# **HIV-TB** study

# **Event Checking Chart**

## **TB Immune Reconstitution Inflammatory Syndrome (IRIS)**

Name of centre and cohort	
Patient ID code:	Gender: [] Male [] Female
Date of birth (dd/mm/yyyy):	Date of IRIS (dd/mm/yyyy):

#### **INSTRUCTIONS:**

- This form is to be used for reporting TB related Immune Reconstitution Inflammatory Syndrome (IRIS) only. The generic criteria for this diagnosis are on the last page of the form.
- CD4<sup>+</sup> cell count and HIV-1 RNA results reported on this form must also be reported on the appropriate HIV-Form, IF they are not reported by the electronic data transfer.
- In general, complete these forms either by writing "X", filling out a numeric field, or by completing the information regarding the day, month, and year for time-variables. If the month is unknown, write only the year. If the month and year are both unknown, write "02/79".
- If an answer leads to a "STOP," do not answer any other questions and submit the form to CHIP.
- Please submit the completed form to CHIP via fax: +45 35455758 or e-mail: hivtb@cphiv.dk

Please read Appendix 1 "Criteria for the Tuberculosis related Immune Reconstitution Inflammatory Syndromes (IRIS)" before completing this form

### 1- Has the study participant recently had one of the following occur?

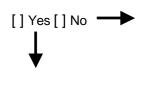
- Initiated antiretroviral therapy/regimen or
- Reintroduced the same or a different antiretroviral therapy/regimen or
- Changed antiretroviral therapy for reasons other than toxicity

[ ] Yes [ ] No <b>_L</b>	<b>→</b>
•	
STOP	
No Diagnosis o	f IRIS

a.	Indicate which event occurred:  [ ] Initiated antiretroviral therapy/regimen  [ ] Reintroduced the same or a different antiretroviral therapy/regimen  [ ] Changed antiretroviral therapy for reasons other than toxicity
b.	Date antiretroviral therapy/regimen initiated/reintroduced or changed:  (dd/mm/yyyy):



- 2- Has the study participant experienced at least one of the following events in response to initiation, reintroduction or change of antiretroviral therapy/regimen?
  - Evidence of an increase in CD4+ cell count of ≥50 cells/mm³, or a ≥2-fold rise in CD4+ cell count and/or
  - Evidence of a decrease in the HIV-1 viral load of >0.5 log<sub>10</sub> and/or
  - Weight gain or other investigator-defined signs of clinical improvement.



Is the study participant being evaluated for an infectious/inflammatory condition at a time that is < 4 weeks after initiation, reintroduction or change in antiretroviral therapy/regimen?



STOP. No Diagnosis of IRIS

Patient ID code:

3- Were any CD4+ cell count results obtained that documented an increase by ≥50 cells/mm3, or a ≥2-fold rise in the CD4+ cell count since the antiretroviral therapy/regimen was initiated/reintroduced or changed?



### **Documenting CD4+ cell count:**

Indicate the date the blood specimen was obtained and the CD4+ absolute cell count that **documents the increase**:

- a. Date specimen obtained (dd/mm/yyyy):\_\_\_\_\_
- b. CD4<sup>+</sup> cell count that **documents increase**: \_\_\_\_\_(cells/mm<sup>3</sup>)

#### Prior CD4+ cell count

Indicate the date the specimen was obtained and the result for the CD4<sup>+</sup> absolute cell count that was obtained **prior to or near** the time of the initiation/reintroduction or change in antiretroviral therapy/regimen.

- c. Date prior specimen obtained (dd/mm/yyyy):\_\_\_\_\_
- d. Prior CD4+ cell count: \_\_\_\_\_(cells/mm<sup>3</sup>)
- 4- Were any HIV-1 RNA viral load results obtained that document a decrease of >0.5 log10 since antiretroviral therapy/regimen was initiated, reintroduced or changed?



#### **Documenting HIV-1 RNA viral load result**

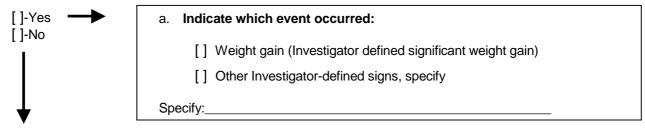
Indicate the date the specimen was obtained and the result for the viral load that documents the decrease.

