OTIS - Serious Adverse Event REPORT FORM (Page 1 of 3)

SAE reference number (*YTU use only*):		Date received: ☐☐ / ☐☐ / ☐☐☐☐

1. Person making report			
Name:			
Job title/role in study:			
Contact address:			
Email address:			
Contact Telephone No:		Fax number:	

2. Details of study				
Title: OTIS	R&D ref:		Ethics No:	

3. Details of subject affected by SAE

Centre ID ☐☐ Participant's trial ID number: ☐☐☐☐☐

DOB: ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

4. Details of SAE

Full description of event, including body site, reported signs and symptoms and diagnosis where possible:

Event is defined as serious because it (cross as many as apply):	*If 'Other', please specify below:
☐ resulted in death	
☐ is/was life threatening	
☐ required hospitalisation	
☐ prolonged an ongoing hospitalisation	
☐ resulted in persistent or significant disability/incapacity	
☐ resulted in a congenital anomaly or birth defect	
☐ surgical or medical intervention to prevent above	
☐ other - please specify*	

Onset Date	**Onset Time (if known)**	**End Date**	**End Time (if known)**
☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)	☐☐:☐☐ (*hh* : *mm*)	☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)	☐☐:☐☐ (*hh* : *mm*)

Date Investigator aware of SAE	**Date SAE Initial report Faxed**	**Time SAE Initial report Faxed**
☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)	☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)	☐☐:☐☐ (*hh* : *mm*)

Signature of person completing page: _____ Date: ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

Print name: _____ Job Title: _____

5. Outcome

☐ Resolved*	☐ Resolved with Sequelae*	☐ Died* (give cause and PM details if available)
☐ Ongoing*	☐ Ongoing with Sequelae*	

*Give details:

Was the patient withdrawn from the study? ☐ Yes ☐ No

6. Location of (onset of) SAE

Setting (e.g. hospital*, GP, nursing home), please specify below:

Exact Location, please specify below:

7. Action taken and further information

Please describe action taken below:

Other information relevant to assessment of case e.g. medical history, family history, test results, please specify below:

Signature of person completing page: _____ Date: ☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

Print name: _____ Job Title: _____

8. Relationship to study treatment and Expectedness (to be completed)		
☐ Not related ☐ Unlikely to be related ☐ Possibly related* ☐ Probably related* ☐ Definitely related*	*If possibly, probably or definitely related, was the SAE unexpected? ☐ Yes ☐ No (Unexpected means not described in the protocol)	**Please complete and return all sections of the follow up report form when further information is available.**

9. Additional information (refer to section number)	
Section no.	Further information

Signature of person completing page: _____ Date: ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

Print name: _____ Job Title: _____

10. Principal Investigator (at this site) [*or suitably qualified person to report SAEs for study*]	
Name:	
Job title/role in study:	
Contact address:	
Email address:	
Telephone No:	
Fax number:	
Signature:	
I confirm that the contents of this form are accurate and complete	

Please fax this form to the York Trials Unit [insert number]. Thank you

OTIS - Serious Adverse Event FOLLOW UP REPORT FORM

Follow Up Report number: *e.g. Follow-up 1*		AE reference number: (*for YTU use only*)	

Date of initial report ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

Centre ID ☐☐

Participant's trial ID number ☐☐☐☐☐

Participant DOB ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

1. Further details of serious adverse event

Further details of event where possible:

2. Outcome

☐ Resolved*	☐ Resolved with Sequelae*	☐ Died* (give cause and PM details if available)
☐ Ongoing*	☐ Ongoing with Sequelae*	

*Give details:

Was the patient withdrawn from the study? ☐ Yes ☐ No

3. Additional action taken and further information since initial report

Please describe further action taken below:

Further information or data relevant to assessment of case e.g. medical history, family history, test results:

I confirm that the contents of this form are accurate and complete

Signature of person completing page:

Name (print please):

