

## **Re: Center for Hyperbaric Medicine and Environmental Physiology Flying After Diving Study**

This study involves a single, dry or immersed chamber dive to 60 fsw for 55 min followed by a specific surface interval and then a simulated flight to 8,000 ft (the maximum cabin altitude allowed in commercial, pressurized aircraft) for four hours. All phases are conducted at the Center for Hyperbaric Medicine and Environmental Physiology (Hyperbaric Center) in Duke University Medical Center. The USN Flying After Diving Study is designed to evaluate the effect of altitude exposure following diving on the production of circulating bubble production and/or the development of decompression sickness. Studies are normally scheduled on one evening and the following day during the week. You may contact Dr. Richard Vann (919-684-3305) or Dr. Neal Pollock (919-684-2948) with questions regarding the study design.

Individuals living within a 60 minute driving radius of Duke University may depart after the medical watch. Individuals living greater than a 60-minute driving radius from Duke University must remain overnight **following** the dive and the flight. All participants must **meet with** the physician the morning following the dive. DAN pays for lodging and food not provided (*up to \$7 for lunch and \$13 for dinner*). Alcoholic beverages will not be paid for and their consumption is discouraged during the study. Participants will receive pro-rated compensation for a total of \$120 per trial. **Completion of the study is required for full payment. This includes the follow-up interview at the Hyperbaric Center the day after the flight and the call-in on the following day. The medical outcome is just as important as the dive. (Pro-rated compensation is \$45 for the dive, \$45 for the flight, \$15 for the morning-after health check, and \$15 for 48-hour health check).** Participants are paid by check sent to the address supplied on the Compensation Form (IRB Personal Data Disclosure Form). Usually, you may expect checks to arrive within four weeks.

Participants must be 18-60 years of age and certified divers or experienced in hyperbaric environments. Since pregnancy is a disqualifying factor, females of childbearing age must submit to blood drawing at least four hours prior to the dive for serum pregnancy determination or have a statement from a physician verifying sterility. Females should wear a **two-piece bathing suit, shorts and halter-top or aerobic type top (exposing as much of the rib cage as possible to facilitate the ultrasound monitoring) and bottoms** for the physical exam. The abdomen, front and back and the chest and legs need to be exposed for the physical/neurologic testing. Body composition will be assessed with a skin-fold caliper. Both males and females should bring a bathing suit (and mask and booties if you have them) because you may be randomly selected to do the immersed portion of the study. You are asked to avoid moderate or high intensity running, high impact aerobics or weightlifting 24 hours prior to the study and 48 hours after the dive. You should not engage in diving 48 hours prior to the study or 48 hours after the study. You should not fly 24 hours prior to the study or 48 hours after the study has concluded. You will be asked to wear a hospital style bracelet that lists contact phone numbers throughout the 48-hour post-study period to remind you of the activity restrictions.

Physical activity will be restricted before, during, and after the dives. Except for essential activities such as medical examinations, clothing changes, ultrasound monitoring, or trips to the bathroom, participants will remain seated for one hour before the dive and for two hours after the dive. Climbing or descending stairs will be avoided during this time.

**Medical/Physical evaluations are conducted prior to the dive (baseline), immediately post-dive, four hours post-dive, the morning after the dive, and Sunday morning.** All interviews are conducted in person with the study physician on the dive and flight days and the morning following the flight. The 48 hour interview will be by phone.

**Study Schedule - 60ft/55 min; 9:00 hr SI; 8000 ft/4:00 hrs**

<b>Date</b>	<b>Time</b>	<b>Activity</b>	
<b>Thursday</b>	1800	Meet at Duke Hyperbaric Center (female subjects must stop by prior to 1630 for blood draw)	
	1815	Study Briefing, sign Consent Forms	
	1900	Pre-Dive Physicals, Body Composition Assessment Pre-dive testing: Baseline Doppler and Ultrasound Dinner	
	1930	Restricted activity begins	
	2030	Commence dive	
	2130	End Dive	
	2200	Doppler examinations at 30 and 60 minutes post-dive	
	2230	Medical check and release	
	<b>Friday</b>	0600	Prep for flight
		0630	Begin flight
1030		End flight	
1130		Dinner	
1230		End of restricted activity	
<b>Saturday</b>	1300	Medical check and release	
	0900	Medical check at Hyperbaric Center	
<b>Sunday</b>	0900	Final medical check phone call	

*Note: Please park in the Duke South Hospital Parking Garage #1. Parking vouchers will be provided. A shuttle from the Millennium Hotel is also available.*