**Concept Sheet for Research Proposal**

*Longitudinal Study of HIV & Aging in Brazil*

**Guidelines**

Complete all sections of the template except those designated as “post-approval.” Research proposals should have a clearly defined objective and be associated with a pre-defined number of publications (e.g., one abstract, one manuscript.) Submit concepts to Shaiana Oliveira, ELEA Program Manager, at [shaiana.oliveira@vumc.org](mailto:shaiana.oliveira@vumc.org)

**Project Title:** Click here to enter text.

**Initial submission date**: Click here to enter a date.

**Post-approval revision date *(if applicable)*:** Click here to enter a date.

**Project Details**

1. **Lead investigator**

|  |  |
| --- | --- |
| **Name:** | Click here to enter text. |
| **Institution:** | Click here to enter text. |
| **Email** **address:** | Click here to enter text. |

*(Identify one point person to manage this concept. List others in #3 below.)*

1. **ELEA liaison (if lead is not an ELEA investigator):**

|  |  |
| --- | --- |
| **Name:** | Click here to enter text. |
| **Institution:** | Click here to enter text. |
| **Email** **address:** | Click here to enter text. |

1. **Co-Investigators:**

Click here to enter text.

1. **Who will be conducting the data analysis?**

Statistician(s): Click here to enter text.

Data Manager(s): Click here to enter text.

1. **Sites included:**

Hospital Universitário Professor Edgard Santos (HUPES)

Universidade de São Paulo (USP)

Centro de Referência e Treinamento DST/AIDS-SP (CRT)

Instituto Nacional de Infectologia Evandro Chagas (INI)

1. **IRB Approval**

Not Applicable

Uncertain if IRB is needed

Pending

Approved - Date:

IRB Study number:

1. **Study Funding Source & Details:**

*Specify source of funding for study team effort to complete proposed project including data analyses and laboratory experiments, as applicable.*

1. Proposed study is related to an existing grant?

Yes, ELEA parent grant

Yes, other than ELEA Parent grant *(Please indicate the sponsor and if NIH-supported indicate the grant number)*

Sponsor: Click here to enter text.

If NIH, Grant Number: Click here to enter text.

No

1. Proposed study is related to a future grant submission?  Yes (*If yes, complete 1 - 4 below*)  No

1)  NIH (Please specify solicitation number below)

NIH Solicitation Number: Click here to enter text.

2)  Other sponsor (*please specify*): Click here to enter text.

3) Your grant submission deadline: Click here to enter a date.

4) Is a letter of support from the ELEA needed?  Yes  No

1. If you answered “No” to both 7.a & 7.b please indicate the source of funding for this proposed study:

Click here to enter text.

**Research Plan**

1. **Specific Aims/Hypotheses**

*Be specific. Include primary and secondary aims as well as hypotheses associated with each aim.*

1. **Background/Significance**

*Describe the importance of study question as it relates to ELEA-Brasil. Cite relevant literature. Include background information to support the proposed study and other studies conducted in the field that address the proposed hypothesis. Explain how this study will contribute to the existing literature.*

1. **Inclusion/Exclusion Criteria**
2. **ELEA Tables and Variables Needed (check all that apply)**

*Include which visits you want each variable to be collected (i.e. baseline visit, phone call consultations, annual visits follow-up)*

**Baseline Visit:**

Enrollment & Visit Information

Baseline Demographics

Clinical Labs (CD4 & CD8, HIV VL, HbA1c, IGRA)

Anthropometrics

Medications: ACTG form

Recent Infections

COVID-19 Questions

COVID-19 Vaccination Log

Social Provision Scale

Food Insecurity Scale

Smoking, alcohol, substance use: ASSIST 3.1

Depression Symptoms: PHQ-9

HIV Stigma Scale

Falls Questions

ER Visits Questions

Hospitalization Questions

Quality of Life: EQ 5D 5L

Perception of Aging: ERA-12

10-TaGA

Fried Frailty Assessment and iPAQ

Multidimensional Fatigue Inventory (MFI)

