SDRN: Scottish Diabetes Research Network

Clinical Study Risk Assessment

Clinical S.O.P. No.: 19

Version 1.0

Compiled by:	Sheona Brearley
Approved by:	
Review date:	November 2016

CHIEF SCIENTIST OFFICE

DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Shona Brearley	

1. Introduction

Research Governance guidelines now require risk assessment of all research studies to be conducted to ensure patient safety and data integrity. Inspectors from regulatory authorities, i.e. the Medicines for Healthcare Regulatory Authority (MHRA) can ask to review these risk assessments so it is important that they are in place for all studies. Most of the risks covered in the risk assessment form should have been defined and explained in the protocol and patient information sheet so it may be beneficial for Investigators to complete the risk assessment form whilst drafting the protocol for a study to ensure that they cover all the relevant points. This may help to speed up the protocol approval process particularly in studies where MHRA approval is required.

2. Objectives

To describe the procedure for the assessment of risk within clinical studies conducted within (as defined by the study being adopted by the SDRN) the Scottish Diabetes Research Network. The use of the forms provided will also ensure that risk assessment is carried out uniformly across SDRN sites in accordance with ICH-GCP guidelines.

3. Responsibility

It is the responsibility of the local Principal Investigator to complete both the delegation of responsibilities log and the risk assessment, though it can be delegated to an experienced Research Nurse, if she/he is appropriately trained. The Principal Investigator should check and sign the list of tasks delegated to each team member as they have ultimate responsibility for the conduct of the study

4. General Points

- Download forms from the 'SOP' area of *www.sdrn.org.uk*
- Use a black ball point pen
- Print all entries legibly
- Once the forms in Appendix A&B are completed, file in study master file.

5. Procedure

- After drafting the basic protocol for study, the Principal Investigator should complete the Clinical Study Risk Assessment Form (see Appendix A). Each box on the form should be completed and the form shown gives examples of factors to be considered in each part of the form. Many of these factors will included in the study protocol and/or the patient information sheet.

- If the protocol undergoes substantial changes once the risk assessment form has been completed, this form may require to be completed again.

- If the protocol has been written by the sponsor (i.e. a pharmaceutical company), then the local PI should carry out a risk assessment on the study before the final contract is signed.

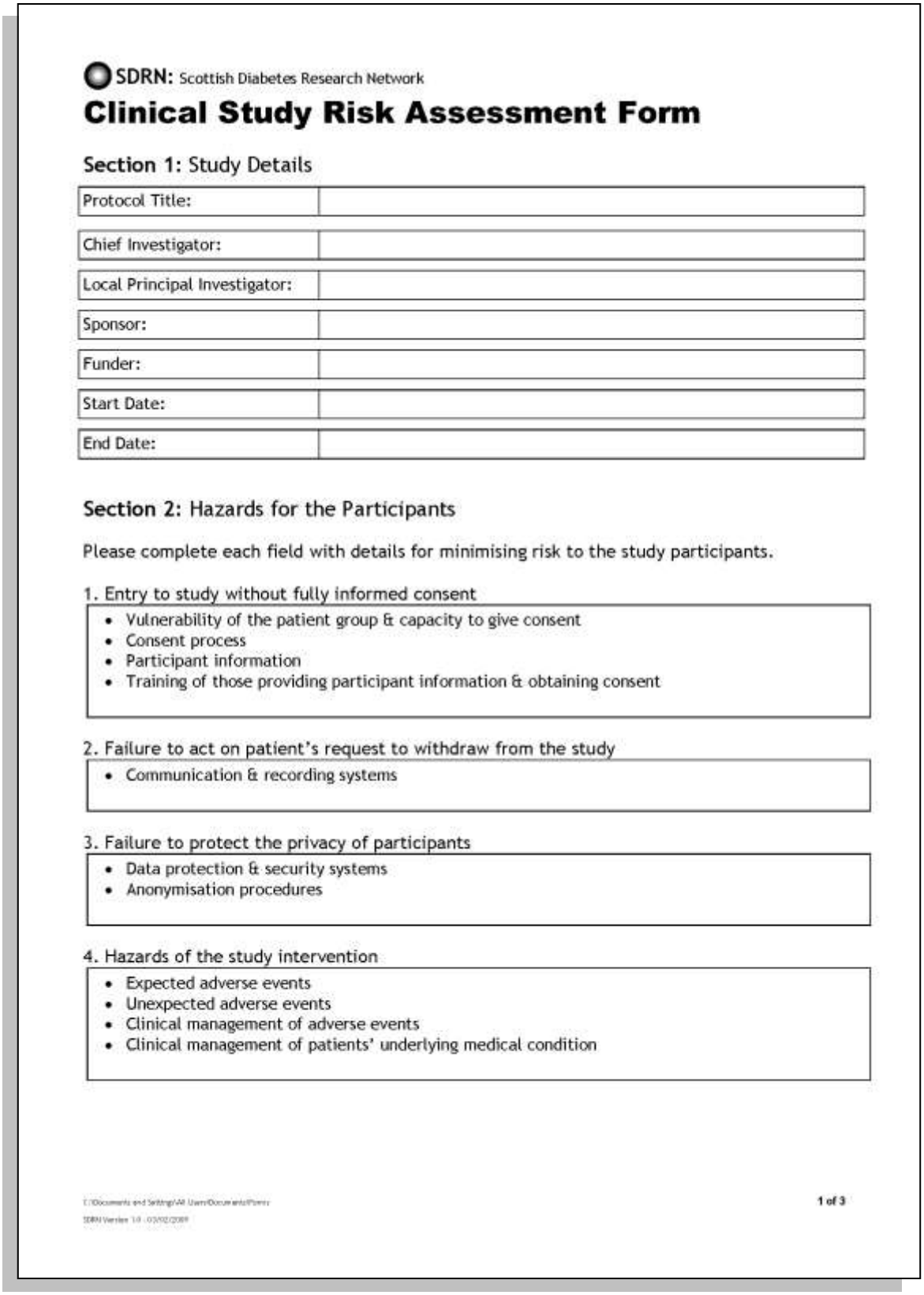
- Before the study begins, the Delegation of responsibilities log (see Appendix B) should be completed. This document should accurately reflect the tasks that each member of the study team conducts and constitutes part of the risk assessment process. The list of tasks given on the example is not exhaustive and can be adapted for each study simply adding extra tasks to the bottom of the list so that each task performed during the study can be accounted for.

