Town Hall Meeting

WITH DR. RUTH O’HARA
SENIOR ASSOCIATE DEAN FOR RESEARCH

March 25, 2022
10:00 - 11:00 AM

We'll start shortly....
SAD-R Town Hall, March 25, 2022
COVID-19 Updates: Update on Masking

At Stanford, March 2nd:

• Face coverings are no longer required but continue to be strongly recommended on-site, regardless of vaccination status.
• In classrooms, face coverings will continue to be required through the beginning of spring quarter. However, individuals may remove face coverings while speaking. We will monitor conditions and re-evaluate this requirement after the beginning of spring quarter.
COVID-19 Updates: Update on Masking

In compliance with State of California protocols, masking will still be required in these settings, regardless of vaccination status:

- **Public transportation**, including Marguerite buses.

- **Healthcare facilities**, including Vaden Health Center and Stanford hospitals and clinics.

- **Childcare facilities** (through March 11, after which masks remain strongly recommended).
COVID-19 Updates: Update on Masking

**SHC Hospital and Clinical Settings:** The following changes in masking policies take effect Monday, March 28:

- **Outdoor masking** – Masks will no longer be required in outdoor spaces.

- **Masking in non-clinical/administrative buildings** – Employees who are up-to-date on their COVID-19 vaccinations will no longer be required to wear a mask in non-clinical/administrative buildings, although masks continue to be recommended.

- **Masking in clinical buildings** - Masks will still be required for everyone in clinical buildings, as mandated by the California Department of Public Health.
COVID-19 Updates: Update on Masking

Clinical Research Settings:

• **Face coverings will continue to be required through the beginning of spring quarter.** We will monitor conditions and re-evaluate this requirement after the beginning of spring quarter.

• Same protocols and procedures continue, and we will re-evaluate these requirements after the beginning of spring quarter.
COVID-19 Updates: Update on Masking

- With this transition, we encourage everyone to respect the choices that individuals will make about their own masking in many settings.

- We expect that some members of our community will choose to continue masking in meetings and other indoor settings, for example.

- In their recent announcements, our state and county public health leaders have emphasized the continued protection afforded to individuals by face coverings, and the value of masking particularly for those who are immunocompromised or otherwise medically vulnerable.
Reminders: COVID-19 Fund to Retain Early-Career Scientists Program

- Applications due on March 31 at 5:00 pm
- Award selection will be in April
- Submission on Stanford Seed funding
- For questions please contact Pooneh Fouladi at Pooneh.Fouladi@stanford.edu
ClinicalTrials.gov Updates & Reminders

Scott Patton, Clinical Trials Manager
Clinical Research Quality

March 25, 2022
ClinicalTrials.gov Updates and Reminders

1. Reminder: Requirement to post informed consent form (ICF)

2. Reminder: Understanding the Primary Completion Date to avoid late results

3. Reminder: Maintain compliance before results are due

4. Update: FDA enforcement final guidance
Posting a Blank ICF for Federally Funded Clinical Trials

- Under the Common Rule, a blank ICF (any version) used during enrollment must be posted to a publicly accessible federal website – this can be done on ClinicalTrials.gov or Regulations.gov

- Posting must be at any time after the trial is closed to recruitment, but no later than 60 days after the last study visit by any participant

- Common Rule agencies that require this include NIH, VA, NSF, and HHS

- Use our help document, ICF Disclosure under the Common Rule

- To upload to ClinicalTrials.gov, documents must be in PDF/A format and have a cover page that includes the official title of the study, the NCT number (ClinicalTrials.gov registration number), and document approval date; see our help documents:
  - Preparation and Submission of Study Documents to ClinicalTrials.gov
  - Study documents cover page template
Primary Completion Date & Preventing Late ClinicalTrials.gov Results

- The primary completion date (PCD) is defined in the regulations – it is the last date data are obtained from an enrolled participant for the primary outcome measure(s) in a clinical study.

- Results compliance depends on understanding this definition.

- When results are required, they are due within 1 year following the primary completion date.

- CRQ outreach to research teams is timed based on the primary completion date entry in the CTgov record, so it is important to keep this data element up to date.

- CRQ can assist researchers with CTgov results submission.

