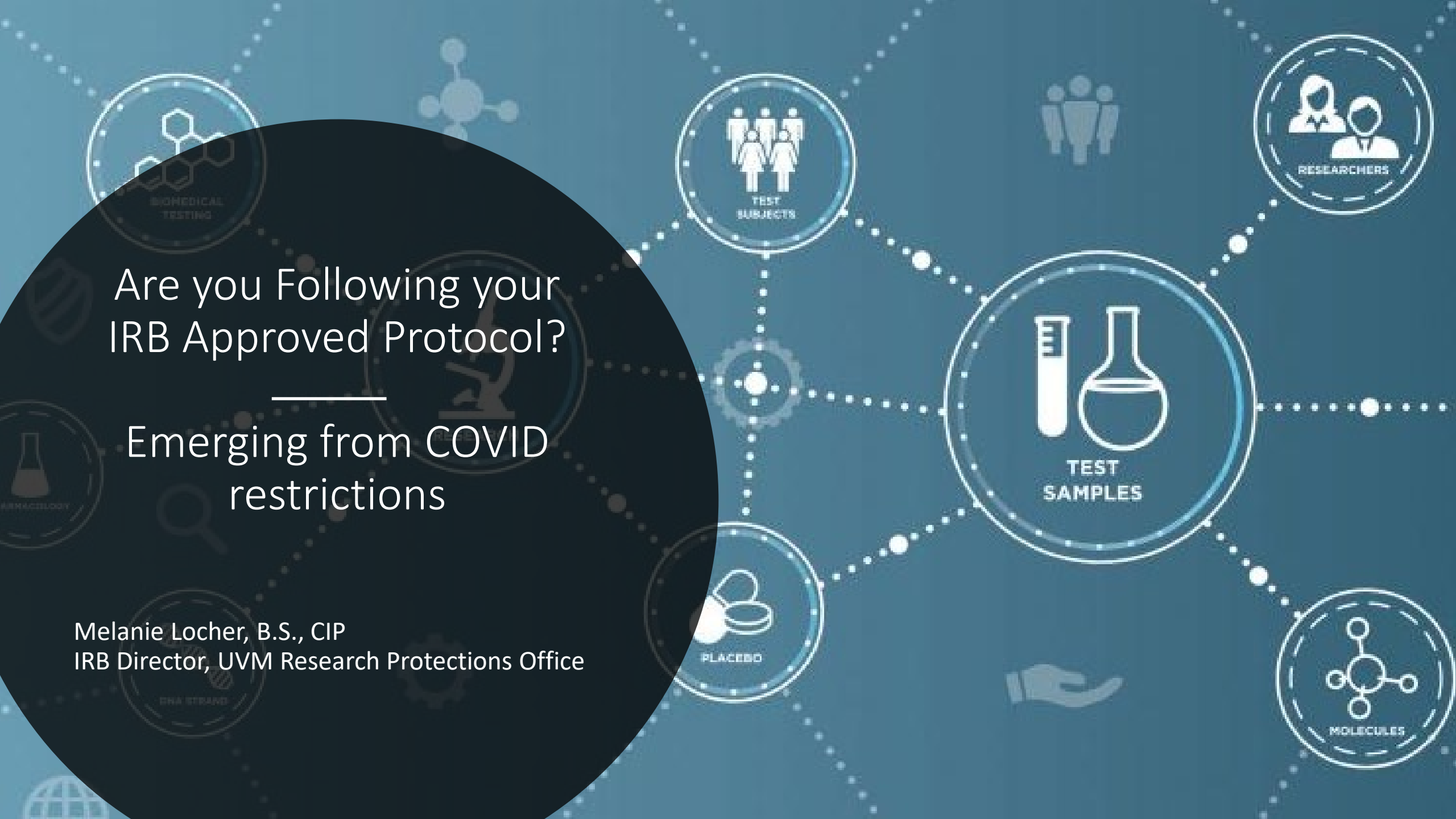


Are you Following your IRB Approved Protocol?

