


**Standard Operating Procedures  
(SOP)  
Research and Development Office**

<b>Title of SOP:</b>	Undertaking Risk Assessment of a Research and Development Project
<b>SOP Number:</b>	33
<b>Version Number:</b>	1.0
<b>Supercedes:</b>	N/A
<b>Effective date:</b>	August 2013
<b>Review date:</b>	August 2015

<b>Author:</b>	Alison Murphy, Research Manager Endorsed by Paul Carlin
<b>Approved by:</b>	Dr David Hill
<b>Signed:</b>	
<b>Date:</b>	01 August 2013

**Version History:**

<b>Version No.</b>	<b>Date</b>	<b>Author</b>	<b>Reason for Change</b>
1.0	Aug 2011	Alison Murphy	N/A

<b>Table of contents</b>	
1. Introduction	
2. Objective	
3. Scope	
4. Procedure	
4.1	Definitions
4.2	When is a Risk Assessment Required?
4.3	Completion of the Risk Assessment Form
4.4	Review of the Risk Assessment Form
5. Regulations, Guidelines, References, SOP Links etc	
6. Appendices	
6.1	Risk Assessment Form
6.2	Numbered Guidance Notes for Completion of Section 2 of Risk Assessment Form Risk Assessment Matrix
6.3	Risk Assessment Criteria and Management Strategies

## 1.0 INTRODUCTION

Under the Research Governance framework for Health and Social Care 2007, it is part of our responsibility as funders, sponsors, employers and organisations providing care to ensure that research is planned and conducted in a safe, robust, high quality manner. An integral part of that is assessing and managing the risk involved in a study. An organisation must understand potential hazards of being research-active and act to minimise and manage potential risks. An integrated approach and standardised tool has been developed across HSC Trusts for this purpose.

Early risk assessment will allow consideration of the suitability of sponsorship, monitoring and audit and indemnity arrangements for the project.

## 2.0 OBJECTIVE

The objective of this Standard Operating Procedure (SOP) is to describe the procedure for undertaking a risk assessment on research projects.

## 3.0 SCOPE

This SOP applies to all research study applications for HSC permissions received by the Research Office.

## 4.0 PROCEDURE

### 4.1 Definitions

**Hazard:** anything that could cause harm

**Risk:** probability that harm will be caused by the hazard

Although the **hazards** of a study may be defined, the **risks** to any one individual or organisation will depend on their role(s) and responsibilities in relation to the study and their ability to control the hazards. All the various individuals and organisations involved in a study need to assess their risks in relation to their responsibilities.

### 4.2 When is a Risk Assessment Required?

A risk assessment is required for all studies. This assessment may be completed by the Trust Permission Committee during its review of a study and the outcome documented in the Governance Report.

For some studies a formal risk assessment is required through the completion of the Risk Assessment Form (Appendix 1). A formal risk assessment must be completed for all Trust sponsored CTIMPS.

The Research Office will request the completion of the Risk Assessment Form when a formal risk assessment is required to be completed.

#### **4.3 Completion of the Risk Assessment Form**

The Chief Investigator (CI)/Principal Investigator (PI), who is directly responsible for the conduct of the research project, must complete Sections 1, 2, and 3 of the Risk Assessment Form (Appendix 1). Under Section 2, the CI/PI must indicate:

- The likelihood of each potential risk occurring
- The severity of impact if the risk should it occur
- How they propose to minimise each risk's occurrence.

The CI/PI must refer to the numbered guidance notes in Appendix 2 for the completion of Section 2 of the Risk Assessment Form.

Appendix 3 contains Guidance for Researchers – Risk Assessment Criteria and Management Strategies for Identified Risks - when completing the Risk Assessment Form and should be read in conjunction with the form.

The document identifies areas that, as a minimum, should be considered when completing the Risk Assessment Form and suggested strategies for minimising any identified hazard.

#### **4.4 Review of the Risk Assessment Form**

The completed Risk Assessment will be reviewed by the Trust Research Permission Committee.

The Associate Medical Director (Research) must sign off the fully completed form at Section 4.