Diagram:
- Clinical protocol document/statistical analysis plan (SAP) → Amendment(s) document changes in measures/methods during the study → Protocol (or latest amendment) and SAP submitted w/results
- ClinicalTrials.gov Registration → Registration Updates → ClinicalTrials.gov Results
  - Register primary and secondary outcome measures prespecified in protocol document
  - Add, delete, change outcome measures in the CTgov record to reflect changes in protocol amendments
  - Outcome measures in the protocol match the CTgov record and results are available

March 25, 2022
Maintaining ClinicalTrials.gov Compliance

- Maintaining ClinicalTrials.gov compliance is about more than just results – ClinicalTrials.gov records must be kept up-to-date while a study is active
  - ClinicalTrials.gov data are automatically downloaded nightly to populate the Stanford Clinical Trials Website – out of date data aren’t helpful to potential participants!
  - Many ClinicalTrials.gov data elements must be updated within 30 days of changes in the study:
    - Change in overall recruitment status
    - Change in IRB status
    - Changes due to a protocol amendment
    - Change in the Responsible Party
    - Changes in milestone dates (e.g., from anticipated to actual, or date change)
      - Study Start Date
      - Primary and Study Completion Dates
FDA Enforcement Final Guidance (August 2022)

1. Violation identified during FDA Inspection (Applicable Clinical Trials), or by public complaint (any record)

2. FDA Center sends the Responsible Party a Preliminary Notice of Noncompliance (e.g., by certified mail)
   - Preliminary Notices are not sent to the institution
   - If you receive a Preliminary Notice, or a Notice, please contact CRQ!

3. If no action by the Responsible Party after 30 days, first FDA investigates, then issues a Notice of Noncompliance if violation is confirmed
   - Notice posted publicly on FDA and CTgov websites

4. If the Responsible Party fails to remediate the record within 30 days, FDA may seek civil money penalties, accounting for noncompliance type and circumstances associated with lack of remediation
   - Notice posting is permanent, even after remediation of the record
To Date, FDA Has Issued 3 Notices (none yet to Stanford)

- One Notice was sent to an academic researcher, two to pharma companies.

- FDA can assess civil monetary penalties against ClinicalTrials.gov Responsible Parties for:
  1. Failure to submit or knowingly submitting a false certification to FDA (Form 3674)
  2. Failure to submit required clinical trial information
  3. Submission of false or misleading information
Getting Help

- Email us at clinicaltrial-gov@lists.stanford.edu
- Visit the CRQ ClinicalTrials.gov support webpage
- Need help? Contact CRQ! Submit a help request

thank you!
Research at Stanford

sadrmedicine@stanford.edu
## Significant Research Resources in SoM to Support Your Research

<table>
<thead>
<tr>
<th>Resource</th>
<th>Director</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Subjects IRB</td>
<td>Kathy McClelland</td>
<td><a href="https://researchcompliance.stanford.edu/panels/hs">https://researchcompliance.stanford.edu/panels/hs</a></td>
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<tr>
<td>APLAC/IACUC</td>
<td>Cheryle Aird</td>
<td><a href="https://researchcompliance.stanford.edu/panels/aplac">https://researchcompliance.stanford.edu/panels/aplac</a></td>
</tr>
<tr>
<td>Service Centers</td>
<td>Bruce Koch</td>
<td><a href="http://corefacilities.stanford.edu">http://corefacilities.stanford.edu</a></td>
</tr>
</tbody>
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Significant Research Resources in SoM to Support Your Research

- Biobank Director
  Justin Vincent-Tompkins
  http://med.stanford.edu/sbc/biobank.html

- Clinical Translational Unit Director
  Rebecca Osborne
  https://med.stanford.edu/ctru.html

- Clinical Research Quality Director
  Jennifer Brown
  https://med.stanford.edu/spectrum/b4_research_quality.html

- SoM RDO Director
  Sandra Holden
  https://med.stanford.edu/srdo/contacts.html

- Quantitative Sciences Unit/BERD Director
  Manisha Desai
  https://med.stanford.edu/qsu.html
No Need to Reinvent the Wheel
What Faculty Can and Can’t Do Under Stanford Research Conflict of Interest (COI) Policies
COI Resources

• DoResearch website:
  – https://doresearch.stanford.edu/research-scholarship/conflicts-interest

• Director: Professor Jon Bernstein

• Contact the Conflict of Interest Review Program:
  – Barbara Flynn at bflynn@stanford.edu or 723-7226
  – Shannon Shankle at sds@stanford.edu or 723-0969
Questions?

sadrmedicine@stanford.edu