**EINSTEIN-ROCKEFELLER-CUNY CENTER FOR AIDS RESEARCH (ERC CFAR)**

**CLINICAL AND TRANSLATIONAL SCIENCE CORE (CTSC)**

**HIV CLINICAL COHORT DATABASE**

**Collaboration Concept Sheet Submission Form**

**SUBMISSION INSTRUCTIONS**

* Email completed Collaboration Concept Sheet Submission Form to [**cfar-clinical-core@einsteinmed.org**](mailto:cfar-clinical-core@einsteinmed.org)
* You will receive an email acknowledging receipt. The review should take 10 business days. If you do not receive a response within this timeframe, please send an additional email asking for a status update.

**A.** **GENERAL INFORMATION**

1. **DATE OF REQUEST**: \_\_\_/\_\_\_/\_\_\_
2. **Key Personnel**
   1. **Principal Investigator:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name | Email | Phone | Einstein (AECOM) | Montefiore (MMC) | Rockefeller University | CUNY: | Jacobi | Other: |
|  |  |  |  |  |  |  |  |  |

* 1. **Primary/Lead Investigator to contact with questions (if different from PI):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Name | Email | Phone | Einstein (AECOM) | Montefiore (MMC) | Rockefeller University | CUNY: | Jacobi | Other: |
|  |  |  |  |  |  |  |  |  |

* 1. **Other Investigator(s):**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Name | Email | Einstein (AECOM) | Montefiore (MMC) | Rockefeller University | CUNY: | Jacobi | Other: |
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* If external (non-Montefiore/Einstein) insititutions are involved, will data need to be provided to the external personnel?

No  Yes  *(A Data Use Agreement must be executed before data delivery)*

1. **Official Study Title** (Use IRB Protocol title, if applicable)**:**

**3. CTSC Liaison (if Lead Investigator is not part of the CTSC):** (*Leave blank if no liaison*)

Kathryn Anastos  Uriel Felsen  David Hanna  Heidi Jones  Mindy Ginsberg

Has CTSC liaison reviewed the completed Concept Sheet?  Yes  No

**4. IRB & Human Subjects Issues:**

1. Has this project already been approved by the Einstein/Montefiore IRB?

Yes  IRB No.:       IRB Initial Approval Date:      IRB Expiration Date:

No  Please provide explanation and timeline for submission, including external IRBs

if applicable:

1. Do you require aggregate numbers only or individual-level data?

Aggregate numbers only  *Skip to Question 5*

Individual-level data  *IRB approval or exemption is required from all participating sites*

* *Certificate/license no.*
* *Vehicle identifier, serial no.*
* *Device identifier, serial no*
* *Health plan beneficiary no.*
* *Any other unique ID no.,*

*characteristic, or code*

* *Geographic subdivision smaller*

*than a state,except for initial*

*3 digits of ZIP Code*

* *Full-face photographic image*
* *Name*
* *MRN*
* *Phone or FAX no.*
* *Email address*
* *SSN*
* *Account no.*
* *URL*
* *IP address*
* *Biometric identifier*

1. Data Type Determination:

* Does the study require that we provide any of the

HIPAA identifiers listed to the right?

No  Yes * Data Type = Identifiable*

* If none of the above identifiers are needed, do you require actual dates (e.g. DOB, DOD, service, admit, discharge dates)?

No  Yes * Data Type = Limited Dataset*

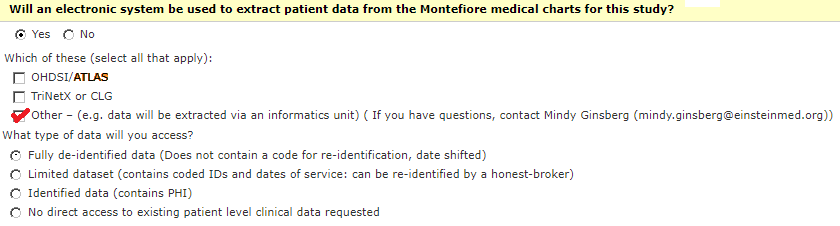
*Data Type= De-identified*  *(Please note: Instead of actual date values, dates that are randomly skewed or date*

*intervals may be provided to comply with HIPAA’s Privacy Rule for de-identified data.)*

1. If submitting a new protocol, you must:
   1. Indicate in the **protocol** that you will be accessing the CFAR Clinical Cohort Database as follows:

*“For our protocol we will obtain data from the HIV Clinical Cohort Database managed by the Einstein-Rockefeller-CUNY Center for AIDS Research (CFAR) under IRB approved protocol 2013-2217. This database, managed by the Epidemiology Informatics Study Management Unit (EISMU), retrieves and centralizes data from the institutional electronic health record. CFAR personnel will extract and provide requested data to the study investigators. Data to be extracted will be <Insert correct data type here – e.g. identifiable, limited dataset etc.)> and will be restricted to data already detailed in the protocol.”*

* 1. Indicate in the **IRB application** that you are using EISMU informatics with the appropriate data type:



* If the protocol has already been submitted, an amendment must be submitted with the paragraph stated above in 4.d.1 and the approval letter submitted to [**cfar-clinical-core@einsteinmed.org**](mailto:cfar-clinical-core@einsteinmed.org)*.*

1. Would you like guidance on submitting your protocol to the Einstein IRB?  Yes  No

**5. Purpose of Database Request** *(Select as many as needed.)*

Abstract/manuscript Protocol support (recruitment)  Grant submission  Other (*specify*):      

**6. Grant Information:**

1. Is proposed study related to an existing grant or pending grant submission?

Yes, existing *Please specify*:  NIH Sponsor:      Grant/Solicitation Number:

Yes, pending  Other sponsor (*please specify*):

No If “No”, please indicate source of funding if any:

**7. Will analytic support be requested from CTSC?**

Yes ** If “Yes”, is funding available?  Yes  No

No ** If “No: a. Who will perform analysis?

b. Has analytic team reviewed this Concept Sheet?  Yes  No

**8. Is there a deadline by when the data are needed?**   No  Yes 

Month Year

**B. STUDY DESIGN** (*Use the following organization to briefly present your study plan. Take whatever space is necessary to respond completely to each section.*)

**1. Background** (*Provide a brief description of the rationale for the study, including references.*)

**2.** **Specific Aims and Hypotheses**

**3. Study Population and Inclusion/Exclusion Criteria**

**4. Study Design and Analysis Plan** (*Summarize the type of study, study procedures, inclusion criteria, sample size, and analysis procedures.*)

**5. Variables Requested** *(Contact* [*cfar-clinical-core@einsteinmed.org*](mailto:cfar-clinical-core@einsteinmed.org) *to receive a copy of the data dictionary.)*

Sociodemographics and behavioral:

|  |  |
| --- | --- |
| Age *as of:*         (e.g., date of study entry, date of death, or a specific date like 11/1/2020) | Race/ethnicity |
| Sex | Transmission risk category (CDC definitions) |

Clinical and laboratory (including associated dates):

|  |  |
| --- | --- |
| HIV serostatus | CD4+ T-cell count |
| Earliest date of HIV diagnosis | HIV RNA level |
| Last date of confirmed HIV-negative status | Hepatitis C serostatus |

Vital status and administrative (including associated dates):

|  |  |
| --- | --- |
| Vital status | Date last seen at MMC |
| Date of death | Insurance status (visit data specific) |

Prescriptions:

|  |  |
| --- | --- |
| ART use | Other medications: |

Other variables requested from the data dictionary:

Other variables that you may be interested in that are not in the data dictionary (please justify):

**C. ADDITIONAL NOTES FOR DATA ANALYST** *(for CTSC use only)*

1. **Final cohort criteria** *For any date-related information (e.g., age, scoping time frames), please provide exact anchor/index  
    dates and not solely relative phrases (e.g., “in the last year”).*
2. **Final variables** *For inherently longitudinal data (e.g., lab results, medications), please provide guidance on whether time-series, miniumum/maximum/average and/or “existence of” or “history of” information is desired.*

|  |  |
| --- | --- |
| **Category** | **Variable(s)** |
|  |  |
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1. **Other notes:**

**APPENDIX: Concept Sheet Guidelines and Policies**

**A. General Instructions**

1. All Concept Sheets must be reviewed and approved by the CTSC leadership.
2. The investigator will be contacted by the CTSC Coordinator with information that the Concept was approved, approved with comments, tabled for further clarification, needs to be revised and reviewed again, or was rejected.
3. Concepts requesting individual-level data records MUST have Einstein-Montefiore IRB approval or IRB official exemption status before they are approved:

|  |  |  |  |
| --- | --- | --- | --- |
| **Prospective investigator** | **Data Requested from the CFAR CTSC** | **What Investigator Needs to Do With Regard to IRB** | **What CTSC Needs to Do With Regard to IRB** |
| Einstein/MMC PI | * Any of the 18 HIPAA identifiers\* * Limted Dataset | Submit new protocol to Einstein IRB in iRIS (or amendment) using language delineated above in Section 4.d. and obtain IRB approval | Nothing |
| Einstein/MMC PI | Truly de-identified (none of the 18 HIPAA identifiers\*) | Submit new protocol to Einstein IRB in iRIS (or amendment) using language delineated above in Section 4.d. and obtain IRB notification that study is not subject to federal human research regulations | Nothing |
| External PI  (e.g., Rockefeller, CUNY, etc.) | * Any of the 18 HIPAA identifiers\* * Limted Dataset | External PI needs to obtain external IRB approval at their home institution. | Submit amendment to add site to the application as “institution’s own IRB review” |
| External PI  (e.g., Rockefeller, CUNY, etc.) | Truly de-identified (none of the 18 HIPAA identifiers\*) | External PI needs to obtain external IRB approval at their home institution and obtain IRB notification that study is not subject to federal human research regulations | Nothing |

\*Skewed dates not included

**B. Policy on Approved Use of Data**

1. After approval of the concept sheet, a Data Use Acess Request (DUAR) will be sent to be signed by Principal Investigator to indicate the key personnel authorized to receive data. When appropriate, an external Data Use Agreement will be intiated and signed by the investigator’s authorized institutional representative
2. Data provided by the CTSC are intended for the express purpose of performing CTSC-approved research. These data must not be provided to other investigators or used for additional non-approved projects without the written consent of the ERC-CFAR CTSC.
3. Data received from the CTSC may only be used for the specific aims of the approved analysis proposed in this concept. Additional research initiatives should be submitted to the CTSC via completion of a new Collaboration Concept Sheet Submission Form.
4. Unauthorized use of data for work not specifically described in the aims of this Concept Sheet will be considered a breach of professional ethics and could result in such actions as withdrawal of abstracts or publications, as well as the prohibition of future use of cohort data.

**C. Policy on Abstracts and Manuscripts**

1. ALL abstracts and manuscripts utilizing CTSC data as the primary data source MUST be submitted to the CTSC for review and approval before they are submitted to a conference or journal. Please allow 2 business days for abstracts and 2 weeks for manuscripts for review, prior to submission.
2. Lead authors should notify the CTSC Coordinator of any and all manuscripts accepted for publication.
3. Lead authors are responsible for complying with the NIH Public Access Policy, that peer-reviewed manuscripts arising from NIH funding and accepted for publication are deposited in PubMed Central (PMC). Once a manuscript is accepted by a journal, the lead author will need to send proof of submittal to NIHMS for assignment of a PMCID to [*cfar-clinical-core@einsteinmed.org*](mailto:cfar-clinical-core@einsteinmed.org). If you have submitted a manuscript to a journal that initiates the PMCID request, investigators may submit proof that the journal has commenced this process (e.g., manuscript acceptance email with confirmation of NIHMS submission).

**D. Acknowledgment**

All publications and presentations of studies utilizing CTSC data as the primary data source should acknowledge the contribution of data, as well as the Einstein-Rockefeller-CUNY Center for AIDS Research. The suggested language for acknowledgment is below:

*The Einstein-Rockefeller-CUNY Center for AIDS Research (P30-AI-124414) is supported by the following NIH Co-Funding and Participating Institutes and Centers: NIAID, NCI, NICHD, NHLBI, NIDA, NIDDK, NIGMS, NIMH, NIMHD, NIA, FIC, and OAR.*