### **5. REGULATIONS, GUIDELINES, REFERENCES, SOP LINKS ETC**

The Risk Assessment Form is based on guidance issued by the Medical Research Council / Department of Health Joint Project to Codify Good Practice:

[www.ct-toolkit.ac.uk/useful\\_info/useful\\_documents.cfm](http://www.ct-toolkit.ac.uk/useful_info/useful_documents.cfm)):

Workstream 4: Trial Management and Monitoring - A) Clinical Trial Risk Assessment

Workstream 2: Quality Partnerships - Notes on Good Practice for Research Organisations in the Management of a Portfolio of Trials

## **6. APPENDICES**

- 6.1 Appendix 1: Risk Assessment Form
- 6.2 Appendix 2: Numbered Guidance Notes for Completion of Section 2 of Risk Assessment Form and Risk Assessment Matrix
- 6.3 Appendix 3: Risk Assessment Form: Risk Assessment Criteria and Management Strategies for Identified Risks

## APPENDIX 1

# RISK ASSESSMENT FORM

## FOR RESEARCHERS

### Definitions

**Hazard:** anything that could cause harm

**Risk:** probability that harm will be caused by the hazard

Although the **hazards** of a study may be defined, the **risks** to any one individual or organisation will depend on their role(s) and responsibilities in relation to the study, and their ability to control the hazards. All of the various individuals and organisations involved in a study need to assess their risks in relation to their responsibilities.

### Procedure

The Chief Investigator (CI) or Principal Investigator (PI), who is directly responsible for the conduct of the research project, must complete Sections 1, 2 and 3 of this form. Under Section 2, the CI/PI must indicate:

- the likelihood of each potential hazard occurring;
- the severity of impact of the hazard should it occur;
- how they propose to minimise each hazard's occurrence.
- 

The Associate Medical Director (Research) must sign off the fully completed form at Section 4.

### 1. DETAILS OF RESEARCH PROJECT:

*This Section must be completed by the CI/PI*

***Please complete as many of the following sections as possible (the R&D Office recognises that some details\* may not yet be available)***

<b>Project Title (in full):</b>	
<b>Trust R&amp;D Project Registration No.*:</b>	
<b>Protocol No.:</b>	
<b>Ethics No.*:</b>	-
<b>EudraCT No.:</b>	-
<b>CTA No.*:</b>	-
<b>Proposed Sponsor Organisation*:</b>	
<b>Proposed Funder:</b>	

**2. RISK ASSESSMENT:** *This Section must be completed by the CI/PI*

**Please refer to the numbered guidance notes in Appendix 2 whilst completing this Section**

**The numbers selected in each of the columns (Likelihood and Severity of Impact) are multiplied and the result will indicate whether the risk is high, moderate, low or very low.**

<b>RISK</b> <b>ASSIGN EACH RISK A SCORE FOR</b> <b><u>LIKELIHOOD</u> AND <u>IMPACT</u></b>  <i>If a particular risk is:</i> - not applicable to your project, state N/A; - not listed on the form, enter details under 'Other'.	<b>LIKELIHOOD</b> <b>of the risk</b> <b>occurring:</b>  1 = Rare 2 = Unlikely 3 = Possible 4 = Likely 5 = Certain	<b>Severity of</b> <b>IMPACT of</b> <b>the risk</b> <b>should it</b> <b>occur:</b> 1 = Minor 2 = Moderate 3 = Significant 4 = Major 5 = Catastrophic	<b>Proposal to</b> <b>minimise the risk:</b>  <i>For each risk listed, please identify how you propose to minimise its occurrence and also how to deal with it should the risk occur.</i>
<b>2.1 RISKS TO PARTICIPANTS' RIGHTS:</b>			
<b>(i) Entry to the study without fully informed consent <sup>(1)</sup></b>			
<b>(ii) Failure to act on a participant's request to withdraw from the study <sup>(2)</sup></b>			
<b>(iii) Failure to protect participants' privacy <sup>(3)</sup></b>			
<b>(iv) Other please give details:</b>			
<b>2.2 RISKS TO PARTICIPANTS' SAFETY:</b>			
<b>(i) Hazards of the intervention <sup>(4)</sup></b>			
<b>(ii) Known hazards within Disease population</b>			
<b>(iii) Hazards of study assessment methods <sup>(5)</sup></b>			
<b>(iv) Potential for an Adverse Event occurring</b>			
<b>(v) Other</b>			
<b>2.3 RISKS TO RESEARCHERS:</b>			
<b>(i) Lack of experience to carry out responsibilities within the study <sup>(7)</sup></b>			
<b>(ii) Inadequate / no / outdated training <sup>(8)</sup></b>			



<b>(iii) Contact with aggressive / violent patients / relatives <sup>(9)</sup></b>			
<b>(iv) Contact with vulnerable patient groups</b>			
<b>(v) Contact with harmful chemicals, substances, equipment or organisms <sup>(10)</sup></b>			
<b>(vi) Study proceeding without the necessary regulatory approvals <sup>(11)</sup></b>			
<b>(vii) Other <sup>(12)</sup> please give details:</b>			
<b><u>2.4 RISKS TO COMPLETION OF THE STUDY:</u></b>			
<b>(i) Lack of Recruitment and follow-up <sup>(13)</sup></b>			
<b>(ii) Inadequacy of study management <sup>(14)</sup></b>			
<b>(iii) Other please give details:</b>			
<b><u>2.5 RISKS TO RELIABILITY OF THE RESULTS:</u></b>			
<b>(i) Insufficient Study power <sup>(15)</sup></b>			
<b>(ii) Violation of eligibility criteria <sup>(16)</sup></b>			
<b>(iv) Ineffective Randomisation procedure <sup>(17)</sup></b>			
<b>(v) Failure of Outcome assessment <sup>(18)</sup></b>			
<b>(vi) Incomplete and inaccurate study data <sup>(19)</sup></b>			
<b>(vii) Non-Adherence to the protocol <sup>(20)</sup></b>			

<b>(viii) Other</b> please give details:			
<b>2.6 RISKS TO THE ORGANISATION:</b>			
<b>(i) Impact of inaccurate costing of research projects at the outset</b> <sup>(21)</sup>			
<b>(ii) Impact on other clinical services affected</b> <sup>(22)</sup>			
<b>(iii) Other</b> please give details:			

**3. DECLARATION:** *This Section must be completed by the CI/PI*

As the Chief/Principal Investigator of the above study, I declare that the above Risk Assessment (Section 2) is true and complete to the best of my knowledge:

Name (PRINT):	
Signature:	
Date (dd/mm/yyyy):	
Contact telephone number:	
Email address:	
Contact address:	

**4. AUTHORISATION:** *This Section must be completed by the Associate Medical Director (Research)*

I have reviewed this Risk Assessment and confirm that the Trust is willing to support the project application to which this form relates.

Signature:	
Name (PRINT):	
Date (dd/mm/yyyy):	

## **APPENDIX 2**

### **GUIDANCE NOTES FOR SECTION 2:**

**As a minimum, the following points should be considered when carrying out the risk assessments listed in Section 2:**

<sup>1</sup> Vulnerability of the patient/study group and capacity to give consent; consent process; participant information; training of those providing participant information and obtaining consent.

<sup>2</sup> Communication and recording systems.

<sup>3</sup> Data protection and security systems; anonymisation.

<sup>4</sup> Expected / unexpected adverse events; clinical management of adverse events / patients' underlying medical condition; nature of the intervention; the treating clinician's previous experience of the intervention; if a medicinal product: development phase, licensing status, indications, clinical experience, pharmacology, pharmacy / drug handling requirements, training and competence of those administering the product; staff training; susceptibility of the study population: disease, genetic, age, sex; any prior adverse data on acceptability / tolerance / toxicity etc of drug/intervention.

<sup>5</sup> E.g. biopsy; X-ray; questionnaires involving 'sensitive' subject areas.

<sup>6</sup> Systems to monitor and review adverse events; systems to maintain awareness of and to act on new knowledge; ability of participants to report adverse events and study outcomes reliably.

<sup>7</sup> Delegated responsibilities e.g. obtaining informed consent, reporting adverse events; track record of research team possibly via CVs.

<sup>8</sup> Training needs of all members of the research team, including updates of existing skills; systems to maintain awareness of and to act on new knowledge.

<sup>9</sup> Likelihood of adverse response to trial-related activities.

<sup>10</sup> Provision for containment, shielding, monitoring etc.

<sup>11</sup> Organisation/R&D approval; Research Ethics Committee approval; Clinical Trial Authorisation.

<sup>12</sup> E.g. risk to staff or other individuals (not necessarily involved in the study).

