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DETAILS OF THE PERSONAL'S WHO CONSENT TO PARTICIPATE FOR THE RESEARCH "EFFECTS OF WELDING ON MALE FERTILITY"

Identification No.:-

Perso	onal Details	
1.	Rate :	
2.	Date of birth :	3. Age :-
4.	Weight : Kg.	5 Height :ftinch
6.	BMI :	
7.	Residency:-	Urban
		Suburban
		Rural
8.	Marital status:-	Single
		Married
		Divorced
		Separated
		Living together
9.	Date of married:	
9.	Date of married:	
		DD / MM / YY
10.	Age to the date of marriage:-	
		DD / MM / YY

11.	Childr	en:-					
	i.	a.	Sex :-	Male Female			
		b.	Date of birth	DD /	MM /	VV	
		c.	Time duration afte				
		d.	Before	Aft Cor		nent of pro	fession
	ii.	a.	Sex :-	Male Female			
		b.	Date of birth				
		c. d.	Time duration afte Before	r marriage:	er		fession
Profes	sional	Details					
1.	Date o	of enlist	ment to Sri Lanka N	avy	DD /	MM /	YY
2.	Incept	ion of p	profession as a welde	er in SLN	DD /	MM /	YY

3.	Professional service in SLN				/	N	ΜМ	/	Y	Y	
4.	Profession prior to j	oint SLN:	•••••	•••					••••	•••••	•••
5.	Professional service prior to joint SLN				/	N	мм	/	YY	Y	
6.	Total service as wel	DI)	/	N	ΜМ	/	YY	· · · · · · · · · · · · · · · · · · ·		
7.	Nature of the presen	nt duty			ard ork	csho	op				
8.	Type of welding	Arc TIG MIG		N	Gas Aul Othe	ti v	weld	ing	T .		
9.	Average time durati	on exposed to active we	lding	pei	r da	ıy:		• • • •		Н	rs
10.	Do you use a respirator during welding? Yes No										
11	Type of dust mask i	f yes:	• • • • • •	•••							
12.	Do you use an apron during welding? Yes No										
13.	Type of apron if yes	s :	•••••		•••						

Standing Normal position of welding:-14. Sitting/squatting **Lifestyle Factors** Yes 1. Smoking if yes, frequency No Yes 2. Tobacco chewing if yes, frequency No Yes 3. Alcohol if yes, frequency No Yes Use of illegal drugs if yes, frequency 4. No Yes 5. Addiction to beverages containing caffeine. No If yes, frequency: - Yes 7. Do you attend physical exercise? No Yes 8. Use of sauna / steam bath No If yes, frequency:-....

Food habits.....

9.

10	Any chronic disease Details if yes	Yes No		
11.	Use of any medication at Details if yes			Yes No
12.	Use of mobile phone			Yes No
13.	If yes, where do you keep	o it?	Shirt po Trouser	pocket
14	Use of cosmetic			Yes No
15.	Use of laptop.	Yes No		On lap Table
16.	Sleep deprivation			Yes No
17	Any domestic / occupation	onal stress		Yes No
18.	Contact with any chemic Details, if yes	Yes No		

			Childhood
19.	Mumps / any viral infection	Yes	Teenage
17.	wamps and that infection	No	Adults
20.	Prolong bicycling	Yes	
		No	
21.	Family planning	Yes	Condom
		No	Drugs
			Natural means
		Yes	
22.	Surgery proceeded on testis	No	
22	D . 11 . 6	X7	
23.	Details of surgery proceeded, if	Y es	
		•••••	
•			
24.	Cultural belief	Yes	
21.	Cultural oction	No	
25		Yes	
25.	Presence of testis	No	
26.	Un-descended testis	Yes	
20.	on-descended testis	No	
27.	Fitness of underpants	Normal	
21.	1	Tight	

28.	Colour of unde pants	Dark			
- 0.	coron of underputies	Light			
29.	Type of unde pants	Cotton			
		Synthet	ics		
		Mix			
30.	Working dress		Overall		
		Other			
31.	Colour of working dress	Dark			
51.	colour of working areas	Light			
		Cotton			
32	Type of working dress	Synthet	ice		
		Mix			
		IVIIA			
33.	Any social transmitted dise	.000	Ye	es	
33.	•		No	О	
	Details, if yes	••••			
34.	Masturbation		Y	es	
	Frequency		N	О	
				I	
2.5					
35.	Any other information's				

Letter of approval received form ethical committee at Kothalawala Defense University



SLN 121/ 1009

The Commander Western Naval Area

Naval Headquarters Colombo 1

30th November 2014

TO OBTAIN APPROVAL TO CONDUCT RESEARCH ON THE TOPIC "EFFECTS OF WELDING ON MALE FERTILITY" COMMANDER (E) NSMDK NANAYAKKARA, NRE 1009

51

03 DEG 2014

Reference: Your letter No. CW 51 dated 29th October 2014.

Please inform above named officer that his submission forwarded vide quoted reference is approved.

GL SUBARINGHE
Lieutenant (S) SLN
Aide & Personal Secretary
for COMMANDER OF THE NAVY

INFORMATION TO PARTICIPANTS AND CONSENT FORM

SI ONSOR.	
INVESTIGATOR (Principal and at least one Co-Investigator):	
Name of Participant:	

Title: study to determine the effects of welding on male fertility

SDONSOD.

- - (1) Identified as occupational welder (or working at office or workshop without exposing to welding) in Sri Lanka Navy.
 - (2) You are exposure to welding (or working at office/workshops without exposing to welding) more than 03 years.
 - (3) Age between 23 to 36 years.

You will be one of the (give total number of participants to be enrolled in the study) participant we plan to recruit in this study. You will be assigned to either of the two study groups. One group of participants (those who will not be exposed to welding) will be tested as a control group while other group of participant (occupational welders) will be the subject group. Investigations and sample testing will be conducted at the Naval General Hospital – Colombo with the approval of the Commander of the Navy.

2. What is the purpose of research?

The purpose of this study is to evaluate the relationship between male fertility and exposure to welding emission. Discussion made with infertile male welders, who

exposed to welding emission long period discovered that a conceptual idea has been established amongst them that the infertility caused by the long term exposure to welding emissions. However it is very hard to find a research in Sri Lanka context to support or expel this concept amongst the welders. Therefore this study will assist to evaluate the so called relationship and to take actions to mitigate exposure.

3. The study design

All participants in the study will be divided into two groups. You will be assigned to either of the two groups. One group is the subject group, composed with welders and the other group is the control group, consist of personals, who will not be exposed to welding. Each participant has to give semen sample thrice at the laboratory of Naval General Hospital – Colombo. Second sample of semen will be tested after six month in case of any abnormalities are found in the first. Third sample of semen will be received in any abnormalities found in the second sample. Healthy personals will be selected for the control group and their SFA parameter will be kept as a reference value to compare with the subject group.

4. Study Procedures

Semen will be collected by self-masturbation into an approved sterile container, at the laboratory of Naval General Hospital – Colombo. Participants should be abstained from ejaculation for 3 -4 days before providing the semen. The fresh semen sample will be incubated for 30 min at 37°C for liquefaction and routine semen fluid analysis (**SFA**) will be performed according to WHO standards to measure volume, sperm Count /ml/10⁶, total motility, and total morphology. Obtained sample will be undergone investigation for approximately 02 hrs. You can collect the sample after the test if not the sample will be washed out as routine procedure by the laboratory staff.

Once you are enrolled in the study, you will be required to follow the instructions given below.

(1) Taking of any medication prescribed by the physician

- (2) Change of any lifestyle factors [diet / take the drugs as instructed and detailed on the envelope / avoid alcohol / smoking / any other precautions].
- (3) Taking any medications other than the ones prescribed by your physician. If you need to take some treatment (drug / physiotherapy / other), you must inform your investigator before taking that treatment

5. Preparation for Semen Analysis

The laboratory technician will let you know what you should do in preparation for the semen analysis. It's very important to follow these instructions to get the best sample for accurate results

- Refrain from any sexual activity, including masturbation, for 3 to 4 days before the test. Longer or shorter periods are also not recommended.
- Avoid alcohol, caffeine, and drugs such as cocaine and marijuana two to five days before test
- Stop taking any herbal medications, what you have already declared to the investigation team
- Avoid any hormone medications
- Give the specimen directly to the laboratory staff or the receptionist to ensure immediate attention.
- Discuss any medications you're taking with your investigator team, if any.

6. Possible risks to you

The study team expects only semen samples from you for the analysis and you will not be given any medications for the study. Certain emotional and physical discomfort risks may be associated with the collection of semen samples by masturbation, unless other than that there is no any potential risk involvement of taking semen samples for this study.

7. Possible benefits to you

You will be able to get following benefits on this research study.

- (1) Free investigation of your semen samples and get to know the quality of your semen sample
- (2) At the end of the study you may be able to know, that any effects of welding emission on your fertility.

