

D2D: The Driven to Discover Research Facility at the Minnesota State Fair 2021 HANDBOOK FOR RESEARCHERS AND STAFF

The D2D Team

Co-Directors: Ellen Demerath, PhD, EpiCH & Logan Spector, PhD, Pediatrics

Manager: Annie Hotop, 651-308-9043 (cell - for during the fair)

Resource Coordinator (June through the Fair): TBD

Email: d2d@umn.edu

Website: <http://d2d.umn.edu>

Social: @D2DMNStateFair

Building Location: 1367 Cosgrove St., Falcon Heights

We are here to help make your research project a success! Contact us at any time. At the fair, at least one member of the D2D team will be present at all times.

The D2D Facility

The D2D building provides over 2,500 square feet of research, storage & office space. Open houses will be held in June/July (also by appointment) to view the research environment prior to the fair.

- Lighting is excellent: a mix of natural and overhead fluorescent lights.
- Floors are sealed concrete.
- The building has large overhead fans and operable windows, but no air conditioning.
- There are no restrooms nor running water in the building. Restrooms are across the street, and a potable water tap on the back (exterior) of the building.
- The building can accommodate up to 10 projects at a time.
- Research bays are approximately 10' x 12', created with pipe and drape partitions.

The following resources are provided by D2D and included in the fee:

- iPads
 - Order all resources from D2D in April/May (watch for email).
 - Order as many iPads as you can use and monitor at once.
 - We will request a link to your survey instruments and/or other study materials in late July. Changes can still be made to your instrument after you create the link. We will create a page of these survey links and make this the homepage for each iPad.
 - We recommend using free survey software supported by the University – either REDCap or Qualtrics. Notify us if you plan to use a different survey platform or software, to ensure iPad compatibility.

- **IMPORTANT:** Thoroughly test your instrument (on an iPad, if possible) before moving it to production status. Test again prior to the fair in the event you made changes. D2D staff are happy to assist you and provide one of our tablets for practice.
 - Pick up your iPads at the D2D office at the beginning of each shift.
 - Never leave iPads unmonitored – they are easily stolen.
 - Charge iPads during downtimes and return fully charged at the end of your shift.
 - Drop off your iPads at the D2D office after your shift.
- Secure eduroam WiFi
 - You may wish to bring a small number of paper surveys in the event internet connection is temporarily lost.
- Admission tickets: 1 per staff, per day.
 - In a typical year we provide up to 4 tickets per shift for each study.
 - For 2021, studies may request 2-3 tickets per shift due to reduced operations.
- Tables (48" x 30")
- Folding chairs (plus 3 rolling arm chairs)
- Tabletop privacy dividers (black cardboard, 16" tall)
- Rolling room partitions (75" tall x 48" wide)
- Anthropometric equipment (scales, stadiometers, BP machine)
- Refrigerator and freezer for temporary biosample storage (residential model)
- Refrigerator and freezer for food and beverages
- Signage
 - D2D provides a large, chalkboard sign on an easel with your catchy title and *brief* eligibility criteria.
 - If your study has extensive inclusion/exclusion criteria, or criteria of a personal nature that you don't want to list on your sign (e.g., "BMI > 35", "pelvic pain"), consider listing these on a card to give people waiting in line at your booth, so as not to waste fairgoer's time.
 - We encourage you to bring additional promotional materials or visuals to draw fairgoers to your bay.
- Other: D2D provides drinking water, fans, paper towels, tissues, hand sanitizer, alcohol wipes, cleaners, garbage cans, storage carts, power strips, extension cords, and a hazardous waste disposal bin. We can rent a hand-washing station, if needed. There are ample electrical outlets and Ethernet connections in the building.