<sup>13</sup> Feasibility, study population, numbers of subjects required, inclusion/exclusion criteria; staff competence and experience at study sites; appropriate time scale of study; length of follow-up; frequency of follow-up; means of follow-up.

<sup>14</sup> Trial Steering and Data Monitoring Committees.

<sup>15</sup> Plausible treatment effects; patient numbers.

<sup>16</sup> Importance to the trial; need for checking and possible procedures; unduly restrictive/prescriptive eligibility criteria.

<sup>17</sup> Robustness of procedure; potential for loss of allocation concealment/unblinding.

<sup>18</sup> Blinding – single, double; objectivity of measure; standardisation of assessment; potential for independent review; potential for simple external verification e.g. death certificate, laboratory investigation result.

<sup>19</sup> Data type and complexity - CRF design; collection method – paper, electronic; data entry method; key data items; staff training; need for and options for verification; Data Monitoring Committee.

<sup>20</sup> Complexity; staff training and trials experience; barriers to compliance with intervention for both trial staff and participants.

<sup>21</sup> The research and treatment costs must be identified correctly and availability of any funding noted; cost of continuation of drugs after research has finished.

<sup>22</sup> Are there likely to be any adverse service implications?

RISK ASSESSMENT MATRIX	CONSEQUENCE (POTENTIAL IMPACT)				
	LIKELIHOOD	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)
<b>Almost Certain (5)</b> (will undoubtedly recur, a persistent issue) 1:10	5	10	15	20	25
<b>Likely (4)</b> (will probably recur, not a persistent issue) 1:100	4	8	12	16	20
<b>Possible (3)</b> (may recur occasionally) 1:1,000	3	6	9	12	15
<b>Unlikely (2)</b> (do not expect it to happen again) 1:10,000	2	4	6	8	10
<b>Rare (1)</b> (can't believe it will ever happen again) 1:100,000	1	2	3	4	5
<b>Green Risks (Very Low = 1 – 5)</b>					
Identified risks which fall in the green area are deemed as very low (acceptable) risks and may require no immediate action, but must be monitored regularly to assess if and when action is required.					
<b>Yellow Risks (Low = 6-11)</b>					
Identified risks which fall in the yellow area are deemed low risk to the Trust but require action to reduce the risk. Responsibility for taking action would normally remain at a local level within the appropriate Service Areas					
<b>Amber Risks (Moderate = 12-19)</b>					
Identified risks which fall in the amber area are deemed moderate risk to the Trust and require prompt action to reduce the risk to an acceptable level.					
<b>Red Risks (High = 20-25)</b>					
Identified risks which fall in the red area are deemed high risk to the Trust and must be reported to the Associate Medical Director (Research). Immediate action is required to reduce the level of risks to an acceptable level.					

**Appendix 3**  
**Risk Assessment Form:**  
**Risk Assessment Criteria and Management Strategies for Identified Risks**

**GUIDANCE FOR RESEARCHERS**

This document should be used in conjunction with the HSC NI Risk Assessment Form (Researchers), version 1. This document identifies:

- The areas that, as a minimum, should be considered when completing the Risk Assessment Form;
- Suggested Management Strategies for minimising any identified Hazard

RISK	Examples	Management Strategies
<b>2.1 RISKS TO PARTICIPANTS' RIGHTS:</b>		
<b><i>(i) fully informed consent</i></b>	<ul style="list-style-type: none"> <li>• Vulnerability of participant group/capacity to give consent</li> <li>• Consent procedures</li> <li>• Clarity of information provided</li> <li>• Time to consider information</li> <li>• Experience &amp; knowledge of person taking consent</li> <li>• Failure to act on participant's request to withdraw from trial</li> <li>• Consent recorded/filed</li> </ul>	<ul style="list-style-type: none"> <li>• Literature and process approved by REC.</li> <li>• Training and awareness</li> <li>• Supervision of consent process</li> <li>• Communication systems e.g. alerts stickers in patient notes, contact details on consent form</li> <li>• Collect signed consent forms at coordinating centre/on site file</li> <li>• Audit of consent procedures including verification of signed consent forms in clinic records</li> </ul>
<b><i>(ii) Failure to protect participants' privacy</i></b>	<ul style="list-style-type: none"> <li>• Breach of Data Protection Act</li> <li>• Breach of confidentiality</li> <li>• Anonymity</li> </ul>	<ul style="list-style-type: none"> <li>• Adherence to normal NHS /HSC systems</li> <li>• Anonymised or anonymised/linked data</li> <li>• Minimise staff who have access to confidential information</li> <li>• Follow REC approved processes</li> <li>• Training and awareness</li> <li>• Computer security systems</li> </ul>