8. Compensation

You will not receive any compensation for the inconvenience and travel. You will be provided only transport facilities. You will also benefit from being on this research study in terms of free investigations/tests. Additionally participants will be provided medical facilities in case of any risk involvement observed during the period of research

9. Possible benefits to the institution and other people

The results of the research may provide benefits to the institution & society in terms of advanced knowledge of welding technology and how to mitigate welding emissions. The results of the study may further support to change the working environment and lifestyle of occupational welders to ensure health and wellbeing

10. Cost to the participant

You will not be required to pay for the semen sample analysis. You will be provided transport facilities to travel from your workstation to Naval General Hospital – Colombo to participate the research study.

11. Who is paying for this research?

Sri Lanka Navy is the sponsors of the study and are providing laboratory facilities at the Nava General Hospital - Colombo for the research. The investigator or any of his/her team member or any participant for the study does not receive any direct payment from the sponsor.

12. Confidentiality of the information obtained from you

You have the right to confidentiality regarding the privacy of your information (personal details, occupational details, lifestyle and results of semen analysis). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, institutional ethics committee and any person or agency required to view your data, if required. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

It is ensured that only research team will have access to review your personal data obtained through questioner. It is further confirmed that the details of semen analysis will not be reflected identification of the participant whilst dissemination of study finding through a research paper or journal or any publication

13. How will your decision to not participate in the study affect you?

Your decision not to participate in this research study will not affect your relationship with the investigator or the institution. You will further not lose any benefits to which you are entitled.

14. Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during the course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to stopping participation. However it is not mandatory to give reason for withdrawing.

15. Can the investigator take you off the study?

You may be taken off the study without your consent if you do not follow instructions of the investigators or the research team or if the investigator thinks that further participation may cause you harm.

16. Right to know information

The obtained results will be disclosed to any participants on their personal request.

17. Right to new information

If the research team gets any new information during this research study that may affect your decision to continue participating in the study, or may raise some doubts, you will be told about that information.

18. Contact persons

For further information / questions, you can contact us at the following address:

Principal Investigator:

Captain (E) N.S.M.D.K. Nanayakkara Ph 071 822 3860

Dept. of Marine Engineering, Sri Lanka Naval Headquarters, Colombo 01

Email: kapila1009@gmail.com / kapila1009@navy.lk

Co-Investigator

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Contact Person(s):

Captain (E) N.S.M.D.K. Nanayakkara Ph 071 822 3860

Dept. of Marine Engineering, Sri Lanka Naval Headquartes, Colombo 01

Email: <u>kapila1009@gmail.com</u> / <u>kapila1009@navy.lk</u>

PARTICIPANTS CONSENT FORM

[Title	e of the study]
Nam	e of the participant:
Nam	e of the Principal (Co-) Investigator:
Nam	e of the Institution:
Nam	e and address of the sponsoring (funding) agency (ies):
Docu	imentation of the informed consent
I	have read the
infor	mation in this form (or it has been read to me). I was free to ask any questions
and t	they have been answered. I am over 18 years of age and, exercising my free
powe	er of choice, hereby give my consent to be included as a participant in "
" (titl	le of the study)
(1)	I have read and understood this consent form and the in formations provided
	to me.
(2)	I have had the consent document explained to me.
(3)	I have been explained about the nature of the study.
(4)	My rights and responsibilities have been explained to me by the investigator.
(5)	I have been advised about the risks associated with my participation in the study.
(6)	I have informed the investigator of all the treatments I am taking or have taken in the past months including any <i>desi</i> (alternative) treatments.
(7)	I agree to cooperate with the investigator and I will inform him/her immediately if I get any medical treatment during the study period
(8)	I have not participated in any research study within the past month(s)

- (9) I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future.
- (10) I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.
- (11) I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.
- (13) My identity will be kept confidential if my data are publicly presented.
- (14) I have had my questions answered to my satisfaction.
- (15) I have decided to be in the research study.

I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent from, I attest that the information given in this document and the consent form has been clearly explained to me and apparently understood by me. I will be given a copy of this consent document.

Name and signature / thumb impression of the participant (or legal representative if

For participants

	U	-		`	_		
participant	incompetent):						
			(Name)				
(Signature)							
Date:		Time:	• • • • • • • • • • • • • • • • • • • •				
Name and	signature of imparti	al witness (requ	ired for ill	iterate p	atient	s):	
			(Name)	•••••			
(Signature)							
Date:		Time:					

Address and contact number of the impartial witness:
and signature of the Investigator or his representative obtaining consent:
(Name)
(Signature)
(Date)
Investigator Certificate
I certify that all the elements including the nature, purpose and possible risks and benefits of the above study as described in this consent document have been fully
explained to the subject. In my judgment, the participant possesses the legal capacity
to give informed consent to participate in this research and is voluntarily and
knowingly giving informed consent to participate,
Signature of the Investigator: Dated:
Name of the Investigator: