td>94%</td>
<td>94%</td>
</tr>
<tr>
<td>% with Previous Exposure to d4T, ddl, ddC</td>
<td>48%</td>
<td>29%</td>
</tr>
<tr>
<td>% with Previous Exposure to Monotherapy</td>
<td>29%</td>
<td>21%</td>
</tr>
<tr>
<td>% Ever with Low CD4:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;500 cells/mm³</td>
<td>88%</td>
<td>90%</td>
</tr>
<tr>
<td>&lt;200 cells/mm³</td>
<td>32%</td>
<td>44%</td>
</tr>
</tbody>
</table>

* At most recent visit
**Antiretroviral Therapy Use Among MACS and WIHS PLWH**
*(active participants only)*

![Graph showing Antiretroviral Therapy Use](image)

**Viral Load Among MACS and WIHS PLWH**
*(active participants only)*

![Graph showing Viral Load](image)

*TaqMan v2.0 HIV-1, sensitive to 20 copies HIV RNA/mL, implemented in 2009*
**CD4 Cell Counts Among MACS and WIHS PLWH (active participants only)**

![CD4 Cell Counts Graph]

**Hepatitis Status at Baseline and Last Test**

<table>
<thead>
<tr>
<th></th>
<th>Former MACS Men</th>
<th>Former WIHS Women</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PLWH</td>
<td>HIV-</td>
</tr>
<tr>
<td><strong>Last Test Result (may be baseline result):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-HCV+</td>
<td>13%</td>
<td>6%</td>
</tr>
<tr>
<td>HCV RNA+</td>
<td>9%</td>
<td>4%</td>
</tr>
<tr>
<td>HBsAg+</td>
<td>7%</td>
<td>3%</td>
</tr>
</tbody>
</table>
Routinely Collected Measures

Types of MWCCS Data Collected

- Demographics
- HIV medication and adherence
- Frailty, aging
- Neuropsychology
- Attitude and beliefs
- Health care utilization
- Quality of life, depression
- Behaviors (substance use and sexual behavior)
- Medical conditions and medication use

- Lab results:
  - Blood Chemistries, Complete Blood Count, Hepatitis, T-Cell Flow Cytometry, HIV Viral Load, Lipid Panel
  - Physical examination
  - Outcomes verification and adjudication
  - Biorepository of samples
  - Registry matching:
    - National Death Index, Cancer Registry, Renal Disease Registry
Committed* Specimens in Central Repository

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Location Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma (CPT)</td>
<td>Urine (clean void)</td>
</tr>
<tr>
<td>Plasma (heparin)</td>
<td>Urine (supernatant)</td>
</tr>
<tr>
<td>Plasma (EDTA)</td>
<td>Cervical Vaginal Lavage (CVL)</td>
</tr>
<tr>
<td>Serum</td>
<td>Stimulated Saliva</td>
</tr>
<tr>
<td>Cells</td>
<td>Stool</td>
</tr>
<tr>
<td>Cell Pellets</td>
<td>Semen</td>
</tr>
</tbody>
</table>

* Committed includes all specimens ever sent to Central Repository.
** Former MACS/WIHS began repositing EDTA plasma at visit 45/48.

MWCCS NHLBI Substudies 2016-2019

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Resting and Ambulatory (ZIO Patch) ECG</td>
<td>MACS</td>
<td></td>
<td>WIHS (resting ECG only)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary Function Testing</td>
<td>MACS</td>
<td></td>
<td>WIHS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECHO</td>
<td>MACS</td>
<td></td>
<td>WIHS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep Study (WIHS substudy)</td>
<td></td>
<td></td>
<td></td>
<td>WIHS</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Some of these data available in >2,000 participants
How does one propose an idea using the MWCCS cohort?

mwccs.org

- Submit a Concept Sheet
- www.mwccs.org is the study website with instructions for submitting a Concept Sheet
Investigators who are not a grant-supported investigator at an MWCCS clinical research site should have an **MWCCS liaison**

A study liaison is responsible for:
- Ensuring the investigator is aware of any data/specimen limitations
- Confirming lack of overlap with existing Concept Sheet(s)
- Making sure that persons with appropriate scientific expertise have provided input
- Confirming the investigator is adherent to the **MWCCS Concept Sheet and Publication Policy**

Please contact the DACC ([mwccs@jhu.edu](mailto:mwccs@jhu.edu)) if you need a study liaison assigned to your project
• www.mwccs.org is the study website with instructions for submitting a Concept Sheet
• Click on the “Investigator Info” tab
Submitting a Concept Sheet
The MACS WIHS Combined Cohort Study (MWCCS)
Concept Sheet Submission Form

NOTE: All CDS MACS Concept Sheet Submission Forms must be submitted online using DACCTrack. This form has been provided to those who have been approved for the study. If you have not been approved, please contact the MACS Coordination Center at 888-MACS-WIHS (888-622-7947) for more information.

