

Exemption 56

An exemption to use a controlled substance for scientific purposes



Redacted Application
Template & Guide



Application form for an exemption to use a controlled substance for scientific purposes

(disponible en français)

Privacy Notice

The personal information you provide to Health Canada is governed in accordance with the Privacy Act. The collection of your personal information is authorized under the Controlled Drugs and Substances Act. This information will be used to process your application for an exemption to use a controlled substance for scientific purposes. Information may be used to provide reports to management. The information may also be used for research, planning, audit and evaluation purposes. In limited and specific situations, your personal information may be disclosed without your consent to law enforcement or in accordance with subsection 8(2) of the Privacy Act. Failure to provide the requested information may result in a refusal to process the application. This personal information collection is described online at [Info Source: Sources of Federal Government and Employee Information Health Canada](#). In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact Health Canada's Privacy Coordinator at hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

1. Application Type

- New
 Extension (no additional quantities)
 Extension (additional quantities)

- Amendment of a valid exemption
 Cancellation of a valid exemption
 Transfer of controlled substances from one researcher to another within an institution

If this is not a new application, please indicate the current authorization number

2. Identification**2.1 Principal Investigator**

Mr.

Mrs.

Dr.

Surname (last name)

Given Name(s)

2.2 Title and Qualifications

- B.Sc. M.Sc. Ph.D. M.D. D.V.M. D.M.D. D.D.S.

Practitioner Permit Number

Field of Study

Internal Medicine

Telephone Number

Email Address

Alternate Contact Name

Alternate Contact Email

Note: The minimum requirement of study for the applicant is a B.Sc. in an appropriate field

2.3 Address (where the substance will be used)

Institution / Company

Department

Drug Checking

Faculty

Street Address

Room Number

1

City

Province

ON

Postal Code

2.4 Mailing Address (where the substance will be shipped)

Same as above address

Institution / Company			
Department		Faculty	
Street Address			Room Number
City	Province	Postal Code	

2.5 Storage Address (where the substance will be stored)

Same as above address provided in section 2.3
 Same as above address provided in section 2.4

Institution / Company			
Department		Faculty	
Street Address			Room Number
City	Province	Postal Code	

3. Project or Study Description

Project Title (same as protocol)	Drug Checking Program- Scatr Device	
<p>Required Documents</p> <p><input checked="" type="checkbox"/> Protocol attached <input type="checkbox"/> Protocol previously submitted, if not amended <input type="checkbox"/> Approval of the Animal Care Committee (for in vivo studies)</p>		

Note: A copy of the protocol of the project and the most recent Approval of the Animal Care Committee (if applicable) must be submitted.

Please provide any further information

[REDACTED] drug checking program currently runs under the exemption of the Consumption and Treatment Services, that is slated to close at the end of March of 2025. After consultation with the community being served at the CTS, it was determined that the drug checking program would be well-received if provided 3 days per week in a mobile format. This requires a new exemption. [REDACTED] will also be applying for second exemption to provide drug checking out of our clinical hub space 2-3 days per week. Our community has noted that testing offered only at one location is a significant barrier to those seeking this service that has become heavily relied on service, test their substances that has proven to save lives.

Please provide a brief description of the use of the substance

Clients bring in their own street acquired/ unregulated substances to test, utilizing the Scatr device.

Please provide the reason for requiring an extension, cancellation or transfer of responsibility (if applicable)

4. In Vivo Administration

In vitro utilization
(*Please skip to section 5)

In vivo administration

When all of the following conditions are met, a subsection 56(1) exemption will not be required:

- The substances will be administered to animals solely by an appropriately licensed veterinarian;
- The animal is a patient of the veterinarian under their professional treatment; and,
- The controlled substance is required for the condition for which the animal is being treated

Administration of the following controlled substances will be performed by a licensed veterinarian, meet the above conditions and therefore do not require a subsection 56(1) exemption:

1	
2	
3	
4	

Animal Species		Number of animals (to be used under this exemption)	
Average Weight per animal		Animal carcasses will be disposed of by:	<input type="checkbox"/> Incineration <input type="checkbox"/> Other (please specify below): <input type="text"/>

4.1 Controlled Substance(s)

Name of Controlled Substance			
Initial Dose		Maintenance Dose	
Frequency of Maintenance Dose		Total Dose per Animal	

Name of Controlled Substance			
Initial Dose		Maintenance Dose	
Frequency of Maintenance Dose		Total Dose per Animal	

5. Supplier Of The Controlled Substance

- The quantity required is an estimate of quantity needed for a maximum period of one year. Attach additional copies of this page as necessary.
- **Please note that if the substance is unavailable in Canada, the Office of Controlled Substances may import on behalf of the applicant. In such cases, the applicant must provide a copy of the purchase order and a Purolator account number. Importation may take up to 3 months.**

Controlled Substance	*Foreign Supplier		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Brand Name	Concentration (if applicable)			
Quantity required for all submitted protocols	Quantity in inventory (from previous exemption if applicable)			
Quantity to be purchased				
Name of Supplier	Contact Name			
Street Address				
City	Province	Postal Code		
Telephone Number	Email address			

*Note: In the case of a Foreign Supplier, please make sure to fill out Appendix A: Import Order Authorization and Permit Application Form.

Controlled Substance		*Foreign Supplier	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Brand Name		Concentration (if applicable)		
Quantity required for all submitted protocols		Quantity in inventory (from previous exemption if applicable)		
Quantity to be purchased				
Name of Supplier			Contact Name	
Street Address				
City		Province	Postal Code	
Telephone Number			Email address	

*Note: In the case of a Foreign Supplier, please make sure to fill out Appendix A: Import Order Authorization and Permit Application Form.

6. Physical Security

Please provide a description of the physical storage and security measures to be used

Please refer to [REDACTED] Drug Checking Program protocols-1.2(a) for a description.

Note: Security must meet the requirements of the "[Directive on Physical Security Requirements for Controlled Substances](#)", available on the Health Canada website.

7. Declaration

7.1 Application Type: New, Extension or Amendment

I hereby declare that I am the principal investigator and that the controlled substance(s) will be used for scientific purposes mentioned in this application. I have read and understand the Directives on Physical Security Requirements of controlled substances and other requirements specified in the Controlled Drugs and Substances Act and its Regulations. The specified requirements are met, or will be met before I commence any activity associated with any exemption issued to me.

I also agree to comply with any terms and conditions that may be specified in any exemption issued to me.

Signature of Principal Investigator:		Date:	
		(YYYY-MM-DD)	

7.2 Application Type: Cancellation

I hereby declare that the exemption with authorization number [REDACTED], is no longer required.

- I attest that the total quantity of controlled substance was used and that there is no remaining inventory.
- I attest that there is a quantity of controlled substance remaining and it will be used for the protocol titled [REDACTED] under existing authorization number: [REDACTED]
- I attest that there is a quantity of controlled substances remaining and it will be destroyed.

