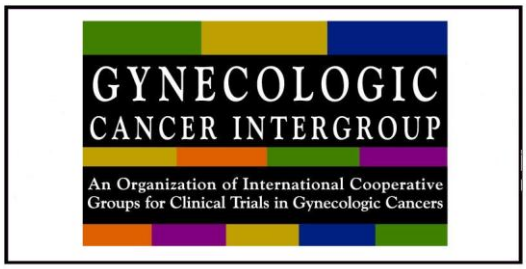

Harmonization Working Group

Insurance and Indemnity

October 2015

GROUP NAME

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating center of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance: _____

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

ACRIN (American College of Radiology Imaging Network)

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance: _____

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

AGO-AUSTRIA (Arbeitsgemeinschaft Gynaekologische Onkologie Austria)

Group Contacts

Name: Email-Address:	Regina Berger Regina.Berger@i-med.ac.at
Country:	Austria

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

It is mandatory to insure trial participants of pharmaceutical and medical product studies.

The sponsor is insurance holder and the clinical trial participant is defined as insurant who is independently entitled for compensation.

The scope of insurance must be proportionate to the risks associated with the clinical trial. Details may be fixed by order of the Minister of Health and Women. Here, the difference resulting from the number of subjects and inspection, the nature of the clinical examination and the state of the substance risk is particularly considered.

Austrian law has to be applied, and claims need to be filed in Austria (AMG § 32 Abs. 2).

Insurance coverage is for death or injury to health of a study participant.

If the medicinal product of a medicinal products trial has a CE-Number then no insurance is mandatory, except if the devise will be implanted into the body.

Patient rights are protected by the relevant ethics committee. The trial participant has to be informed about the trial and must give his consent before taking part in the trial. The participant must be informed about the contracted insurance.

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Insurance protection is only valid if the death or injury to the health is an obvious consequence of the clinical trial due to pharmaceutical, medical products or physical interventions, which are executed during the trial.

Other causes of death or injury to health, which are not connected with treatments in the clinical study won't be covered by the insurance company.

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

In trials regarding new medical methods or techniques the insurance is only valid if death or injury to the health of a study participant occurs during the medical intervention or a maximum of 3 years afterwards.

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☒ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No
☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor (can be delegated)

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☒ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law? NO**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: 500.000 €
- b) per study: 3.000.000 €
- c) per year: _____

v. **Cover period after end of trial:**
_____

vi. **Who is ensured?**
- ☒ patient
- ☒ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☒ required only in following cases / trials: - interventional trials
  - any risk to the welfare of the patient

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☒ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**

☒ yes
☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**

☒ Protocol
☒ Informed Consent Form
☐ Synopsis in local language
☐ Risk-Benefit information
☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

AGO Study Group (Arbeitsgemeinschaft Gynaekologische Onkologie)

Group Contacts

Name: Email-Address:	Sandra Polleis spolleis@ago-ovar.de
Country:	Germany

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

Prior to the start of the clinical trial the existence of a patient's insurance must be proven according to AMG § 40 Abs. 1 S. 3 no. 8 and Abs. 3, MPG § 20 Abs. 1 no. 9 and Abs. 3, and ICH-GCP point 5.8. Patient's insurance shall cover any death or injury to the health of trial subjects which is directly related to the clinical trial. The scope of insurance must be proportionate to the risks associated with the clinical trial.

Not insured are damages only indirectly related to the trial (e.g. travel accidents on the way to the trial site). For these cases an insurance for travel between patient's home and trial site may be established (depending on kind of trial, e.g. if more visits are necessary in comparison to the standard of care).

Each patient has to be provided with the insurance policy as well as insurance terms and conditions. Patient has to be notified about special contents of the insurance terms and conditions, especially on the paragraph for exclusions.

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Excluded from patient's insurance protection are:

- Injuries to the health of trial subject which are caused by effects/events which are sure to occur in the clinical trial's indication and which was announced to the patient and which do not exceed an acceptable extent according to knowledge of medical science
- Injuries to the health of trial subject or worsening of existing diseases, which would also have been occurred or persist if the patient would not have participate in the trial.
- Injuries to the health of trial subject which occurred due to the fact that the trial's subject act wilfully and knowingly against instructions of site staff

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

Liability of site and investigator for negligence and willful misconduct is limited to double the sum of the reimbursement agreed with the site. Under no circumstances site and investigator are liable for any loss of profit.

Each contractual partner agrees to indemnify and hold the contractual partner, its officers, directors, employees and agents harmless from any and all losses, reasonable costs, claims, demands, judgments and liability (including reasonable attorney fees) arising out of or resulting from own negligence or willful misconduct, except to the extent that such losses,

costs, claims, demands, judgments or liability are due to the negligence or wrongful act(s) of the other contractual partner.

5. Which kind of insurance is required by law in your country?

a)	General liability insurance for Investigators / sites	☒	Yes	☐	No
b)	General liability insurance for your group / national coordinating centre of your group	☒	Yes	☐	No
c)	Insurance for travel between patient's home and trial site	☐	Yes	☐	No
		☒	case by case		
	If yes, who has to establish this insurance:	Sponsor (general); in academic trial local participating group has to establish this, if applicable			
d)	Insurance for any trial-related side effects or injuries or trial-related deaths	☒	Yes	☐	No
	If yes, who has to establish this insurance:	Sponsor (general); in academic trial local participating group has to establish this			

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☒ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☒ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: € 500.000
- b) per study: € 50.000.000 (50 million)
- c) per year: NA

iv. **Usual insurance sum in practice**
- a) per patient: € 500.00
- b) per study: € 50.000.000 (50 million)
- c) per year: NA

v. **Cover period after end of trial:**
Insurance covers injuries which occurred within 5 years after end of trial

vi. **Who is ensured?**
- ☒ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☒ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)

☒ required only in following cases / trials: - trials with drugs (AMG)
- trials with medical devices (MPG)

ix. **Is there a minimum amount for indemnity per patient?**

☒ yes: € 500.000
☐ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**

☒ yes
☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**

☒ Protocol
☒ Informed Consent Form
☐ Synopsis in local language
☒ Risk-Benefit information
☒ Other, please specify:
number of patients (total & in local country), list of sites, expected duration of the trial

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
Generally no, but exceptions can be made provided that separate funding is available. In some trials there is compensation for travel costs provided to patients - especially in trials with only small number of sites which cause a long way here/there. Details of compensation have to be stated in the informed consent and have to be specified in the application documents which will be provided to Ethics Committee.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

no

9. Additional remarks and/or comments:

no

ANZGOG (Australia New Zealand Gynaecological Oncology Group)

Group Contacts

Name: Email-Address:	NHMRC CTC, University of Sydney. Sponsor and coordinating centre for ANZGOG trials contracts@ctc.usyd.edu.au
Country:	Australia, New Zealand

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

University shall be responsible to accord with the principles that have their origin in the Declaration of Helsinki, the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) as adopted by the TGA; and the NHMRC National Statement on Ethical Conduct in Human Research (2007) as amended from time to time, and any other relevant NHMRC publication or guideline that relates or may relate to research studies.

GCP requires the sponsor to have provision of appropriate insurance and indemnity for the trial and trial-related staff, as well as measures for subject compensation for trial-related injury.

The main types of insurance necessary for clinical trials activity are:

- Clinical trials insurance
- Professional Indemnity insurance
- Public Liability insurance
- Workers Compensation

Study participants are selected in accordance with the eligibility criteria specified in the Protocol and only after all necessary legal, regulatory or other approvals have been granted including those of the IRB or HREC, at the Sites and strictly in accordance with the terms of any such approval.

Each Party shall (except as otherwise indicated) be solely responsible for those tasks allocated to it.
Reciprocal arrangements whereby each party shall each indemnify, release and discharge each other, their agents and employees from any loss, costs, claims, demands or actions which may be made by reason of personal injury (including death) to any person, or damage to property, arising out of or in connection with liability resulting from:

- The performance of the Study in Sites

- A negligent act or omission of each other, its agents or employees in the performance of its obligations pursuant to the Agreement

except to the extent that any loss arises from the negligent act or omission of the other party, its agents and employees.

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

The National Statement requires appropriate arrangements, an insurance statement which documents the compensation that will be available to the participants for trial related injuries to ensure adequate compensation to participants for any injury suffered as a result of participation in a clinical trial. A HREC must be satisfied, before approving a clinical trial, that such arrangements exist. The sponsor must have, before the trial formally starts, an insurance statement which documents the compensation that will be available to participants for trial-related injuries. Further the sponsor will usually be responsible for maintaining insurance coverage under the CTRA. The Medicines Australia Guideline for Compensation for Injury Resulting from Participation in a company-sponsored clinical trial are an industry standard which most sponsors in Australia abide by when conducting clinical trials. The guidelines provide that the “amount of compensation paid should be appropriate to the nature, severity and persistence of the injury” and set out a procedure for determining this.

Medicines Australia recommends that member companies sponsoring a clinical trial provide written assurance to the investigator and the HREC that the guidelines will be adhered to in the event of injury to a subject.

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

Ensure that clinical trial insurance to the coverage limits normally applicable to a trial is in place for all Sites.

Ensure that each Site Agreement contains provisions requiring each Site and Investigator to have appropriate insurance for the duration of the Study to cover against any claims for compensation by participants in the Study arising out of the negligence of the Site or Investigator.

5. Which kind of insurance are required by law in your country?

a)	General liability insurance for Investigators / sites	☒ Yes	☐ No
b)	General liability insurance for your group / national coordinating centre of your group	☒ Yes	☐ No
c)	Insurance for travel between patient's home and trial site	☐ Yes ☐ case by case	☒ No
	If yes, who has to establish this insurance:	_____	
d)	Insurance for any trial-related side effects or injuries or trial-related deaths	☒ Yes	☐ No
	If yes, who has to establish this insurance:	Local sponsor	

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☒ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: n/a
- b) per study: n/a
- c) per year: n/a

iv. **Usual insurance sum in practice**
- a) per patient: n/a

b) per study: n/a
c) per year: AUD$20,000,000

v. **Cover period after end of trial:**
n/a, insurances are renewed annually

vi. **Who is ensured?**
☒ patient
☒ investigator/site
☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes ☐ no

viii. **In which cases / trials is insurance required?**
☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
☐ required only in following cases / trials: _____
_____
_____
_____

ix. **Is there a minimum amount for indemnity per patient?**
☐ yes:
☒ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
☒ yes - certificate of currency usually required for site governance approval
☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
☐ Protocol
☐ Informed Consent Form
☐ Synopsis in local language
☒ Risk-Benefit information
☒ Other, please specify:
Study details including Study name, site locations and number of participants

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No sometimes we cover patient costs if there is sufficient budget

If yes, please specify the compensation:
Participants are not normally paid to take part in a clinical trial, but may be reimbursed for some out-of-pocket expenses.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

no

9. Additional remarks and/or comments:

no

BGOG (Belgium Gynecology Oncology Group)

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance: _____

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

xii. **Indemnification source**

- ☐ private policies
- ☐ national mechanism
- ☐ both

xiii. **Indemnification type**

- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

xiv. **Indemnification limit imposed by law?**

a) per patient: _____
b) per study: _____
c) per year: _____

xv. **Usual insurance sum in practice**

a) per patient: _____
b) per study: _____
c) per year: _____

xvi. **Cover period after end of trial:**

_____

xvii. **Who is ensured?**

- ☐ patient
- ☐ investigator/site
- ☐ sponsor

xviii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**

☐ yes ☐ no

xix. **In which cases / trials is insurance required?**

- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

xx. **Is there a minimum amount for indemnity per patient?**

- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

xxi. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**

- ☐ yes
- ☐ no

xxii. **Which documents have to be provided to the insurance company to receive the insurance police?**

- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

COGi (Cooperative Ovarian Cancer Group)

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance: _____

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

DGOG (Dutch Gynecologic Oncology Group)

Group Contacts

Name: Email-Address:	C. L. Creutzberg c.l.creutzberg@lumc.nl, k.verhoeven@iknl.nl
Country:	Netherlands

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

Patient rights:

- right to withdraw informed consent at any time without giving reason
- right to receive every aspect of normal patient care also if deciding not to take part or withdrawing consent
- right to receive every information needed before deciding, right on insurance as required by law, etc

Indemnity: required by law

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Not specified, but maximums apply per study and per year etc

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☒ Yes* ☐ No

*In the Netherlands, it is standard (and required by law) that every subject/person/patient has a health insurance.

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes* ☐ No

If yes, please specify:

Insurance has to cover at least €650.000 per subject and €5.000.000 per trial, the PI's site has to establish the insurance for all participating sites in case of multicenter trial, per year min €7.500.000, but if many subjects submit claims than the maximum per subject becomes lower

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☒ No*

* not as long as DGOG does not signs contracts or coordinates the trials, this is done by DGOG – PI's medical center and all standard insurances required by law apply

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☒ case by case

If yes, who has to establish this insurance: each participating center*

For multicenter trials, new rules as per July 1 2015 require that for multicenter trials the PI's center takes care of the insurance for all participating center

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: each participating center*

For multicenter trials, new rules as per July 1 2015 require that for multicenter trials the PI's center takes care of the insurance for all participating center

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type**
- ☒ no fault accident based
- ☒ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
a) per patient: minimum of € 650.000
b) per study: minimum of € 5.000.000
c) per year: minimum of € 7.500.000

iv. **Usual insurance sum in practice**
a) per patient: minimum of € 650.000
b) per study: minimum of € 5.000.000
c) per year: minimum of € 7.500.000

v. **Cover period after end of trial:**
4 years

vi. **Who is ensured?**
- ☒ patient (for trial)
- ☒ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes ☐ no
Trials of no added risk over normal treatment (e.g., questionnaires) can be allowed to have no specific insurance (other than each hospital's standard insurances) – the Ethics Committee will decide on such as request

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____

_____
_____

ix. **Is there a minimum amount for indemnity per patient?**
☒ yes: see 6 iii
☐ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
☒ yes, but these are standard polices as approved by the collaborating insurance companies and medical centers and according to the requirements by law
☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
☐ Protocol
☐ Informed Consent Form
☐ Synopsis in local language
☐ Risk-Benefit information
☒ Other, please specify:
not to company, but to Ethics Committee, they will decide on the requirements for the specific (standard) insurance

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
This depends on the type of trial, generally speaking: no, but often payment is made for transport and parking in case of extra visits, sometimes a small fee (e.g., €20) for doing something extra

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

Yes, discussion that for international multicenter trial, participating groups required lead group to establish insurance for all groups/subjects in the trial, while Dutch law requires only insurance for Dutch subjects and (for non-industry sponsored trials) insurance for the participating international group's subjects has to be taken care of by the participating group.

9. Additional remarks and/or comments:

EORTC (European Organisation for Research and Treatment of Cancer)

Group Contacts

Name: Email-Address:	
Country:	

NOTE: Please refer to separate document

GEICO (The Grupo Español de Investigación en Cáncer de Ovario)

Group Contacts

Name: Email-Address:	Federico Nepote secretaria@grupogeico.org
Country:	Spain

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

Helsinki Declaration

Royal Decree 223/2004

2. Are there any limitations of liability in your country?

☐ Yes ☒ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☒ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☒ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☒ no fault accident based
- ☒ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: 250.000 €
- b) per study: 2.500.000 €
- c) per year: 25.000 €

iv. **Usual insurance sum in practice**
- a) per patient: 250.000 €
- b) per study: 2.500.000 €
- c) per year: 25.000 €

v. **Cover period after end of trial:**
12 months

vi. **Who is ensured?**
- ☒ patient
- ☒ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☒ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☒ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☒ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☒ Protocol
- ☒ Informed Consent Form
- ☒ Synopsis in local language
- ☐ Risk-Benefit information
- ☒ Other, please specify:
  Sites, investigators information, insurance policy, summary of expected toxicities (obtained in SmPC)

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

Nothing

G-GOC (MD Anderson Consortium)

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance: _____

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

GICOM (Grupo de Investigación en Cáncer de Ovario y Tumores Ginecológicos de México, A.C.)

Group Contacts

Name: Email-Address:	Adriana Chávez-Blanco adrianachavezblanco@gmail.com
Country:	Mexico

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

In México, it is mandatory for the sponsor to have a Drug Liability Insurance, covering any injury /adverse event/death caused to the trial subject as a result of a protocol process and or study drug(s) ,during the life of the clinical trial and three years after the study has finished.

As per Law, the Insurance has to be issued by an Insurance Company legally established in the Country. If it is the case that such Insurance is issued by a foreign company, then a worldwide coverage with branch office in México is required.

2. Are there any limitations of liability in your country?

☐ Yes ☒ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

NOTE In México, when a subject has a private medical Insurance, Social Security services (IMSS) or Federal Health Services Affiliation (ISSSTE); and decides to participate in a clinical trial, the Insurance as well as IMSS/ISSSTE rights lapse temporarily until the study has finished*. *Any medical treatment (exams, procedures, drugs conmeds,etc), related to the clinical trial are covered by the Sponsor*

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:
The Sponsor should provide a Drug Liability Insurance.

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☒ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: Depending on the amount agreed in the Study Insurance
- b) per study: Depending on the amount agreed in the Study Insurance
- c) per year: _____

iv. **Usual insurance sum in practice**

v.
- a) per patient: _____
- b) per study: _____
- c) per year: _____

vi. **Cover period after end of trial:**

3 years

vii. **Who is ensured?**
- ☐ patient
- ☒ investigator/site
- ☒ sponsor

viii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**

☒ yes ☐ no

ix. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

x. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☐ no minimum stated by law
- ☒ no general minimum as it is depending on Phase / risk of trial

xi. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☒ no

xii. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☒ Protocol in Spanish and already approved be Local EC and MOH
- ☒ Informed Consent Form in Spanish and already approved be Local EC and MOH

☐ Synopsis in local language
☐ Risk-Benefit information
☒ Other, please specify: _
- ✕ PI/Co-I(s) CVs
- ✕ List of Approved Study Sites
- ✕ Investigator´s Brochure in Spanish or Study Drug (including comparators) Prescription Information in Spanish approved by the MOH
- ✕ Local EC and MOH Approvals _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
Compensation for transportation and meals only. As per law, a trial subject cannot receive a payment for participating in the trial.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

no

9. Additional remarks and/or comments:

no

GINECO (Group d'Investigateurs Nationaux pour l'Etude des Cancers Ovariens)

Group Contacts

Name: Email-Address:	ARCAGY nlefur@arcagy.org
Country:	France

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

The French law states that you have to purchase a specific insurance policy to cover possible damages to patients in relationship with the aim of the study

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

The sponsor has to purchase an insurance with a maximum limit of 1.000.000 euros per patient and maximum 6.000.000 euros per protocol.

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☒ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

The definition of the insured in the specific insurance policy is : the sponsor and the investigators and the medical staff.

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☒ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No

☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: the insurance company with the help of the insurance broker

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: 1 million
- b) per study: 6 million
- c) per year: 10 million

iv. **Usual insurance sum in practice**
- a) per patient: 1 million
- b) per study: 6 million
- c) per year: 10 million

v. **Cover period after end of trial:**
10 years

vi. **Who is ensured?**
- ☒ patient
- ☒ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes (for the insurance calculation no change for the indemnification) ☐ no

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☐ no minimum stated by law
- ☒ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☒ yes
- ☐ no

xi. Which documents have to be provided to the insurance company to receive the insurance police?
- ☒ Protocol
- ☒ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

No

GOG (Gynecologic Oncology Group)

Group Contacts

Name: Email-Address:	Bette Stonebraker stonebraker@gogstats.org
Country:	USA

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

For federal studies, see the Federal Tort Claims Act

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

For federal studies, see the Federal Tort Claims Act

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☒ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

This would be site specific based on state law and/or site policy.

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☒ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No ☐ case by case

If yes, who has to establish this insurance: Site/Group/Sponsor

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Site/Group/Sponsor

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**

☐ private policies
☐ national mechanism
☒ both

ii. **Indemnification type**

☐ no fault accident based
☐ no fault liability
☒ fault based liability

iii. **Indemnification limit imposed by law?** **Policy based**

a) per patient: _____
b) per study: _____
c) per year: _____

iv. **Usual insurance sum in practice** **Policy based**

a) per patient: _____
b) per study: _____
c) per year: _____

v. **Cover period after end of trial:** **Policy based**

_____

vi. **Who is ensured?**

☐ patient
☒ investigator/site
☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**

☒ yes ☐ no

viii. **In which cases / trials is insurance required?**

☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
☐ required only in following cases / trials: _____
_____
_____
_____

ix. **Is there a minimum amount for indemnity per patient?**

☐ yes:
☐ no minimum stated by law
☒ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**

☐ yes
☒ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**

☒ Protocol
☒ Informed Consent Form
☐ Synopsis in local language
☐ Risk-Benefit information
☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:
Sites may provide but our organization does not provide funds directly to patients. There are federal mechanisms that provide funds to patients as well.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

N/A

GOTIC (Gynecologic Oncology Trial and Investigation Consortium)

Group Contacts

Name: Email-Address:	Eriko Aotani gh-aotani@newkast.or.jp gh-gcig@newkast.or.jp
Country:	Japan

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

The patient needs to be provided with information to help deciding whether or not to participate in the trial.

The investigator is responsible for the patient to be fully informed and understood the trial, including indemnity and patient rights related to the trial.

The sponsor and the trial sites must in advance take necessary measures to deliver medical care in the event of trial-related health injuries.

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

-Product liability is usually covered by pharmaceutical or medical device company insurance.

-Definite fault of the investigator or the site is covered by the insurance for the investigators or sites themselves.

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

Not requested from investigators/sites.

5. Which kind of insurance is required by law in your country?

a)	General liability insurance for Investigators / sites	☒ Yes	☐ No
b)	General liability insurance for your group / national coordinating centre of your group	☐ Yes	☒ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No

☐ case by case * If AE related, it may be covered by insurance.

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor of the trial

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type** *depending on the type of insurance*
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____ *Not specified*
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: 100,000,000 Yen
- b) per study: 300,000,000 Yen
- c) per year: not applicable

v. **Cover period after end of trial:**
usually a year

vi. **Who is ensured?**
- ☒ patient
- ☒ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes evaluated by the insurance company ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☒ required only in following cases / trials: indication directed trials _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☒ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?** *<u>Depending on the IRB</u>*
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**

☒ Protocol
☐ Informed Consent Form
☒ Synopsis in local language (usually fully translated version)
☐ Risk-Benefit information
☒ Other, please specify: Group specific appendix

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

Depending on the protocol

If yes, please specify the compensation:
For indication trials with un-approved drugs, monetary compensation per visit is usually provided for the patients participating in the trial.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

ICORG (All Ireland Cooperative Oncology Research Group)

Group Contacts

Name: Email-Address:	Beata Sapetto-Rebow and Glen Webb beata.sapetto@icorg.ie
Country:	Ireland

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

Clinical trials are covered by national government Clinical Indemnity Scheme for public hospitals

Sponsor needs to have insurance in place

All investigators have their own private malpractice insurance

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Sponsor's insurance must be minimum 6.5 million euro

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☒ Yes ☐ No

Not relevant when study conducted in a public hospital, unless there are additional procedures which are outside normal cover. Relevant when study conducted in a private hospital

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

Sites must have indemnity in place in case of negligence (see above CI scheme for public hospitals and private hospitals must have indemnity). Sponsor must have an insurance of clinical trial

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☒ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: YES_____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: 6.5 million (per study/year)
- c) per year: _____

v. **Cover period after end of trial:**
N/A_____

vi. **Who is ensured?**
- ☒ patient
- ☒ investigator/site
- ☒ sponsor (if ICORG is sponsor. When commercial sponsor – then the two above)

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☒ no

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☒ yes: 6.5 million per study/ per year
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☒ yes (ICORG/sponsor provides a copy of the clinical trials insurance certificate as evidence of such a policy being in place. This certificate is normally renewed annually.
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☒ Protocol (occasionally)
- ☐ Informed Consent Form
- ☒ Synopsis in local language
- ☐ Risk-Benefit information
- ☒ Other, please specify: summary of trial participation, EC approval

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
Dependent on sponsor

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

- When we conduct trials for academic sponsors based in the UK, their insurance policy does not cover design of the study
- Sponsor's insurance must be 6.5 million euro for study to be run in Ireland

9. Additional remarks and/or comments:

A copy of the EC approval is provided to the insurer of the national Clinical Indemnity Scheme (CIS) in Ireland which covers clinical trial indemnity of public hospital sites. On receipt, the insurer will provide a letter confirming indemnity cover under the CIS for the specific study to be conducted at each site that has been approved by the EC.

JGOG (Japanese Gynecologic Oncology Group)

Group Contacts

Name: Email-Address:	Ayumi Murayama muraya-a@insti.kitasato-u.ac.jp GCIG-ope@insti.kitasato-u.ac.jp
Country:	Japan

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

The patient needs to be provided with information to help deciding whether or not to participate in the trial.

The investigator is responsible for the patient to be fully informed and understood the trial, including indemnity and patient rights related to the trial.

The sponsor and the trial sites must in advance take necessary measures to deliver medical care in the event of trial-related health injuries.

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

-Product liability is usually covered by pharmaceutical or medical device company insurance.

-Definite fault of the investigator or the site is covered by the insurance for the investigators or sites themselves.

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

Not requested from investigators/sites.

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☒ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No

☐ case by case * If AE related, it may be covered by insurance.

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor of the trial

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☒ both

ii. **Indemnification type** *depending on the type of insurance*
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____ *Not specified*
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: 100,000,000 Yen
- b) per study: 300,000,000 Yen
- c) per year: not applicable

v. **Cover period after end of trial:**
usually a year

vi. **Who is ensured?**
- ☒ patient
- ☒ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes evaluated by the insurance company ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☒ required only in following cases / trials: indication trials_____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☒ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?** *<u>Depending on the IRB</u>*
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**

☒ Protocol
☐ Informed Consent Form
☒ Synopsis in local language (usually fully translated version)
☐ Risk-Benefit information
☒ Other, please specify: ___Group specific appendix_____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

Depending on the protocol

If yes, please specify the compensation:
For indication trials with un-approved drugs, monetary compensation is usually provided for the patients participating in the trial.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

We neither have remarks nor comments.

KGOG (Korean Gynecological Oncology Group)

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance: _____

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

MaNGO (Mario Negri Gynecologic Oncology)

Group Contacts

Name: Email-Address:	Roldano Fossati
Country:	Italy

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

There must be a specific policy in place for medicinal interventional trials. The insurance policy is to grant specific coverage in connection with the reimbursement of damages caused to the subjects following their participation in the trial, thus covering any civil liability of investigator and sponsor of the clinical trial, without excluding any damage which may be unintentionally caused by accident and/or be attributed to negligence, imprudence or inexperience.

There is a Ministerial decree that provides specific indemnity and insurance requirements, and the Sponsor is required to submit to the Ethics Committee an insurance certificate that meets these requirements at the time of the Clinical Trial Application.

Clinical trial participants must be informed of the insurance policy as part of informed consent

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Length of coverage:

- minimum of 24 months after completion of trial, but may be extended depending on nature of trial
- 10 years mandatory for pediatric, gene therapy, cellular therapy, or radiopharmaceutical trials

Minimum coverage:

- Per individual no less than € 1 million
- Per protocol
  € 5 million if 50 or less participants in Italy

  € 7 million 51-199 participants in Italy

  € 10 million if 200 or more participants in Italy

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

Yes and no. Though not required by clinical trial law, sites are not exempt from having their own liability insurance. The clinical trial insurance decree does state that sponsor will provide coverage for ANY damages. This permits patients to

receive immediate benefits, no matter who is at fault. However, there is no legal limitation for a site or individual to be held liable for negligence, etc in Italian civil courts

5. Which kind of insurance is required by law in your country?

a)	General liability insurance for Investigators / sites	☒	Yes	☐	No
b)	General liability insurance for your group / national coordinating centre of your group	☒	Yes	☐	No
c)	Insurance for travel between patient's home and trial site	☐	Yes	☒	No
		☐	case by case		
	If yes, who has to establish this insurance:	_____			
d)	Insurance for any trial-related side effects or injuries or trial-related deaths	☒	Yes	☐	No
	If yes, who has to establish this insurance:	Sponsor			

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☒ private policies SPECIFIC CLINICAL TRIAL POLICY
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: not less than € 1,000,000
- b) per study: not less than €5,000,000 for trials with up to 50 pts, €7,500,000 50-200 patients, €10,000,000 for more than 200 pts
- c) per year: no, but totals may be revised every 3 years

iv. **Usual insurance sum in practice**
- a) per patient: € 120-150
- b) per study: € minimum 50,000_increased with sample size
- c) per year: total policy usually paid in 2 payments ... least 25,000 each year x 2 years

v. **Cover period after end of trial:**
and injury within 24 months after completion of trial , reporting of injury within 36 months of trial completion
EXTENDED TO 10 YEARS IN TRIALS IN CHILDREN OR TRIALS WITH GENETIC, CELL AND RADIOPHARMACEUTICAL THERAPIES

vi. **Who is ensured?**
- ☐ patient
- ☒ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☒ yes but by private insurer ☐ no

viii. **In which cases / trials is insurance required?**

☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)

☐ required only in following cases / trials: _____

_____

_____

_____

ix. **Is there a minimum amount for indemnity per patient?**

☒ yes: € 1,000,000

☐ no minimum stated by law

☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**

☒ yes

☐ no

xi. Which documents have to be provided to the insurance company to receive the insurance police?

☐ Protocol

☒ Informed Consent Form

☒ Synopsis in local language

☐ Risk-Benefit information

☒ Other, please specify:

n. Centers, n. Patients in Italy to be covered by policy, length of study, profit or nonprofit sponsor, inclusion of minors or pregnant patients, use of gene or cellular therapy or radiopharmaceuticals

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

In the case of multicentre nonprofit trials, each centre may, by law, refer to its own insurance policy to cover participants from its centre, with the competent Ethics Committee assessment/approval. However, this is rarely done, as the Sponsor generally provides an insurance policy for all participating centres, since most Ethics Committees find the general site policies to be inadequate.

MITO (Multicenter Italian Trials in Ovarian cancer and gynecologic malignancies group)

Group Contacts

Name: Email-Address:	Jane Bryce Jane_bryce@hotmail.com; Jane.bryce@usc-intnapoli.net
Country:	Italy

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

There must be a specific policy in place for medicinal interventional trials. The insurance policy is to grant specific coverage in connection with the reimbursement of damages caused to the subjects following their participation in the trial, thus covering any civil liability of investigator and sponsor of the clinical trial, without excluding any damage which may be unintentionally caused by accident and/or be attributed to negligence, imprudence or inexperience.

There is a Ministerial decree that provides specific indemnity and insurance requirements, and the Sponsor is required to submit to the Ethics Committee an insurance certificate that meets these requirements at the time of the Clinical Trial Application.

Clinical trial participants must be informed of the insurance policy as part of informed consent

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Length of coverage:

- minimum of 24 months after completion of trial, but may be extended depending on nature of trial
- 10 years mandatory for pediatric, gene therapy, cellular therapy, or radiopharmaceutical trials

Minimum coverage:

- Per individual no less than € 1 million
- Per protocol
  € 5 million if 50 or less participants in Italy

  € 7 million 51-199 partipants in Italy

  € 10 million if 200 or more participants in Italy

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

Yes and no. Though not required by clinical trial law, sites are not exempt from having their own liability insurance. The clinical trial insurance decree does state that sponsor will provide coverage for ANY damages. This permits patients to

receive immediate benefits, no matter who is at fault. However, there is no legal limitation for a site or individual to be held liable for negligence, etc in Italian civil courts

5. Which kind of insurance is required by law in your country?

a)	General liability insurance for Investigators / sites	☒	Yes	☐	No
b)	General liability insurance for your group / national coordinating centre of your group	☒	Yes	☐	No
c)	Insurance for travel between patient's home and trial site	☐	Yes	☒	No
		☐	case by case		
	If yes, who has to establish this insurance:	_____			
d)	Insurance for any trial-related side effects or injuries or trial-related deaths	☒	Yes	☐	No
	If yes, who has to establish this insurance:	Sponsor			

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

xii. **Indemnification source**
- ☒ private policies SPECIFIC CLINICAL TRIAL POLICY
- ☐ national mechanism
- ☐ both

xiii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☒ fault based liability

xiv. **Indemnification limit imposed by law?**
- a) per patient: not less than € 1,000,000
- b) per study: not less than €5,000,000 for trials with up to 50 pts, €7,500,000 50-200 patients, €10,000,000 for more than 200 pts
- c) per year: no, but totals may be revised every 3 years

xv. **Usual insurance sum in practice**
- a) per patient: € 120-150
- b) per study: € minimum 50,000_increased with sample size
- c) per year: total policy usually paid in 2 payments ... least 25,000 each year x 2 years

xvi. **Cover period after end of trial:**
and injury within 24 months after completion of trial , reporting of injury within 36 months of trial completion
EXTENDED TO 10 YEARS IN TRIALS IN CHILDREN OR TRIALS WITH GENETIC, CELL AND RADIOPHARMACEUTICAL THERAPIES

xvii. **Who is ensured?**
- ☐ patient
- ☒ investigator/site
- ☒ sponsor

xviii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☒ yes but by private insurer ☐ no

xix. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)

☐ required only in following cases / trials: _____
_____
_____
_____

xx. **Is there a minimum amount for indemnity per patient?**
☒ yes: € 1,000,000
☐ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

xxi. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
☒ yes
☐ no

xxii. Which documents have to be provided to the insurance company to receive the insurance police?
☐ Protocol
☒ Informed Consent Form
☒ Synopsis in local language
☐ Risk-Benefit information
☒ Other, please specify:
n. Centers, n. Patients in Italy to be covered by policy, length of study, profit or nonprofit sponsor, inclusion of minors or pregnant patients, use of gene or cellular therapy or radiopharmaceuticals

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

In the case of multicentre nonprofit trials, each centre may, by law, refer to its own insurance policy to cover participants from its centre, with the competent Ethics Committee assessment/approval. However, this is rarely done, as the Sponsor generally provides an insurance policy for all participating centres, since most Ethics Committees find the general site policies to be inadequate.

National Cancer Research Institute UK (NCRI) and MRC CTU/ UCL CTC

Group Contacts

Name: Email-Address:	Dr. Susan Kerrison s.kerrison@ucl.ac.uk; l.farrelly@ucl.ac.uk; n.gower@ucl.ac.uk
Country:	UK

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

The UK Medicines for Human Use (Clinical Trial) Regulations 2004 require the following which follows the EU directives -

- Provision for indemnity or compensation in the event of injury or death attributable to a clinical trial (Article 6.3(h) of 2001/20/EC).
- Insurance or indemnity to cover the liability of the investigator and sponsor (Article 6.3(i) of 2001/20/EC).

Note there is no requirement for the sponsor to provide the insurance only to ensure that insurance is in place.

It is also important to note that in English law there is no cap or limit to claims for personal injury. So, in the event that a claim from the research subject for negligence were proved the claim would be unlimited but decided by the court. There are no legal specific legal requirements for studies that do not fall under the UK Clinical Trial Regulations.

2. Are there any limitations of liability in your country?

☐ Yes ☒ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

In theory, it is not relevant. It is unclear whether the UK National Health Service would pick up the costs of treatment for any injury or otherwise. But this has never been tested.

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☒ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor

- Trial related side effects or injuries are treated free of charge by NHS.
- Sponsor must hold insurance to cover its own negligence and liability in relation to claims from participants for harm attributable to participation in the study.
- Some academic sponsors also purchase 'no fault' insurance from which patients could claim for unforeseen injuries, side effects or death. The Research Ethics Committee may also require such cover to be in place for risky trials. Where we are not the sponsor we would expect the sponsor to hold the required cover.

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☒ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☒ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: none
- b) per study: none
- c) per year: none

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

The current UCL policy (which covers the entire research portfolio) has the following indemnity limits: GBP 15.000.000 any one claim and GBP 15.000.000 in the aggregate.

v. **Cover period after end of trial:**
unlimited

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
_____

ix. **Is there a minimum amount for indemnity per patient?**

☐ yes:
☒ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**

☐ yes
☐ no
The policy is not submitted, however evidence that appropriate insurance is in place is required, for example by providing a 'cover note'. This is a note from the insurer explaining the level and type of cover.

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
If the trial does not meet any of the exclusions for the sponsor insurance policy no additional documents are required per trial as a sponsor policy will often cover a portfolio of trials. Where an insurer is being asked to quote for an individual trial, then a lay summary (e.g. copy of the patient information sheet) and/or protocol are likely to be requested. They would always have to be in English.

☒ Protocol
☒ Informed Consent Form
☒ Synopsis in local language
☐ Risk-Benefit information
☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:
Not always required, but increasingly ethics committees require patients to have travel costs reimbursed, in particular where the visits are additional to those required under routine care.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

As a sponsor we can have difficulty with trials which involve enrolling patients at sites outside the UK when a country require a "local" policy from the sponsor, as this is generally at considerable extra cost.

9. Additional remarks and/or comments:

NCIC CTG (NCIC Clinical Trials Group)

Group Contacts

Name: Email-Address:	Alison Urton, Group Administrator; Lawrence Cleary, Manager Finance and Operations aurton@ctg.queensu.ca and lcleary@ctg.queensu.ca
Country:	Canada

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

Declaration of Helsinki, ICH Good Clinical Practice, Canadian Food and Drug Regulations, and Privacy Laws (ie PHIPA)

2. Are there any limitations of liability in your country?

☐ Yes ☒ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

They want to have indemnity for the negligence of others. They expect to be reimbursed for all reasonable and necessary expenses incurred for medical care sustained by a study subject as a result of his/her participation in the study except to the extent that the cost is covered by a public health care system.

5. Which kind of insurance is required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☒ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Whoever is responsible for the injuries establishes insurance r

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☒ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type** No standard as this is provincially based
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: NA
- b) per study: NA
- c) per year: NA

iv. **Usual insurance sum in practice**
- a) per patient: UNK
- b) per study: UNK
- c) per year: UNK

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☒ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☒ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☒ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☒ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☒ Other, please specify: none

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☒ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

none

9. Additional remarks and/or comments:

none

NOGGO (North-Eastern-German Society of Gynaecological Oncology)

Group Contacts

Name: Email-Address:	Maren Keller m.keller@charite.de
Country:	Germany

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

Prior to the start of the clinical trial the existence of a patient's insurance must be proven according to AMG § 40 Abs. 1 S. 3 no. 8 and Abs. 3, MPG § 20 Abs. 1 no. 9 and Abs. 3, and ICH-GCP point 5.8. Patient's insurance shall cover any death or injury to the health of trial subjects which is directly related to the clinical trial. The scope of insurance must be proportionate to the risks associated with the clinical trial.

Not insured are damages only indirectly related to the trial (e.g. travel accidents on the way to the trial site). For these cases an insurance for travel between patient's home and trial site may be established (depending on kind of trial, e.g. if more visits are necessary in comparison to the standard of care).

Each patient has to be provided with the insurance policy as well as insurance terms and conditions. Patient has to be notified about special contents of the insurance terms and conditions, especially on the paragraph for exclusions.

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Excluded from patient's insurance protection are:

- injuries to the health of trial subject which are caused by effects/events which are sure to occur in the clinical trial's indication and which was announced to the patient and which do not exceed an acceptable extent according to knowledge of medical science
- injuries to the health of trial subject or worsening of existing diseases, which would also have been occurred or persist if the patient would not have participate in the trial.
- Injuries to the health of trial subject which occurred due to the fact that the trial's subject act wilfully and knowingly against instructions of site staff

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☒ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

Liability of site and investigator for negligence and wilful misconduct is limited to double the sum of the reimbursement agreed with the site. Under no circumstances site and investigator are liable for any loss of profit.

Each contractual partner agrees to indemnify and hold the contractual partner, its officers, directors, employees and agents harmless from any and all losses, reasonable costs, claims, demands, judgments and liability (including reasonable attorney fees) arising out of or resulting from own negligence or wilful misconduct, except to the extent that such losses,

costs, claims, demands, judgments or liability are due to the negligence or wrongful act(s) of the other contractual partner.