The MACS/WIHS Combined Cohort Study (CDS) welcomes proposals from internal or external investigators for the conduct of studies on specimens and new instruments and protocols. All investigators are required to submit their concept statement online, using the form to be reviewed by the CDS Concept Sheet Submission Committee. Investigators are then asked to complete a Research Plan for approval prior to implementation.

Prior to concept sheet submission, investigators must review the Concept Sheet Submission Form Instructions that provide the use of data and specimens from the CDS. Please read these instructions carefully before submitting any concept sheet regarding any data or specimens from the MACS/WIHS cohort and MACS/WIHS biological samples.

Would you like any questions regarding the concept sheet submission process? Please contact DACC at DACC@jhu.edu.

The online form includes:
1. Collection of administrative information related to the concept sheet.
2. A list to upload a signed Word document (Research Plan) summarizing the proposed research and analysis plan.
3. Instructions for additional documentation (applicable) (description of reasons for review, request for review, and statement of support for student projects).

This link to download the Research Plan template.

Study Resources Requested
- Are you requesting data?
- Are you requesting within a specific collection or specimens from the repository?
- Are you requesting a specific protocol?

(please check all that apply) *
Data
Specimens
DACC Lab Analysis

4. General Information
1. Lead Investigator *
   - First Name
   - Last Name
   - Middle initial
   - Phone
   - Email
2. Lead Investigator/Investigator Team*
   - First Name
   - Last Name
3. Institute *
4. Telephone Number *
5. More contact info different from lead investigator
   - First Name
   - Last Name
6. Additional contact info
7. Is the lead investigator a current MACS/WIHS investigator in an active role in this proposal?
   - Yes
   - No
8. Is the lead investigator a current MACS/WIHS investigator in an active role in this proposal?
   - Yes
   - No

All investigators are not PI's should have a study leader. The role of a study leader is to make sure the investigation is consistent with CDS guidelines (as specified elsewhere in the document) and to ensure their study is in line with CDS guidelines. In addition, the leader will ensure that their investigation is aware of any other data sharing initiatives, i.e., what data and specimens are available, and will coordinate as needed to study design. The site PI or CCS liaison who is assisting in the development of the concept sheet should ensure that persons with the appropriate scientific expertise have provided input. If appropriate expertise or a certain area is found lacking, the site PI or CCS liaison can consult the relevant working group chair to identify an investigator who may be able to provide the expert support.

Sample Only
II. Concept Title

II. Submission Types

- Initial
- Addendum
- Revision
- Amendment
- Summary

III. Concept Information

1. Proposal includes: *
   - All CCS sites
   - One CCS site (selectively only)
   - All WIHS sites
   - All WIHS sites excluding LA
   - All WIHS sites excluding LA and V37

   a. Sites included in proposal, indicate centers (select all that apply): *
      - Atlanta
      - Boston
      - New Haven
      - Chicago
      - Pittsburgh
      - Los Angeles (UCLA)
      - San Francisco
      - Other:

   Approval of manuscript proposals for changes to instruments, specimens, and other data collection during the core protocol is made only collectively at the time of the concept sheet review, except in unusual situations. First draft designs are reviewed and approved by the DC; as a semi-annual basis.

2. New additional participant burden: (select all that apply): *
   - No
   - Additional specimen collection(s)
   - New questionnaire(s)
   - New procedure(s) (e.g., ECG)
2a. Will this require an additional visit?**
   ( ) Yes: *  ( ) No: *

2b. Will results of any blood or procedures performed be returned to the participant? *
   ( ) Yes: *  ( ) No: *

2c. Please indicate type ofoperator, procedure, or questionnaire to be added: *

3. Does this project involve additional CTS site staff burden (pick all that apply)? **
   ( ) No new/additional site staff burden
   ( ) 140 admission
   ( ) Staff training
   ( ) Providing/conducting participant incentives

Please provide a Lay Language summary for this project. This summary should be written at an 8th grade education level or lower. The sentence should be grammatically correct. These summaries are provided to study participants so they can understand the study and the impact it may have on them. Please keep the language simple, short, and clear. Include any burden the study will have on participants. Participant burden includes: new questionnaires, new study questionnaires, requiring the participant to do a new exam or procedure, requiring the participant to come in for a separate visit, etc.

