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**Research with Human  
Volunteers  
“Section 4”**

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## Section 4 – Research with Human Volunteers

**Victorian-Specific Module**



**Completion of the Victorian-Specific Module is mandatory for all research conducted in the State of Victoria.**

**Site's should not be using “old” Ionising Radiation “Module 4” template.**

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## Section 4 – Research with Human Volunteers

Victorian-Specific Module



### Requirements for Section 4 Use of Ionising Radiation

**Must be addressed when the research includes the use of ionising radiation.**

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## Section 4 – Research with Human Volunteers

Victorian-Specific Module



# Requirements for Section 4

## Two levels of assessment:

- 1) Ionising radiation is used as part of **standard care**
- 2) Ionising radiation is used in addition to **standard care**

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## Section 4 – Research with Human Volunteers

Victorian-Specific Module



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### Requirements for Section 4

For research where ionising radiation is used as part of  
**standard care**

Classification of radiation exposure that participants (including volunteers) will receive.

If a participant was not enrolled in this clinical trial, would they still receive the same number of examinations involving the use of ionising radiation at the specified intervals as stated in the research protocol?

Yes



No





# Requirements for Section 4

Detail the <u>type</u> , <u>number</u> and frequency of ionising investigations			(Please mark one box)	
Type of exam	Number performed*	Frequency	Deemed to be Standard Care	Additional to Standard Care
<i>Example: CT exam of chest</i>	<i>x 3</i>	<i>Every 8 weeks</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.			<input type="checkbox"/>	<input type="checkbox"/>
2.			<input type="checkbox"/>	<input type="checkbox"/>
3.			<input type="checkbox"/>	<input type="checkbox"/>
4.			<input type="checkbox"/>	<input type="checkbox"/>
5.			<input type="checkbox"/>	<input type="checkbox"/>
6.			<input type="checkbox"/>	<input type="checkbox"/>
7.			<input type="checkbox"/>	<input type="checkbox"/>
8.			<input type="checkbox"/>	<input type="checkbox"/>
<i>Additional comments (if necessary):</i>				

**\*Note:** Where the exact number of examinations is not known, please indicate the anticipated maximum number likely to be performed over the duration of the research. And, indicate "(Max)" next to value stated.

## Section 4 – Research with Human Volunteers

**Victorian-Specific Module**



### **Check list for “Standard Care” research proposals:**

- 1. Must be confident that all procedures listed are deemed to be Standard Care;**
- 2. Ensure all procedures involving ionising radiation have been identified.** *Ionising Radiation procedures can be hidden in the detail, ie MUGA scans, DXA, Bone Scintigraphy*

*When in doubt:*

- 3. Consult a Medical Physicist, relevant Imaging Department or your Radiation Safety Officer**

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## Section 4 – Research with Human Volunteers

**Victorian-Specific Module**



*Test used to determine whether the ionising procedure is “Standard Care” or Not:*

**“If a volunteer was NOT enrolled in the proposed research would they still receive the procedures:**

- 1. Involving ionising radiation;**
- 2. The modality (ie. CT, DXA unit etc.);**
- 3. Frequency and number of the exams proposed.”**

**An answer of NO to any of points 1 -3:**

***Ionising Radiation Procedure is in  
“Addition to Standard Care”***

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## Section 4 – Research with Human Volunteers

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### Requirements for Section 4

Classification of radiation exposure that participants (including volunteers) will receive.

If a participant was not enrolled in this clinical trial, would they still receive the same number of examinations involving the use of ionising radiation at the specified intervals as stated in the research protocol?

Yes

No

## Section 4 – Research with Human Volunteers

**Victorian-Specific Module**



### **For these research proposals:**

- 1. Engage the services of an approved medical physicist**
- 2. Notify the site's Radiation Safety Officer**
- 3. Complete fully Section 4 of the VSM**

Following Ethics Committee Approval & prior to commencing:

- 4. Have the research reviewed and approved by the Department of Health** (*Added to the site's licence issued by the Department of Health*)

## Section 4 – Research with Human Volunteers

### Victorian-Specific Module



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### Medical Physics Report:

1. Medical Physicist require machine & exposure details to perform calculation.
2. Generate a report will outline doses, risk assessment, approved wording for PICF

*(Allow completion of Section 4).*

3. The report provided will be site specific.
4. Report should be used by Ethics Committees to enable them to assess the benefits obtained against the risks associated with the exposure from conducting the research.