Signature of Principal Investigator:	Date:
	(YYYY-MM-DD)

7.3 Application Type: Transfer

I hereby certify that I am transferring the controlled substance(s) named in the exemption with authorization number [REDACTED] to [REDACTED], to the Principal Investigator taking over responsibility of the controlled substance(s). The quantities being transferred are:

Name of Controlled Substance(s)	Quantity Remaining
[REDACTED]	
[REDACTED]	
[REDACTED]	

Signature of Outgoing Principal Investigator:	Date:
	(YYYY-MM-DD)

Signature of Incoming Principal Investigator:	Date:
	(YYYY-MM-DD)

8. Submission

Please email this completed Application Form and required documents to the Office of Controlled Substances at hc.exemption.sc@canada.ca or mail to the following address:

**Exemptions Section
Authorizations Division
Office of Controlled Substances
Health Canada
AL 0300B
161 Goldenrod Drwy
Ottawa ON K1A 0K9**

For further information, please contact the Exemptions Section at hc.exemption.sc@canada.ca

Appendix A: Import Order Authorization and Permit Application Form

The importation process will be initiated once an exemption for research purposes has been granted to the applicant pursuant to subsection 56(1) of the Controlled Drugs and Substances Act. Please ensure that your order is placed with the supplier prior to submitting this form. Note: This request is valid for one shipment only.

1. Purchaser Information And Shipping Address

Name of Principal Investigator			
Street Address (shipping)			
City	Province	Postal Code	
Country	Name of contact		
Telephone Number	Email address		

2. Order Information

Name of Supplier			
Street Address	City		
Province	Postal Code	Country	
Supplier Contact Name	Telephone Number		
Product Name	Catalogue Number		
Substance Name	Quantity		
Purolator Account Number	Purchase Order (PO) Number		

3. Certification

I hereby certify, that the above mentioned order, of which I am requesting, all costs associated with the importation, including cost of substance(s), customs duties and shipping of permit(s) and substance(s), will be paid by the applicant to the supplier.		
Name		
Signature:	Date	(YYYY-MM-DD)

For Office Only

Pursuant to the provision of the Controlled Drugs and Substances Act, application is hereby made for a permit to import the controlled substance listed above.					
HC Authorization Number		Import Permit Number		Valid until	(YYYY-MM-DD)
Port of Entry	Ottawa	Conveyance	Air		
QPIC Signature:			Date	(YYYY-MM-DD)	

Checklist for an application for an exemption to use a controlled substance for scientific purposes

This checklist is provided to assist you in ensuring that all the required information has been included in your application for a scientific exemption. Incomplete applications will be put on hold until the required information is received.

Completed Information

<input checked="" type="checkbox"/> Section 1	Application type.
<input checked="" type="checkbox"/> Section 2	Exemptions are issued to the Principal Investigator of each protocol. The address on the application is where the substance will be used.
<input checked="" type="checkbox"/> Section 3	The project title must be the same as the protocol along with a brief description of the use of the controlled substance.
<input type="checkbox"/> Section 4	Only include the number of animals and dosing information to be used under this exemption. For multi-year protocols, this number is the number to be used in one year.
<input type="checkbox"/> Section 5	Full details concerning the purchase of each controlled substance is required.
<input checked="" type="checkbox"/> Section 6	A description of storage and security that will meet the requirements of the “Directive on Physical Security Requirements for Controlled Substances”.
<input checked="" type="checkbox"/> Section 7	The declaration must be signed and dated by the principal investigator, or in the case of a transfer, both the incoming and outgoing principal investigators, and the original form submitted to our office.

Attachments

<input checked="" type="checkbox"/>	A copy of the protocol is attached with the application form or has been previously submitted and the protocol has not been amended.
<input type="checkbox"/>	In the case of a Foreign Supplier, Appendix A: Import Order Authorization and Permit Application Form is attached.
<input type="checkbox"/>	The most recent approval or renewal from the Animal Care Committee (if applicable)

Note: Additional copies of sections 4 and 5 may be submitted if required.

[REDACTED] Drug Checking

Program-Policies and Procedures

Application: Class 56(1) for exemption to use controlled substances for research purposes

Date: Feb 5, 2025

CONTENTS

- 1.1 [REDACTED] [Drug Checking Program - Background & Scatr](#)
 - 1.1(a) [Drug checking data reports](#)
 - 1.1(b) [Staffing and Hours of Operation](#)
 - 1.1(c) [Hours of operation](#)
- 1.2 [Staff Roles and Responsibilities](#)
 - 1.2(a) [Drug Checking Program Lead](#)
 - 1.2(b) [Security Plan](#)
 - 1.2(c) [Drug Checking Program Peer](#)
 - 1.2(d) [Staff Training Requirements](#)
 - 1.2(e) [Confidentiality](#)
- 1.3 [Equipment](#)
- 1.4 [Disclaimer Script for Clients](#)
- 1.5 [Protocol: Drug Checking Program Substance Preparation for Analysis](#)
- 1.6 [Protocol for \[REDACTED\] or Drug Checking Infection Control Routine Practices](#)
- 1.7 [Protocol for Storage, Substances Left Behind and Handover of Substances to University of Western Ontario for the Purposes of Drug Checking](#)
 - 1.7(a) [Managing Substances Voluntarily Submitted For The Purposes Of Quantitative and Trace Data Testing at The University of Western Ontario](#)
 - 1.7(b) [Storage](#)
 - 1.7(c) [Handover](#)
 - 1.7(d) [Protocol for Unidentified Substances Left Behind](#)
 - 1.7(e) [Protocol: Prevention of Unidentified Substances Left Behind](#)
 - 1.7(f) [Management of Unidentified Substances Left Behind](#)
- 1.8 [Protocol for Loss or Theft of Substances](#)

1.1 [REDACTED] Drug Checking Program - Background & Scatr

Scatr Series One uses dual spectroscopy technology to detect potentially toxic contents in drug samples, without compromising the integrity of the substance. By obtaining and analyzing both Raman and Near-Infrared spectra, the device will provide instant, real-time reporting on the identity and concentration of drug mixtures and their analogues. Using a cloud-based infrastructure, the Scatr Series One continuously updates to adapt to a constantly increasing sample size and the latest in spectroscopy science.

Drug checking is a community-based health service that allows people to test their drugs and receive real time results about what is in their substances, along with customized strategies to reduce harm. The program obtains real time results, therefore able to combine data from all samples checked to monitor the unregulated street drug supply. This prompt collection of data has allowed the program to monitor and provide same day drug alerts and disseminated everyday data to inform partners, emergency services and the broader community of toxic drug trends.

Drug Checking Program services will be available in the [REDACTED] Clinical Hub using the Scatr Series One drug checking device. No device is 100% reliable. Therefore, client education is important during every drug-checking encounter to ensure clients understand the possibility of inaccurate results.

Drug Checking Program services will be offered to clients who identify as being 18 years of age and older. *As per *University of Western Ontario Research requirements.* (**see page 3 of attached application documents**)

Data collection is a requirement of Health Canada for Drug Checking Program services. Each Drug Checking Program encounter must be recorded on the related Data Collection Form. (**See page 4 of attached application documents**)

Please note that [REDACTED] clinical hub has been in place for a period of 3 years and the private owner of the property is aware of all programs that are onsite.

1.1(a) Drug Checking Data Reports:

- A monthly report shall be generated from the Scatr drug checking device and submitted monthly (by the 15 th of each month) to the OCS at exemption@hc-sc.gc.ca.
- The monthly report shall include the requirements listed below:
- The number of drug checks performed at the Site;

- The results of drugs checking performed at the Site, including whether the substances identified were as expected, or inconclusive;
- The number of illegal substance samples sent off site for drug checking;
- If known, the results of drug checks conducted offsite, including whether the substances identified were as expected, or inconclusive.
- The general demographics of the clients served, such as age and gender; and
- Whether the results of the drug checking influenced the client's decision to retain or discard the illegal substance.