Emerging from COVID restrictions

Melanie Locher, B.S., CIP
IRB Director, UVM Research Protections Office

March 2020 – NIH and FDA Guidance

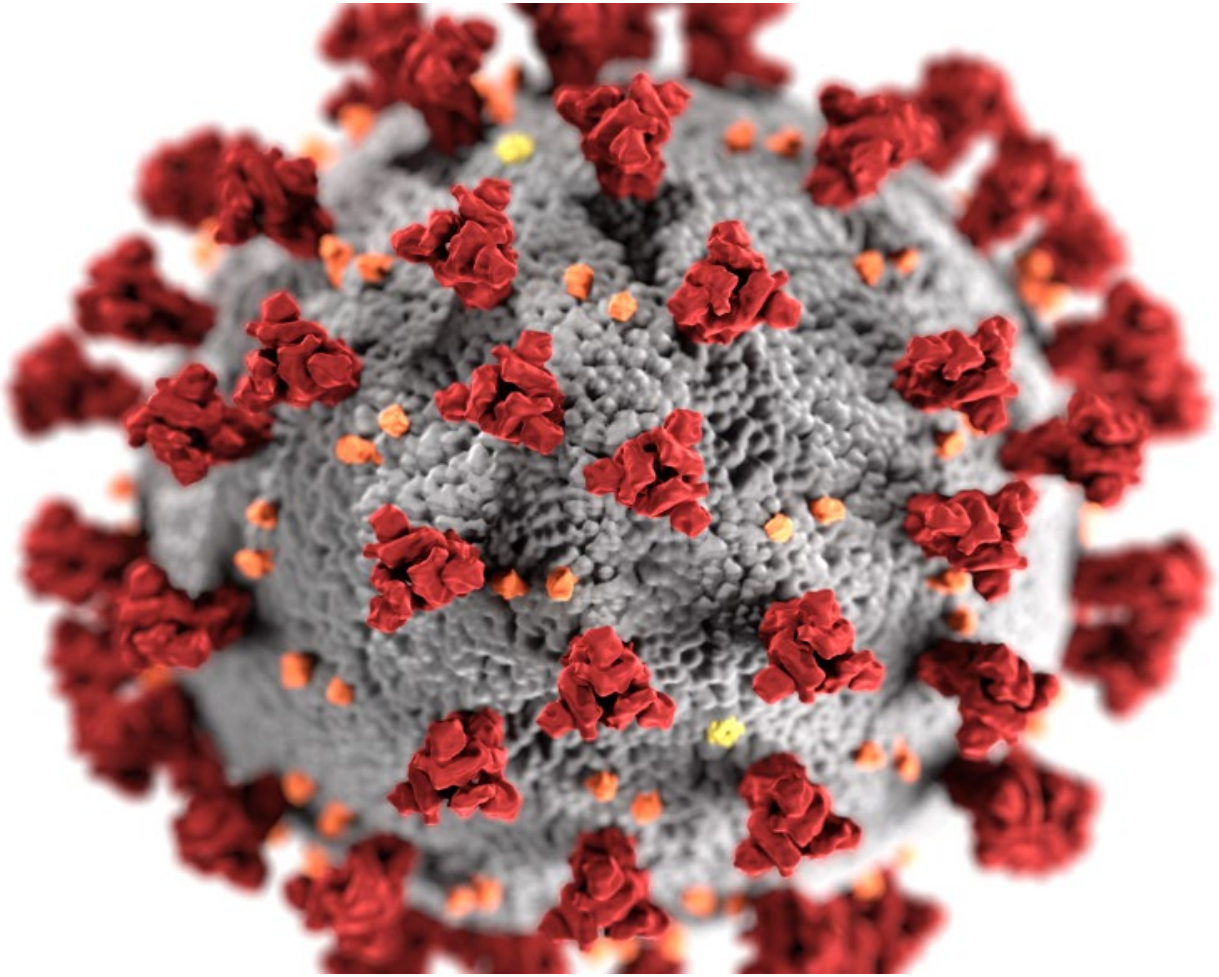
- Protocol modifications may be required and that protocol deviations due to COVID-19 illness and/or control measures may become unavoidable.
- Ensuring the safety of trial participants and preserving data integrity by documenting measures taken in response to disruptions to study conduct caused by COVID-19.
- Alternative methods may include the use of telephone contacts, telemedicine contacts, or alternative locations for assessments, such as using a local laboratory in place of the study site's laboratory.
- Health care system-mandated COVID-19 screening procedures do not need to be reported as an amendment to the clinical trial protocol unless the Sponsor is using the data collected from the screening as part of a new research objective

Local Pandemic Restrictions to Research

- Social distancing, screening procedures
- Closing of UVM research labs
- UVM and UVMMC mandated temporary halt to all new enrollment of participants
- Restrictions on study interactions- masks, face shields, gloves, number of persons allowed during research visits
- Early pandemic restrictions on PPE used for research

Federal and local updated research policies related to the pandemic

- 9.11 Technical Guidance for Virtual Research Visits, Electronic Consent, Electronic Data Capture, and Communications
- 9.10 Virtual Research Visits
- 9.9 Electronic Consent
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency
- FDA Guidance on Use of Electronic Informed Consent
- FDA Emergency Use Authorization
- UVM HN COVID 19 Vaccine Policy



Types of COVID Modifications Approved by the IRB

- Consent form changes
- Use of Electronic consent
- Increase use of Redcap for surveys and data collection
- Temperature checks, additional screening procedures
- limiting study visits to those necessary for participant safety or coincident with clinical care
- utilizing virtual study visits – ZOOM!
- allowing flexibility for required laboratory tests or imaging to occur locally.

