## TRI CRF - PROJECT RISK STRATIFICATION TABLE

### HEALTH STATUS

<table>
<thead>
<tr>
<th>MINIMAL HEALTH RISK</th>
<th>LOW HEALTH RISK</th>
<th>INTERMEDIATE HEALTH RISK</th>
<th>HIGH HEALTH RISK</th>
<th>EXTREMELY HIGH HEALTH RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy</td>
<td>Single Disease (Well Controlled)</td>
<td>2 - 3 Comorbid Diseases (Well Controlled)</td>
<td>Compromised Health Multiple Comorbid Diseases (All Well Controlled)</td>
<td>Unhealthy Multiple Comorbid Conditions (Partially Controlled)</td>
</tr>
</tbody>
</table>

### PROCEDURAL RISK

**Minimal Health Risk**
- Focus groups, information collection, interviews, imaging, psychometric testing, clinical examination, vital sign measurements, ECG, EEG, biometric training, spirometry testing, indirect calorimetry, body composition scans, pulse wave velocity, strain gauge pletysmography.

**Low Health 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 clinical drug trials (self-administration medications).
  - Diagnostic tests e.g. Glucose tolerance, short synacthen, metyrapone stimulation, dexamethasone challenge, sputum induction, skin prick allergy tests, methacholine challenge, allergen challenge, lipid metabolism.

**Intermediate Health Risk**
- Invasive or experimental procedures
- Phase 1 and 2a drug trials (oral, iv, im), medical device trials

**Higher Health Risk**
- Invasive or experimental procedures
- Cardio- pulmonary stress testing

**Extremely High Health Risk**
- Surgical procedures, anaesthetic procedures

### RISK STRATIFICATION COLOUR CODES

<table>
<thead>
<tr>
<th>BLUE</th>
<th>GREEN</th>
<th>YELLOW</th>
<th>RED</th>
<th>BLACK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal Health Risk: Projects Suitable for CRF</td>
<td>Minimal or Low Risk: Projects Suitable for CRF</td>
<td>Intermediate Risk: Projects Suitable for CRF</td>
<td>High Risk: Project only suitable for CRF if low - intermediate risk procedures conducted in CRF</td>
<td>Extreme High Risk: Not Suitable for CRF, use PAH</td>
</tr>
</tbody>
</table>

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CRF Expanded Research Risk Stratification Assessment Tool_Verison 1 Final 9 April 2015.xlsx