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

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IRB Brown Bag
June 24, 2020
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

- 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)
Need to create safety plan

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
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

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IRB Brown Bag
June 24, 2020
Process

Associate Dean Research

Associate Dean Administration & Finance

Chairs or Chair-Designees

PIs/Faculty

Labs/Groups
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.
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 or 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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IRB Brown Bag
June 24, 2020
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](https://example.com) on Physician Forum (no login required)
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/
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
- Pls 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) if you have questions.
Resources

- https://www.irb.northwestern.edu/covid-19-resources/
- https://www.feinberg.northwestern.edu/sites/covid-19/
- https://www.northwestern.edu/coronavirus-covid-19-updates/
- https://researchsafety.northwestern.edu/
Questions?