C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Data Processing Cover Sheet
(Administrative)

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RCID: _____

Completed prior to data entry at Intake visit

CONTACT: ☐ Contact Number 0: Intake Visit

	Date	Initials	Comment
Review Completed Forms:			
Entry:			

Encryption Number: __ __ __ __ __ __ __ __ __ __ __ __

C	**Clinical**	**Packet A:**	**Patient ID:** _____
F	**Core**	**Screening Checklist**	**Patient Initials:** _____
A	**Cohort**		**Clinical Center:** _____
R	**Registry**		**Contact Number:** _____
			Date: _____
		[Research Coordinator Completed]	**RC ID:** _____

Inclusion Criteria:
(Responses to questions 1, 2 and 3 must be "***YES***" to meet eligibility requirements.)

1. Is the patient HIV-infected as confirmed by lab diagnosis? ☐1 Yes ☐0 No

2. Patient receives his/her care at or volunteered for HIV-related studies at one of the UPenn-affiliated hospitals? ☐1 Yes ☐0 No

3. Has the patient or parent/legal guardian signed and dated the Informed Consent? ☐1 Yes ☐0 No

   a. If ***YES,*** record the date the form was signed. __ __ / __ __ / __ __ __ __ (month / day / year)

Deferral Criteria:
(Responses to questions 4 and 5 must be "***NO***" to meet eligibility requirements.)

4. Does the patient wish to take additional time to consider enrolling in the registry? ☐1 Yes ☐0 No

5. Does the patient present an emotional and / or physical state that prohibits him / her from properly considering enrollment in the registry? ☐1 Yes ☐0 No

6. Is the patient eligible for the study at this time? ☐1 Yes ☐0 No ☐2 Deferred

   ➧ If ***YES***, please continue.

   ➧ If ***Deferred,*** please indicate the date of re-assessment. __ __ / __ __ / __ __ __ __ (month / day / year)

Eligibility Confirmation:

7. Has this patient been fully screened and is now eligible to participate in the CCCR? ☐1 Yes ☐0 No ☐2 Deferred

8. Research Coordinator's signature: _____

9. Research Coordinator's ID _____ Date: __ __ / __ __ / __ __ __ __ (month / day / year)

C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Patient Contact Information

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RCID: _____

This form contains confidential information for Clinical Center use only. DO NOT forward to Clinical Core.

1. Name: _____ (LAST) _____ (FIRST) _____ (MIDDLE)

2. Social Security Number: __ __ __ - __ __ - __ __ __ __ ~~Date of Birth: __ __ / __ __ / __ __ __ __~~

Encryption Number generated by the Data Management System is recorded on the Data Processing Cover Sheet (DPCS).

3. Institution Medical Records Number: ____ ____ ____ ____ ____ ____ ____ ____ ____

4. Address: _____ (STREET ADDRESS)

_____ (CITY) _____ (STATE) _____ (ZIP CODE)

Mailing address, if different than above:

_____ (STREET ADDRESS)

_____ (CITY) _____ (STATE) _____ (ZIP CODE)

5. Home Phone Number: _____ (AREA CODE) - _____ - _____

6. Work Phone Number: _____ (AREA CODE) - _____ - _____

7. Cell Phone Number: _____ (AREA CODE) - _____ - _____

8. eMail Address: _____ @ _____

9 What is the best way to contact you? ☐ Home ☐ Work ☐ Cell ☐ E-mail

10. What is the best time to contact you? _____

11. Who is your usual primary care physician?

Name: _____ (LAST) _____ (FIRST) _____ (MIDDLE)

Address: _____ (STREET ADDRESS)

_____ (CITY) _____ (STATE) _____ (ZIP CODE)

Phone Number: _____ (AREA CODE) - _____ - _____

Other Contacts (name, address and telephone number of relatives/friends if we cannot contact you directly):

12. Name: _____ (LAST) _____ (FIRST) _____ (MIDDLE)

Address: _____ (STREET ADDRESS)

_____ (CITY) _____ (STATE) _____ (ZIP CODE)

Phone Number: _____ (AREA CODE) - _____ - _____

Relationship to you: _____

13. Is this person aware of your HIV status? ☐1 Yes ☐0 No

Note: Previous Question 13a referring to where a participant obtained their HIV medications has been dropped from this section. To view this question, please refer to an older archived version to view this question.

For CHOP patients only: If the patient is currently 18 years old or younger AND has had HIV since birth, please complete 14-17.

14. What is your father's first and last name?

_____ (FIRST NAME) _____ (LAST NAME)

15. What is your father's Social Security Number? ___ __ __ - __ __ - __ __ __ __

Encryption Number generated by the Data Management System is recorded on the Data Processing Cover Sheet (DPCS).

16. What is your mother's first and last name?

_____ (FIRST NAME) _____ (LAST NAME)

17. What is your mother's Social Security Number? __ __ __ - __ __ - __ __ __ __

Note: Previous Question18 and subsequent Questions 18a – 18j referring to a participants children and their demographic information have been dropped from this section, please refer to an older archived version to view these questions.