1.1(b) Staffing and Hours of Operation

The following outlines the minimum staffing requirements for the operation of the Drug Checking Program:

Staffing for the Drug Checking Program consists of 1 FTE Drug Checking Program Peer, and 1 FTE Drug Checking Program Lead.

- The Drug Checking Program will be offered only when there is a minimum of 1 Drug Checking Program Peer and 1 Drug Checking Program Lead.
- Drug Checking staff will rely on other staff that will be present in the clinical hub should the drug checking staff need to use the panic buttons located inside the drug checking room.
- The Drug Checking Program will run for 40 hours a week. The hours of programming will run on a 5 day a week schedule. An example of the Drug Checking Program schedule is as follows:

1.1(c) Hours of operation:

Mondays- 9:30am-4:30pm at ([REDACTED] st location)

Tuesdays- 11:00pm-1:45pm (stop1)2:00pm-5:00pm (stop2)(mobile service)

Wednesday-(stop1)10:00-12:00 pm, (stop 2)12:15 pm-2:00 pm, (stop3)2:15-5:00pm(mobile service)

Thursday-(stop1)11:00am-2:00pm, (stop2)2:15-5:45 pm, (stop3)6:00pm-7:30pm, (stop4) 7:45pm-9:30pm(mobile service)

Friday- 11:00am-4:30pm at ([REDACTED] location)

1.2 Staff Roles and Responsibilities

1.2(a) Drug Checking Program Lead

The Drug Checking Program Lead will support the development and oversight of a Drug Checking Program at [REDACTED] Clinical Hub. This will include all aspects of the Drug Checking Program development and delivery, oversight of program activities, and reporting and evaluation responsibilities. Responsibilities of the Drug Checking Program Lead include, but are not limited to:

- Contributing to the overall supervision of the Drug checking program, as well as the supervision of project staff.
- Developing processes and protocols associated with the program.
- Scheduling Drug Checking Program staff, and maintaining minimum staffing requirements for operation of the program.
- Coordinating staff training, orientation and ongoing professional development, including Drug Checking Program device training and installation.
- Overseeing the operation of the Drug Checking Program device.
- Ensuring necessary supplies are ordered for the Drug Checking Program.
- Promoting the Drug Checking Program in the community.
- Coordinating with external agencies who serve people experiencing homelessness/precariously housed and/or using drugs to provide information and community presentations related to the Drug Checking Program.
- Providing support and direction for managing the Protocol for the Storage and Handover of Substances to University of Western Ontario for the Purposes of Drug Checking.
- Providing support when substances are left behind or which involve loss/theft of unknown substances as outlined in: [REDACTED], Unknown Substances Left Behind and Loss/Theft of Substances.
- Ensuring Drug Checking Program visits are completed in a timely manner.
- Collecting feedback from clients regarding the service.
- Overseeing the gathering of statistical information and record keeping, as per the established evaluation criteria.

- Ensures that all records are retained onsite for a minimum of 2 years, or for the duration of the exemption, whichever is longer.
- Participating in regular supervision meetings with the Clinical Services Director.
- Ensuring staff are aware of emergency evacuation procedures.
- Ensuring the overall safety of staff and clients during drug testing.
- Ensuring that peers are supported in interpreting test results of testing are interpreted correctly by peers and delivered to clients accurately.
- Ensuring that confidentiality of the client during their visit is maintained at all times.
- Ongoing evaluation of the effectiveness and appropriateness of the services.

1.2(b) Security

Clients will arrive at the [REDACTED] Street location and will be let in the front locked door by the admin. All clients are signed in and out of the building on a log form. Administration will call back to drug checking staff to let them know the client has arrived. Drug Checking staff will then escort clients through another locked set of doors, into the hallway, then into the drug checking office, which also locks.

All doors are key access only, which are issued to staff at the [REDACTED] Hub. All Keys are marked with a number which is assigned to each individual staff member.

If keys are lost or stolen, staff call the RPIC on duty or after hours on call to let them know. Locks will then have to be changed within 24 hours.

RPIC and A/RPIC will be the only key holders for the drug checking office. This also includes the keys to the drug checking safe and the substances left behind safe. There will also be a keypad entry number for both safes.

There will be two panic buttons located in the drug checking room space. One that is slightly hidden below the upper cupboards behind the sink. The second panic button will be located on the staff side of the drug checking table on the leg closest to the door, out of sight of clients. (*Please refer to page 6-floor plan*)

The panic button alarm will be located in the admin area and RPIC(Managers office), who will respond immediately to the drug checking office. Staff will also carry walkie talkies on their person at all times.

Clients will sit farthest from the door in the drug checking office and staff will sit on the opposite side of the table near the door.

After the visit is complete in the drug checking office, staff will then escort the client out of the building.

1.2(c) Drug Checking Program Peer

The Drug Checking Program Peers are individuals who have lived/living experience as a person who has used/ uses drugs and/or has been street involved. They have insight into the culture of the community [REDACTED] serves. Their role is focused on deepening the relationships with the community and building trust with the goal of increasing participation in [REDACTED] services. Peers also advise and educate Sanguen on how to better care for people with diverse needs. In addition, Drug Checking Program Peers will take every available opportunity to provide teaching and/or counseling (e.g. assess need for naloxone training, safer injection strategies, overdose/drug poisoning prevention, etc.) to clients.

Responsibilities of the Drug Checking Program Peer include, but are not limited to:

- Supporting relationship building with people who use drugs in the community. Peers also support clients who don't use drugs that come in to test out of concern of loved ones.
- Acting as a first point of connection with clients who access the [REDACTED] Health Centres Drug Checking Program by introducing self and role.
- Orienting clients to [REDACTED] Health Center services provided, including the Drug Checking Program and the many other programs [REDACTED] Health Center offers. Providing care/interventions as appropriate including but not limited to, in collaboration with the team lead, emergency and non-emergency medical care, teaching, counselling, drug checking, and referrals to harm reduction services and treatment programs.
- Communicating results of Drug Checking Program scans with clients, with the support of the Drug Checking Program Lead.
- Educating, coaching and training clients about the Drug Checking Program, drugs and drug safety, harm reduction supplies, Harm Reduction key messaging and assessing the need for naloxone training.
- Ensuring routine precautions and infection control practices are performed in accordance with Procedure 1.6 *Protocol for (CTS) Infection Control Routine Practices*, by disinfecting common surfaces once client vacates the room and at the beginning and end of each shift including:

- Table and chair surfaces
 - Phone equipment
 - Computer equipment
 - Drug Checking Device and Aluminum Chips (See step #17 in Protocol 1.5)
 - Door handles
 - counter tops
 - any mobile unit surfaces
- Performing routine precautions and promptly cleaning-up any spills and bodily fluids as needed throughout the shift. Maintaining a culture of safety and respect in accordance with [REDACTED] Health Centers Client Agreement, Code of Conduct, and Critical Incident policy and procedure by:
 - Not tolerating, ignoring, or condoning discrimination, harassment or other harmful conduct, and
 - Responding to any incident of violence, discrimination, harassment or other harmful conduct in accordance with The [REDACTED] Critical Incident and The [REDACTED] Restricting Client Access procedures as appropriate.
- Preventing the loss, theft and diversion of controlled substances by adhering to policy #1.7 *Protocol for Loss or Theft of Substances* and substances left behind
 - Assessing the Drug Checking Program office for substances left behind when a client vacates the space.
- With the support of the Drug Checking Program Lead, Drug Checking Program Peers will collect demographic data and report to the Drug Checking Program Lead.
- Informing clients about broader services available including but not limited to [REDACTED] Health Centre services, wound care, immunization, screening for BBSTIs, counselling, opioid substitution therapy, primary care, shelter, food, etc. and providing referrals to treatment, as appropriate.
- Promoting the Drug Checking Program and sharing other information from the project to community members including those who might not access [REDACTED] Health Centers services and to staff at other agencies.
- With the support of the program lead and at the end of the shift ensuring all documentation and logs, laptops and any devices are stored and locked in a specified cabinet.

1.2(d) Staff Training Requirements

- Online WHIMIS
- Online workplace violence, harassment and bullying training
- Online privacy training
- Online AODA
- Health and safety awareness
- De escalation training
- Valid/up to date CPR training
- Review of expectations for clean up and disposal of used harm reduction supplies
- Naloxone training
- Familiarity with the relevant *Decision Support Tool for the use of Naloxone HCI (Narcan) in the Management of Suspected Overdose in Outreach and Harm Reduction Settings*
- Mobile Van training
- [REDACTED] Health Centres harm reduction 101
- Hep C
- Training on drug testing device and result interpretation/safe use

1.2(e) Confidentiality

Drug Checking Program staff will not share any results of Drug Checking Program scans on or off site in order to protect the privacy and anonymity of the clients participating in the Drug Checking Program. Data will only be shared for the purposes of reporting to Health Canada and the Ontario Ministry of Health, and University of Western Ontario/Scatr for the purposes of their research project.

1.3 Equipment

The Drug Checking Program will be equipped with the following:

- Drug Checking Device
- Laptop
- Aluminum chips
- Timer
- Pill Crusher
- Scale
- Cavicide wipes

- Isopropyl alcohol wipes (70%)
- Hand sanitizers on the desk area of the drug checking room.
- Gloves in a variety of sizes (small, medium, large)
- Dime bags and envelopes
- One large biohazard storage container and tongs
- Hand sanitizer and moist towelettes for hand washing
- An emergency first aid kit that includes a Naloxone supply, syringes, needles for IM injection (1"-1 ½" 22-25 gauge), alcohol swabs, cotton swabs, tape, oximeter, scissors/shears.
- Emergency over dose response flow sheet

1.4 Disclaimer Script for Clients

Prior to drug checking, staff will use their professional assessment to determine if the client has sufficient cognitive capacity in the moment to understand what is being asked of them.

Review the following information with the client:

- All participation is anonymous and confidential. You can choose to share your results with others if you wish.
- The test is not 100% accurate. A test can warn you of many substances that may be in your sample, but cannot confirm all the contents of the drug sample provided. There is a small possibility of false negatives or positives and the findings are not necessarily conclusive.
- Substances can be irregularly distributed within the sample.
- The portion of the sample that is prepared after testing may differ from the results provided.
- We will need between 1-2 mg to get a good result. The sample will be returned to you after the test and the device does not destroy the sample.
- The results will take either 4 minutes (short scan), 8 minutes or 14 minutes (long scan). The longer the test, the more accurate the results.
- Results do not guarantee your next dose will be the same, even if the drugs come from the same “batch” or the same dealer.
- Staff will not provide guidance, advice, or recommendations on consumption based on results, as each individual’s biochemical ability to process drugs is

unpredictable, thus making recommendations risky.

- If an unknown substance is identified during testing, you have the option to send the sample to be further tested at Western University under a mass spectrometer. You will not receive this sample back due to the dilution process for the mass spectrometer.
- Do you have any questions? Are you interested in learning more about this service?

1.5 Protocol: Drug Checking Program Substance Preparation for Analysis:

Only Drug Checking Program staff trained to handle controlled substances will be permitted to handle the drug samples as well as the on-site SCATR device and SCATR software for data recording.

1. Staff will review the information noted above with the client.
2. Staff will explain to clients that their █ code will be used for the purposes of the Drug Checking Program and will allow them to access previous scans.
3. The client will be provided with a Letter of Information and Consent provided by University of Western Ontario Health Sciences that explains the research study.
*See below.
4. Staff will ask the client what the substance sample is expected to be, and the staff will describe the physical appearance of the sample, and record it in the Scatr dashboard.
5. The client will place an approximate 1-2 mg amount of crushed-powder form of the substance they are intending to use on one of the aluminum Scatr chips provided.
6. Staff will insert the chip into the Scatr mapping system.
7. Staff will activate the Raman spectroscopy system via Bluetooth through the online SCATR Dashboard (via on an onsite laptop).

8. The substance sample will be scanned and results will appear in real-time. The scan can be cancelled and the substance sample can be returned to the client at any time. (*an incomplete scan will affect the accuracy of the results).
9. While the client is awaiting the results of the testing they will be asked the following demographic information requested by UWO for the purposes of their research project (clients should be given the option whether or not to respond).
 - o What is your gender?
 - o What is your age?
 - o Do you live with chronic pain? (Y/N)
 - o Do you identify as Indigenous? (Y/N)
 - o Do you identify as black, racialized or a person of colour? (Y/N)
 - o What is your preferred language?
 - o Do you identify as 2SLGBTQI+ or another sexual orientation or gender identity? (Y/N)
10. Staff will communicate the results of the scan via a laptop monitor handled only by staff.
11. The results are compiled and stored in the Scatr database.
12. Staff will advise the client if their sample has been identified as statistically significantly similar to a substance that has been associated with a past drug poisoning/overdose.
13. The sample will be returned to the client on the aluminum Scatr chip. The client can transfer the sample to a container of choice (ie. cooker, bag, jar, foil wrapper) for consumption at a later date/time or to be sent for mass spectrometry (see step or to be discarded).

*For procedures on how to deal with substances left behind or discarded, see Policy #1.7(d) *Protocol for Substances Left Behind*.

*For procedures on how to deal with substances voluntarily submitted, see Policy #1.7 *Protocol for Storage and Handover to University of Western Ontario for the Purposes of Drug Checking*.

14. Staff are required to clean each Scatr aluminum chip following the scanning process.
 - o Once the client has removed their substances from the chip, using protective gloves, staff will wipe the chip with 70% Isopropyl Alcohol

wipes, to ensure no substance debris is left behind and to avoid cross contamination with any future substance scans.

- o Any wipes used for the cleaning process can be discarded in a biohazard storage container. Staff will refer to policy # **1.6 Infection Control Routine Practices**

15. Staff will complete the documentation of the drug checking interaction and verbally ask the client how the results of the scan will affect the client's decision to consume. Examples of which are:

- a. Reducing drug quantity
- b. Discarding the drug
- c. Making no change to their plan
- d. Unknown

This is a good opportunity to provide some further education, and harm reduction tips.

**All documentation will be recorded on the Drug Checking Program Data Spreadsheet.*

16. If the client is interested in quantitative and trace data, their sample can be sent to University of Western Ontario via process and courier arranged by Scatr Inc.

See policy # **1.7 Protocol for Storage and Handover of Substances to University of Western Ontario for the Purposes of Drug Checking.*

17. Staff will clean the Drug Checking Program office in accordance with the Sanguen Health Center policy **1.6 Protocol for Infection Control Routine Practices** procedure in between each client visit.

1.6 Protocol for [REDACTED] or Drug Checking, Infection Control Routine Practices

Background

This policy outlines the routine precautions for infection control and provides direction in preventing or reducing the risk of transmission of microorganisms to service users and staff of the [REDACTED] Health Centres Clinical Hub.

Maintaining a clean and safe health care environment is an essential component of infection prevention and control (IPAC) and is integral to the safety of clients and staff.