Date: ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

Please fax this form to the York Trials Unit [insert number]. Thank you

OTIS - Non-Serious Adverse Event REPORT FORM (Page 1 of 2)

AE reference number (*YTU use only*):		Date received: ☐☐ / ☐☐ / ☐☐☐☐

1. Person making report

Name:			
Job title/role in study:			
Contact address:			
Email address:			
Contact Telephone No:		Fax number:	

2. Details of study

Title: OTIS	Name of Principal Investigator:	

3. Details of participant affected by AE

Centre ID ☐☐ Participant's trial ID number: ☐☐☐☐☐

DOB: ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

4. Details of AE

Full description of event, including body site, reported signs and symptoms and diagnosis where possible:

Action taken (cross as many as apply):

- ☐ None
- ☐ Study treatment interrupted/ halted
- ☐ *Therapy prescribed/ other likely action*
- ☐ Discountinued study
- ☐ other - please specify*

*If 'Other', please specify below:

Onset Date ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

Onset Time (if known) ☐☐:☐☐ (*hh* : *mm*)

End Date ☐☐ / ☐☐ / ☐☐☐☐ (*day* / *month* / *year*)

End Time (if known) ☐☐:☐☐ (*hh* : *mm*)

5. Outcome

☐ Resolved*	☐ Resolved with Sequelae*	☐ Died* (give cause and PM details if available)
☐ Ongoing*	☐ Ongoing with Sequelae*	

*Give details:

Was the patient withdrawn from the study? ☐ Yes ☐ No

6. Relationship to study treatment and Expectedness (to be completed)		
☐ Not related ☐ Unlikely to be related ☐ Possibly related* ☐ Probably related* ☐ Definitely related*	*If possibly, probably or definitely related, was the AE unexpected? ☐ Yes ☐ No (Unexpected means not described in the protocol)	**Please complete and return all sections of the follow up report form when further information is available.**

Is the event defined as serious? i.e. resulted in death, is/was life threatening required hospitalization, prolonged and ongoing hospitalization, resulted in persistent or significant disability/incapacity, resulted in congential anomaly or birth defect.

☐ Yes* *If 'YES', an OTIS Serious Adverse Event (SAE) Form must be completed

☐ No

***Fax* a copy of this form to York Trials Unit [insert number] within 5 days of becoming aware of the event**

*If considered SERIOUS the please complete the OTIS Serious Adverse Event (SAE) form and fax to the **York Trials Unit on [insert number]** within 48 hours of becoming aware of the event.

I confirm that the contents of this form are accurate and complete

Signature of person completing page: _____ Date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Assessor ID: ☐☐

Print name: _____ Job Title: _____

Please fax this form to the York Trials Unit [insert number]. Thank you

OTIS - Non-Serious Adverse Event FOLLOW UP RECORDING FORM

Follow Up Report number: *e.g. Follow-up 1*		AE reference number: (*for YTU use only*)	

Date of initial report ☐☐ / ☐☐ / ☐☐☐☐ (*day / month / year*)

Centre ID ☐☐

Participant's trial ID number ☐☐☐☐☐

Participant DOB ☐☐ / ☐☐ / ☐☐☐☐ (*day / month / year*)

1. Further details of adverse event

Further details of event where possible:

2. Outcome

☐ Resolved*	☐ Resolved with Sequelae*	☐ Died* (give cause and PM details if available)
☐ Ongoing*	☐ Ongoing with Sequelae*	

*Give details:

Was the patient withdrawn from the study? ☐ Yes ☐ No

3. Additional action taken and further information since initial report

Please describe further action taken below:

Further information or data relevant to assessment of case e.g. medical history, family history, test results:

I confirm that the contents of this form are accurate and complete

Signature of person completing page: _____ Name (print please): _____ Date: ☐☐ / ☐☐ / ☐☐☐☐ (*day / month / year*)

Please fax this form to the York Trials Unit [insert number]. Thank you