**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

**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

[ ]  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

[ ]  Fried Frailty Assessment and iPAQ

[ ]  Short Physical Performance Battery (SPPB)

[ ]  Montreal Cognitive Assessment (MoCA)

[ ]  Lawton-Brody

[ ]  Barthel Index: Activity of Daily Living

[ ]  Death Record

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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