C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Demographics

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RCID: _____

---

1. What is your date of birth? __ __ / __ __ / __ __ __ __ (month / day / year)

Note: Previous Questions 1a – 1d referring to Parent's DOB and serostatus have been dropped from this section; please refer to an older archived version to view these questions.

2. What is your present gender?

☐ 1 Male
☐ 2 Female
☐ 3 ~~Male living as a female~~
☐ 4 ~~Female living as a male~~

2a. What is your birth gender?

☐ 1 Male ☐ 2 Female

Note: Previous Question 3 referring to an individual's race / ethnic group have been dropped from this section; please refer to an older archived version to view these questions.

3a. Were you born in the United States?

☐ 1 Yes (skip to question #4) ☐ 0 No (go to question #3b)

3b. If ***NO***, are you a United States citizen?

☐ 1 Yes ☐ 0 No

4. What is the highest grade of education that you have completed?

☐ 1 Less than high school graduate
☐ 2 High school graduate or GED
☐ 3 Some college
☐ 4 Graduated from college
☐ 5 Graduate or professional school after college
☐ 6 Trade school/Technical school

5. What is your current employment status?

☐ 1 Employed
☐ 2 Unemployed
☐ 3 Student
☐ 4 Retired
☐ 5 Disabled

6. What is your current annual gross family income (members living in the same household)?

☐ 1 $10,000 or less
☐ 2 $10,001 to $25,000
☐ 3 $25,001 to $50,000
☐ 4 $50,001 to $100,000
☐ 5 More than $100,000
☐ 6 Prefer not to answer

7. How many children do you have?

___ ___

(If you have children, please indicate their birth years and HIV status for each below.)

		Initials	Year of Birth (last 2 digits only)	Is this child HIV+?	
7a.	Child # 1:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7b.	Child # 2:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7c.	Child # 3:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7d.	Child # 4:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7e.	Child # 5:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7f.	Child # 6:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7g.	Child # 7:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7h.	Child # 8:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7i.	Child # 9:	___ ___ ___	___ ___	☐1 Yes	☐0 No
7j.	Child # 10:	___ ___ ___	___ ___	☐1 Yes	☐0 No

7k. (For female participants) Are you currently pregnant?

☐1 Yes ☐0 No ☐98 N/A (for male participants)

8. What is your ~~primary~~ current insurance plan?

☐1 Fee-for-service/BC/BS
☐2 Medicare only
☐3 Medicaid only
☐4 Medicare and Medicaid
☐5 Medicare and supplemental
☐6 HMO/POS-BC/BS
☐7 Medicare/HMO
☐8 Medicaid/HMO
☐9 VA/CHAMPUS
☐10 PPO
☐11 Self-pay
☐12 Uninsured
☐98 Other

9. What is the first and last name of the provider that you currently see for management of your HIV?

FIRST NAME _____ LAST NAME _____

Note: Previous Question 10a – 10d referring to an individual's Alcohol and Drug Use have been dropped from this section; please refer to an older archived version to view these questions.

Note: Previous Question 11 – 14 referring to an individual's Sexual History have been dropped from this section; please refer to an older archived version to view these questions.

15. What is your ethnicity?

☐1 Hispanic or Latino ☐2 Not Hispanic or Latino

16. What race do you most identify with?

☐1 American Indian / Native Alaskan
☐2 Asian
☐3 Native Hawaiian / Other Pacific Islander
☐4 Black / African American
☐5 White / Caucasian
☐6 Multiracial
☐98 Other

C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Medical History

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RCID: _____

HIV History

1. To the best of your knowledge what ~~month and~~ year were you diagnosed with HIV? __ __ / _ _ _ _ (~~month~~ year)

2. ~~What month and~~ What year do you think you contracted HIV? __ __ / _ _ _ _ (~~month~~ year)

3. How do you think you contracted HIV?
   - ☐ 1 At birth, from mother
   - ☐ 2 Sexual activity
   - ☐ 3 Drug use/Sharing needles
   - ☐ 4 Blood transfusion
   - ☐ 88 Unknown
   - ☐ 98 Other, please specify _____

4. Prior to your HIV positive diagnosis, did you have any HIV tests done that were negative? ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

5. What is your current weight? _ _ _ lbs

   5a. What would you consider your usual body weight? _ _ _ lbs

6. What is your current height? _ _ ft. _ _ ins.

7. Have you ever been hospitalized for an HIV-related problem? ☐ 1 Yes ☐ 0 No

General History

8. Have you ever had or do you currently have any of the following?

8a. Cancer (include Kaposi's sarcoma)	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8b. Cardiac disease/heart problems	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8c. Central nervous system/brain problems	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8d. Hepatitis B	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8e. Hepatitis C	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8f. Hepatitis, other/type unknown	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8g. Lipodystrophy Syndrome (~~my body and/or face has changed~~ changes in face/body shape)	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8h. Orthopedic disease (bone/joint probems)	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8i. Psychiatric (mental) disease such as depression	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8j. Cytomegalovirus disease (CMV)	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8k. Cryptococcal disease	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8l. Mycobacterium avium intracellulare (~~"~~MAC or ~~" (~~MAI~~) infection~~)	☐ 1 Yes	☐ 0 No	☐ 88 Unknown
8m. Pneumonia	☐ 1 Yes	☐ 0 No	☐ 88 Unknown

8n. Abnormal Pap Smear (Women Only)
- ☐ 1 Yes
- ☐ 0 No
- ☐ 88 Unknown
- ☐ 99 Not Applicable

8o. Sexual Transmitted Disease~~, such as~~ (includes Herpes, Gonorrhea, Chlamydia, Trichomonas, Syphilis — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

8o-i. Genital Herpes outbreak — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

8o-ii. Syphilis diagnosis (RPR positive) — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

8o-iii. Genital warts (HPV) — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

8p. Trouble with high blood sugar/diabetes — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

If response to question #8p is ***NO*** (0), skip to question #8r.

8q. Have you ever or do you now take medication to regulate your high ~~for~~ blood sugar (diabetic medicine)? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

8r. Shingles (Herpes zoster) — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

8s. Kidney disease — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

8t. Have you ever been diagnosed with Tuberculosis or had a positive skin test (positive PPD)? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

9. Have you ever had a blood transfusion? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

10. ~~Have you had~~ Do you have occasional memory loss or difficulty ~~with your thinking~~ concentrating? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

11. Have you ever had tingling, ~~or~~ numbness, persistent burning or pain in your feet or hands ~~that lasted more than a few minutes~~ or been diagnosed with neuropathy? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

12. How much help do you need with normal daily activities?
- ☐ 1 None
- ☐ 2 A little
- ☐ 3 Quite a lot
- ☐ 4 All

13. Have you ever had high blood pressure? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

14. Do you have a family history of high blood sugar/diabetes? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

15. Do you have a family history of heart disease? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

If ***YES***, please answer question #s 15a and 15b.

15a. Was your father/brother diagnosed before the age 55? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

15b. Was your mother/sister diagnosed before the age of 65? — ☐ 1 Yes ☐ 0 No ☐ 88 Unknown

C	**Clinical**	**Packet A:**	**Patient ID: _____**
F	**Core**	**Present and Previous**	**Patient Initials: _____**
A	**Cohort**	**Antiviral Treatments**	**Clinical Center: _____**
R	**Registry**		**Contact Number: _____**
			Date: _____
		[Research Coordinator Completed]	**RC ID: _____**

Past Antiviral Treatment(s):

1. Have you ever taken medications for HIV for one month or more?..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

   If ***YES***, please answer question #1a. If ***NO***, please skip to question #12.

   1a. Please provide the approximate month and year when you first started anti-HIV medication. ..... __ __ / __ __ __ __ (month / year)

2. Have you ever taken a protease inhibitor for more than 7 days?..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

   2a. If ***YES***, which ones? (Check all that apply)

2a-i.	Amprenavir/Fosamprenavir (Agenerase, Lexiva).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-ii.	Indinavir (Crixivan).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-iii.	Nelfinavir (Viracept).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-iv.	Ritonavir (Norvir)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-v.	Saquinavir (Invirase, Fortovase)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-vi.	Lopinavir/Ritonavir (Kaletra).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-vii.	Atazanavir (Reyataz).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-viii.	Tipranavir (Aptivus)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
2a-ix.	Darunavir (TMC114).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown

3. Have you ever taken a non-nucleoside reverse transcriptase inhibitor (NNRTI) for more than 7 days?..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

   3a. If ***YES***, which ones? (Check all that apply)

3a-i.	Delavirdine (Rescriptor).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
3a-ii.	Efavirenz (Sustiva)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
3a-iii.	Nevirapine (Viramune).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown

4. Have you ever taken a nucleoside reverse transcriptase inhibitor (NRTI) or nucleotide reverse transcriptase inhibitor (NtRTI) for more than 7 days? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

   4a. If ***YES***, which ones? (Check all that apply)

4a-i	Lamivudine/Zidovudine (Combivir).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-ii.	Lamivudine - 3TC (Epivir).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-iii.	Zalcitabine - ddC (Hivid).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-iv.	Zidovudine - AZT (Retrovir).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-v.	Didanosine - ddI (Videx).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-vi.	Stavudine - d4T (Zerit).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-vii.	Abacavir (Ziagen)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-viii.	AZT/3TC/Abacavir (Trizivir).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-ix.	Tenofovir (Viread).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-x.	Emtricitabine (Emtriva)	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-xi.	Abacavir/Lamuvidine (Epzicom).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown
4a-xii.	Emtricitabine/Tenofovir (Truvada).....	☐$_1$ Yes	☐$_0$ No	☐$_{88}$ Unknown

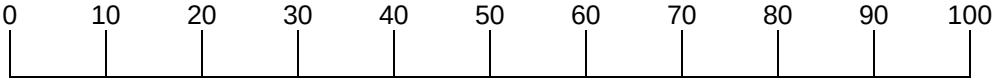
5. Have you ever interrupted or stopped anti-HIV medications for more than 7 days? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

Current Anti-HIV ~~viral~~ Treatment(s):

6. Are you currently on HIV medications? ..... ☐1 Yes ☐0 No ☐88 Unknown

   If ***YES***, continue. If ***NO***, do NOT answer question #s 6a, 7, 8 or 9, skip to question #12.