Environmental cleaning and disinfection should be performed on a routine and consistent basis to provide a safe and sanitary environment.

PROTOCOL:

The following measures will be implemented in the [REDACTED]/Drug Checking Program office:

- Upon entry into the Drug Checking office, service users will be encouraged to wash or sanitize their hands.
- Following drug testing, each service user will be instructed to dispose of their baggies or used containers in the biohazard container accessible in the mobile unit.
- Staff are responsible for supervising the disposal process
- If staff need to dispose of a syringe or other drug use equipment they must do so with gloves and tongs provided in the drug checking office.
- Surfaces must be cleaned of visible soil before being disinfected, as organic material may inactivate a disinfectant. Staff will be required to clean each exam room using protective gloves and approved disinfectants. One wipe should be used for each surface. Clean and disinfect all surfaces of the booth and chair, from least frequently touched to most frequently touched (cleanest to dirtiest) and from high to low. Allow the surface to dry to maximize contact time with the disinfectant.
- [REDACTED] or Drug Checking staff are responsible for removing filled biohazard containers, placing filled biohazard containers into the larger biohazard storage containers and replacing filled biohazard containers.

Staff are not required to wear additional Personal Protective Equipment (PPE) while conducting Drug Checking Program services, as staff are not handling the drug. Staff may choose to utilize gloves during the drug-checking encounter. Staff should use protective gloves during the cleaning protocol . Wearing a mask during drug checking is not required. There is no risk to staff regarding airborne particles or any other inhalation risk during the procedure. Wearing a mask unnecessarily can increase stigmatization and isolation for clients.

**Staff should follow the COVID protocols in place at the site regarding PPE.*

1.7 Protocol for Storage, Substances left behind and Handover of Substances to University of Western Ontario for the Purposes of Drug Checking

BACKGROUND

This protocol provides Drug Checking Program staff with direction on how to manage substances voluntarily submitted for the purposes of mass spectrometry testing via Scatr Inc. at the University of Western Ontario (UWO) by clients of the Drug Checking Program.

Any substances that are voluntarily submitted with the Drug Checking Program for mass spectrometry testing at UWO will immediately be brought to the attention of the Responsible Person in Charge (RPIC) or Alternative Responsible Person in Charge (A/RPIC) on duty for safe storage and reporting to Scatr Inc. Substances submitted will not be returned to service users and service users will not receive any reimbursement for the substances submitted.

PROTOCOLS

1.7(a) Managing Substances Voluntarily Submitted For The Purposes Of Quantitative And Trace Data Testing AtThe UniversityOf WesternOntario

If the service user of the Drug Checking Program is interested in quantitative and trace data, their sample can be sent to University of Western Ontario via process and courier arranged by Scatr Inc. University of Western Ontario will conduct Raman spectroscopy scanning and mass spectroscopy testing (to provide quantitative data). The quantitative results will be provided within two weeks of sample submission in addition to Raman spectroscopy data. In order to access the mass spectroscopy results, a service user will need to inform a Drug Checking Program staff member the client used to originally save the scan. As mass spectroscopy destroys samples, these samples will not be returned to service users.

Staff can use the following script with service users who are participating in the Drug Checking Program:

"Would you be willing to give the substance to us to send to Western University in London Ontario for a detailed analysis? This will destroy the sample. You can use the client code or sample serial code provided to check the results of this analysis in about

2 weeks time and a hard copy of the result will be sent back here with your client code that the drug checking program uses.”

In the event that a service user voluntarily gives a substance to the Drug Checking Program for the purposes of mass spectrometry testing at the UWO, Drug Checking Program staff will follow the procedure below:

1.7(b)Storage:

- Staff will immediately inform the Responsible Person in Charge (RPIC) or Alternative Responsible Person in Charge (A/RPIC) that a service user has agreed to submit their substance for quantitative and trace data testing (mass spectrometry).
- The RPIC or A/RPIC will login to the Scatr dashboard, under the laboratory tests subsection, click on the plus sign to generate a Unique ID for the substance. Enter in the expected substance name and description of the substance. This Unique ID is generated for each sample that is to be couriered to UWO. If there are multiple samples to be sent out, then each sample will have its own Unique ID. Entering the substance into the Scatr dashboard under “laboratory tests” lets Scatr know that samples are ready to be picked up.
- The RPIC or A/RPIC will put on gloves and place the substance in an envelope, which is then sealed. The RPIC or A/RPIC will ensure that each sample envelope is labelled with its own entry number, Unique ID, and date of submission, and two staff signatures.
- The RPIC or A/RPIC will place the envelope in the pink safe located in the locked cupboard on the right hand side under the sink. The pink safe is labelled “substances to be sent away for further testing”. Only the RPIC and A/RPIC will have access to the locked safe.
- The RPIC or A/RPIC will then enter the sample identifiers into the “substances to be sent away for further testing” log book. A courier will advise the site when the planned pick up will occur.
- If any substance is lost or stolen once in the possession of [REDACTED] staff or a client reports the loss or theft of a substance, staff will follow the Protocol for Loss or Theft of Substances.
- If the courier does not arrive within eight days since the substance has been placed in the pink Drug Checking Program Safe, the RPIC or A/RIPC will follow the Protocol for Substances Left Behind.

1.7(c) Handover:

- When a new courier arrives to transport the substance, RPIC or the A/RPIC will request proof of ID and photocopy the ID provided. The photocopied ID will be stored in the Drug Checking Program safe for future reference.
- When the courier arrives to transport the substance, the RPIC or the A/RPIC will unlock the Drug Checking Program safe and transport the envelope containing the substance into the lockbox the courier has brought. The RPIC or A/RPIC will lock the lockbox with the combination provided by Scatr Inc. and send the lockbox with the courier to the UWO laboratory, as arranged by Scatr Inc.
- The handover occurrence will be logged into a record-keeping book. The log book will contain the following information:(**see page 8 of the attached application documents**)
 - Entry Number (label envelope with this number)
 - Date and time substance was submitted by the service user
 - Location of where substance was submitted by the service user (i.e. Drug Checking Program).
 - Name of staff person completing the log/placing substance in the safe.Date and time that entry was completed on the Scatr dashboard to request pick up of the substance.
 - Name and signature of courier who removed substance.
 - Verification the name of the courier matches the photocopied ID.
 - Date and time substance was removed from (Name, signature and initials of witnessing authorized staff member) (i.e. RPIC or the A/RPIC)
- At this point, Scatr Inc. is responsible for tracking the lock box and reporting any missing/stolen substances and/or tracking devices. [REDACTED] Health Centre and the Region of [REDACTED] will not be held accountable for the substance after the lockbox has left the [REDACTED] Clinical Hub location.
- Scatr will track the lockbox with Apple Airtags and an independent software engineer team lead from GeoTab. This will be arranged by and the responsibility of Scatr Inc. If any substance is missing after leaving the Clinical Hub location OR an Apple Airtag is lost/stolen/taken to a location not permitted while holding substances, the RPIC must be informed immediately.

Results:

- Scatr Inc. will email the RPIC or A/RPIC a PDF with the results of mass spectrometry within two weeks after a substance has been transported to UWO.

When a service user wants to check the results of the substance they submitted through this process, they will book an appointment with the Drug Checking Program or drop in during Drug Checking Program operating hours. The service user will provide the Drug Checking Program staff member with their client code.

1.7(d)Protocol for Unidentified Substances Left Behind

BACKGROUND

This protocol provides Drug checking Program (DCP) staff with direction on how to manage unidentified substances left behind by clients in the Drug Checking program area.