End of the COVID-19 Public Health Emergency

World Health Organization

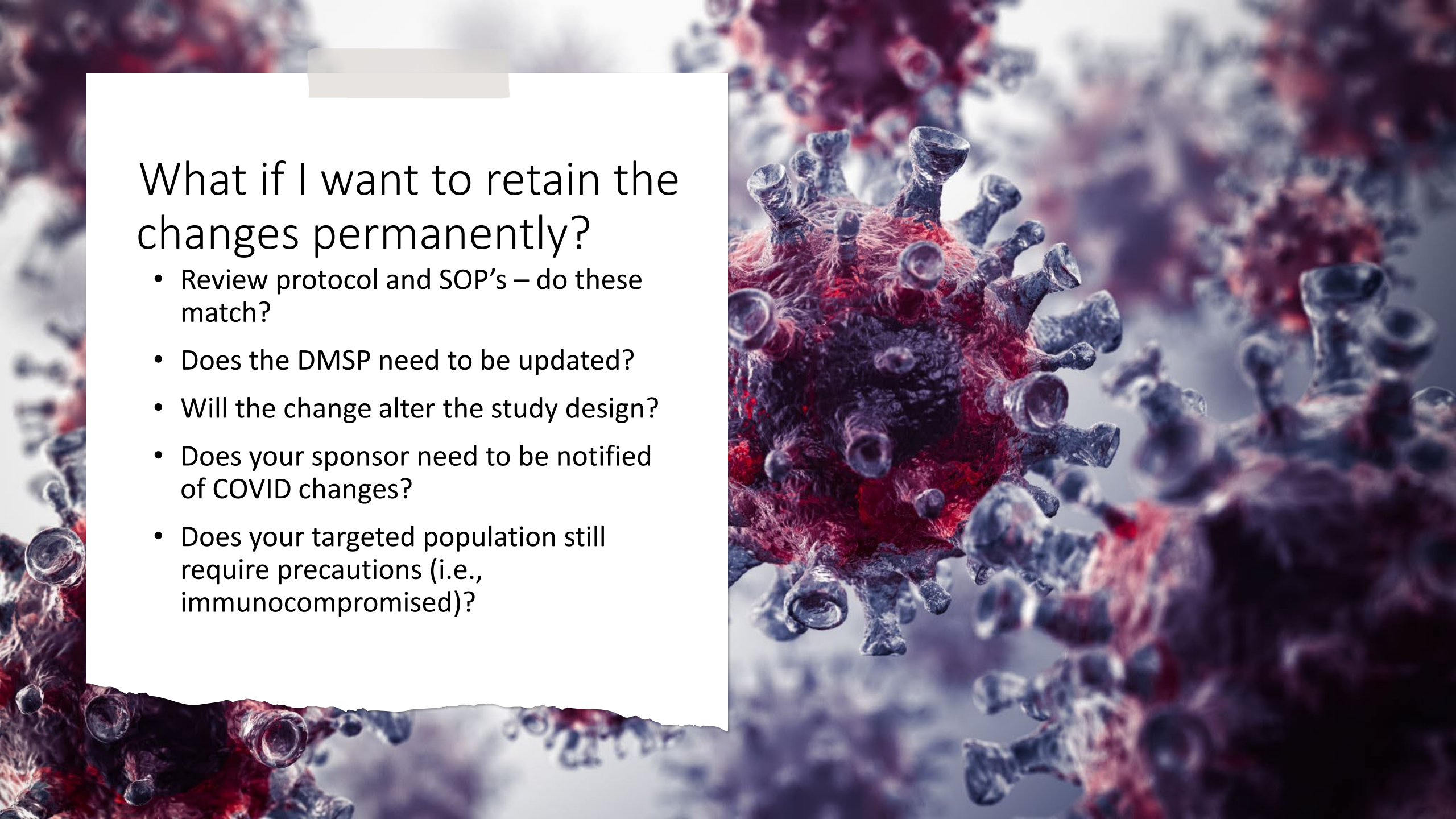
5/4/2023

The World Health Organization determined that COVID-19 is now an established and ongoing health issue which no longer constitutes a public health emergency of international concern

U.S. Department of Health and Human Services

5/11/2023

The Department of Health and Human Services announced the federal Public Health Emergency for COVID-19, has ended.



