

Phasing Back Human Research Activities at Northwestern: Social and Behavioral Sciences

Edith Chen
IRB Brown Bag
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Remote vs. In Person

- Remote if possible: Zoom, Qualtrics, REDCap
- Can split up your protocol and do parts of it remotely
- Make changes and submit Reportable New Information form to IRB
- NU IT protections against Zoombombing: <https://www.it.northwestern.edu/transitions/2020/zoombombing.html>

In-Person: COVID screening

- Social & Behavioral Sciences researchers - use IRB COVID prescreener:
https://sites.northwestern.edu/irb2/files/2020/06/COVID-PreScreener_v6-19-2020.docx
- Within 24 hrs of in-person visit
- If don't pass, cancel visit, re-screen after 14 days
- Consider 2nd pre-screening when participant arrives for visit, send home if don't pass
- Consider doing temperature check

General Procedures to Follow

- If in-person visit is being done in your lab on Evanston campus, follow Northwestern guidelines in Return to Campus Policy:
<https://www.northwestern.edu/coronavirus-covid-19-updates/campus-return/policy/index.html>
- If conducting visits at an outside location, follow requirements of that organization

General Procedures to Follow

- All research study team member need to complete MyHR Pandemic Essentials training module before returning to campus
- COVID risk and COVID prescreening do not get added to informed consent or IRB protocols (no study modification required)

Safety Plan

- Need to create safety plan
- Pandemic Research Plan template:
https://cpb-us-e1.wpmucdn.com/sites.northwestern.edu/dist/d/2780/files/2020/05/ORS_Bus_Content_COVID-19_Pandemic_Research_Plan_Template_FINAL_FILLABLE_0521202.pdf

Social Distancing

- Determine maximum number of people permitted in each room of your lab, based on social distancing guidelines
- Determine how you can achieve this in your lab: staggered shifts, balance of remote versus in-lab work
- Create a lab-wide shared Google document for research team members' in-lab schedules

Cleaning Procedures

- Enhanced cleaning procedures need to be detailed
- What cleaning done after each participant visit?
- What cleaning done in shared spaces of lab?
- Procurement provides wipes, disinfectant spray, hand sanitizer, face masks:
<https://www.northwestern.edu/coronavirus-covid-19-updates/resources/return/order-ppe.html>

Personal Protective Equipment

- Determine exposure risk based on study procedures and participants
- One way to do this is to use OSHA guidelines:
<https://www.osha.gov/SLTC/covid-19/hazardrecognition.html>
- Most social & behavioral research likely lower or medium risk

Personal Protective Equipment

- Determine appropriate PPE
- One way to do this is to use CDC guidelines for safety precautions in accordance with OSHA risk:
<https://www.cdc.gov/infectioncontrol/basics/index.html>
- Most social & behavioral research will fall under standard precautions

Personal Protective Equipment

- Follow CDC guidelines for what PPE needed based on what study procedures are being done:
<https://www.cdc.gov/hai/pdfs/ppe/PPEslides6-29-04.pdf>
- For example, consider whether study procedures require physical contact with participant or not and adjust PPE accordingly

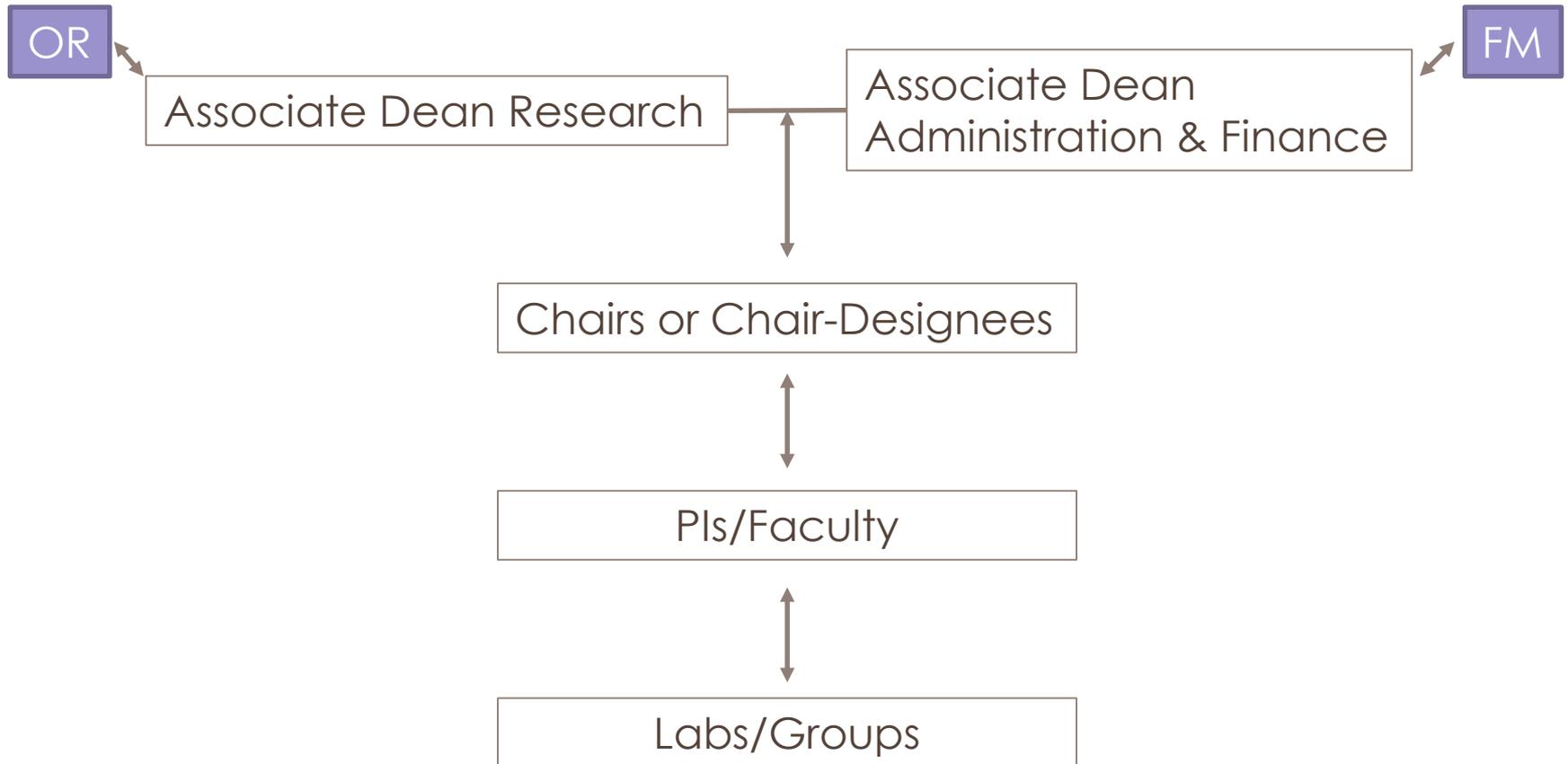
School-Wide Planning: School of Communication

Sumit Dhar

IRB Brown Bag

June 24, 2020

Process



Nuances

- ▣ Advantage – Starting with one building.
- ▣ Advantage – Starting with a relatively small number of labs.
- ▣ Complication – Wide variety of research methods and practices (including home visits).
- ▣ Complication – Nuances of an older building.
- ▣ Complication – PPE (e.g., masks) interfere with experimental observations.

Solutions

- PIs create the Pandemic Research Plan (encouraged to include lab/research group in planning).
- Plan review ongoing so labs are not under any deadline.
- Chairs approve and file with school research office.
- Planning group has outlined specific policies for the building (e.g., one-way stairwells).
- Research office is distributing helpline posters for all spaces.