*“Is the use of ionising radiation in this research justified based on the objectives being investigated?”*

*Is the amount of dose being received by the volunteers enrolled in the research acceptable?”*

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## Section 4 – Research with Human Volunteers

**Victorian-Specific Module**



**The Medical Physicist will:**

**Provide a risk assessment based on the information supplied.**

***The supply of a report should not be interpreted as the research gaining “approval”, but, should be used to assist in the approval process  
(Typically by Ethics)***

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# Requirements for Section 4

Detail the <u>type</u> , <u>number</u> and frequency of ionising investigations			(Please mark one box)	
Type of exam	Number performed*	Frequency	Deemed to be Standard Care	Additional to Standard Care
<i>Example: CT exam of chest</i>	<i>x 3</i>	<i>Every 8 weeks</i>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
1.			<input type="checkbox"/>	<input type="checkbox"/>
2.			<input type="checkbox"/>	<input type="checkbox"/>
3.			<input type="checkbox"/>	<input type="checkbox"/>
4.			<input type="checkbox"/>	<input type="checkbox"/>
5.			<input type="checkbox"/>	<input type="checkbox"/>
6.			<input type="checkbox"/>	<input type="checkbox"/>
7.			<input type="checkbox"/>	<input type="checkbox"/>
8.			<input type="checkbox"/>	<input type="checkbox"/>
<i>Additional comments (if necessary):</i>				

\***Note:** Where the exact number of examinations is not known, please indicate the anticipated maximum number likely to be performed over the duration of the research. And, indicate "(Max)" next to value stated.



# Requirements for Section 4

Type of exam	Number performed*	Frequency (Weeks/days)
<i>Example: CT exam of chest</i>	x 3	Every 8 weeks

1. The number of exams?
2. What is the minimum age of participants irradiated?
3. Will women who are pregnant or breastfeeding be irradiated in this research?
4. Will babies, infants or foetuses be irradiated in this research?
5. Is the median life expectancy of the participants less than five years?

The amount of dose received, and who receives it will impact on the medical physicist's assessment & the DoH approval process.

**(a) Radiology & DEXA**

	Procedure 1	Procedure 2
1. Type of Investigation		
2. Will all participants undergo this investigation?		
3. Institution at which the procedure will be performed		
4. Effective Dose [mSv] per investigation		
5. Number of Investigations		
6. Effective Dose (total) in addition to standard care (per participant) [mSv]		
7. Relevant organ dose [mSv] (state organs) <u>for deterministic effects</u>		

**(b) Nuclear Medicine & PET**

	Procedure 1	Procedure 2
1. Type of Investigation		
2. Will all participants undergo this investigation?		
3. Institution at which the procedure will be performed		
4. Radionuclide		
5. Chemical / Pharmaceutical Form		
6. Activity to be administered [MBq]		
7. Effective Dose [mSv] per investigation		
8. Number of Investigations		
8. Effective Dose (total) in addition to standard care (per participant) [mSv]		
9. Relevant organ dose [mSv] (state organs) <u>for deterministic effects</u>		

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## Section 4 – Research with Human Volunteers

### Victorian-Specific Module



### Risk Statements:

1. Victorian requirements – slight variance to National ARPANSA Code (*therefore other States*).
2. Approved wording used in PICF calculates a risk of age weighted fatal & non-fatal cancer induction.
3. ARPANSA Code recommends the calculation of risk be age weighted based on fatal cancer induction only.
4. Required where the median life expectancy is greater than 5 years (*regardless of the patient's condition or cancer status*).

### Example:

20 mSv delivered to male & females ranging in age 0 – 80.