<b>2.2 RISKS TO PARTICIPANTS' SAFETY:</b>		
<b>(i) Hazards of the intervention</b>	<ul style="list-style-type: none"> <li>• Potential for unexpected adverse events</li> <li>• Clinical management of adverse events</li> <li>• Clinician's experience of intervention</li> <li>• Novel medicinal product / procedure (licensing status, indications, pharmacology, etc)</li> <li>• Unproven effectiveness</li> <li>• Use for new indication</li> <li>• Increased susceptibility of patient population</li> <li>• Novel handling requirements</li> <li>• Equipment safety</li> <li>• Prior clinical study data on intervention</li> </ul>	<ul style="list-style-type: none"> <li>• MHRA approval (CTA)</li> <li>• REC approval</li> <li>• NHS R&amp;D approval</li> <li>• Data Monitoring and Ethics Committee – specify review processes</li> <li>• Adverse event reporting system</li> <li>• Check participant case notes for adverse events</li> <li>• Investigator meeting to review trial and procedures</li> <li>• Local Investigator(s) to sign protocol/declaration</li> </ul>
<b>(ii) Hazards of study assessment methods</b>	<ul style="list-style-type: none"> <li>• Additional invasive tests (e.g. biopsy)</li> <li>• Increased radiological exposure (X-ray)</li> </ul>	<ul style="list-style-type: none"> <li>• Data Monitoring and Ethics Committee</li> <li>• IRMER / ARSAC review</li> <li>• Adverse event reporting systems</li> </ul>
<b>(iii) Other please give details:</b>	<ul style="list-style-type: none"> <li>• Systems to monitor and review adverse events</li> <li>• Systems to maintain awareness of and to act on new knowledge</li> <li>• Ability of participants to report adverse events and study outcomes reliably</li> </ul>	<ul style="list-style-type: none"> <li>• Adverse event reporting systems</li> <li>• Data Monitoring and Ethics Committee</li> </ul>
<b>2.3 RISKS TO RESEARCHERS:</b>		
<b>(i) Staff competence / experience to carry out responsibilities</b>	<ul style="list-style-type: none"> <li>• New clinicians</li> <li>• Clinician's experience of intervention</li> <li>• Clinician's understanding of methodology</li> <li>• Unfamiliar with underlying condition</li> <li>• Unfamiliar with expected adverse events</li> <li>• Inadequate training</li> </ul>	<ul style="list-style-type: none"> <li>• Delegated responsibilities clearly identified and agreed in site file (including supervision requirements)</li> <li>• Assess training needs of research team</li> <li>• systems to maintain awareness of and to act on new knowledge</li> <li>• Investigator meeting to review trial and procedures</li> <li>• Local Investigator(s) to sign protocol/declaration</li> <li>• Project team meetings</li> <li>• CVs for trial staff held in Trial Master File</li> </ul>

<b><i>(iii) Contact with aggressive / violent patients / relatives</i></b>		
<b><i>(iii) Contact with harmful chemicals, substances, equipment or organisms</i></b>	<ul style="list-style-type: none"> <li>• Provision for containment, shielding, monitoring etc</li> </ul>	<ul style="list-style-type: none"> <li>• Reference to department SOPs</li> </ul>
<b><i>(iv) Trial proceeding without the necessary regulatory approvals</i></b>	<ul style="list-style-type: none"> <li>• Organisation/R&amp;D approval</li> <li>• Research Ethics Committee approval</li> <li>• Clinical Trial Authorisation</li> </ul>	<ul style="list-style-type: none"> <li>• Register all site approvals with trial co-ordinating centre prior to commencement at each site</li> <li>• Site agreements</li> </ul>