SoC Overall Plan

- ▣ Starting with Frances Searle.
- ▣ Moving some activities from other buildings into Frances Searle.
- ▣ Planning on phased opening of other SoC spaces later in the summer.
- ▣ Using the foundational guidelines created by the Office of Research and IRB.
- ▣ Minor overlay of guidelines to customize the plan to our research methods and spaces.

Phased Reactivation of Clinical Research at FSM

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In Clinics and Other Spaces (v 1.2; 6/19/20)

- Follow clinical affiliate – as well as NU IRB, FSM, and departmental – guidelines
 - PPE, pre-visit/entry screens, physical distance/"#/flow control", cleaning per affiliate
 - Affiliate guidelines first / IRB's are alternate (eg, pre-screening)
 - Cooperate/coordinate with clinical / diagnostic spaces to ensure visit volume OK
 - University/FSM buildings ONLY when open
 - Leased spaces (eg, 645 MI): follow building guidelines (consider IRB pre-screening guidelines, and your own entry screen)
- Research in clinical affiliate space is defined as being done at
 - Lurie Children's Hospital (LCH)
 - Northwestern Memorial HealthCare (NMHC)
 - NMH Feinberg, Galter, Arkes, and Lavin Pavilions
 - Prentice Women's Hospital
 - Shirley Ryan AbilityLab (SRAL)
- Participant visits can continue/restart following affiliate clinical guidelines
 - [Ambulatory Reactivation Playbook](#) on Physician Forum (no login required)

Lurie Children's Hospital (LCH)

- ▣ Researchers working with Lurie Children's Hospital (LCH) should refer to the following site for more information:
<https://www.luriechildrens.org/en/for-healthcareprofessionals/education/2019-novel-coronavirus-2019-ncov-faq-for-lurie-childrenshealthcare-providers/>

Reactivation Plans

- ❑ Complete [Pandemic Essentials training module](#) in myHR Learn
- ❑ Then submit reactivation plan (Pandemic template from Research Safety) to FSMReactivationPlans@northwestern.edu (not via LUMEN)
 - ❑ Focus on spaces used for human participant research.
 - ❑ Feinberg PI's should send a single plan for all projects and/or research units; if plans must vary by study, separate submissions are recommended.
 - ❑ Plans in FSM and FSM-leased spaces must be approved before non-essential research restarts
 - ❑ Work within prioritization set by department/division/unit leadership to determine which studies/visits should resume first and consider shortening, or decreasing numbers of, visits. Also consider limiting secondary outcome measures
 - ❑ Do as much virtually as possible
- ❑ If all work is on the Northwestern Medicine (NM) Clinical Research Unit and/or Lurie Children's CRU, a separate reactivation plan not needed
 - ❑ PIs work with the relevant CRU to phase-in visits and follow their guidelines

Companions and Aerosols

- No one other than study team members and patient/participants are allowed on campus.
 - Exceptions allowed by a clinical affiliate (e.g.; companion needed to assist research participant) are permitted by this policy as well.
- Aerosol generating procedures, such as spirometry, should not be performed by research staff at this time. Please contact Abby Cosentino-Boehm ([a-cosentinoboehm@northwestern.edu](mailto:ac-cosentinoboehm@northwestern.edu)) if you have questions.

Resources

- ▣ <https://www.irb.northwestern.edu/covid-19-resources/>
- ▣ <https://www.research.northwestern.edu/coronavirus-covid-19-updates-and-northwestern-research/>
- ▣ <https://www.feinberg.northwestern.edu/sites/covid-19/>
- ▣ <https://www.luriechildrens.org/en/news-stories/novel-coronavirus-covid-19-resources/>
- ▣ https://www.sralab.org/articles/news/precautionary-measures-seasonal-illness?utm_source=emergency_banner
- ▣ <https://www.northwestern.edu/coronavirus-covid-19-updates/>
- ▣ <https://researchsafety.northwestern.edu/>

Questions?