Timeline Overview

- April: Kickoff Meeting
- April/May: *Scheduling & Resources Survey*: Provide shift preferences, catchy title, brief lay description, and final eligibility criteria. Order tickets, iPads, backpacks (if any), and other equipment & supplies.
- June 1: Backpack requests due
- June 1: UMN IRB applications due (see IRB section for details)
- June/July: Shift schedule finalized, building open houses
- August: Drop off supplies & equipment
- August 26 - September 6: State Fair
- October: Report enrollee demographics, feedback survey, billing

Shift Scheduling

There are two research shifts each day: the Morning shift (9am to 2pm) and the Evening shift (2:30pm to 9pm). The Evening shift is longer because fairgoer traffic tends to be lighter in the evening. Building doors are closed from 2:00 to 2:30 to allow time for the shift change. Project staff should arrive 30 minutes before their shift to set up. Morning shift studies should stop recruiting before 2pm to allow the Evening shift enough time to set up before the doors reopen. You may choose to work 12 hours (back-to-back) shifts.

We accept 40-60 projects each year. We request scheduling preferences in April and work with you through early June to create a shift schedule. We try to accommodate all requests, but flexibility is necessary due to the competing needs and preferences, as well as our desire to have something in the building for every fairgoer. All researchers should be prepared to work both evening and weekend shifts.

The State Fair requires us to be open from 9am to 9pm for the 12 days of the fair. Once the schedule is finalized, *you must be present during all of your shifts, even if you reached your recruitment goal in a previous shift.* If you have reached your goal, or have no more incentives to give away, you may talk with fairgoers while not enrolling them. It is allowable to talk with the public about your research, your lab, or department, and is considered community engagement. This is allowable by the IRB.

Traditionally, the Fair offers discounted tickets for Promotional Days. As of April 19, 2021 the dates for the upcoming fair are not yet advertised. It is unknown if the fair will have discounts for 2021, but based on previous years, we could expect the following:

- Aug 26: Thrifty Thursday – Discounted tickets (\$13 for adults, \$10 for seniors 65+ & kids 5-12)
- Aug 31: Seniors and Kids Day – Seniors (65+) and kids (5-12)
- Sept 1: Military Appreciation Day – Military families (active & vets)
- Sept 2: Read & Ride Day – Public library card holders
- Sept 3: Seniors Day – Seniors (65+)
- Sept 6: Kids Day – Kids (5-12)

IRB

All studies must have IRB approval to conduct their studies at D2D, or demonstrate exemption from review. This includes ongoing studies with already-approved applications. The UMN IRB holds a special session to review D2D studies for considerations unique to conducting research at the State Fair. Please add “D2D” to the short title of your IRB submission. Contact Clinton Dietrich at dietr006@umn.edu if you have questions about your UMN IRB application.

If you are coming to D2D from an external institution, you should submit to, and receive approval from, your local IRB. D2D asks that you send a pdf of your approval letter to us, to have on record.

UMN IRB Timeline:

- June 1: Protocol and all ETHOS documents are due to the IRB, including modifications to existing applications.

- Please start your submission well before June 1 to allow plenty of time to collect the required materials, especially if you have never used ETHOS before.
- Please start your short title with “D2D” on your submission to help the IRB identify D2D studies.
- June 22: The IRB notifies researchers of approval, or modifications required to secure approval.
- July 24: All remaining follow-on submissions are due, including staffing changes. The only changes the IRB will accept after this date are enrollment increases, necessary due to fluctuating nature of state fair attendance.

All study staff must comply with IRB requirements and complete human subject’s research training (CITI) prior to working their first shift. Again, give staff plenty of time to complete the training as it generally takes longer than expected.

Consent/Assent Best Practice

All consent/assent forms must be approved by the IRB. Projects conducting survey research without collecting identifiable data are encouraged to request a Waiver of Documentation of Informed Consent. Intoxicated individuals are not able to provide informed consent. Persons obtaining informed consent must use their best judgment as to potential participants’ level of intoxication and may inquire about recent alcohol consumption as necessary. Train your staff accordingly.

Consent or Assent for Children: Typically a study should plan to consent the parent/guardian of someone under age 18 AND assent the child to participate in a study at the fair. However, a PI may request a Waiver of Parental Permission in order to engage with children under age 18 where parental permission is not reasonable, for example, teenagers visiting the fair with their friends, unaccompanied by parents/legal guardians. The IRB will consider these requests on a case-by-case basis.