   6a. What percent of your anti-HIV medication doses have you taken in the past 30 days? Please indicate by marking on the scale below. ..... __ __ __%
   ..... ☐88 Unknown
   ..... ☐97 Not Answered



7. Are you currently on protease inhibitors? ..... ☐1 Yes ☐0 No ☐88 Unknown

   7a. If ***YES***, which ones? (Check all that apply)

7a-i.	Amprenavir/Fosamprenavir (Agenerase, Lexiva)	☐1 Yes	☐0 No	☐88 Unknown
7a-ii.	Indinavir (Crixivan)	☐1 Yes	☐0 No	☐88 Unknown
7a-iii.	Nelfinavir (Viracept)	☐1 Yes	☐0 No	☐88 Unknown
7a-iv.	Ritonavir (Norvir)	☐1 Yes	☐0 No	☐88 Unknown
7a-v.	Saquinavir (Invirase, Fortovase)	☐1 Yes	☐0 No	☐88 Unknown
7a-vi.	Lopinavir/Ritonavir (Kaletra)	☐1 Yes	☐0 No	☐88 Unknown
7a-vii.	Atazanavir (Reyataz)	☐1 Yes	☐0 No	☐88 Unknown
7a-viii.	Tipranavir (Aptivus)	☐1 Yes	☐0 No	☐88 Unknown
7a-ix.	Darunavir (TMC114)	☐1 Yes	☐0 No	☐88 Unknown

8. Are you currently on non-nucleoside reverse transcriptase inhibitor (NNRTI)? ..... ☐1 Yes ☐0 No ☐88 Unknown

   8a. If ***YES***, which ones? (Check all that apply)

8a-i.	Delavirdine (Rescriptor)	☐1 Yes	☐0 No	☐88 Unknown
8a-ii.	Efavirenz (Sustiva)	☐1 Yes	☐0 No	☐88 Unknown
8a-iii.	Nevirapine (Viramune)	☐1 Yes	☐0 No	☐88 Unknown

9. Are you currently on nucleoside reverse transcriptase inhibitor (NRTI) or nucleotide reverse transcriptase inhibitor (NtRTI)? ..... ☐1 Yes ☐0 No ☐88 Unknown

   9a. If ***YES***, which ones? (Check all that apply)

9a-i.	Lamivudine/Zidovudine (Combivir)	☐1 Yes	☐0 No	☐88 Unknown
9a-ii.	Lamivudine - 3TC (Epivir)	☐1 Yes	☐0 No	☐88 Unknown
9a-iii.	Zalcitabine - ddC (Hivid)	☐1 Yes	☐0 No	☐88 Unknown
9a-iv.	Zidovudine - AZT (Retrovir)	☐1 Yes	☐0 No	☐88 Unknown
9a-v.	Didanosine - ddI (Videx)	☐1 Yes	☐0 No	☐88 Unknown
9a-vi.	Stavudine - d4T (Zerit)	☐1 Yes	☐0 No	☐88 Unknown
9a-vii.	Abacavir (Ziagen)	☐1 Yes	☐0 No	☐88 Unknown
9a-viii.	AZT/3TC/Abacavir (Trizivir)	☐1 Yes	☐0 No	☐88 Unknown
9a-ix.	Tenofovir (Viread)	☐1 Yes	☐0 No	☐88 Unknown
9a-x.	Emtricitabine (Emtriva)	☐1 Yes	☐0 No	☐88 Unknown
9a-xi.	Abacavir/Lamuvidine (Epzicom)	☐1 Yes	☐0 No	☐88 Unknown
9a-xii.	Emtricitabine/Tenofovir (Truvada)	☐1 Yes	☐0 No	☐88 Unknown

Packet A:
Present and Previous
Antiviral Treatments

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RC ID: _____

Other Antiviral Treatment(s):

10. Have you ever taken a fusion inhibitor for more than 7 days? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

    10a. If ***YES***, is it/was it Enfuviritide (Fuzeon)?..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

11. Are you currently taking a fusion inhibitor?..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

    11a. If ***YES***, is it Enfuviritide (Fuzeon)? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

12. Are you currently taking alternative/complimentary therapies for your HIV? ..... ☐$_1$ Yes ☐$_0$ No

13. Are you currently taking any other anti-HIV drug, treatment or vaccine (excluding those already listed)? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

14. Are you in a clinical trial/study testing HIV Treatment? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

    14a. If ***YES***, specify: _____

15. Have you ever taken a CCR5 inhibitor for more than 7 days? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

16. Are you currently taking a CCR5 inhibitor?..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

17. Have you ever taken an integrase inhibitor for more than 7 days? ..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

18. Are you currently taking an integrase inhibitor?..... ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Adherence Questions

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RC ID: _____

1. Where do you get your HIV prescriptions, if any, filled?

   Pharmacy name: _____
   ☐$_{88}$ Not available

2. Availability of pharmacy information on index drug:

   ☐$_{1}$ Available (proceed to ***Adherence Log*** below)
   ☐$_{2}$ Unavailable (patient is treatment naïve; proceed to ***Clinical Laboratory Measures***)
   ☐$_{88}$ Unavailable (patient is NOT treatment naïve, but pharmacy information is not available)

Adherence Log

Refills	Refill date	Index drug	# of pills per dose	Frequency 1 = qd 2 = bid 3 = tid 4 = qid 5 = qod	# of pills dispensed
Last Refill	__ __/__ __/__ __ __ __				
Prior Refill 1	__ __/__ __/__ __ __ __				
Prior Refill 2	__ __/__ __/__ __ __ __				
Prior Refill 3	__ __/__ __/__ __ __ __				

C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Hepatitis Treatment

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RCID: _____

---

1. Have you received treatment for Hepatitis C? ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
(If ***No*** or ***Unknown***, skip to question #2)

1a. Which treatment(s) have you used?

		Ever treated?	Currently treated?
1a-i.	Pegylated interferon (once a week)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
1a-ii.	Regular interferon (3 times a week)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
1a-iii.	Ribavirin (Copegus, Virazole, Rebetol)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

2. Have you received treatment for Hepatitis B? ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
(If ***No*** or ***Unknown***, skip to ***Metabolics***)

2a. Which treatment(s) have you used?

		Ever treated?	Currently treated?
2a-i.	Hepsera (Adefovir)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
2a-ii.	Baraclude (Entecavir)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
2a-iii.	Pegylated interferon (once a week)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
2a-iv.	Regular interferon (3 times a week)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown
2a-v.	Tyzeka (Telbivudine)	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown	☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Unknown

C	**Clinical**	**Packet A:**	**Patient ID: _____**
F	**Core**	**Metabolics**	**Patient Initials: _____**
A	**Cohort**		**Clinical Center: _____**
R	**Registry**		**Contact Number: _____**
			Date: _____
		[Research Coordinator Completed]	**RCID: _____**

Metabolics (for individuals on anti-HIV therapy):

1. Are you currently on anti-HIV therapy?
   - ☐ 1 Yes
   - ☐ 0 No (skip to question #3)

2. Since starting your anti-HIV therapy, have you noticed any of the following?

   2a. Loss of fat in face?
   - ☐ 0 Big loss
   - ☐ 1 Slight loss
   - ☐ 2 No change

   2b. Change in body fat in arms or legs?
   - ☐ 0 Big loss
   - ☐ 1 Slight loss
   - ☐ 2 No change
   - ☐ 3 Slight gain
   - ☐ 4 Big gain

   2c. Change in body fat in abdomen?
   - ☐ 0 Big loss
   - ☐ 1 Slight loss
   - ☐ 2 No change
   - ☐ 3 Slight gain
   - ☐ 4 Big gain

   2d. FOR WOMEN, change in breast size?
   - ☐ 0 Decrease
   - ☐ 1 No change
   - ☐ 2 Increase
   - ☐ 99 N/A

   2e. FOR MEN, presence of fatty tissues in chest?
   - ☐ 0 Yes
   - ☐ 1 No
   - ☐ 99 N/A

3. How many times a week do you exercise for at least30 minutes?
   - ☐ 0 Never
   - ☐ 1 Once or twice
   - ☐ 2 3 to 5 times
   - ☐ 3 6 to 7 times

C	**Clinical**	**Packet A:**	**Patient ID: _____**
F	**Core**	**Clinical Laboratory Measures**	**Patient Initials: _____**
A	**Cohort**		**Clinical Center: _____**
R	**Registry**		**Contact Number: _____**
			Date: _____
		[Research Coordinator Completed]	**RCID: _____**

Mental Status (MS) Test:

1. Thirty (30) second MS test [Alternating numbers and letters] Result: _____
   ☐ 1 Language Barrier
   ☐ 97 Refused

2. Spell "WORLD" backwards:
   __ __ __ __ __
   ☐ 1 Language Barrier
   ☐ 97 Refused

Laboratory Results:

Pre-treatment:	**Date**	**Result**
1. Viral Load	__ __ / __ __ / __ __ __ __	☐ 1 Less than threshold of _____ copies/ml ☐ 2 Actual count recorded as _____ copies/ml ☐ 3 Greater than threshold of _____ copies/ml ☐ 88 Not available
2. CD 4 Count	__ __ / __ __ / __ __ __ __	_____ ul ☐ 88 Not available

