



บันทึกข้อความ

ส่วนราชการ _____ (หน่วยงานของผู้ขอรับพิจารณาฯ โทร. xxxx)

ที่ อว 0603.xx.xx/xxxx วันที่

เรื่อง การขอยื่นรับการพิจารณารายงานความปลอดภัย

เรียน ประธานคณะกรรมการจريยธรรมการวิจัยในมนุษย์ มหาวิทยาลัย
นเรศวร

ด้วย ข้าพเจ้า [Click or tap here to enter text.](#) สถานภาพ [Choose an item.](#) ตำแหน่ง [Click or tap here to enter text.](#) สังกัด [Choose an item.](#) มหาวิทยาลัยนเรศวร ขอยื่นรับการพิจารณารายงานความปลอดภัยโครงการวิจัยเรื่อง (ชื่อภาษาไทย) [Click or tap here to enter text.](#) (ภาษาอังกฤษ) [Click or tap here to enter text.](#) หมายเลขโครงการวิจัย [Click or tap here to enter text.](#) ซึ่งได้ผ่านการรับรองจากคณะกรรมการจريยธรรมการวิจัยในมนุษย์ มหาวิทยาลัยนเรศวร เมื่อวันที่ [Click or tap here to enter date.](#) และขอยื่นพิจารณาโครงการวิจัยภายหลังการรับรอง ดังนี้

- Serious Adverse Event (SAE)
- Suspected Unexpected Serious Adverse Reaction (SUSARs)
- Suspected Unexpected Serious Adverse Reaction Line Listing
 - Independent Data-Monitoring Committee (IDMC)
 - Data and Safety Monitoring Board (DSMB)
 - Data Monitoring Committee (DMC)
 - Other safety report

จึงเรียนมาเพื่อโปรดพิจารณา

ลงนาม 

(Click or tap here to enter text.)

หัวหน้าโครงการวิจัย

ลงนาม 

(Click or tap here to enter text.)

อาจารย์ที่ปรึกษาโครงการ
กรณีหัวหน้าโครงการวิจัยเป็นนิสิต

	Institutional Review Board Naresuan University	Submission for Safety Report
Protocol Title (TH)	Click or tap here to enter text.	
Protocol Title (ENG)	Click or tap here to enter text.	
Principal Investigator's name	Click or tap here to enter text.	
Department	Click or tap here to enter text.	
Faculty	Choose an item.	
Phone number	Click or tap here to enter text.	
E-mail	Click or tap here to enter text.	
Sponsor	Click or tap here to enter text.	
Study Code	Click or tap here to enter text.	
Study Site	Click or tap here to enter text.	
Date of Initial Protocol Approval	Click or tap here to enter date.	
Type of Safety Report Submission	<input type="checkbox"/> Serious Adverse Event (SAE) (Section A)	
	<input type="checkbox"/> Suspected Unexpected Serious Adverse Reaction (SUSARs) (Section B)	
	<input type="checkbox"/> Suspected Unexpected Serious Adverse Reaction Line Listing (Section B)	
	<input type="checkbox"/> Independent Data-Monitoring Committee (IDMC) (Section C)	
	<input type="checkbox"/> Data and Safety Monitoring Board (DSMB) (Section C)	
	<input type="checkbox"/> Data Monitoring Committee (DMC) (Section C)	
	<input type="checkbox"/> Other safety report (Section C)	
Current Status of Research	Choose an item.	

----- List of Additional Attached Document Needed-----

List of Attached Document(s)	<input type="checkbox"/> Certificate of Approval NU-IRB <input type="checkbox"/> CIOMS FORM <input type="checkbox"/> Line Listing <input type="checkbox"/> Other related documents
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Instruction: Please fill in the form or tick in the box that applied, and attach documents if necessary.

-----Section A - Serious Adverse Event (SAE) Reports-----

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Do you want to submit Serious Adverse Event (SAE) in this report?