D2D advocates for best practice procedures for participant consent in the very busy fair environment. Investigators should allow adequate time for informed consent, which will be proportional to the complexity, commitment, and personal implications of the study to participants. At minimum, a participant should be verbally instructed as to the following:

1. Aim of study
2. Length of time estimated for participation
3. Privacy/confidentiality
4. Voluntary nature

Listing Staff on IRB Applications - check with Clinton if you have specific questions.

- VA staff working on studies that fall under the UMN IRB: If PI has both UMN and VA appointments and needs to seek IRB approval at the VA, the VA-only staff only need to be listed on the VA protocol.
- Independent scholars: Contact relyirb@umn.edu early in the process.
- Unaffiliated volunteers: must be listed on HRP-216 – External Team Member Form.
- For studies led by UMN researchers who are including faculty from other institutions, those collaborators should contact their own IRB regarding institution-specific requirements and approvals.

Preparing Your Measures

Please practice your measures ahead of time. D2D recommends you prepare office space to simulate a booth to practice with various layouts, and practice participant flow. Train your staff so they are prepared for work, and determine your measures are valid, ready to collect the information you want.

Practice your survey. If you wish to practice on an iPad once the links page has been created, this can be arranged. D2D *highly recommends* practicing and simulating data collection prior to the start of the fair.

Remember, questions should be voluntary, thus you may wish to add a “Refused” response option to your survey so you know if someone chose not to answer, or if they missed a response by mistake. If all questions are required for participation (as with screening questions, for example), consider adding an introductory statement explaining this and/or verbally instructing the participant as such. If someone chooses to not answer some of your required questions, D2D recommends they still be given a reimbursement.

Remember, even if you have reached your recruitment goal, or run out of incentives, ***you are required to still staff your booth and engage with fairgoers, even if you don’t enroll them.*** This is community engagement and is allowed by the IRB.

Incentives

Offering an incentive will increase your enrollment. If the cost of giveaways is beyond your budget, consider having a drawing (e.g., gift cards, electronic gadget, etc). If you offer an incentive, the IRB will require you to offer one to every participant, even if you enroll more subjects than you planned. The potential to overshoot your enrollment goal exists, so we suggest having extras on hand, if possible.

- Example IRB language: “A UMN drawstring backpack or other token gift worth less than \$1.XX will be provided.”
 - Tip: We recommend including the phrase “or other comparable incentives of equal value” when describing your incentives in your IRB application. Your original incentive may be unavailable at the time you need to purchase more.

All giveaways and drawings must be registered and approved by the Minnesota State Fair. We will provide you with the proper registration forms when the Fair releases them in June. Investigators utilizing a drawing must keep identifiable information used to contact winning participants separate from the study data. Investigators will destroy all drawing entry data after notifying the winners.

UMN drawstring backpacks are very popular with fairgoers. In a normal year, we request orders in April, and the bags are delivered directly to the fairgrounds in early August. For 2021, we have already ordered incentives and have extras on hand:

- Running Goldy or M backpacks: \$1.75 per bag
- Clear plastic M tote bags: \$2.85 per bag

Please let us know asap if you’d like to purchase incentives from us. We sell them to you at cost, in packages of 25.

The State Fair prohibits adhesive-backed labels, stickers and balloons on the fairgrounds. They also prohibit free food or beverage samples as giveaways since they would compete with fair vendors.

Delivery of Supplies & Equipment

Vehicles are not allowed on the fairgrounds during the fair. We will ask you to box and label your supplies and deliver them to the facility 1-2 weeks before the fair. Backpacks ordered through D2D are delivered directly to the facility. Unused supplies can be picked up after the fair is over.

Contact D2D in early August to arrange delivery of large or sensitive equipment. D2D freezers are residential models, so if you are collecting biospecimens, determine if you need to take these with you at the end of each shift.