<b><u>2.4 RISKS TO COMPLETION OF THE TRIAL:</u></b>		
<b><i>(i) Study Power &amp; Recruitment</i></b>	<ul style="list-style-type: none"> <li>• Feasibility of study population (restricted access to patients, insufficient patient pool)</li> <li>• Plausibility of treatment effect</li> <li>• Restrictive inclusion/exclusion criteria</li> <li>• Staff competence and experience at study sites;</li> <li>• Appropriate time scale of study;</li> <li>• Length, frequency and means of follow-up</li> <li>• Competing trials</li> <li>• Ineffective communication with patient (before and after trial)</li> <li>• Failure to record consent</li> </ul>	<ul style="list-style-type: none"> <li>• Statistical input to design and power</li> <li>• Recruitment assessment</li> <li>• Pilot studies</li> <li>• External communication and trial promotion</li> <li>• Training in consent process</li> <li>• Trial steering Committee</li> <li>• Trial management group</li> </ul>
<b><i>(ii) Organisational Complexity</i></b>	<ul style="list-style-type: none"> <li>• Competence of partner organisations</li> <li>• Multi-centre studies</li> <li>• Multi-disciplinary studies</li> <li>• Non-standardised methods</li> </ul>	<ul style="list-style-type: none"> <li>• Site registration process</li> <li>• Trial coordinator/manager</li> <li>• Site visits</li> <li>• Investigator initiation meetings</li> <li>• Site agreements</li> </ul>
<b><i>(iii) Adequacy of trial management</i></b>	<ul style="list-style-type: none"> <li>• Responsibilities/accountability must be defined</li> </ul>	<ul style="list-style-type: none"> <li>• Summary of Trial Management Systems document</li> <li>• Trial Steering Committee</li> <li>• Trial delegation log</li> </ul>

<b>2.5 RISKS TO RELIABILITY OF THE RESULTS:</b>		
<b>(i) Study Results</b>	<ul style="list-style-type: none"> <li>• Violation of Inclusion / exclusion criteria</li> <li>• Financial / non-financial incentives</li> <li>• Robustness of randomisation procedure</li> <li>• Anonymisation arrangements (potential for loss of Blinding)</li> <li>• Source data availability for verification e.g. death certificate, laboratory investigation result.</li> <li>• Results not disseminated / implemented</li> </ul>	<ul style="list-style-type: none"> <li>• Suitability of eligibility criteria</li> <li>• Trial Management Protocol</li> <li>• Independent randomisation</li> <li>• Statistical input to data monitoring and audit</li> <li>• Interim reports</li> <li>• Standardised data collection forms</li> <li>• See section 2.1(i)</li> </ul>
<b>(ii) Completeness and accuracy of assessment / data</b>	<ul style="list-style-type: none"> <li>• Data type and complexity</li> <li>• Familiarity with data collection and entry method</li> <li>• Poor data quality and integrity</li> </ul>	<ul style="list-style-type: none"> <li>• CRF design</li> <li>• Data Monitoring Committee. staff training</li> <li>• standardisation of assessment</li> <li>• Regular Data quality checks</li> <li>• Source Data verification</li> </ul>
<b>(iii) Adherence to the protocol</b>	See 2.3(i) and 2.4(ii)	<ul style="list-style-type: none"> <li>• Mechanism for version control</li> </ul>

<b>2.6 RISKS TO THE ORGANISATION:</b>		
<b>(i) Knock on costs of research projects being inaccurately costed at the outset</b>	The research and treatment costs must be identified correctly and availability of any funding noted; cost of continuation of drugs after research has finished.	
<b>(ii) Impact on clinical services</b>	<ul style="list-style-type: none"> <li>• Direct impact via tests required</li> <li>• Indirect impact via staff time</li> </ul>	<ul style="list-style-type: none"> <li>• Contact with service early in planning and throughout the trial</li> </ul>



		<ul style="list-style-type: none"> <li>• Multidisciplinary project teams</li> </ul>
<b>(iii) Liability</b>	<ul style="list-style-type: none"> <li>• Clarity of liability arrangements with collaborators</li> <li>• Legal obligations under NI Regulations for medicinal trials</li> <li>• Clarity of liability information in patient information sheet e.g. arrangements for non-negligent harm</li> </ul>	<ul style="list-style-type: none"> <li>• Clear identification of sponsor</li> <li>• Partnership agreements</li> <li>• Monitoring of collaborating sites</li> <li>• Delegated responsibilities clearly identified and agreed in site file (including supervision requirements)</li> <li>• Systems to ensure reporting obligations for medicinal trials (SUSARs, amendments, termination)</li> </ul>