5. Which kind of insurance is required by law in your country?

e)	General liability insurance for Investigators / sites	☒ Yes	☐ No
f)	General liability insurance for your group / national coordinating centre of your group	☒ Yes	☐ No
g)	Insurance for travel between patient's home and trial site	☐ Yes ☒ case by case	☐ No
	If yes, who has to establish this insurance:	Sponsor (general); in academic trial local participating group has to establish this	
h)	Insurance for any trial-related side effects or injuries or trial-related deaths	☒ Yes	☐ No
	If yes, who has to establish this insurance:	Sponsor (general); in academic trial local participating group has to establish this	

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

xii. **Indemnification source**
- ☒ private policies
- ☐ national mechanism
- ☐ both

xiii. **Indemnification type**
- ☒ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

xiv. **Indemnification limit imposed by law?**
- a) per patient: € 500.000
- b) per study: € 50.000.000 (50 million)
- c) per year: NA

xv. **Usual insurance sum in practice**
- a) per patient: € 500.00
- b) per study: € 50.000.000 (50 million)
- c) per year: NA

xvi. **Cover period after end of trial:**
Insurance covers injuries which occurred within 5 years after end of trial

xvii. **Who is ensured?**
- ☒ patient
- ☐ investigator/site
- ☐ sponsor

xviii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
☒ yes ☐ no

xix. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)

☒ required only in following cases / trials: trials with drugs (AMG)
trials with medical devices (MPG)

xx. **Is there a minimum amount for indemnity per patient?**
☒ yes: € 500.000
☐ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

xxi. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
☒ yes
☐ no

xxii. **Which documents have to be provided to the insurance company to receive the insurance police?**
☒ Protocol
☒ Informed Consent Form
☐ Synopsis in local language
☒ Risk-Benefit information
☒ Other, please specify:
number of patients (total & in local country), list of sites, expected duration of the trial

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
Generally no, but exceptions can be made provided that separate funding is available. In some trials there is compensation for travel costs provided to patients - especially in trials with only small number of sites which cause a long way here/there. Details of compensation have to be stated in the informed consent and have to be specified in the application documents which will be provided to Ethics Committee.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

no

9. Additional remarks and/or comments:

no

NSGO (Nordic Society of Gynaecological Oncology)

Group Contacts

Name: Email-Address:	Tinne Kirkegaard Tinne.kirkegaard@regionh.dk
Country:	Denmark, Finland, Norway and Sweden

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

NSGO has four different countries involved in clinical trials. Sweden, Norway, Finland and Denmark. Rules differs from country to country.

Sweden: Sponsors of clinical trials are liable for trial subject injuries in accordance with Swedish law and should establish insurance coverage. Läkemedelförsäkringen (www.LFF.se) offers coverage for trial subjects suffering adverse reactions from participation in clinical trials. Membership of LFF is not compulsory, but as the trial subject gains easier access to compensation, most sponsors will elect to insure under LFF.
LFF has a maximum sealing for compensation payments annually.

Norway: The product liability act contains special rules for injuries caused by drugs. According to these rules, manufacturers and importers of drugs and sponsors conducting clinical trials are obliged to take out a special drug insurance on a no-fault basis. Such insurance must be carries through membership of the Drug Liability Association, Legemiddelansvarsforeningen (www.LAF.no).
Failure to comply with the obligation of membership entails unlimited personal liability for any claim for compensation following a clinical trial.

Finland: Establishing coverage for sponsor liability for trial related injury is compulsory, so a trial sponsor must have insurance for the trial subjects / patients entering a clinical trial.

Denmark: All trial subjects / patients treated at the public hospitals are covered by a state insurance scheme (www.patientforsikring.dk). Any treatment or drug related injury is evaluated by Patientforsikring and compensation is decided according to the Danish law. Compensations are paid only if it is evaluated to exceed minimums of DKK 10000/DKK 3000. There is a sealing for maximum compensation per subject, per trial and per annum.

There are, however, still risks for the sponsor of a trial, for example:

- If Patientforsikring pays compensation to a trial subject and evaluates that the injury is caused by a defective product, it retains a right of recourse against Sponsor / the manufacturer.
- If a compensation amount is evaluated to be under the minimum amounts or exceed the maximum limits of state determined sealing, the trial subject may claim sponsor
- Mental injury to patients is not covered by state compensation

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Denmark: Compensations are paid only if it is evaluated to exceed minimums of DKK 10000/DKK 3000. There is a sealing for maximum compensation per subject, per trial and per annum.

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☒ Yes ☐ No

Yes, health insurance is covered by the state for all patients in all four countries. No patient need to have a private health insurance

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

5. Which kind of insurance is required by law in your country?

a)	General liability insurance for Investigators / sites **For all four countries**	☐	Yes	☒	No
b)	General liability insurance for your group / national coordinating centre of your group **Required if NSGO is sponsor**	☐	Yes	☒	No
c)	Insurance for travel between patient's home and trial site **For all four countries**	☐	Yes	☒	No
		☐	case by case		
	If yes, who has to establish this insurance:	_____			
d)	Insurance for any trial-related side effects or injuries or trial-related deaths	☒	Yes	☐	No
	If yes, who has to establish this insurance:	Sponsor			

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☒ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☒ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**

☒ patient
☒ investigator/site
☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**

☐ yes ☒ no

viii. **In which cases / trials is insurance required?**

☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
☐ required only in following cases / trials: _____
_____
_____
_____

ix. **Is there a minimum amount for indemnity per patient?**

☒ yes: Stated by law, see above
☐ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**

☐ yes
☒ no

xi. Which documents have to be provided to the insurance company to receive the insurance police?

☒ Protocol
☐ Informed Consent Form
☒ Synopsis in local language
☒ Risk-Benefit information
☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
Not in general, though for some trials patients can have compensation for transportation

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No, never

9. Additional remarks and/or comments:

no

PMHC (Princess Margaret Consortium)

Group Contacts

Name: Email-Address:	Chantale Blattler Chantale.blattler@uhn.ca
Country:	Canada

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

Very briefly, in Canada patients have rights protected most directly by Research Ethics Board review of the Protocol and accompanying documents. They have rights to be completely informed by the consent document, and to withdraw their consent if they wish. They also have privacy rights under law, and rights to any of their tissue involved in the study. Our contracts are written so that the sponsor indemnifies the Institution and Investigator for claims brought by or on behalf of injured subjects in the study (as well as for certain other things not directly related to patient rights).

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Not statutory limitations, but we contractually agree that no party will be responsible for indirect or consequential damages, or loss of profit etc. of another party.

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

Even if the subjects have personal insurance, the Institution does not feel they should have to call on it as a result of participation in a clinical study. Procedures that are covered by the subjects' government-sponsored healthcare are not charged to the Sponsor**.**

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☒ Yes ☐ No

If yes, please specify:

Yes. We require sponsor indemnity for Investigator, Institution, et al, for claims arising from the study drug and performance of the protocol, for sponsor's (and authorized agents') use of the data and results of the study, for patent infringement claims, and for negligence and wilful malfeasance of Sponsor and agents.

Separately from the indemnification, we require a statement that the Sponsor will compensate/reimburse for subject injury or illness arising as a result of the Study (that is not covered by the subject's government-sponsored insurance. The subject is not expected to call upon any personal insurance he/she might have in the event of illness/injury from study.

