|  |  |
| --- | --- |
| **APPENDIX N: EVALUATION FORM FOR A SAFETY REPORT** | **Version Number 1.0****Effective Date: 1st April 2015****Supersedes Document: 2009** |

**Name and Signature of Reviewer:**

**Title of proposal:**

**Principal Investigator(s)**

**SSC/NON-SSC/SERU/NON-SERU No.:**

1. What is the event?
2. How many study participants experienced the event?
3. What is the PI’s determination of the event?
	1. Serious or not serious?
	2. Expected or unexpected?
4. Does the event place the study participant or others at greater risk or harm than is previously known?
5. What is the PI’s determination of the events relationship with the participation in the study?
6. Comments, suggestions or recommendations:
7. Comments during meeting: