

## ACTIB

### Assessing Cognitive behavioural Therapy in Irritable Bowel

#### Serious Adverse Event Report Form

##### Instruction

In case of a Serious Adverse Event (SAE), please complete this form and fax to 023 80522299 within 24 hours and telephone/email Gilly O'Reilly 023 80241066 [actibstudy@soton.ac.uk](mailto:actibstudy@soton.ac.uk) 07887517663

Study ID

Date of Birth   
ddmmyyy

Please tick one      Initial report       Follow up report (one month)

Description of SAE.....

Description of Treatment .....

Date Onset SAE ddmmyyyy

Stop Date SAE ddmmyyyy

##### SAE Classification

Death

- Life-threatening
- In-patient hospitalisation
- Disability/incapacity
- Congenital anomaly/birth defect

Other medical events requiring intervention to prevent one of the outcomes listed above

**Relationship to Study**

- None
- Remote
- Possible
- Probable
- Definite

**Subject Outcome**

- Resolved
- Resolved with sequelae
- Ongoing

Investigators Name .....

Investigators Signature .....

Date .....