- The Delegation of Responsibilities Log must be updated if members join or leave the study team so that it accurately reflects the study conduct throughout the course of that particular study.

- Both the Delegation of Responsibilities Log and the Clinical Study Risk Assessment Form should be filed in the study master file and must be archived at the end of the study for the appropriate time period.

- In the case of multicentre studies, the Delegation of Responsibilities Log will need to be completed for each individual site but the risk assessment should be the same for each site and should be completed centrally. However, each individual site will need a copy of the risk assessment form for the site file.

(APPENDIX A)



SDRN: Scottish Diabetes Research Network

Clinical Study Risk Assessment Form

Section 1: Study Details

Protocol Title:	
Chief Investigator:	
Local Principal Investigator:	
Sponsor:	
Funder:	
Start Date:	
End Date:	

Section 2: Hazards for the Participants

Please complete each field with details for minimising risk to the study participants.

1. Entry to study without fully informed consent

- Vulnerability of the patient group & capacity to give consent
- Consent process
- Participant information
- Training of those providing participant information & obtaining consent

2. Failure to act on patient's request to withdraw from the study

- Communication & recording systems

3. Failure to protect the privacy of participants

- Data protection & security systems
- Anonymisation procedures

4. Hazards of the study intervention

- Expected adverse events
- Unexpected adverse events
- Clinical management of adverse events
- Clinical management of patients' underlying medical condition

C:\Documents and Settings\All Users\Documents\Forms

SDRN Version 1.0 - 03/02/2009

1 of 3

5. Likely risk/benefit ratio of the study intervention in the study population

- Systems to monitor & review adverse effects
- Systems to maintain awareness of & to act on new knowledge
- Ability of participants to report adverse events & study outcomes reliably

6. Hazards of assessment methods

- Venepuncture
- Biopsy
- Xray, MRI, CT scan

Section3: Hazards of the Study

1. To the completion of the study - recruitment and follow-up

- Feasibility - population and number of subjects required
- Staff competence and experience at sites
- Length of follow-up
- Frequency of visits and follow-up
- Alternative means of follow-up (e.g. ONS flagging)

2. To the Reliability of the results

a) Study power

- Plausible treatment effects
- Patient numbers

b) Major violation of eligibility criteria

- Importance of violation to the trial
- Need for monitoring of inclusion/exclusion criteria and procedures for monitoring
- Unduly restrictive eligibility criteria

c) Fraud

- Potential within trial
- Incentives-financial & non-financial
- Consequences - size & severity of threat to results
- Options for checking

d) Randomisation procedures

- Robustness of procedure
- Potential for loss of allocation concealment/unblinding

All SDRN SOPs can now be downloaded from: http://www.sdrn.org.uk/?q=node/45

e) Outcome assessment

- Blinding (single, double)
- Objectivity of measure
- Standardisation of assessment
- Potential for independent review
- Potential for simple external verification e.g. death certificate, lab sample result

f) Other data - completeness & accuracy

- Data type & complexity (CRF design)
- Data collection method (paper, electronic)
- Data entry method
- Key data items
- Staff training
- Need & options for data verification

g) Adherence to the protocol

- Complexity
- Staff training & study experience
- Barriers to compliance with study intervention (for research team & participants)

Form completed by:

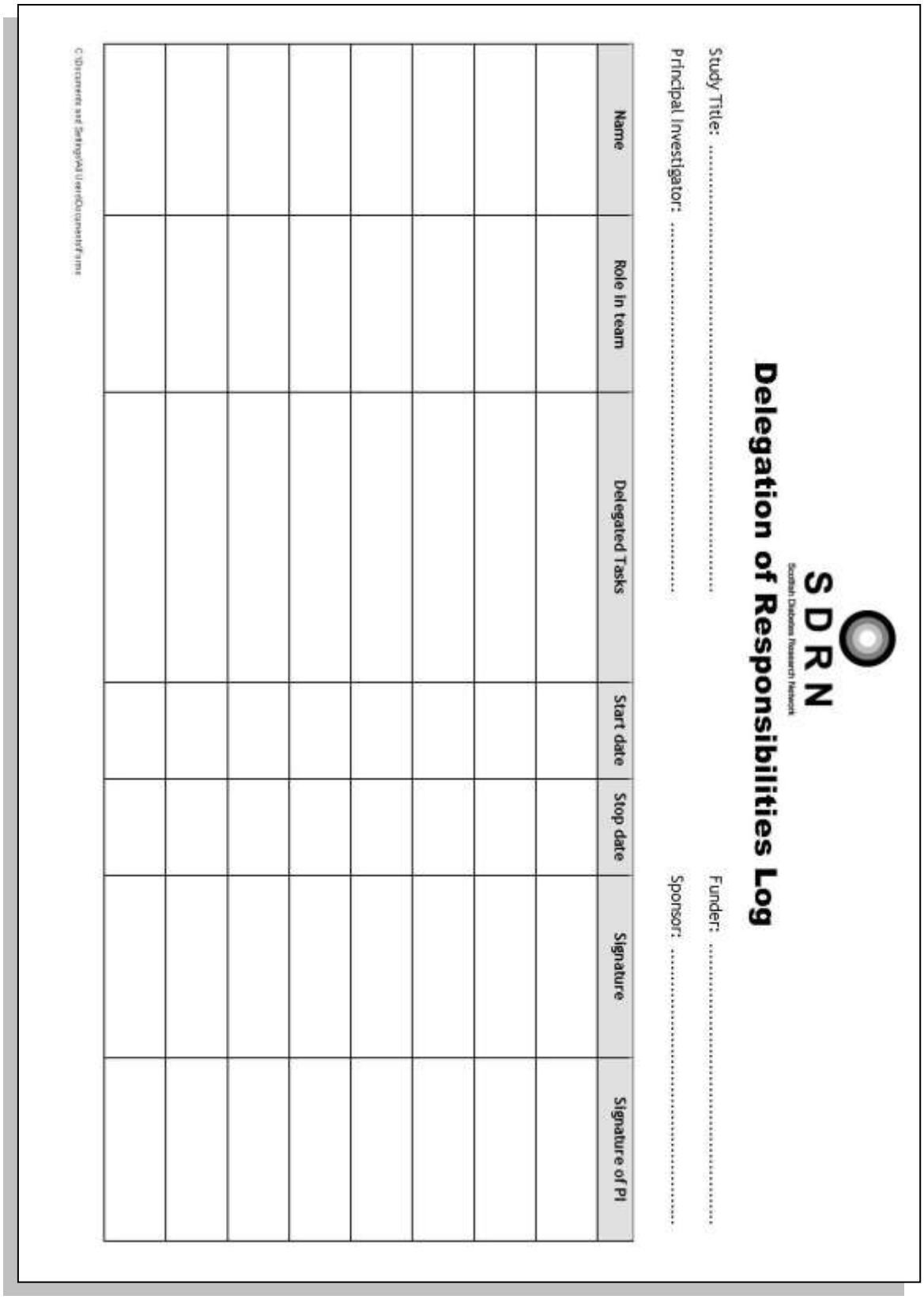
Full Name:		Position:	
Signature:		Date:	

Local Principal Investigator:

Full Name:		Position:	
Signature:		Date:	

All SDRN SOPs can now be downloaded from: http://www.sdrn.org.uk/?q=node/45

(APPENDIX B)



SDRN
Scottish Diabetes Research Network

Delegation of Responsibilities Log

Study Title: .....

Principal Investigator: .....

Funder: .....

Sponsor: .....

Name	Role in team	Delegated Tasks	Start date	Stop date	Signature	Signature of PI

C:\Documents and Settings\All Users\Documents\Forms

(APPENDIX C)

SDRN: Scottish Diabetes Research Network

Delegation of Responsibilities Log

Delegated Tasks

1. Informed consent
2. Assessing causality of adverse events
3. Review of inclusion/exclusion criteria
4. Physical Examination
5. Evaluation of lab results
6. CRF sign-off
7. recruitment of participants
8. Venepuncture/blood sampling
9. Recording vital signs (e.g. BP/P, respiratory rate, temperature)
10. Recording weight and waist/hip measurements
11. Patient education of new techniques (e.g. blood glucose monitoring, injection techniques).
12. Drug/device dispensing
13. Drug/device storage
14. Drug/device accountability
15. Recording adverse events
16. Data entry into CRF and source documents
17. Resolution of data queries
18. Processing and packaging of blood samples
19. Urinalysis
20. Scans - dexa, CT, MRI, PET
21. Dietary/lifestyle advice
22. Storage of patient records
23. Updating/storage of study files/documentation
24. Fridge/Freezer logs
25. Record of patient expenses
26. Writing source documentation (if required)

C:\Documents and Settings\All Users\Documents\Reference Information\
SDRN Version 1.0 - 03/01/2009

1 of 1