Onsite Staffing

You are responsible for staffing your booth. You must have a minimum of two staff at all times to accommodate employee breaks. At least one person must oversee the booth at all times. Each study is responsible for scheduling lunch or dinner breaks for staff.

The more gregarious and outgoing your staff is, the better your recruitment and engagement will be. We recommend recruiting student volunteers throughout spring semester. This can be a cost effective way to staff your booth and gives students hands-on research experience.

Staff Training

Studies must provide staff training prior to the start of the fair as D2D staff will not know the nuances of individual projects. Staff should be trained on the following:

1. **Purpose of Study**: Study staff should have enough information to be able to speak to fairgoers confidently about the study they represent and be able to answer questions. All staff must be briefed by their PI regarding the purpose and use of the data, as well as the study protocol prior to recruiting any participants.
2. **Consenting**: Staff should be trained to consent fairgoers appropriately, despite the unique research environment. Staff should explain the purpose and goals of the study, eligibility criteria, a brief description of what the participant will be asked to do, and how long it will take.
3. **Data Collection**: D2D strongly encourages staff training on data collection protocols *prior* to the fair as very busy, noisy conditions during the study shift are not conducive to training on site.

D2D best practices are included at the end of the Handbook for reference and staff training.

The IRB requires all staff to complete CITI training prior to working at the fair:

<https://about.citiprogram.org/en/homepage/>

All research staff must wear University of Minnesota (or their home institution) related shirts and close-toed shoes (for safety reasons). Shorts are acceptable. Please be prepared for inclement weather (e.g., heat, rain).

At the Fair

Admission: D2D provides one ticket per staff, per day. Due to 2021 reduced operations, D2D will purchase 2-3 tickets per shift depending on your staffing decisions. If you need additional tickets,

reduced price tickets can be purchased online, at Cub Foods, or at Coffman Union prior to the fair. (As of April 19, 2021 ticket pricing has not yet been announced. Pricing for the 2019 fair was: \$12 if purchased in advance, \$15 if purchased after the fair starts.)

Transportation and Parking: Driving on the fairgrounds is prohibited on fair days between 8am and 11pm. Access roads (Como, Snelling and Larpenter) get completely jammed at times. We recommend taking the bus. There are many free Park & Ride lots around the University and the Twin Cities; plan ahead as parking can be sparse for the afternoon shift as more and more fairgoers take the bus. **Leave plenty of time.** Parking lots and bus stops on the fairgrounds are at least a 15-minute walk from the D2D building, so factor this into your plans. Consider bringing a wheeled cart/wagon if you plan to carry in supplies.

Working your shift:

- Arrive at the fair a half hour before your shift.
- Go to the office and announce your arrival to D2D staff so we can help you set up.
- Arrange the tables and chairs in your research bay however you wish, as appropriate for your study.
- Carry your supplies, equipment and incentives to your research bay (D2D staff can help).
- Check out your iPads and test the link on each one. We recommend you open the instrument for each participant before handing them the iPad, so they don't accidentally complete the wrong survey. Please try to keep iPads plugged in and charging when not in use, particularly during the morning shift.
- Wipe the iPads (and any other equipment) clean after each use. Wipes are provided.
- At the end of your shift, return your iPads (clean and charged) to the office and store your supplies.
- Working at the fair can be exhausting, and some fairgoers can test your patience. However, we are committed to treating every fairgoer with kindness and respect, as we want them to come back next year (and tell their friends about us)!

Promotions

University Relations will promote D2D studies on social and local media, including TV, radio and print. The State Fair includes our study schedule in their mobile app, and lists some of our incentives and prize drawings in their "Deals, Drawings & Giveaways" brochure. We do daily postings on the D2D Facebook & Twitter pages during the Fair, and submit information to organizations catering to special eligibility groups for inclusion in newsletters, bulletins, etc. To help us promote your study, we ask you to provide (in the April Scheduling and Resources Survey):

- A short, catchy title for your study
- A brief lay description of your study (100 word maximum)
- The eligibility criteria you would like displayed on your sign (the fewer words, the better; e.g., do not include "English-speaking")

You are encouraged to advertise your projects on your own as well, especially if you have limiting eligibility criteria. Typically, you are encouraged to recruit outside, within the building lot perimeter, but *recruiting, advertising, or posting study materials elsewhere on the fairgrounds is prohibited.* For 2021, it is still yet uncertain as to whether or not this will be allowed.