Any unidentified substances that are left in the DCP area will immediately be brought to the attention of the RPIC or A/RPIC on duty for safe storage and reporting to police. Unknown or controlled substances left behind will not be returned to service users.

1.7(e)Protocol: Prevention of Unidentified Substances Left Behind

Before drug testing happens: DCP Staff will ensure that new clients are aware of the protocols and their responsibilities as they relate to unidentified substances left behind. DCP staff will inform clients that:

- They must have pre-obtained their drugs before entering the DCP area
- They must remain in possession of their own drugs at all times
- Drug dealing is prohibited at the [REDACTED] Health Centres clinical hub/Drug checking program and all activity will be monitored by [REDACTED]/DCP staff
- Any used drug use equipment (ie: baggies, containers used to bring samples in) will be discarded in the yellow biohazard/sharps bin in the DC room.
- Any substances abandoned or accidentally left behind in any of the [REDACTED]/DCP areas will be removed immediately and transferred to the Waterloo Region Police Service without option for client retrieval.

Staff will address any client questions or concerns related to [REDACTED]/DCP protocols and drug possession.

1.7(f) Management of Unidentified Substances Left Behind:

In the event that any substance(s) or precursors are left behind in the service area by a service user:

- The RPIC or A/RPIC will put on gloves and place the substance in an envelope, which is then sealed, dated and signed.
- If the A/RPIC is on site they will inform the Responsible Person in Charge.
- The RPIC or A/RPIC will then place the envelope in the black safe labeled “Unidentified Substances Left Behind”, which is located in a locked cupboard located under the sink on the left side, in the drug checking office. The safe is bolted down in this cupboard. Only the Responsible Person in Charge and Alternative Person in Charge will have access to this locked safe.
- The [REDACTED] Region Police Services [REDACTED] will be contacted immediately and a request will be made for the substance to be picked up. The [REDACTED] staff member will log out the envelope(s).
- The occurrence will be logged into a record-keeping book. The log book will contain the following information:(***See page 9 of the attached documents of the application***)
 - Entry Number (label envelope with this number)
 - Date and time substance was found
 - Location where substance was found
 - Name of staff person completing the log/placing substance in locked box
 - Date and time that the [REDACTED] Region Police Service was requested to pick up the substance
 - Name, badge number, and signature of Police Officer who removed substance
 - Date and time substance was removed from drug checking space.
 - Name, signature and initials of witnessing authorized staff member (i.e. RPIC or the A/RPIC)

1.8 Protocol for Loss or Theft of Substances

BACKGROUND

This protocol provides [REDACTED] Health Centres Drug Checking program (DCP) staff with direction on how to prevent and address the loss or theft of substances left behind by clients in the drug checking office.

In the event a client reports substances lost or stolen, local police will be notified immediately and the Office of Controlled Substances will be notified within 24 hours.

PROTOCOLS

Loss or Theft of Substances between Clients

If a client reports the loss or theft of a substance in the Drug Checking area, the following steps will be taken:

1. Staff will inform the Responsible Person in Charge or Alternate with any reported details of the incident.
2. If appropriate, the RPIC or ARPIC will report the incident to [REDACTED] Region Police Services and complete the Incident Reporting Form.

Loss or Theft of Substances from Drug Checking staff

If any controlled or unknown substance is lost or stolen once in possession of the CTS staff, the following steps will be taken:

1. Staff will inform the Responsible Person in Charge or Alternate with any reported details of the incident. A formal incident report form will be submitted as per Sanguen Health Centres policies within 24 hours.
2. The RPIC or ARPIC will immediately report the incident to the [REDACTED] Region Police Services and to the Office of Controlled Substance within 24 hours. The following form should be accessed, completed in entirety and submitted by email to hc.exemption.sc@canada.ca.

<https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances/compliance-monitoring/loss-theft-forgery.html>

Letter of Information and Consent**Client Code:** _____

Use your client code above to get results at the site.

Your client code is the number you can use to check your drug test results.

Project Title: Creating a Drug Checking Network Using Machine Learning Enabled Spectrometers

Principal Investigator (PI): Professor Francois Lagugne-Labarthet, Faculty of Science, Western University, London, ON, Canada. 519-661-2111 x81006 – flagugne@uwo.ca

Dear Prospective Participant,

We are inviting you to participate in a research study conducted by Dr. Francois Lagugne-Labarthet and Dr. Abe Oudshoorn of Western University. This project will provide voluntary drug testing to clients of supervised consumption sites in Ontario.

Participants must be 18 years of age or older and have 0.5mg of substance or greater for testing.

What is the purpose of the study?

The purpose of this study is to give Canadians data regarding drug consumption. Currently, there is very limited access to drug-checking across Canada for people who use drugs (PWUD). The lack of drug-checking services leads to people consuming substances that they do not intend to consume such as fentanyl and its analogs. This leads to accidental overdoses and deaths. We want to understand both what drugs are being consumed in Ontario, but more importantly, how learning about what is in your sample might impact decisions you make around using. This is taking place in 10 supervised consumption sites across Ontario and we will conduct 24,000-65,000 drug tests.

What will I do?

Your sample test will take either 5 minutes (short scan) or 15 minutes (long scan). The length of the scan means basically how detailed a view we take of your sample. This effects how precise we can be in terms of understanding exactly what is in your sample and in what amount. (In technical terms, the scan is using spectroscopy and a short scan uses 625 spectra whereas a long scan uses 2500 spectra.) While you wait for your drug test result we will ask you some demographic questions. It's your choice to answer these or not. When the result comes back, you can learn about what is in your sample and then we will ask if you will still be using this sample today, delaying use, reducing use, or choosing not to use the substance. Please note that the results are not 100% guaranteed and there is a small possibility of false positives or false negatives and the findings are not necessarily conclusive. If not using the substance, we will request your permission to send this to Western University in London Ontario for detailed analysis. The results of this analysis will be returned here for you to pick up if you wish. You can also access the results of today's scan or the Western University analysis online using a code we will provide. Choosing to participate or not today will not affect your access to other services here at the harm reduction site.

Letter of Information and Consent

What are the risks and benefits of the study?

There are risks to anonymity associated with the study. This includes the possibility that a worker unintentionally records identifying information about you. In order to prevent this, the device will delete a scan from the database if it contains a name, email, phone number, or address.

Secondly, we acknowledge that the information provided from the scan can put you in a tough situation to make choices about your use. Your harm reduction worker can't counsel you regarding what is in your test, but can provide you information about substances and substance use.

A final risk is that you may overdose after participating in the drug checking. Whether or not a controlled substance is detected by the device, your results will include a statement clarifying that the risk of consuming an unknown sample can result in adverse side effects, overdose, or death.

Can I withdraw from the study?

Yes, you may withdraw from the study at any time prior to publication of the findings without negative consequences. If you would like to completely remove your data from the study, you can use their client code from the top of this letter of information. They are able to do so by asking a harm reduction worker who will forward this request to the lead researcher for deletion of your data.

Compensation

There is no compensation for participation in this study.

Is the study voluntary and confidential?

Participation in this study is completely voluntary. The research team will strive to maintain privacy and confidentiality. You will not be required to provide any directly identifiable information such as your name or date of birth. With your permission, we will record your gender, age, racial/ethnic identity, preferred language, and if you identify as LGBTQ or another minority sexual orientation or gender identity. These will only be reported all together for all participants at a site, not individually.

Western University Health Sciences Research Ethics Board and representatives may access study materials for monitoring purposes.