- a. Date specimen obtained (dd/mm/yyyy):\_\_\_\_\_
- b. HIV-1 RNA (copies/mL):

#### Prior HIV-1 RNA viral load result

Indicate the date the specimen was obtained and the result for the HIV-1 RNA that was obtained **prior to or near** the time of the initiation/reintroduction or change in antiretroviral therapy/regimen

- c. Date specimen obtained (dd/mm/yyyy):\_\_\_\_\_
- d. Prior HIV-1 RNA (copies/mL):\_\_\_\_\_
- 5- Has the study participant experienced any weight gain or other investigator-defined signs of clinical improvement since antiretroviral therapy/regimen was initiated, reintroduced or changed?



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Patient ID code:
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<b>)</b> -	Has the study	partici p	pant had an	y signs/s	ymptoms	that meet	the following	conditions?
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- Signs/symptoms are consistent with TB AND
- They cannot be explained by any other newly acquired infection, the expected clinical course of TB, or the side effects of antiretroviral therapy itself.

[]-Yes, []-No <b>STOP.</b>	No diagnosis of IRIS	
a New or worsening of a previous	ously diagnosed TR	
[] New TB diagnosis	[] Worsening of a previously diagnosed TB	
Please specify (several answers	s are possible)	
[] Tuberculosis lymphadenitis		
[] Tuberculosis abscesses with	prominent acute inflammatory features	
[] Pulmonary tuberculosis that is syndrome	s complicated by respiratory failure due to adult re	spiratory distress
[] Marked systemic inflammator	ry syndrome related to tuberculosis?	
[] New or enlarging lymph node	s, cold abscesses, or other focal tissue involveme	nt-eg, tuberculous arthritis
[] New or worsening radiologica ultrasonography, CT, or MRI)	al features of tuberculosis (found by chest radiogra	phy, abdominal
[] New or worsening CNS tuber	culosis (meningitis or focal neurological deficit-eg.	, caused by tuberculoma)
[] New or worsening serositis (p	oleural effusion, ascites, or pericardial effusion)	
		1 "Criteria for the
[] Confirmed	[] Probable	
Has patient received steroids	during TB treatment? [] Yes [] No [] Unknow	vn
If Yes, please indicate: Drug nar	me Initial dose	mg
Date of start (dd/mm/yyyy):	and stop (dd/mm/yyyy):	
Has the patient needed surger	ry/ hospitalisation after New TB diagnosis/ Wo	rsening of previous TB?
Surgery	[ ] Hospitalisation	[] None
	a. New or worsening of a previous [] New TB diagnosis  Please specify (several answers [] Tuberculosis lymphadenitis [] Tuberculosis abscesses with [] Pulmonary tuberculosis that is syndrome [] Marked systemic inflammator [] New or enlarging lymph node [] New or worsening radiological ultrasonography, CT, or MRI) [] New or worsening CNS tuber [] New or worsening serositis (p. 1)  b. Date of New or Worsening To (Date of Diagnosis of IRI (Date of Diagnosis o	[] New TB diagnosis [] Worsening of a previously diagnosed TB  Please specify (several answers are possible)  [] Tuberculosis lymphadenitis  [] Tuberculosis abscesses with prominent acute inflammatory features  [] Pulmonary tuberculosis that is complicated by respiratory failure due to adult re syndrome  [] Marked systemic inflammatory syndrome related to tuberculosis?  [] New or enlarging lymph nodes, cold abscesses, or other focal tissue involveme  [] New or worsening radiological features of tuberculosis (found by chest radiogra ultrasonography, CT, or MRI)  [] New or worsening CNS tuberculosis (meningitis or focal neurological deficit–eg.  [] New or worsening serositis (pleural effusion, ascites, or pericardial effusion)  b. Date of New or Worsening TB diagnosis (dd/mm/yyyy):

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Patient ID code:\_\_\_\_\_

- Comment if there is other per	tinent information relevant to this dia	gnosis:
IYSICIAN REVIEW		
	Il supporting data and concur with the dia	agnosis.
_	Physician's Signature	Date
Name of reviewing physician:		
Last Name:		
First Name:		