After Fair Reporting

We ask each study to complete a brief follow-up survey on your experience conducting research at D2D and your suggestions for improvement. In addition, we request final enrollment numbers and the following raw data, including the date/time stamp: age, sex, race, education, and zip code of participants. This information is helpful to future researchers, and help us target promotional materials. Finally, in the spring, we'll ask for information on any peer-reviewed publications, graduate dissertations and theses, or grant applications submitted using data collected at D2D. We provide this information to potential sponsors and fairgoers looking for information on studies they participate in.

Billing and Shift Estimation

Each UMN study will be billed for shifts (and backpacks, if applicable) after the fair. Fees are \$867 per half-day shift for on-site studies and \$450 per shift for recruitment-only studies (no data collection). Studies with no UMN investigator will be charged additional administrative overhead fees.

Important: Please notify the D2D Manager immediately if you would like to change the number of shifts that have been reserved for you so we can attempt to fill your shifts from the waiting list. D2D is a self-supporting facility and depends on shift fees to cover operating expenses.

As described in the D2D Request for Applications, the number of shifts needed to reach your enrollment goal can be estimated based on the previous years' enrollment numbers or the following formula:

- *Number of shifts = enrollment goal x minutes participants spend engaged with study / number of participants (or iPads) your staff can manage at one time / 300, i.e., the number of minutes in a 5-hour shift.*

This estimate must then be adjusted up or down based on additional factors, such as your inclusion/exclusion criteria, methods, incentive, and recruitment efforts. Enrollment can also be affected by the weather and the mix of studies in the building at the time.

Handbook version date: 4/19/2021

Best Practice Guidelines for Recruitment & Consent of D2D Research Participants

1. Staff Training – prior to start of fair
 - a. All staff must be briefed by their PI/Coordinator regarding the study’s purpose, use of study data, and trained on all study protocols prior to the fair and recruiting participants.
 - b. Also consider a brief 5 minute team meeting at the beginning of each D2D shift to get team members re-oriented to study procedures prior to starting work. This may be especially helpful when utilizing students or volunteers who do not typically work on the project.

2. Participant Recruitment (1 minute)
 - a. Be a good research ambassador! Whether inside or outside of the D2D building, engage with fairgoers and invite them to learn about your study and the other projects in the building that day. Explain your study’s purpose and goals, eligibility criteria, a brief description of study activities, and expected time commitment.
 - i. If a fairgoer is not interested nor eligible for your study, consider recommending another study they may find more suitable.

3. Participant Consent (1-2 minutes)
 - a. If the fairgoer is interested in participating, after the initial engagement and overview of study goals, eligibility and activities, staff should go into more detail and discuss risks/benefits, confidentiality, voluntary nature, and compensation.
 - b. Take your time, allow the participant to calmly read the information, ask if they have questions, and answer all of their questions prior to consent.
 - i. Even if the participant seems disengaged with the consent process, it is the responsibility of the investigators and all study staff, to carry out a complete informed consent, allowing the participant time to consider whether or not to participate.
 - ii. The fair can be a hectic environment, but it is still very important make every participant feel cared for, answer all of their questions, with the goal being that they understand what they are agreeing to when they decide to participate.

4. Participant Assistance
 - a. Sufficient staff should be available to answer questions while participants are completing the study activities, monitor the correct completion of the study protocols, and insure confidentiality of responses by closing out the Redcap/Qualtrics forms after each participant completes a survey (iPad) or that forms are stored safely (paper).
 - b. Remember to thank participants and invite them to return again to D2D!