[Choose an item.](#)

1.1 Detail of medicine or cosmetic or device	Click or tap here to enter text.
1.2 Date of event	Click or tap here to enter date.
1.3 Describe adverse event	Click or tap here to enter text.
1.4 Onset of SAE	Choose an item. Click or tap here to enter date.
1.5 Severity of event	Choose an item.
1.6 Causality of event	Choose an item.
1.7 Is the reaction expected?	Choose an item.
1.8 Is the event classified as a SUSAR	Choose an item.
1.9 Progression	Is the event due to progression of an underlying illness? Choose an item.
1.10 Action take with study treatment	Choose an item.
1.11 Outcome of SAE	Choose an item.

1.12 Other actions taken	Choose an item.				
1.13 Have Similar Adverse Events Occurred on this protocol?	Choose an item. How many? Click or tap here to enter text.				
1.14 Comment by principal investigator	Choose an item.				
1.15 Comment by sponsor	Click or tap here to enter text.				
2. Type of Serious Adverse Event (SAE) Report	<p>Choose an item.</p> <p>Number of Click or tap here to enter text. reports</p> <table border="1"> <tr> <td>Occurred on-site</td><td>Number of Click or tap here to enter text. cases</td></tr> <tr> <td>Occurred in the country</td><td>Number of Click or tap here to enter text. cases</td></tr> </table>	Occurred on-site	Number of Click or tap here to enter text. cases	Occurred in the country	Number of Click or tap here to enter text. cases
Occurred on-site	Number of Click or tap here to enter text. cases				
Occurred in the country	Number of Click or tap here to enter text. cases				
<u>Summary</u> Events and Causal Relationship	Click or tap here to enter text.				

NOTE: 1. Please attach related documents

-----Section B - Suspected Unexpected Serious Adverse - External-----

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Do you want to submit **Suspected Unexpected Serious Adverse - External** in this report? Choose an item.

Initial Report

No.	Country or Site	ID No	Sex	Age	Event (Description)	Onset	Causality (A)	Severity (B)	Action Medication (C)	Action taken (D)	Outcome (E)
1											
2											

Follow up Report

No.	Country or Site	ID No	Sex	Age	Event (Description)	Onset	Causality (A)	Severity (B)	Action Medication (C)	Action taken (D)	Outcome (E)
1											
2											

(A) 1 = Unrelated, 2 = Unlikely, 3 = Possible, 4 = Probable, 5 = Definite
Causality:

(B) Severity: 1 = Death, 2 = Life threatening, 3 = Hospitalization or prolongation of hospitalization, 4 = Persistent or significant disability or incapacity,
5 = Congenital anomaly or birth defect, 6 = Required intervention to prevent permanent impairment,
7 = other significant medical event

(C) Action medication: 1 = Continued, 2 = Reduced, 3 = Increased, 4 = Temporary stop, 5 = Permanent stop

(D) Action taken: 1 = No action, 2 = Amend consent document, 3 = Amend protocol, 4 = Inform current subjects, 5 = Terminate or suspend protocol, 6 = others

(E) Outcome: 1 = Resolved, 2 = Resolved with sequelae, 3 = Improved, 4 = Persistent, 5 = Worsened, 6 = Fatal, 7 = Unknown

1. Type of Serious and Unexpected Adverse Event Report (SUSAR)

	Choose an item.
	Number of Click or tap here to enter text. reports
	Date of event/Line Listing period Click or tap here to enter text.
Occurred on-site	Number of Click or tap here to enter text. cases

	Occurred in the country	Number of Click or tap here to enter text. cases
	Occurred outside the country	Number of Click or tap here to enter text. cases
2. <u>Summary</u> Events and Causal Relationship	Click or tap here to enter text.	

NOTE: 1. Please attach related documents

-----Section C - Other safety report-----

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Do you want to submit **Other safety report** in this report? Choose an item.

Number of [Click or tap here to enter text.](#) reports

1. Safety Report	Choose an item.
Date of Report	Click or tap here to enter text.
Summary of the Report	Click or tap here to enter text.
2. Safety Report	Choose an item.
Date of Report	Click or tap here to enter text.
Summary of the Report	Click or tap here to enter text.

NOTE: 1. If more than two safety reports are submitted, please insert additional rows in the table.

2. Please attach related documents

-----Section D - Signature-----

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Principal Investigator signature (Reported by)		Date	Click or tap here to enter date.
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