Victorian Risk estimate: 1 in 361

ARPANSA Risk estimate: 1 in 855

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## Section 4 – Research with Human Volunteers

### Victorian-Specific Module



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### Risk Statements:

**Example: For studies delivering >20 mSv**

#### **Life Expectancy: > 5 years**

This research study involves exposure to an amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The effective dose from this study is about **x mSv**. The benefits from the study should be weighed against the possible detrimental effects of the additional radiation exposures, including an increased risk of cancer induction. In this particular study, the risk is moderate and the estimated risk of such harm is about 1 in **y**.

#### **Life Expectancy: < 5 years**

This research study involves exposure to a (very small, small, significant as appropriate) amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The effective dose from this study is about **x mSv**.

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## Section 4 – Research with Human Volunteers

### 4.5 Categories of Risk & Dose

For ionising radiation 'additional to standard care' only.

Choose the level of dose and risk from the table below. The medical physicist will provide advice.

Level of Risk	Risk Category	Effective Dose Range (adults) (mSv)	Level of Societal Benefit Expected	Total Radiation Risk (Please tick one box)
Minimal	Category I ( $\sim 10^{-5}$ or less)	< 0.2	Minor	<input type="checkbox"/>
Very Low	Category IIa ( $\sim 10^{-5}$ or $10^{-4}$ )	$\geq 0.2$ and < 2	Intermediate	<input type="checkbox"/>
Low	Category IIb ( $\sim 10^{-4}$ or $10^{-3}$ )	$\geq 2$ and $\leq 20$	Moderate	<input type="checkbox"/>
Moderate	Category III ( $\sim 10^{-3}$ or more)	> 20	Substantial	<input type="checkbox"/>

## Section 4 – Research with Human Volunteers

### 4.6 Expected Societal Benefit

Please explain the benefit(s) for the individual and society that can be expected to accrue from this research and why the radiological investigations are required. *This information should be provided to the medical physicist to assist in the preparation of the report.*

Effective Dose Range (adults) (mSv)	Level of Societal Benefit Expected
< 0.2	Minor
$\geq 0.2$ and < 2	Intermediate
$\geq 2$ and $\leq 20$	Moderate
> 20	Substantial

## Section 4 – Research with Human Volunteers

Effective Dose Range (adults) (mSv)	Level of Societal Benefit Expected
< 0.2	Minor
≥ 0.2 and < 2	Intermediate
≥ 2 and ≤ 20	Moderate
> 20	Substantial

The level of benefit needed as the basis for approval of research with doses in this category will be minor and will include those investigations expected only to increase knowledge.

To justify risks in this category the benefit will probably be related to increases in knowledge leading to health benefit.

To justify the risks a moderate benefit will be needed. The benefit will be more directly aimed at the diagnosis, cure or prevention of disease.

To justify research involving doses or risks in this category, the benefit will have to be substantial and usually directly related to the saving of life or the prevention or mitigation of serious disease.

## Section 4 – Research with Human Volunteers

### 4.6 Expected Societal Benefit

Please explain the benefit(s) for the individual and society that can be expected to accrue from this research and why the radiological investigations are required. *This information should be provided to the medical physicist to assist in the preparation of the report.*

**Leaving this Section blank will not assist you in gaining approval!**

**Justify why the volunteers need to be exposed to radiation and the net benefits (to the individual or society) that may result.**

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## Section 4 – Research with Human Volunteers

### Certification by an approved Medical Physicist

I have reviewed the information in **Section 4.3 "Radiation Assessment"** and I am satisfied that the information is accurate and that it complies with the recommendations of:

(ARPANSA) *RPS 8. Code of Practice - Exposure of Humans to Ionising Radiation for Research Purposes* Radiation Protection Series Publication No. 100

Signature of Medical Physicist: \_\_\_\_\_

Medical Physicist name: \_\_\_\_\_

Date: \_\_\_\_\_

### Certification by the representative of the instrument's licence holder

I have reviewed the information to be submitted for review by the relevant Human Research Ethics Committee and I am satisfied that it is necessary to the Department of Health for their consideration.

The proposal is in accordance with *RPS 8. Code of Practice - Exposure of Humans to Ionising Radiation for Research* (2005).

Signature of representative: \_\_\_\_\_

Representative's name: \_\_\_\_\_

Date: \_\_\_\_\_

Position held within Organisation: \_\_\_\_\_

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Sign Off

# That's All Folks



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