Your data from the scan device database will be provided electronically to the Western researchers named above for analysis. This research data will be stored for 7 years post-publication, and subsequently deleted.

Results of the Study

Results of the scans will be shared monthly in a report to each supervised consumption site. The results of the study may be published in scholarly journals, presented at research conferences, and shared with relevant stakeholders in the health sector. The results will also be shared in a report to the project funder, Health Canada.

Letter of Information and Consent

Conflict of Interest

The testing devices are created by a company called Scatr. The study researchers have no conflict of interest in the work and no financial relationship to Scatr. Scatr has no on-site involvement in regards to data collection. All will be done by the SCS harm reduction workers who have no conflict of interest. Additionally, Scatr is not doing the data analysis or generating the site reports. Data is simply being provided to the research team who will do the analysis and dissemination of results independently.

As the developer of the drug testing device, Scatr may financially benefit from the results of the study.

Consent

Providing your sample for testing is indication of your consent to participate.

Dr. Lagugne-Labarthet and/or others intend to claim sole ownership of any research results consistent with this consent. By consenting to this study, you agree that Dr. Lagugne-Labarthet can apply for patents and you will not receive any financial benefit that might come from the research.

For More Information:

Western University Health Sciences Research Ethics Board (HSREB) requires access to the study records to monitor the conduct of this research. Please contact the Office of Human Research ethics if you have questions or concerns about your rights as a participant and/or the conduct of this study.

Phone: (519) 661-3036

Email: ethics@uwo.ca

Please contact Dr. Lagugne-Labarthet, the Principal Investigator, with any questions pertaining to the study, including the purpose and participant requirements.