Click here to edit a Readability Calculation. You can copy and paste your 100 into the readability calculator and it will give you the grade level using different literacy scales. As long as one scale is between 6 to 12 it is sufficient.

Click here to read an article “How to Write for an Eighth Grade Reading Level”.

This is an example of an augmented lay language summary:

Medicines used to treat people living with HIV help them to live longer and healthier lives. However, people on these medicines can have problems with their blood concentrations. We want to understand how this affects their lives and needs to do these problems. We will do some research and ask questions about using and reporting on medicines and new HIV. We plan to look at 100 people. None of these people will have HIV and some will not. All the people will also get another type of brain scan to look at information in the brain. Information is your body’s response to things that are trying to happen.

4. Lay Language summary **

( ) 150 words in lay language, website impact on participation: 5/10

5. Is this in assigning meaning, please check balance. Is is of the following topics (multiply topic). Selection can delay concept level meaning, **

   Aging
   Behavioral Health/Behavioral
   Biometrics
   Cardiometabolic
   Clinical Outcomes/Pharmacology
   Data Analysis/Methods
   Genetics/Humanism
   Geographic/Census/Idaho/Data
   Gynecology
   Infectious
   Liver
   Laboratory/Immunology
   Midwifery
   Minimally
   Metabolism
   Microbiology
   Neurology/Neurology
   Obstetrics
   Pathogenesis/Pharmacology/Immunology
   Pharmacology
   Psychiatry
   Pediatrics
   Renal
   Sleep
   Tobacco/Smoke
   Substance/Abuse
   ...
6. Funding source(s) *
   - Existing Core CCS grants
   - Other already funded grants or contracts
   - Concept sheet will be part of a new funding application
   - Not applicable

6a. Current Sponsor(s) *
    Please indicate the sponsor

6b. Grant number(s) *
    Please indicate the grant number

6c. Future Sponsor(s) *
    Please indicate the sponsor

6d. NIH or other Solicitation Number *
    Please specify solicitation number

6e. Is a letter of support from the CCS needed? *
    - Yes * 
    - No

6f. Submission deadline *
    Please indicate your grant submission deadline

6g. Submission title *
    Please indicate the title of the funding submission

7. Will this collaboration involve individuals, institutions, and/or companies that are not located in the United States? *
    - Yes * 
    - No

7a. Name of non-US institution and investigator(s) *

8. Do any of the investigators have any financial conflicts of interest to disclose? *
    - Yes * 
    - No

8a. Please disclose potential financial conflicts of interest *
Please submit your research plan using the following template: [CCS Concept Sheet Research Plan Form]. Once complete, upload the form as a single PDF file to your online concept sheet submission using "LastName_Date" as the file's nomenclature.

1. **Abstract** *

2. **Specific Aims (please omit hypotheses)** *

   

3. **Research Plan Upload** *

   Browse

   Please Upload your Research Plan and any other relevant documents in a single file.

4. **Letter to the CCS Executive Committee addressing changes** *

   Browse

   Please Upload all relevant information.

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### D. Sample Specifications

1. **Sample Type (check all that apply)** *
   - Anal Swabs (MACS only)
   - Beads (pellets)
   - Buccal Cells (MACS only)
   - Buccal Wash (MACS only)
   - Citrate Plasma (WIHS only)
   - CPT Plasma (WIHS only)
   - Dry Cell Pellet (CPT; WIHS only)
   - Dry Cell Pellet (extracted MACS only)
   - EDTA Plasma
   - Hair
   - Host DNA
   - Oral Rinse
   - PBMC (viable, MACS only)
   - PBMC (viable, WIHS only)
   - Plasma (extracted MACS only)
   - Plasma (WIHS only)
   - Saliva
   - Saliva (obtained from all)
   - Saliva (pellets)
   - Saliva (supematant)
   - Stool
   - Stool (obtained from all)

   Please list specimen type and quantity for every sample type being requested (ml or cell/vial).

2. **Sample Quantity:**

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. Indicate if, and which, high value samples will be requested (link to description) *

- Not requesting high value samples
- HIV seroconverters
- Pre-HAART deaths
- HAART failures
- Long term non-progressors
- Elite non-progressors
- Rapid progressors
- Fast progressors
- Treatment failures
- Treatment successes

4. Expected number of person visits to be requested

[ ]

**E. Statement of Agreement**

Please review the MACS/WIHS CCS Concept Sheet and Publication Policies and Procedures prior to submitting the concept sheet.

Before submission, please review, acknowledge, and agree to the following: *

- I have reviewed and agree to abide by the MACS/WIHS Concept Sheet and Publication Policies and Procedures.
- All information I provide in this concept sheet is complete and correct as submitted.
- Use of specimens and/or data is restricted to the aims outlined in the Research Plan.
- All information I provide in this concept sheet is complete and correct as submitted.
- I will complete a CCS Data Use Agreement (DUA) if this proposal receives approved and requires one.
- IRB approval has, or will be, obtained before any data and/or specimens are received.
- I will submit a CCS Material Transfer Agreement (MTA) if this proposal requires approval and requires one.
- Abstracts resulting from approved concepts MUST be submitted to the DACC for CCS EC prior to submission to a conference. Manuscripts must be submitted to the DACC to be shared with the CCS EC prior to submission to a journal.
- Author/sponsor/coauthor/s will make any CCS study subject/individual(s) to either documents or presentations, e.g., journal articles, abstracts, and oral/poster presentations, or an any website.
- The lead investigator for each approved concept sheet must submit an annual progress report. If no progress report is received after two email reminders approval for the concept sheet will expire.
- My signature below indicates a complete review and acceptance of the guidelines for collaborations, publication, and acknowledgment as outlined in the “Statement of Agreement”.

[ ]

**Please add any additional information you feel is important to the review of this concept sheet below.**

Additional Concept Information

[ ]
Quick Glance Summary: MWCCS Concept Sheet Review Process

Submit CS Using DACCTrack
- Fill out online admin form
- Upload Research Plan
- Students require LoS
- External Investigators require MWCCS Liaison

CS Review Timeline for all reviews

Working Group (WG) Review, 1-2 assigned

Lab Review (LR) if CS requests specimens

Project Director (PD) Review if CS proposes new specimens/data

If all reviewers agree on decision, concept proceeds

Decision to:
- Approve
- Reject
- Request revision

If reviewers disagree, Scientific Reviewer (SR) assigned to adjudicate

Next Steps (in Investigator View):
- When ready for data/samples/analysis: Submit DACC Resource Request Form
- When ready to submit revision: Submit Revision/Addendum Form, using link in Investigator View

1. This process applies to multi-site concept sheets and single-site concept sheets that will request specimens from the central repository. Single-site investigations that propose to utilize and/or collect data/specimens from ONE CCS site should still be submitted via DACCTrack, but will only require review by the PI from that specific site.

2. Concept sheets proposing new specimen or data collection only receive provisionally approval until discussed during the annual CCS protocol review process.

3. If requesting VIP samples in DACC Resource Request, assigned to CCS Specimen Allocation Committee (CSAC) Review.

MACS/WIHS Combined Cohort Study

- Johns Hopkins serves as the MWCCS Data Analysis and Coordination Center (DACC)
- 57-Member Executive Committee
- >30 Scientific & Operational Working Groups

US Map from AIDSVu with shading reflecting 2016 HIV Prevalence per 100K
Thank you!

On behalf of

Deborah.Gustafson@downstate.edu
MPI of the MWCCS Brooklyn Clinical Research Site
MWCCS Aging Working Group co-Chair

Thank You

GSA: Advancing Innovation in Aging

- The nation’s oldest and largest interdisciplinary organization devoted to research, education, and practice in the field of aging
  - 5,500+ interdisciplinary members around the world touching all facets of aging
- Mission
  - Promote multi- and interdisciplinary research in aging
  - Translate and disseminate research findings
  - Promote/advocate for education/awareness on aging across disciplines
  - Foster application of research into policy development
- To view other GSA webinars, visit geron.org/webinar
- Continue the conversation—Join GSA’s HIV, AIDS, and Older Adults Interest Group
  - Click here for information on how to join a GSA Interest Group
HIV and Aging: Data Access, Availability, and Research Funding Opportunities

- GSA Webinar Series
  1. The Multicenter AIDS Cohort Study (MACS)/Women’s Interagency HIV Study (WIHS) Combined Cohort Study (MWCCS)
  2. Veterans Aging Cohort Study (VACS)
  3. NIH Centers for AIDS Research (CFAR) Network of Integrated Clinical Systems (CNICS)
  4. University of California, San Diego (UCSD) and Collaborating Sites Data Sources
  5. NIH National Institute on Aging (NIA) Funding Opportunities and Data Sources

Register at [www.geron.org/webinars](http://www.geron.org/webinars)

Webinar Evaluation

- In an effort for continual improvement, we would like to hear your thoughts. Please provide feedback by clicking the survey link at the end of the webinar.

- Thank you again and we hope you enjoyed the program!