## TN14 (Canakinumab) Eligibility Form 12AUG2010 Version 1.4 Page 1 of 2 Site Number: Participant ID: Date of Visit: Person Completing Form:

A. INCLUSION CRITERIA			
1. Subject is between 6 and 45 years of age (inclusive)?	ΟY	O N	O Not Done
2. Subject is within 3-months (100 days) of diagnosis of type 1 diabetes based on ADA criteria?	ОΥ	O N	O Not Done
3. Subject has at least one diabetes-related autoantibody present?	ОΥ	O N	O Not Done
4. Subject has stimulated C-peptide levels ≥ 0.2 pmol/ml?	ОΥ	O N	O Not Done
5. Subject has not had any live immunizations in the preceding month?	ОΥ	O N	O Not Done
6. Subject is willing to forgo live vaccinations during the 12 months of treatment and for an additional 3 months?	ОΥ	O N	O Not Done
7. Subject is willing to comply with intensive diabetes management?	ОΥ	O N	O Not Done
8. Subject weighs at least 20 kg (44 lb) at study entry?	ОΥ	O N	O Not Done
9. Subject has signed written informed intervention consent for participation	ОΥ	O N	O Not Done
If yes, date consent was obtained:	/	/_	
If yes, was permission given for samples of the participant's blood to be stored for other tests?  If yes:   with DNA   without DNA (this answer will not affect eligibility)	O Y	O N	YEAR O Not Done
ii yes.			20.10
			20.10
B. EXCLUSION CRITERIA  1. Subject is immunodeficient or has clinically significant chronic lymphopenia?	ОΥ	O N	O Not
B. EXCLUSION CRITERIA	0 Y 0 Y	O N O N	O Not Done O Not
B. EXCLUSION CRITERIA  1. Subject is immunodeficient or has clinically significant chronic lymphopenia?			O Not Done O Not Done O Not
B. EXCLUSION CRITERIA  1. Subject is immunodeficient or has clinically significant chronic lymphopenia?  2. Subject has an active infection?	ОΥ	O N	O Not Done O Not Done O Not Done O Not
<ul> <li>B. EXCLUSION CRITERIA</li> <li>1. Subject is immunodeficient or has clinically significant chronic lymphopenia?</li> <li>2. Subject has an active infection?</li> <li>3. Subject has a positive PPD test result?</li> </ul>	0 Y 0 Y	O N O N	O Not Done O Not
B. EXCLUSION CRITERIA  1. Subject is immunodeficient or has clinically significant chronic lymphopenia?  2. Subject has an active infection?  3. Subject has a positive PPD test result?  4. Subject is currently using medications known to influence glucose tolerance?	о y о y о y	O N O N O N	O Not Done O Not
B. EXCLUSION CRITERIA  1. Subject is immunodeficient or has clinically significant chronic lymphopenia?  2. Subject has an active infection?  3. Subject has a positive PPD test result?  4. Subject is currently using medications known to influence glucose tolerance?  5. Subject requires use of other immunosuppressive agents?  6. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection?  7. Subject has complicating medical issues or abnormal clinical laboratory results that in the opinion of the investigator would interfere with study conduct or cause increased risk (including pre-existing cardiac disease, COPD, neurological or blood count abnormalities such as	о y о y о y о y	O N O N O N O N	O Not Done
B. EXCLUSION CRITERIA  1. Subject is immunodeficient or has clinically significant chronic lymphopenia?  2. Subject has an active infection?  3. Subject has a positive PPD test result?  4. Subject is currently using medications known to influence glucose tolerance?  5. Subject requires use of other immunosuppressive agents?  6. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection?  7. Subject has complicating medical issues or abnormal clinical laboratory results that in the opinion of the investigator would interfere with study conduct or cause increased risk (including	<ul><li>O Y</li><li>O Y</li><li>O Y</li><li>O Y</li><li>O Y</li></ul>	O N O N O N O N O N	O Not Done
B. EXCLUSION CRITERIA  1. Subject is immunodeficient or has clinically significant chronic lymphopenia?  2. Subject has an active infection?  3. Subject has a positive PPD test result?  4. Subject is currently using medications known to influence glucose tolerance?  5. Subject requires use of other immunosuppressive agents?  6. Subject has serologic evidence of current or past HIV, Hepatitis B or C infection?  7. Subject has complicating medical issues or abnormal clinical laboratory results that in the opinion of the investigator would interfere with study conduct or cause increased risk (including pre-existing cardiac disease, COPD, neurological or blood count abnormalities such as lymphopenia, leucopenia or thrombocytopenia)?	<ul><li>O Y</li><li>O Y</li><li>O Y</li><li>O Y</li><li>O Y</li></ul>	O N O N O N O N O N O N	O Not Done

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Site Number:	Participant ID:			
Date of Visit:	Participant Letters:			
Person Completing Form:				
	ses to use an effective form of birth control?	ΟY	$\circ$ N	O N/A
12. Subject has reproductive potential report possible or confirmed pregnan	and refuses to undergo pregnancy testing and/or promptly cies during the course of the study?	ОΥ	O N	O N/A
13. Subject has reproductive potential and refuses to promptly report possible or confirmed pregnancies during the course of the study?		ОΥ	O N	O N/A
14. Subject is currently pregnant?	•	ΟY	$\circ$ N	O N/A
15. Subject is currently breastfeeding?		ΟY	$\circ$ N	O N/A

16. Subject anticipates becoming pregnant?17. Subject refused or did not complete the pregnancy test at this visit?

12AUG2010

O N/A

O N/A

ΟY

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