Phone: 519-661-2111 x81006

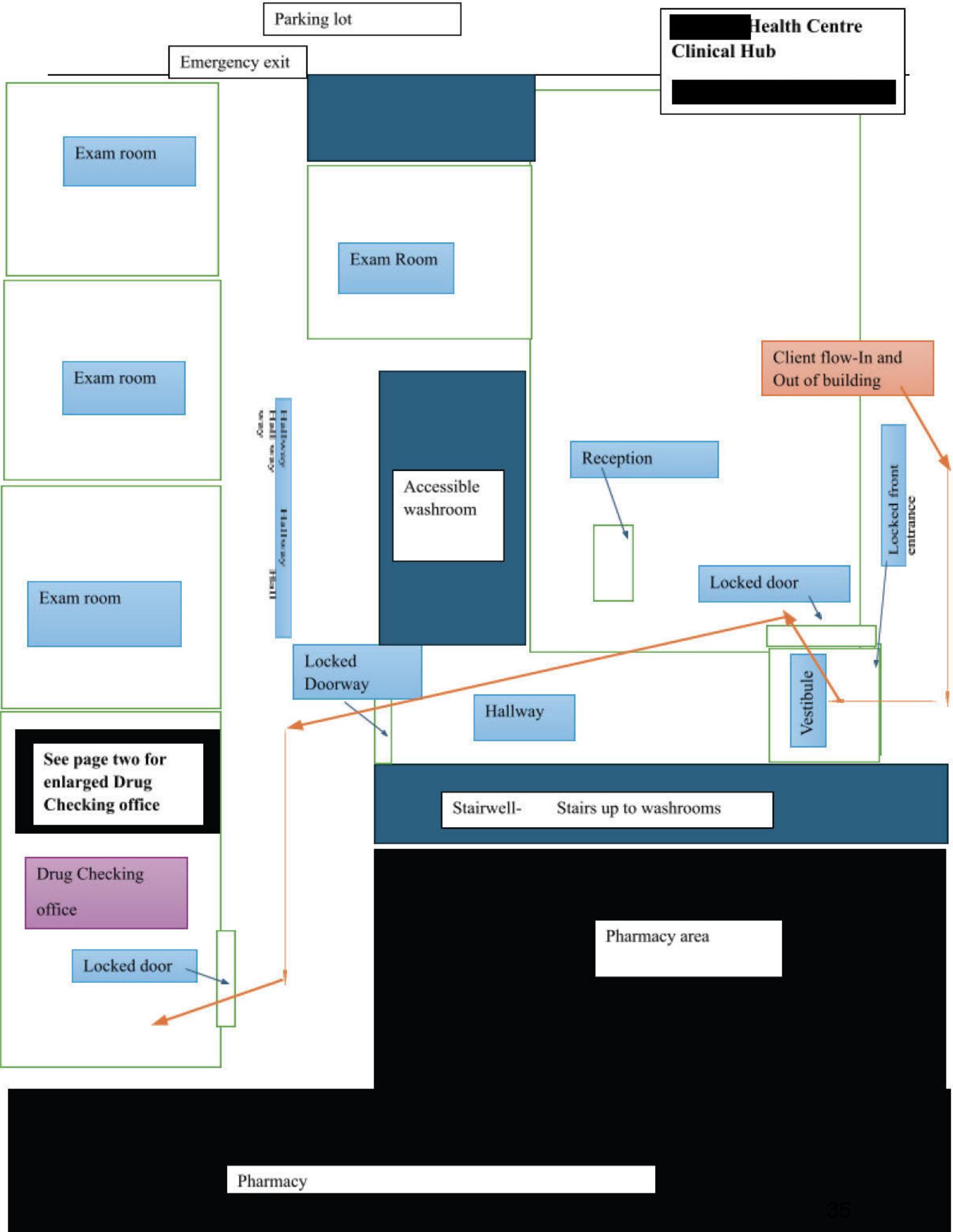
Email: flagugne@uwo.ca

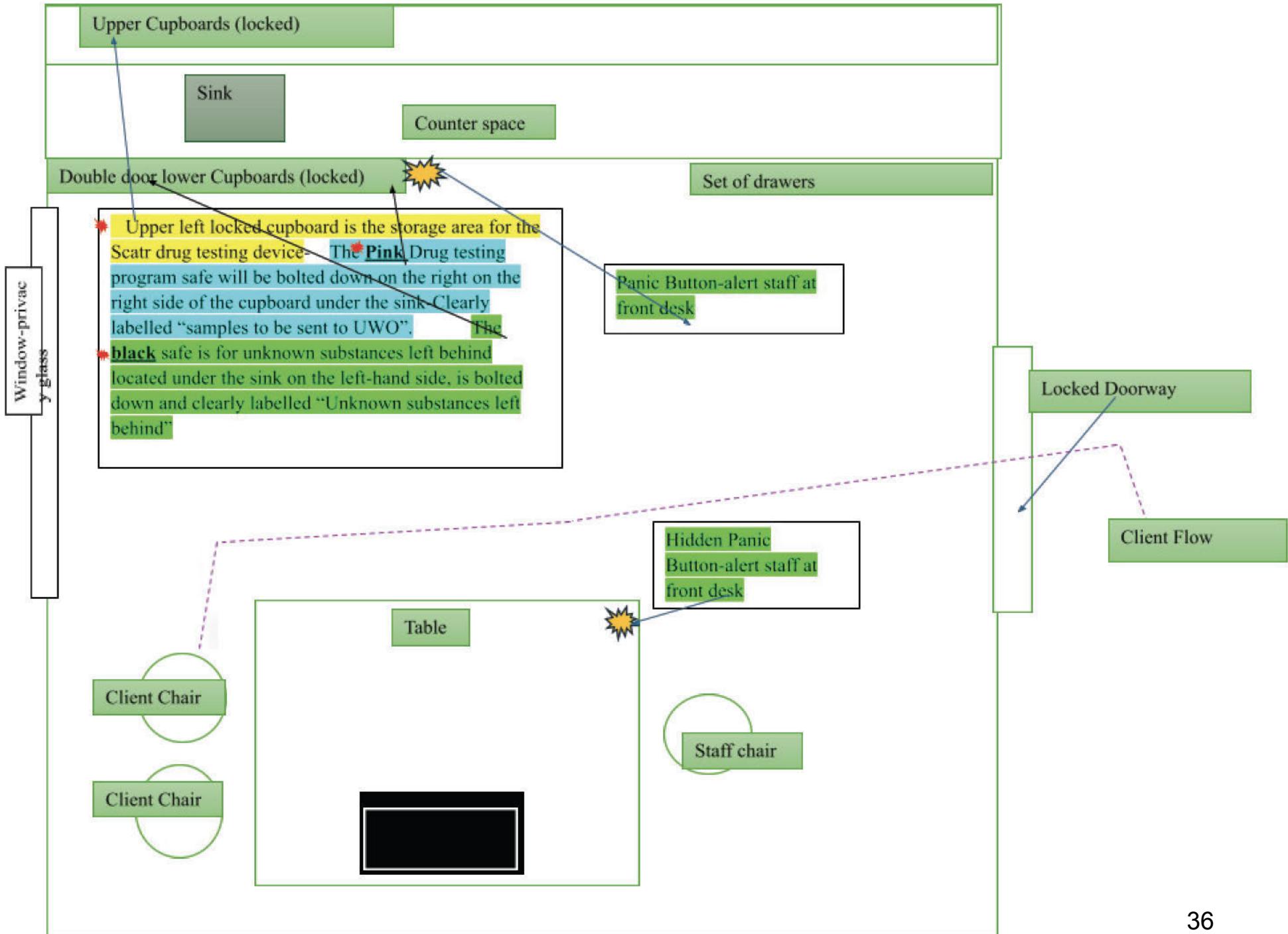
Sincerely,

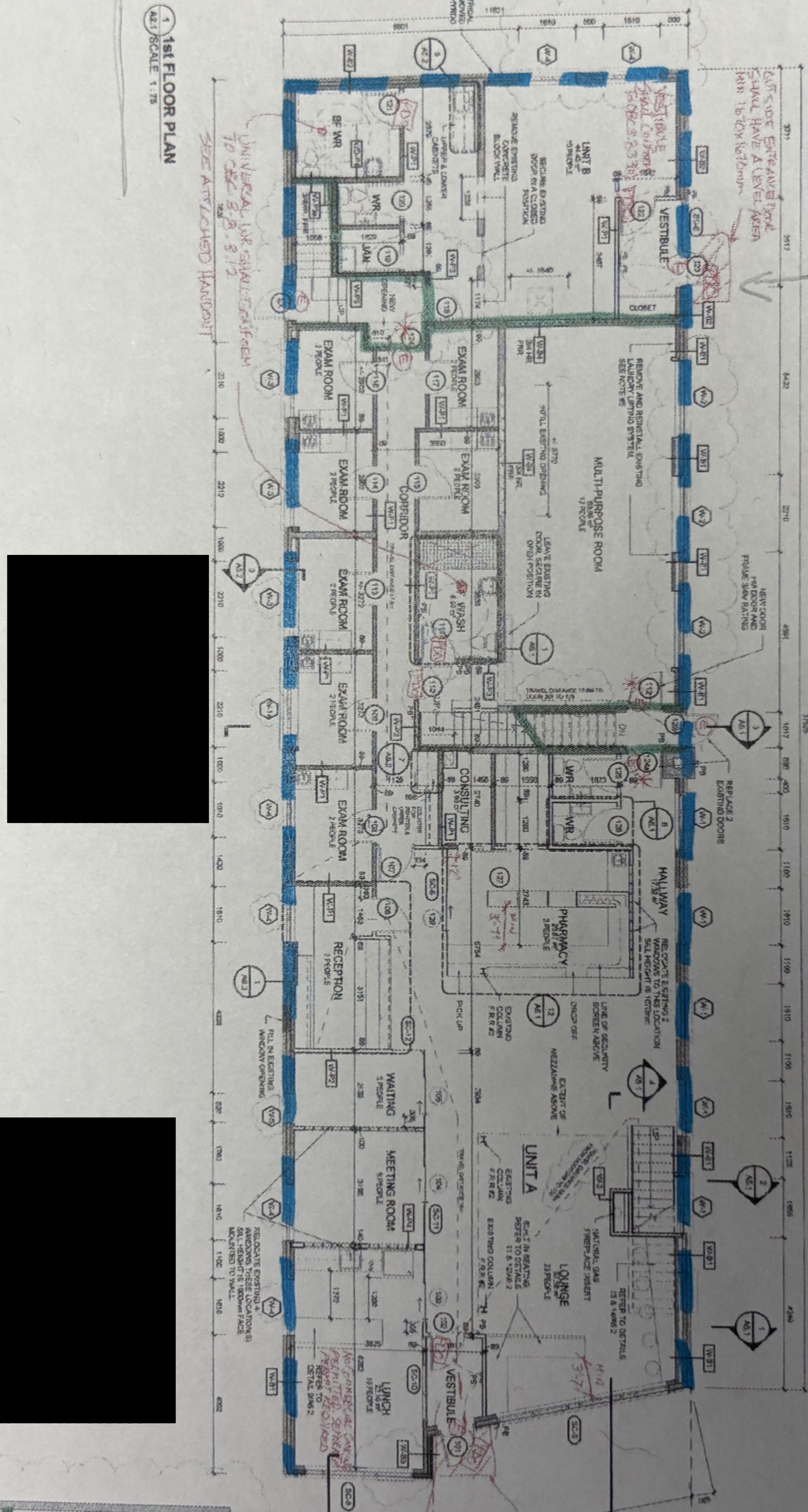
Professor Francois Lagugne-Labarthet

Western University

flagugne@uwo.ca







Substances to be sent to University of Western for further testing and Log for Courier

Entry #	Date Substance is Entered in DC Safe		Name of Staff Completing log	Signature of Staff #1 Signature of Staff #2	Description of Substance Colour/drug	Unique ID	Client Code	SC	Signature of Courier/Date substances out for delivery

[REDACTED] Drug Checking-Unknown Substances Left Behind Log([REDACTED])

Entry #	Date / Time Found	Location where substance was found	Name of Staff Person Completing Log	Signature of Staff Person
	Date / Time WRPS Contacted	Date / Time Substance removed from site	Name / Badge # of Officer	WRPS Officer's Signature
Entry #	Date / Time Found	Location where substance was found	Name of Staff Person Completing Log	Signature of Staff Person
	Date / Time WRPS Contacted	Date / Time Substance removed from site	Name / Badge # of Officer	WRPS Officer's Signature
Entry #	Date / Time Found	Location where substance was found	Name of Staff Person Completing Log	Signature of Staff Person
	Date / Time WRPS Contacted	Date / Time Substance removed from site	Name / Badge # of Officer	WRPS Officer's Signature
Entry #	Date / Time Found	Location where substance was found	Name of Staff Person Completing Log	Signature of Staff Person
	Date / Time WRPS Contacted	Date / Time Substance removed from site	Name / Badge # of Officer	WRPS Officer's Signature



Names of Current RPICS and A/RPICS

Dr. [REDACTED] -RPIC

[REDACTED] -A/RPIC

[REDACTED] -A/RPIC