COVID-19 Health & Safety for 2021

D2D is in communication with the Fair and have been told to expect their announcement as to whether the fair will happen this year, and in what form, the first week of June. Until we hear definitively, we will continue with our usual planning and look forward to helping you. We are working closely with the University Health & Safety team to provide all those working in and visiting D2D with a safe environment. Information provided here is what is proposed in our Facility Sunrise Plan as of April 19, 2021. Undoubtedly, public health conditions and expert guidance will change between now and Day 1 of the fair, thus you can expect updates from us regarding building operations and protocols. For now, we are planning for the worst and hoping for the best.

Here are some of the things we're working on:

Together with University Health & Safety, D2D will develop BUILDING-LEVEL operational guidance and safety protocols. You are responsible for your STUDY-SPECIFIC sunrise plan, safety protocols and IRB approvals. We will work together to make sure our plans align to keep everyone safe. We are advised to think of the D2D building as an extension of the UMN campus, thus we will follow guidance for any research labs/clinics the same as on campus.

Operational Guidelines (as of 4/19/21):

Health check requirements

- All faculty, staff, students and volunteers entering D2D are required to personally log their temperature both before and after their visit. If any symptoms of COVID-19 are noted prior to a shift (including, but not limited to: fever, cough, shortness of breath, chills, headache, muscle pain, sore throat, fatigue, congestion, loss of taste or smell, or gastrointestinal symptoms), the person should notify their supervisor and not come to the fair.
- D2D will be tracking the names of all faculty, staff, students and volunteers who work each shift in the event that contact tracing becomes necessary. All those working in D2D will be required to sign in with a D2D staff member at the beginning of their shift and document their name and phone/email.

PPE requirements

Per University Health & Safety guidance, all persons inside the D2D building are required to wear a mask at all times. Faculty, staff, students, and volunteers are required to wear either:

- One KN95 mask OR
- Two non-medical grade masks, such as 1 disposable and 1 cloth face mask.

D2D will provide masks to all those working inside D2D. Shields and goggles will also be supplied for workers, however will not be required. Fairgoers or other visitors to D2D are required to wear a mask at all times, either surgical or cloth are acceptable. D2D will provide surgical masks to those fairgoers who do not have one at the front entrance. D2D will have signage inside and outside the building as reminders for everyone to keep their masks on.

Social distancing & capacity requirements

- Per University Health & Safety guidance, building capacity will be monitored to ensure approximately 1 person per 50 square feet of space. This means the building will be set up with only five studies at a time (unlike the typical 10) and building entry/exit will be restricted.
- Tables and chairs will be spaced out to ensure social distancing. After their study participation is complete, fairgoers will be asked to exit thru the side door to ensure one-way foot traffic patterns.
- D2D will have signage and floor markers to remind people to adhere to 6ft social distancing.
- Studies recruiting children or those with a protocol over 15 minutes will be housed under a tent in front of the building, on the concrete pad.
- The advice of University Health & Safety is to limit the building capacity to a maximum of 40 people; this total includes D2D staff, research team members, and fairgoers.
- Each study will be limited in the number of staff and participants, depending on their individual study needs. Either:
 - 2 staff with a maximum 5 participants at a time, OR
 - 3 staff with a maximum 4 participants at a time.

Disinfection protocol

Everyone working in the D2D building are responsible for helping to maintain a clean, disinfected and safe environment. D2D will provide all necessary cleaning supplies (unless specialized supplies are needed for specialized study equipment, those studies are asked to bring their own necessary supplies). D2D staff will assist with routine cleaning when appropriate, while maintaining social distancing. Research teams are required to disinfect all surfaces and equipment in-between study participants (tablets/keyboards/stylus, tabletop, chairs, study specific equipment). Cleaning protocol for will be to disinfect touch- points with Clorox wipes and/or alcohol spray. Gloves will be available for anyone who would like to use them during their post-participant disinfection. Hand sanitizer will be provided to each research booth and its use will be strongly encouraged. Fairgoers, once seated at the study station, should be provided the opportunity to sanitize their hands prior to consenting to participate. All those working at D2D will have soap and water available to wash hands at the back, exterior of the building whenever they choose.