**Is the change or modification for an active IRB application?**

- **Yes**
  - **Is this to eliminate an apparent immediate hazard to subjects?**
    - **Yes**
      **This is uncommon. Are you sure this is to eliminate an immediate hazard?**
        - **Yes**
          Proceed with the change. Submit an ORIO within 5 calendar days by following the instructions from the IRBMED COVID guidance
        - **No**
          Consult with Sponsor and/or IRBMED
    - **No**
      **Consult with Sponsor and/or IRBMED**

- **No**
  - **Is this a time sensitive change?**
    - **Yes**
      **Create an Amendment in eResearch**
      - Follow the appropriate labelling instructions from the IRBMED COVID guidance
    - **No**
      **Submit an ORIO in eResearch**
      - Follow the appropriate labelling instructions from the IRBMED COVID guidance

**Do you currently have an amendment in eResearch?**

- **Yes**
  - **Submit an ORIO in eResearch**
    - Follow the appropriate labelling instructions from the IRBMED COVID guidance
- **No**
  - **Consult with Sponsor and/or IRBMED**