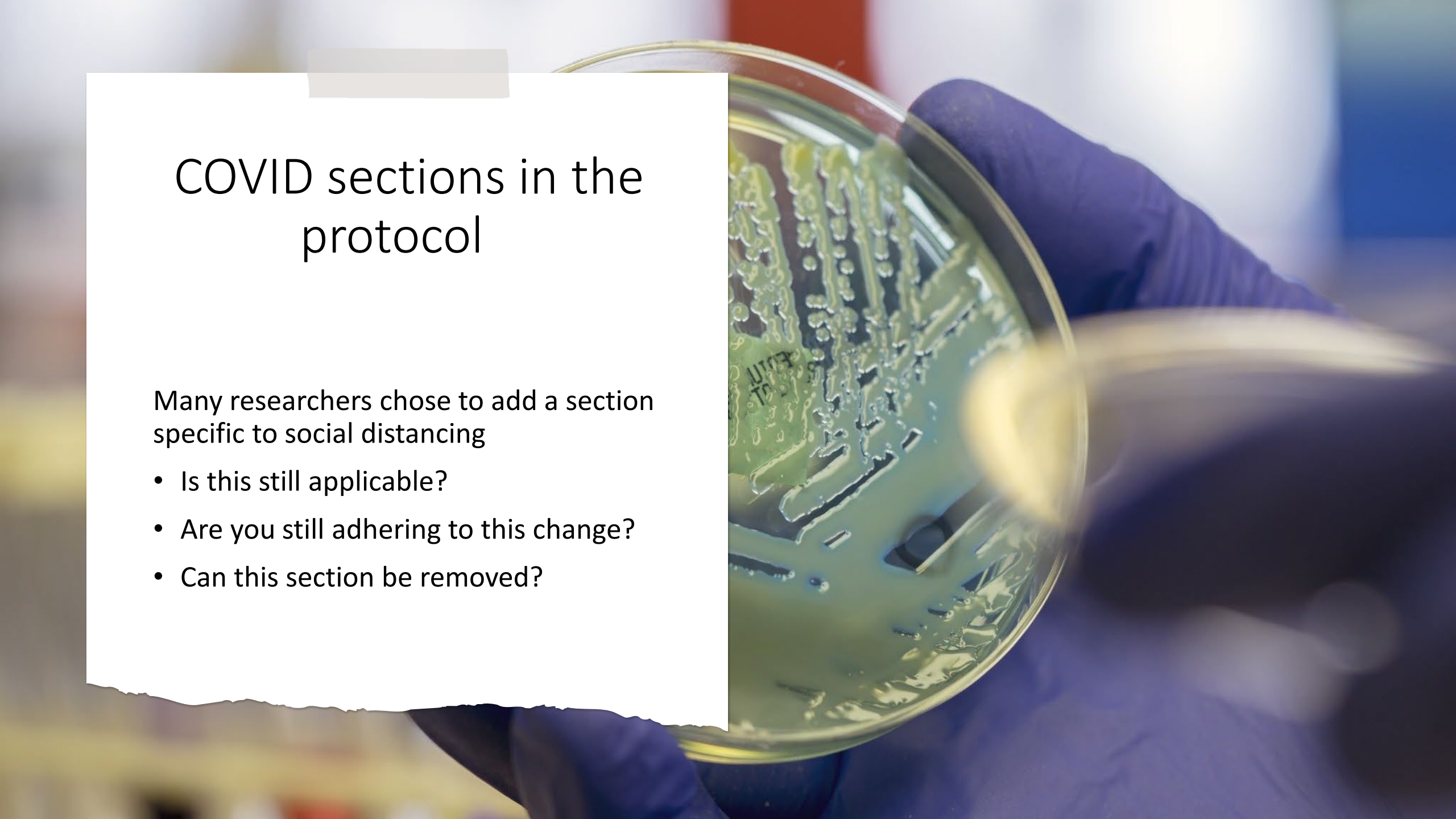
What if I want to retain the changes permanently?

- Review protocol and SOP's – do these match?
- Does the DMSP need to be updated?
- Will the change alter the study design?
- Does your sponsor need to be notified of COVID changes?
- Does your targeted population still require precautions (i.e., immunocompromised)?

COVID sections in the protocol

Many researchers chose to add a section specific to social distancing

- Is this still applicable?
- Are you still adhering to this change?
- Can this section be removed?



the end of the coronavirus restrictions

Review your methods and procedures!

- Submit a modification to remove restrictions
- Ensure consent form also has covid precautions removed
- Check the DMSP

Protocols with a specific COVID component

- Changes to the consent and protocol may still need to be made
  - UVMMC policy has changed
  - State of Vermont covid policies have changed
  - Vaccination is widespread and available to all
  - Have treatment options changed?