

NASA Flight Analogs Project Study Feasibility Assessment Form

The information provided on this form will be used to evaluate the feasibility of the NASA Flight Analogs Project (FAP) implementing your study in the Flight Analogs Research Unit (FARU) at the University of Texas Medical Branch (UTMB) in Galveston, TX.

This form references the *Human Research Program Bed Rest Experiment Information Package* located at this website:

<http://humanresearch.jsc.nasa.gov/elements/smo/nra.asp>

Please familiarize yourself with the FAP services and standard methods for preparing and implementing research protocols. Review the HRP Bed Rest Experiment Information Package for a guide to the bed rest standard conditions and standard measures. Refer to the sections indicated for specific information as you fill out this form.

1. PRINCIPAL INVESTIGATOR

Name:

Affiliation:

Mailing Address:

E-Mail Address:

Telephone Number:

Fax Number:

2. PROPOSED STUDY

2.1. Title:

2.2. Date of Proposed Study Start:

3. SUBJECTS

(Refer to Section 9.0 of the HRP Bed Rest Information Package - Bed Rest Subject Recruitment and Screening)

3.1. Provide the number of subjects by gender required for your study.

3.2. List any additional subject inclusion or exclusion criteria for your study.

3.3. List any additional subject screening required for your study.

4. STUDY PROCEDURES and EXPERIMENTAL PROTOCOLS

4.1. Provide a brief overview of your study protocol and testing methods.

4.2. List hardware that you plan to bring to the FARU to conduct your study.

4.3. List any hospital services you will require (Research Pharmacy, Imaging Services, such as MRI, CT, etc.)

4.4. Standardized Conditions

Check “YES” or “NO” to indicate which of the standardized conditions listed below are compatible with your protocol. If “NO”, explain any modifications or deletions below. If additional standardized conditions are required, include this information below.

YES	NO	BED REST STANDARDIZED CONDITIONS
		Duration: 30 days of bed rest
		Duration: 60 days of bed rest
		Duration: 90 days of bed rest
		Bed Position: 6 degrees head down tilt, continuous for the duration of the study
		Environmental: 70-74 degrees F.
		Light/Dark Cycle: Lights on 0600, lights out 2200 (no napping)
		Daily Measurements: as defined in section 6.0 of the HRP Bed Rest Information Package
		Monitoring: By Subject Monitors in person or via in room camera 24 hours per day
		Stretching Regimen: Twice daily
		Physiotherapy: Every other day during bed rest and every day for the first seven days post bed rest.

4.4.1. Modifications/Deletions/Additions

Explain any modifications, deletions, or additions to the standardized conditions.

4.5. Standard Measures

(Refer to Section 8.0 of the HRP Bed Rest Information Package - Bed Rest Standard Measures)

Check “YES” if a Standard Measure listed below is compatible with your protocol or check “NO” if a Standard Measure will compromise your study in any way.

YES	NO	BED REST STANDARD MEASURE
		Bone Densitometry (DXA)
		Bone Mass and Geometry (QCT)
		Clinical Nutritional Assessment
		Clinical Laboratory Assessment
		Cycle Ergometry (VO ₂ max testing)
		Isokinetic Testing
		Functional Fitness
		Computerized Dynamic Posturography
		T-Reflex testing
		Neuroendocrine and Cardiovascular Response to Tilt
		Plasma volume
		Cardiac Function
		Immune Function Assessment

5. DIET

(Please refer to Section 7.0 of the HRP Bed Rest Information Package - Bed Rest Standardized Diet)

Check “YES” or “NO” to indicate which requirements of the Standardized Diet are compatible with your protocol. If “NO”, explain any modifications or deletions below. If your protocol has additional dietary requirements, include this information below.

YES	NO	STANDARDIZED DIET
		Standardized diet based on the NASA space flight nutritional requirements Carbohydrate: Fat: Protein ratio - 55:30:15
		Minimal fluid intake of 28.5 ml/kg body wt (2000 ml/70 kg subject). No caffeine, cocoa, chocolate, tea or herbal beverages.
		All food must be consumed
		Caloric intake adjusted to maintain weight within 3% of day 3 of bed rest weight
		Iron supplementation
		Vitamin D supplementation throughout the bed rest phase of the study.

Additional dietary requirements:

5.1. Modifications/Deletions/Additions

Explain any modifications, deletions, or additions to the Standardized Diet.

5.2. Nutrition Intake Recommendations

(Refer to Figure 1 of the HRP Bed Rest Information Package - Bed Rest Nutrition Intake Recommendations)

Indicate if any nutrients or recommended nutrient quantity may interfere with the collection or interpretation of your study data.

6. Physiological Differences Based on Gender

Is your study designed to detect differences between male and female subjects? In other words, is gender an independent variable in your study?

	Yes
	No

If yes, is the sample size for this study powered to detect differences between males and females?

If no, provide a rationale for not studying gender differences as part of your study. Include relevant references in your explanation.