Short Physical Performance Battery (SPPB)

Montreal Cognitive Assessment (MoCA)

Lawton-Brody

Barthel Index: Activity of Daily Living

Carotid Intima Thickness measurements

Biospecimen Processing & Storage

Social Vulnerability Index

Cytokine Panel

IL-32 & Trail Measurements

Multiplex serology panel (specify pathogens)

☐ Geriatric Form

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**Follow-up 6 months phone calls (50-64yrs):**

Phone Interview Contact Attempt

Recent Infections

COVID-19 Questions

COVID-19 Vaccination Log

Hospitalization Questions

ER Visit Questions

Falls Questions

Lawton-Brody

Barthel Index: Activities of Daily Living

Death Record

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**Follow-up annual visits (>65yrs):**

Anthropometrics

Phone Interview Contact Attempt

Medications: ACTG

Recent Infections

COVID-19 Questions

COVID-19 Vaccination Log

10-TaGA

Social Provision Scale

Food Insecurity

Smoking, alcohol, substance use: ASSIST 3.1

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**Medical History:**

Medical Record Review Log

HIV History

HIV ART Regimen

Comorbidity History

Other Comorbidities

CD4 & CD8 Lab

HIV Viral Load Lab

CMV Testing

Chagas Disease testing

HTLV-1 testing

Hepatitis B virus testing

Hepatitis C virus testing

Herpes Simplex (HSV) testing

Toxoplasma testing

TB exam/test

TB diagnosis

Malaria infection

Dengue infection

Zika infection

Chikungunya infection

Leishmaniasis infection

Paracoccidiomycosis infection

Varicella Zoster virus (VZV) Testing

Death Record

**COVID-19 Supplement:**

Supplement Visit

Depression symptoms: PHQ-9

COVID-19 anxiety scale (CAS)

WAIS-III Digit Span

Trail-Making Parts A & B (TMT)

CERAD

Other tables and variables needed:

**Will specimens from biorepository be requested?**  Yes  No

1. *If “Yes,” the deadline date you will require specimens (mm/dd/yyyy): Click here to enter text.*
2. *Following approval of the concept, you will need to complete the MACS Materials Transfer Agreement (MTA) that will be sent to you.*
   1. **If YES, specify sample type:**

☐ Urine: Click here to enter text. *(specify volume,* **(ex: 1 μL)***)*

Plasma: Click here to enter text. *(specify volume,* **(ex: 1 μL)***)*

Sera:Click here to enter text. *(specify amount)*

PBMCs:Click here to enter text. *(specify # of cells)*

* 1. **Indicate the # of samples (patients):** Click here to enter text.
  2. **Briefly Describe the Laboratory Methodology (if applicable)**

1. **Study Methods and Planned Statistical Analyses**

*Describe the methods, outcome variable(s), covariates, and analytic plan.*

1. **External Data Sources**
2. **Sample Size Estimate**
3. **References**

**Goals and Timeline**

1. **Target Journal(s):**

Click here to enter text.

1. **Provide a timeline for this concept sheet:**

Proposed data collection date *(if needed):* Click here to enter a date.

Proposed analysis completion date: Click here to enter a date.

Proposed manuscript circulation date: Click here to enter a date.

**Statement of Agreement**

I hereby acknowledge and agree that:

* All information that 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 Section.
* IRB approval has been, or will be, obtained before any data and/or specimens are received.
* I will complete an ELEA Data Use Agreement (DUA) if this proposal receives approval.
* I will submit an ELEA Material Transfer Agreement (MTA) if this proposal receives approval.
* Under no circumstances will I make any ELEA study ID number public whether in documents or presentations, e.g., journal articles, abstracts, oral or poster presentations, or on any website.
* At completion of the project, all data and specimens, as applicable, will be destroyed or returned to source institution. Written and signed documentation of data and specimen destruction will be provided.

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Investigator Signature Date