Attachment 2 WI2024-335 Version No. 1.0

CRF Risk Assessment Matrix

Procedural Risk	Health Status					
	Minimal		Low	Intermediate Health	High	Extremely High Health
	Healthy	Single Disease Well Controlled	Health Risk 2 - 3 Comorbid Diseases Well Controlled	Risk Compromised Health Multiple Comorbid Diseases All Well Controlled	Health Risk Unhealthy Multiple Comorbid Conditions Partially Controlled	Risk Unhealthy Multiple Comorbid Conditions Not Well Controlled
	No Known Disease No Medications (except contraceptives) Non Smoker	Single Disease Well Controlled Minimal Medications No Abnormalities on Examination Average Fitness and Mobility	2 - 3 Comorbidities (e.g. skin diseases, GIT Disorders, hypertension, diabetes, BMI 30 - 40) Controlled disease No Recent Known Adverse Medical or Surgical History No Significant Abnormality on Examination Average Fitness	Active Disease or Disorders responding to Treatments (e.g. Rheumatoid Arthritis, Cancer, Lung, Kidney or Liver disease) Comorbidities Well controlled with Medications Reduced Fitness and Mobility	Active Disease or Disorders not responding to standard Treatments (e.g. Solid Organ or Blood Cancers, Unstable CVD, End stage Kidney Disease) One serious and active comorbidity partially controlled Abnormality on Examination Strong Family History of illness Low Fitness and Mobility Potential for health incidents requiring hospital admission	Disease)
Minimal Risk						
Focus Groups, Information Collection, Interviews, Imaging, Psychometric testing, Clinical Examination, Vital Sign Measurements, ECG, EEG, Biometric Training, Spirometery testing, indirect calorimetry, Body Composition Scans, Pulse Wave Velocity, Strain Gauge Plethysmography.	Minimal	Minimal	Minimal	Minimal	Minimal	Minimal
Low Risk Minor Invasive Procedures including Routine Diagnostic Tests Phlebotomy, Skin biopsy, Fine needle biopsies, Procedures involving motion and exercise e.g. 6 minute Walk Tests, Moderate Ergometry testing, Phase 2B, 3 and 4	Minimal or Low	Minimal or Low	Minimal or Low	Intermediate	Intermediate	Intermediate
Clinical Drug Trials (Self Administration Medications) Diagnostic Tests e.g. Glucose Tolerance, Short Synacthen, Metyrapone Stimulation, Dexamethasone challenge, Sputum Induction, Skin Prick Allergy Tests, Methacoline Challenge, Allergen Challenge, Lipid Metabolism						
Intermediate Risk Invasive or Experimental Procedures Phase 1 and 2A Drug Trials (Oral, IM, SC or IV), Medical Device Trials	Minimal or Low	Minimal or Low	Minimal or Low	Intermediate	Intermediate	High
Higher Risk Invasive or Experimental Procedure Cardio- pulmonary Stress Testing	Minimal or Low	Minimal or Low	Intermediate	Intermediate	High	Extremely High
Extremely High Risk Surgical procedures, Anaesthetic procedures	Extremely High	Extremely High	Extremely High	Extremely High	Extremely High	Extremely High
Risk Stratification Colour Codes		Blue = Minimal Health Risk: Projects Suitable for CRF	Green = Minimal or Low Risk: Projects Suitable for CRF	: Yellow = Intermediate Risk: Projects Suitable for CRF	Red = High Risk: Project only suitable for CRF if low - intermediate risk procedures conducted in CRF.	Black = Extreme High Risk - Not Suitable for CRF, Use PAH

