Type 1 Diabetes TrialNet		A-4 Ig Study TY EVENT FORM	Form	Form CTL13M 01 JAN 2008 Version 1.0 Page 1 of 2		
Site Number:	Screening ID:		Participant Letters:			

Complete this form if a participant dies during the study, <u>regardless</u> of whether the death was <u>related</u> to the study medication.

- This form should be sent to the Coordinating Center within 24 hours of notification of the death.
- Once a death certificate has been obtained, a copy MUST be sent to the Coordinating Center.

A. REPORT INFORMATION  1. Date of report:  2. Date of death:  3. Type of report:  1. Uhere did the death occur? (check one)  1. Hospital  2. Home  3. School/Work  4. Long-term care institution  3. School/Work  5. Uhknown  3. School/Work  5. Uhknown  3. School/Work  5. Uhknown  4. Sudden, explained  5. Uhknown  5. Will an autopsy report be available?  5. Will an autopsy report on fatal illness?  4. No,  5. Autopsy report?  4. No,  5. Hospital report on fatal illness?  5. Will an untopsy report?  5. Will an autopsy report?  5. Wi		<b>m(s) that need to be completed</b> ent Report Form ( <b>CTL13</b> )									
2. Date of death: 3. Type of report: <b>B. GENERAL EVENT CLASSIFICATION</b> 1. Where did the death occur? ( <i>check one</i> ) 1 Hospital 2 Home 3 School/Work I OTHER, a. Specify: 2. The death was ( <i>check one</i> ): 1 Sudden, explained 2 Sudden, unexplained 3. Was the participant receiving study medication at the time of the death event? 4. Was the participant receiving a study infusion at the time of the death event? 5. Will an autopsy report be available? 6. Has a death certificate been obtained? 1 f NO, a. Has one been requested? 7. Record the sources of information that were used to complete this form: a. Death certificate? b. Autopsy report? c. Hospital report on fatal illness? Y N b. Autopsy report? C. Hospital report on fatal illness? Y N FOUND COMPANY AND CO	A. REPORT II	NFORMATION									
3. Type of report:       Image: DAY MONTH       YEAR         3. Type of report:       Image: DAY MONTH       YEAR         3. Type of report:       Image: DAY MONTH       YEAR         B. GENERAL EVENT CLASSIFICATION       Image: DAY MONTH       Image: DAY MONTH       Year         1. Where did the death occur? (check one)       Image: Day Month       Image: Day Month       Image: Day Month       Image: Day Month         2. Home       Image: Day Month         3. School/Work       Image: Day Month       Image: Day Mont       Image: Day Mont	1. Date of re	port:						DAY MONT	/	YEA	 R
3. Type of report:	2. Date of de	eath:						/	/	YEA	 R
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<ul> <li>4. Was the participant receiving a study infusion at the time of the death event?</li> <li>5. Will an autopsy report be available?</li> <li>6. Has a death certificate been obtained? If NO, a. Has one been requested?</li> <li>7. Record the sources of information that were used to complete this form:</li> <li>a. Death certificate?</li> <li>b. Autopsy report?</li> <li>b. Autopsy report on fatal illness?</li> <li>Y</li> <li>N</li> <li>M</li> <li>M</li></ul>		Sudden, unexplained									
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If NO, a. Has one been requested?								Y	Ν		
a. Has one been requested?YN7. Record the sources of information that were used to complete this form:YNa. Death certificate?YNd. Interview of attending physician?YNb. Autopsy report?YNe. Interview of family member?YNc. Hospital report on fatal illness?YNf. Other?YNIf OTHER,								Y	Ν		
7. Record the sources of information that were used to complete this form:         a. Death certificate?       Y       N       d. Interview of attending physician?       Y       N         b. Autopsy report?       Y       N       e. Interview of family member?       Y       N         c. Hospital report on fatal illness?       Y       N       f. Other?       Y       N         If OTHER,       V       V       N       Y       N       Y       N											
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c. Hospital report on fatal illness? Y N f. Other? Y N If OTHER,	a. Death	certificate?	Y	Ν	d. Iı	nterview	of attend	ding physician?	)	Y	Ν
If OTHER,	b. Autopsy report?		Y	Ν	e. Ir	nterview	of famil	y member?		Y	Ν
						Y	Ν				

On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "\*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).

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Site Number:	Screening ID:	Participant Letters:

## C. SPECIFIC EVENT INFORMATION

1. Describe the immediate cause of death:

2. Describe the underlying cause of death:

3. Describe any contributory causes of death:

4. Specify which of the immediate, underlying and/or contributory causes of death were present at randomization:

	Initials (first, middle, last) of person comp	F M L			
	Date form completed:	DAY / MONTH /	YEAR		
Signature of Principal Investigator:					
	Signature		Date		
On all questions write "?" if the desired information is currently unavailable, but is being checked and will be known in future updates. Write "*" if the desired information is permanently unavailable (i.e. will not be known in any future updates).					