5. Which kind of insurance are required by law in your country?

a) General liability insurance for Investigators / sites ☒ Yes ☐ No

Yes. We require that the sponsor have general liability insurance and clinical trial insurance for the particular trial. The policy should clearly state that it will respond to claims brought in Canada. Insurance should be a minimum of $5 Million per occurrence, and $5 million annual aggregate. The insurance required does not represent a limit on the liability of the sponsor. The above is not required by law. It is required by institution's policy.

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☒ No

No – Not apart from the coverage above, which is for both Institution and Investigator

c) Insurance for travel between patient's home and trial site ☐ Yes ☒ No

☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☒ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: $5 million. Sometimes on insurer's advice we will ask for $10 million aggregate
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☒ no

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)

☐ required only in following cases / trials: _____
_____
_____
_____

ix. **Is there a minimum amount for indemnity per patient?**
☒ yes: $5 million per occurrence, by Institution's policy
☐ no minimum stated by law
☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
☐ yes
☒ no, not to health authority or ethics committee, but we say in contracts that investigator or institution may request a copy of the policy (and we usually do request it). The purpose of requesting it is to confirm that the requirements (responds to Canadian Claims, relates to the specific trial, ia $5 Million and $5 Million aggregate) are present

xi. **Which documents have to be provided to the insurance company to receive the insurance police**?
☐ Protocol
☐ Informed Consent Form
☐ Synopsis in local language
☐ Risk-Benefit information
☐ Other, please specify:
If the institution needs to provide a certificate of insurance, we provide to our insurer: protocol, informed consent and contract

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
Typically, just for parking

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

No

9. Additional remarks and/or comments:

Investigators do not indemnify Sponsors. The contract will state that the investigators are responsible for their actions, negligence, willful malfeasance, and for that of their employees and agents for whom they are responsible in law. Investigators who are licensed physicians maintain membership in the Canadian Medical Protective Association, which supports them in the event of liability claims

RTOG (Radiation Therapy Oncology Group)

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance are required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance: _____

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

SGOG (Shanghai Gynecologic Oncology Group)

Group Contacts

Name: Email-Address:	
Country:	

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

2. Are there any limitations of liability in your country?

☐ Yes ☐ No

If yes, please specify:

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☐ Yes ☐ No

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☐ No

If yes, please specify:

5. Which kind of insurance are required by law in your country?

a) General liability insurance for Investigators / sites ☐ Yes ☐ No

b) General liability insurance for your group / national coordinating centre of your group ☐ Yes ☐ No

c) Insurance for travel between patient's home and trial site ☐ Yes ☐ No ☐ case by case

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☐ Yes ☐ No

If yes, who has to establish this insurance:

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☐ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☐ no fault accident based
- ☐ no fault liability
- ☐ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: _____

v. **Cover period after end of trial:**

_____

vi. **Who is ensured?**
- ☐ patient
- ☐ investigator/site
- ☐ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**
- ☐ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☐ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes: _____
- ☐ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☐ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☐ Synopsis in local language
- ☐ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☐ Yes ☐ No

If yes, please specify the compensation:

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

9. Additional remarks and/or comments:

SGCTG (Scottish Gynaecological Cancer Trials Group)

Group Contacts

Name: Email-Address:	Karen Carty Karen.carty@glasgow.ac.uk
Country:	UK (Scottland)

1. What general rules do you have in your country regarding indemnity and patient rights in clinical trials?

For academic studies conducted in UK in NHS setting, Standard NHS liability applies providing indemnity against clinical negligence. This does not provide cover for non-negligence e.g. harm caused by an unexpected side effect of participating in the study.

It is responsibility of sponsor of study to ensure appropriate clinical trials insurance in place for the trial (to cover protocol, trial design, management & conduct) in the countries the study is conducted. Participating groups participating in a study would be expected to ensure cover was available for their own negligence (and those of their employees) and is available at sites for negligent acts including clinical negligence.

2. Are there any limitations of liability in your country?

☒ Yes ☐ No

If yes, please specify:

Standard NHS liability only applies to UK sites

3. Is it relevant for the conduct of clinical trial in regard to insurance and indemnity if the clinical trial subject has a health insurance which covers costs for medical treatment?

☒ Yes ☐ No

Have added note to state patients in UK are advised in patient information sheet if they have private medical insurance, they should check with company before agreeing to take part in study to ensure their participation in the study will not affect their insurance cover

4. Are there any special requirements regarding indemnity or liability requested from your investigators / sites?

☐ Yes ☒ No

If yes, please specify:

5. Which kind of insurance are required by law in your country?

a)	General liability insurance for Investigators / sites	☒	Yes	☐	No
b)	General liability insurance for your group / national coordinating centre of your group	☒	Yes	☐	No
c)	Insurance for travel between patient's home and trial site	☐	Yes	☒	No
		☐	case by case		

If yes, who has to establish this insurance: _____

d) Insurance for any trial-related side effects or injuries or trial-related deaths ☒ Yes ☐ No

If yes, who has to establish this insurance: Sponsor

6. Details for Indemnification of trial-related side effects or injuries or trial-related deaths?

i. **Indemnification source**
- ☒ private policies
- ☐ national mechanism
- ☐ both

ii. **Indemnification type**
- ☒ no fault accident based
- ☐ no fault liability
- ☒ fault based liability

iii. **Indemnification limit imposed by law?**
- a) per patient: none
- b) per study: none
- c) per year: none

iv. **Usual insurance sum in practice**
- a) per patient: _____
- b) per study: _____
- c) per year: £10,000,000 any one event and all events happening during any period of insurance.

Please note our sponsor has general clinical trials insurance policy to cover trials they sponsor

v. **Cover period after end of trial:**

Not specified

vi. **Who is ensured?**
- ☒ patient
- ☐ investigator/site
- ☒ sponsor

vii. **Is insurance / indemnification already risk based (i.e. is the risk of the clinical trial and/or the likelihood of damage to trial participants been taken into account)?**

☒ yes ☐ no

viii. **In which cases / trials is insurance required?**
- ☒ general required in all trials (trials with drugs, trials with medicinal devices, surveys, radiation, surgical trials, case series etc)
- ☐ required only in following cases / trials: _____
  _____
  _____
  _____

ix. **Is there a minimum amount for indemnity per patient?**
- ☐ yes:
- ☒ no minimum stated by law
- ☐ no general minimum as it is depending on Phase / risk of trial

x. **Is it necessary to submit the insurance police to Ethics Committee / Health Authority <u>prior to approval</u>?**
- ☒ yes
- ☐ no

xi. **Which documents have to be provided to the insurance company to receive the insurance police?**
- ☐ Protocol
- ☐ Informed Consent Form
- ☒ Synopsis in local language
- ☒ Risk-Benefit information
- ☐ Other, please specify: _____

7. Do you provide any compensation to the patient (i.e. payment for participating in the trial, transportation, parking etc.)?

☒ Yes ☐ No

If yes, please specify the compensation:
On occasion patients may receive travel expenses reimbursed for additional visits required for trial over and above standard of care if funding allows.

8. Did you face any issues with insurance in one of your trials? If yes, please specify:

no

9. Additional remarks and/or comments:

no