**Y-SBNT Study Adverse Event Form** University logo Other relevant logos

**Brief study title:**

**Chief/ Principal investigator:**

*Hospital /Centre name:*

**Participant's DoB:** / / 

*Centre ID number:*

**Participant's study ID number:**

**Description of event** (medical terminology):

**Start date:** / / **Stop date:** / /

**Duration if less than 24 hours** (hrs: mins) : **Grade of event:** Mild Moderate Severe

**Outcome:** Resolved On-going

Resolved with sequelae (specify below & give date): On-going with sequelae (specify below):

**Action taken:** None *Therapy prescribed/ other likely action*

Study treatment interrupted/halted Discontinued study

Other (please specify):

**Causality:** (relationship to study treatment)

| Not related | Unlikely to be related | Possibly related | Probably related | Definitely related |
|---|---|---|---|---|
| | | | | |

**Expectedness of event:** Expected Unexpected (i.e. not described in the protocol or other safety information for study treatment)

**Seriousness:** Is this event considered to be a serious adverse event (SAE)?

**Yes*** No

**Fax a copy of this form to the York Trials Unit on 01904 321387 within 5 days of becoming aware of the event**

*If considered SERIOUS please complete a **[*study name*] Serious Adverse Event (SAE) form.** Please fax it **AND** this form (if completed) to the **York Trials Unit on 01904 321387** within 48 hours of becoming aware of the event.

Signature

*[of authorised person/ professional according to individual study]*

Print name

Date / /

## Y-SBNT Study Serious Adverse Event Form

University logo  Other relevant logos

**Brief study title:**

**Today's Date:** / /

*Centre ID number:*

**Participant's study ID number:**

**Date of Birth:** / /  ☐ **Male**  ☐ **Female**

**Location and description of event :**

**Start date:** / /  **Stop date:** / /

**Duration if less than 24 hours** (hrs:mins) :

**Classification of Serious Adverse Event** ***(please cross one box only)*****:**

- ☐ Death
- ☐ Persistent or significant disability/ incapacity
- ☐ Congenital anomaly/ birth defect
- ☐ Prolonged hospitalisation
- ☐ Required hospitalisation
- ☐ Other medically important condition
- ☐ Life-threatening

**Please state outcome of event at time of this report:**

☐ Resolved  Date resolved / /

☐ Resolved with sequelae (specify below & give date)

☐ On-going with sequelae (specify below)

☐ On-going

☐ Died  Date of death / /

Cause of death

**Action taken:**

- ☐ None
- ☐ *Therapy prescribed/ other likely action*
- ☐ Study treatment interrupted/halted
- ☐ Discontinued treatment
- ☐ Other (please specify)

**Relationship of the event to any of the research procedures (to be completed by [***authorised person/ professional according to study***])**

| Not related | Unlikely to be related | Possibly related | Probably related | Definitely related |
|---|---|---|---|---|
| ☐ | ☐ | ☐ | ☐ | ☐ |

**Is this event expected? (to be completed by [***authorised person/ professional according to study***])** ☐ Yes ☐ No

**Researcher's name**  **Researcher's signature**  **Date** / /

**Local PI's name**  **Local PI's signature**  **Date** / /

**CI** *[name]* **signature**  **Date** / /

Please fax this form to **York Trials Unit on 01904 321387** within 48 hours of becoming aware of the event.

Version 1 (19.12.2013)

# Y-SBNT Study Adverse Event Review Form

**Participant ID number:** ☐☐☐☐

**Details of the initial event this review relates to**

| |
|---|
| |

**Date of initial event** ☐☐ / ☐☐ / 2 0 ☐☐ (DD/MM/YYYY)

**Was event classed as a serious adverse event?** ☐ **Yes** ☐ **No**

**Date of this review** ☐☐ / ☐☐ / 2 0 ☐☐ (DD/MM/YYYY)

**Please report additional action taken and any further information since initial report**

| |
|---|
| |

**Is this event now resolved?** ☐ **Yes** ☐ **No**

**Name of person completing review**

**Signature of person completing review**

**Date** ☐☐ / ☐☐ / 2 0 ☐☐ (DD/MM/YYYY)

**Please fax to York Trials Unit: 01904 321387**

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*For York Use Only*

**Date reviewed by TMG** ☐☐ / ☐☐ / 2 0 ☐☐ (DD/MM/YYYY)

**Date reviewed by TSC** ☐☐ / ☐☐ / 2 0 ☐☐ (DD/MM/YYYY)

**Date reviewed by DMEC** ☐☐ / ☐☐ / 2 0 ☐☐ (DD/MM/YYYY)