



**Compelling Circumstances Review (Institutional):**

**Basic Risk-Benefit Analysis Questions:**

- Is there a risk to human subject safety?
- Is there a risk to data integrity?
- Could the research benefit the MSK patient population and public?

**The following factors should be considered when performing a compelling circumstances analysis:**

**One or more criteria may be met and/or considered in order for the COIC to make a determination that the research may proceed despite institutional interests, taking into account the extent to which institutional interests could impact research objectivity or human research subject rights and welfare AND the extent to which study design, structure, or management strategies can protect against this**

Factor	PI Responses & Study Design Information
■ Specialized or unique expertise ( <i>institutional</i> )	Does the institution and/or MSK research or clinical staff have specialized or unique experience or knowledge relative to the product, procedure, therapeutic, data collection, interpretation of results, etc. that is critical to the progress and success of the research?
■ Unique patient population / patient need:	Is there a unique patient population at MSK relative to this study or a specific need to make this research available to MSK patients?
■ Special facilities and equipment:	Are there special facilities and/or equipment at MSK necessary for the research?
■ Risk level to human subjects	Is this research itself minimal or greater than minimal risk?
■ Existing/inherent controls against bias or risk	Is the study structure and/or design such that risk of bias may be mitigated?
■ Correlation of conflict to aims of research	Are MSK's institutional interests directly related to study outcomes?
■ Other considerations	