Current:	**Date**	**Result**
3. Current Viral Load	__ __ / __ __ / __ __ __ __	☐ 1 Less than threshold of _____ copies/ml ☐ 2 Actual count recorded as _____ copies/ml ☐ 3 Greater than threshold of _____ copies/ml ☐ 88 Not available
4. CD 4 Count	__ __ / __ __ / __ __ __ __	_____ ul ☐ 88 Not available
5. CD 4 Percentage	__ __ / __ __ / __ __ __ __	_____ % ☐ 88 Not available
6. CD 8, absolute number	__ __ / __ __ / __ __ __ __	_____ ul ☐ 88 Not available

7. Have you ever had an HIV resistance test? ☐ 1 Yes ☐ 0 No

   7a. If ***YES***, when was your most recent HIV resistance test? Date: __ __ / __ __ / __ __ __ __

8. Free testosterone __ __ / __ __ / __ __ __ __ _____ pg/dL ☐88 Not available

9. Most recent metabolic panel: __ __ / __ __ / __ __ __ __

9a. Triglycerides: __ __ / __ __ / __ __ __ __ _____ mg/dL ☐88 Not available

9b. Total Cholesterol: __ __ / __ __ / __ __ __ __ _____ mg/dL ☐88 Not available

9c. HDL Cholesterol: __ __ / __ __ / __ __ __ __ _____ mg/dL ☐88 Not available

9d. LDL Cholesterol: __ __ / __ __ / __ __ __ __ _____ mg/dL ☐88 Not available

9e. Glucose: __ __ / __ __ / __ __ __ __ _____ mg/dL ☐88 Not available

10. Most recent hepatic serologies:

10a. Anti-HBcAg: __ __ / __ __ / __ __ __ __ ☐1 Positive ☐0 Negative ☐88 Not available

10b. Anti-HBsAg: __ __ / __ __ / __ __ __ __ ☐1 Positive ☐0 Negative ☐88 Not available

10c. Anti-HBeAg: __ __ / __ __ / __ __ __ __ ☐1 Positive ☐0 Negative ☐88 Not available

10d. HBsAg: __ __ / __ __ / __ __ __ __ ☐1 Positive ☐0 Negative ☐88 Not available

10e. HBeAg: __ __ / __ __ / __ __ __ __ ☐1 Positive ☐0 Negative ☐88 Not available

10f. HBV DNA level: __ __ / __ __ / __ __ __ __ ☐1 Positive ☐0 Negative ☐88 Not available

10g. Anti-HCV: __ __ / __ __ / __ __ __ __ ☐1 Reactive ☐0 Non-reactive ☐88 Not available

10g-i. If ***POSITIVE***, HCV genotype:
☐1 Type 1
☐2 Type 2
☐3 Type 3
☐4 Type 4
☐5 Unknown type
☐88 Not available
☐98 Other

10g-ii. If ***POSITIVE***, HCV RNA level: _____.____ units ☐88 Not available

C	**Clinical**	**Packet A:**	**Patient ID: _____**
F	**Core**	**Biological Specimen**	**Patient Initials: _____**
A	**Cohort**		**Clinical Center: _____**
R	**Registry**		**Contact Number: _____**
			Date: _____
		[Research Coordinator Completed]	**RCID: _____**

1. Was a research blood sample obtained? ☐1 Yes ☐0 No

   1a. If ***YES***, date blood sample sent to lab for storage: __ __ / __ __ / __ __ __ __
   month day year

C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Alcohol & Drug Use Addendum

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RCID: _____

A. Have you ever had a drink containing alcohol (such as beer, wine, or liquor)?

☐1 Yes
☐0 No (skip to question B)

NOTE:

A "drink" is defined as one of the following:
1) 12 oz. of beer
2) 1.5 oz shot of liquor
3) 5 oz. glass of wine

A1. Have you used alcohol in the past 6 months?

☐1 Yes
☐0 No

A2. How often did you have a drink containing alcohol over the last month?

☐0 Never
☐1 Once
☐2 Two to four times a month
☐3 Two to three times per week
☐4 Four or more times a week

A3. How many drinks containing alcohol did you have on a typical day when you were drinking over the last month?

☐0 0
☐1 1 or 2
☐2 3 or 4
☐3 5 or 6
☐4 7 – 9
☐5 10 or more

A4. How often did you have six or more drinks on one occasion over the last month?

☐0 Never
☐1 Less than monthly
☐2 Monthly
☐3 Two or three times per week
☐4 Four or more times per week

B. Have you ever smoked marijuana (pot, weed, joints, or blunts)?

☐1 Yes
☐0 No (skip to question C)

B1. Have you used marijuana in the past 6 months?

☐1 Yes
☐0 No

B2. How often have you used marijuana over the last month?

☐0 Not at all
☐1 Once
☐2 A few times
☐3 A few times a week
☐4 Everyday

C. Have you ever used cocaine or methamphetamines in any form (including freebasing, speedball, or crack)?

☐1 Yes →
☐0 No (skip to question D)

C1. Have you used cocaine in the past 6 months?

☐1 Yes
☐0 No

C2. How often have you used cocaine over the last month?

☐0 Not at all
☐1 A few times
☐2 A few times a week
☐3 Everyday

C3. Have you used methamphetamines in the past 6 months?

☐1 Yes
☐0 No

C4. How often have you used methamphetamines over the last month?

☐0 Not at all
☐1 A few times
☐2 A few times a week
☐3 Everyday

D. Have you ever used heroin or other opiates?

☐1 Yes →
☐0 No (skip to question E)

D1. Have you used heroin in the past 6 months?

☐1 Yes
☐0 No

D2. How often have you used heroin over the last month?

☐0 Not at all
☐1 A few times
☐2 A few times a week
☐3 Everyday

E. Have you ever used pills in a non-prescribed way to get high, relax, kill pain, or go to sleep (such as Xanax, Ecstasy, Vicodin, Percocets, Oxycotin)?

☐1 Yes
☐0 No (skip to question F)

E1. Have you used pills to get high, relax, kill pain, or sleep in the past 6 months?

☐1 Yes
☐0 No

E2. How often have you used pills to get high, relax, kill pain, or sleep over the last month?

☐0 Not at all
☐1 A few times
☐2 A few times a week
☐3 Everyday

F. Have you ever smoked cigarettes or used other nicotine products (chewing tobacco, cigars, pipes)?

☐1 Yes → F1
☐0 No (skip to question G)

F1. Have you smoked cigarettes/used tobacco products in the past 6 months?

☐1 Yes
☐0 No

F2. How often have you smoked cigarettes/used tobacco products over the last month?

☐0 Not at all
☐1 A few times
☐2 A few times a week
☐3 Everyday

G. Have you ever been in treatment for drug or alcohol problems (treatment includes inpatient, outpatient, detox, residential programs, etc.)?

☐1 Yes
☐0 No

H. Have you ever injected any drugs?

☐1 Yes → H1
☐0 No (skip to question I)

H1. How old were you when you first injected drugs?

_____ years

H2. In the past 6 months, how often have you injected any drugs?

☐0 Not at all (skip to question I)
☐1 A few times
☐2 A few times a week
☐3 Everyday

H3. In the past 6 months, how often did you share needles or works?

☐0 Not at all
☐1 A few times
☐2 A few times a week
☐3 Everyday

I. Has a psychologist, therapist, doctor, or other clinician ever told you that you were depressed, schizophrenic, or bipolar?

☐1 Yes → I1
☐0 No (skip to Sexual History questions)

I1. Have you received any medications to treat your mental condition in the past 6 months?

☐1 Yes

Please specify: _____

☐0 No

C	**Clinical**	**Packet A:**	**Patient ID: _____**
F	**Core**	**Sexual History Addendum**	**Patient Initials: _____**
A	**Cohort**		**Clinical Center: _____**
R	**Registry**		**Contact Number: _____**
			Date: _____
		[Research Coordinator Completed]	**RCID: _____**

1. Do you consider yourself:

   ☐$_1$ Gay / Lesbian
   ☐$_2$ Straight / Heterosexual
   ☐$_3$ Bisexual
   ☐$_{98}$ Other

2. Have you <u>ever</u> had anal, vaginal or oral sex?

   ☐$_1$ Yes ☐$_0$ No

   If ***NO***, skip to Depression Screen (***CES_D***). If ***YES***, continue.

3. Approximately how many sexual partners have you had in your lifetime?

   — — — — —

4. Approximately how many partners have you had <u>in the past 6 months</u>?

   — — — — —

5. Do you have a regular sex partner?

   ☐$_1$ Yes ☐$_0$ No (skip to question 8)

6. Is your regular sex partner HIV Positive?

   ☐$_1$ Yes ☐$_0$ No ☐$_{88}$ Don't Know

7. Approximately how often do <u>you and your regular sex partner</u> use condoms?

   ☐$_0$ Never ☐$_2$ Most of the time
   ☐$_1$ Some of the time ☐$_3$ All the time

8. Have you had sex with anyone (other than your regular sex partner) <u>in the past 6 months</u>?
   (If ***YES***, answer question 9. If ***NO***, skip to question 10.)

   ☐$_1$ Yes ☐$_0$ No ☐$_{99}$ Have not had sex in the past 6 months

9. Approximately how often do <u>you and your other sex partner(s)</u> use condoms?

   ☐$_0$ Never ☐$_2$ Most of the time
   ☐$_1$ Some of the time ☐$_3$ All the time

10. How often do you disclose your HIV status to your sexual partners?

    ☐$_0$ Never ☐$_2$ Most of the time
    ☐$_1$ Some of the time ☐$_3$ All the time

11. Have you ever given or received money or drugs for sex?

☐0 Never
☐1 A few times or less
☐2 A few times each month
☐3 A few times each week

12. Have you ever used substances to enhance your sexual performance or pleasure (substances may include Viagra, Cialis, Levitra, testosterone replacement therapy, etc)?

☐0 Never (skip to question #14)
☐1 A few times or less
☐2 A few times each month
☐3 A few times each week
☐99 Not applicable (for females)

13. Were these sexually enhancing substances prescribed by a doctor or a clinician?

☐1 Yes ☐0 No

Column ONE	**Column TWO**
14. Have you ever had vaginal sex? ☐1 Yes ☐0 No (skip to column TWO)	20. Have you ever had anal sex? ☐1 Yes ☐0 No (skip to ***CES_D***)
15. With how many people have you had vaginal sex in the past 6 months? ☐0 0 (skip to column TWO) ☐1 1 ☐2 Other __ __ (fill in blank)	21. With how many people have you had anal sex in the past 6 months? ☐0 0 (skip to depression screen) ☐1 1 ☐2 Other __ __ (fill in blank)
16. How often have you had vaginal sex in the past 6 months? ☐1 A few times or less ☐2 A few times each month ☐3 A few times each week	22. How often have you had anal sex in the past 6 months? ☐1 A few times or less ☐2 A few times each month ☐3 A few times each week
17. In the past 6 months, how often have you had vaginal sex with someone whose HIV status you did not know? ☐0 Never ☐1 A few times or less ☐2 A few times each month ☐3 A few times each week	23. In the past 6 months, how often have you had anal sex with someone whose HIV status you did not know? ☐0 Never ☐1 A few times or less ☐2 A few times each month ☐3 A few times each week

18. In the past 6 months, how often have you had vaginal sex with someone who was HIV-positive? ☐0 Never ☐1 A few times or less ☐2 A few times each month ☐3 A few times each week ☐88 Unknown	24. In the past 6 months, how often have you had anal sex with someone who was HIV-positive? ☐0 Never ☐1 A few times or less ☐2 A few times each month ☐3 A few times each week ☐88 Unknown
19. In the past 6 months how often did you use condoms when you had vaginal sex? ☐0 Never ☐1 Some of the time ☐2 Most of the time ☐3 All the time ☐88 Unknown	25. In the past 6 months, how often did you use condoms when you had anal sex? ☐0 Never ☐1 Some of the time ☐2 Most of the time ☐3 All the time ☐88 Unknown

C	**Clinical**	**Packet A:**	**Patient ID: _____**
F	**Core**	**CES_D**	**Patient Initials: _____**
A	**Cohort**		**Clinical Center: _____**
R	**Registry**		**Contact Number: _____**
			Date: _____
		[Research Coordinator Completed]	**RCID: _____**

Below is a list of some of the ways you may have felt or behaved over the past week. Please indicate how often you have felt this way during the past week by checking the appropriate response.

	Rarely or none of the time	**Some or little of the time**	**Occasionally or a moderate amount of time**	**Most or all of the time**
1. I was bothered by things that usually don't bother me.	☐1	☐2	☐3	☐4
2. I did not feel like eating; my appetite was poor.	☐1	☐2	☐3	☐4
3. I felt that I could not shake off the blues even with help from my family or friends.	☐1	☐2	☐3	☐4
4. I felt that I was just as good as other people.	☐1	☐2	☐3	☐4
5. I had trouble keeping my mind on what I was doing.	☐1	☐2	☐3	☐4
6. I felt depressed.	☐1	☐2	☐3	☐4
7. I felt that everything I did was an effort.	☐1	☐2	☐3	☐4
8. I felt hopeful about the future.	☐1	☐2	☐3	☐4
9. I thought my life had been a failure.	☐1	☐2	☐3	☐4
10. I felt fearful.	☐1	☐2	☐3	☐4
11. My sleep was restless.	☐1	☐2	☐3	☐4
12. I was happy.	☐1	☐2	☐3	☐4
13. I talked less than usual.	☐1	☐2	☐3	☐4
14. I felt lonely.	☐1	☐2	☐3	☐4
15. People were unfriendly.	☐1	☐2	☐3	☐4
16. I enjoyed life.	☐1	☐2	☐3	☐4
17. I had crying spells.	☐1	☐2	☐3	☐4
18. I felt sad.	☐1	☐2	☐3	☐4
19. I felt that people dislike me.	☐1	☐2	☐3	☐4
20. I could not get "going."	☐1	☐2	☐3	☐4

C **Clinical**
F **Core**
A **Cohort**
R **Registry**

Packet A:
Contact Checklist
(Administrative)

[Research Coordinator Completed]

Patient ID: _____
Patient Initials: _____
Clinical Center: _____
Contact Number: _____
Date: _____
RCID: _____

CRF	Abbreviated Name	Version	Completed
Data Processing Cover Sheet	DPCS		☐
Screening Checklist	SCREEN		☐
Patient Contact Information	PTCTIN		☐
Demographics	DEMO		☐
Medical History	MED		☐
Present and Previous Antiviral Treatments	PRIOR		☐
Adherence Questions	ADHERE		☐
Hepatitis Treatment	HEPTX		☐
Metabolics	METAB		☐
Clinical Laboratory Measures	LAB		☐
Biological Specimen	SERUM		☐
Alcohol and Drug Use Addendum	ALCDADD		☐
Sexual History Addendum	SEXHXADD		☐
CES_D	CES_D		☐
Contact Checklist	CTCK		☐

Specimen sent to Laboratory: ☐$_1$ Yes ☐$_0$ No