The CEGIIR Lunch'N'Learn News

1. WHAT IS CEGIIR?

The Center of Excellence for Gastrointestinal Inflammation and Immunity Research (CEGIIR) is an innovative multidisciplinary research centre. CEGIIR is devoted to research of gastrointestinal and liver disease aiming to create benefits to Canada to improve quality of life and reduce economic burden. Our internationally recognized scientists and their outstanding research teams focus on inflammatory gastrointestinal disorders, non-ulcer dyspepsia, gastric infection with Helicobacter pylori, inflammatory bowel disease (IBD), viral hepatic and biliary disorders, and their associated gastrointestinal cancers.

2. WHO IS THE DIRECTOR OF CEGIIR?

The current director of CEGIIR is Dr. Karen Madsen. CEGIIR was initially founded and directed by Dr. Richard Fedorak.

Dr. Karen Madsen

Dr. Richard Fedorak

3. WHAT IS THE ROLE OF A PATIENT IN CEGIIR?

In order for researchers to study the roles of bacteria and viruses in gastrointestinal and liver diseases, and to identify why some people get diseases from bacteria and viruses and other people do not, they need samples of blood, urine, and stool from volunteer patients. The purpose of storing the blood, urine, DNA and the intestinal tissues is to allow the study of groups of samples, from several patients, at one time. Therefore, the patient plays a very important role in the research conducted by CEGIIR.

4. HOW ARE SAMPLES COLLECTED AND IDENTIFIED?

Each sample is obtained from biopsies or collections performed during colonoscopy, gastroscopy, colectomy, spyglass, etc. There are special kits used for each type of procedure. Each kit is labelled with a barcode.

5. WHY DO WE USE BARCODES?

Simple. Samples labelled with barcodes are rarely lost. Each barcode generated contains a 4 letter/6 digit code. Each sample is pre-labelled, minimized human error during data entry. Barcodes also help simplify the sample de-identification process. The use of barcode labels help with automation of samples, important when assigning multiple tubes to one participant, scanning multiple tubes and making it easier to incorporate samples into the inventory database.

6. WHAT IS THE CEGIIR BIOBANK?

The CEGIIR Biobank, established in 2008, contains a collection of samples that are used for research. The Canadian Biosample Repository (CBSR), located in the Li Ka Shing Centre for Health Research Innovation, curates the biosample collection. The biobank allows safe and secure storage of samples. The CEGIIR biosample collection currently contains greater than 80 000 samples of human origin.

7. HOW IS THE CEGIIR BIOBANK USED?

The biobanking program entails working with investigators to screen and enroll patients. Enrolled patients provide CEGIIR with samples to work with. Around 50-150 samples a month are collected from blood, urine, human tissue, breast milk, cord blood, etc. These samples are then clinically phenotyped, stored in the Biobank and used for data collection in the CEGIIR database.

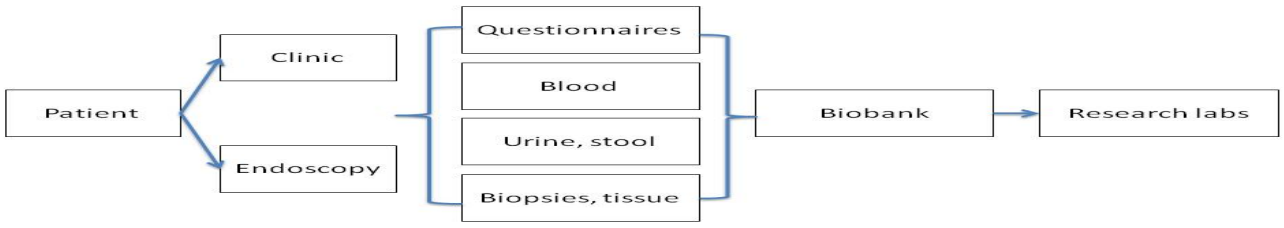
2008		2009		2010		2011		2012		2013		2014	
Month	# of Pts	Month	# of Pts	Month	# of Pts	Month	# of Pts	Month	# of Pts	Month	# of Pts	Month	# of Pts
Jan	0	Jan	17	Jan	50	Jan	35	Jan	122	Jan	27	Jan	47
Feb	0	Feb	17	Feb	46	Feb	34	Feb	73	Feb	25	Feb	29
Mar	0	Mar	0	Mar	72	Mar	60	Mar	44	Mar	31	Mar	54
Apr	0	Apr	10	Apr	61	Apr	62	Apr	64	Apr	29	Apr	48
May	0	May	15	May	60	May	82	May	155	May	10	May	59
Jun	0	Jun	11	Jun	60	Jun	87	Jun	7	Jun	20	Jun	62
Jul	0	Jul	40	Jul	45	Jul	49	Jul	43	Jul	18	Jul	69
Aug	0	Aug	15	Aug	53	Aug	51	Aug	48	Aug	22	Aug	77
Sep	0	Sep	22	Sep	36	Sep	60	Sep	14	Sep	23	Sep	63
Oct	0	Oct	24	Oct	64	Oct	106	Oct	27	Oct	10	Oct	91
Nov	0	Nov	19	Nov	52	Nov	78	Nov	45	Nov	34	Nov	22
Dec	8	Dec	18	Dec	38	Dec	103	Dec	29	Dec	21	Dec	23
Total 2008	8	Total 2009	208	Total 2010	637	Total 2011	807	Total 2012	671	Total 2013	270	Total 2014	644

Total Enrolled to Date = 3245

Biobank Patient Enrollment by Date

8. WHY DO WE USE A BIOBANK?

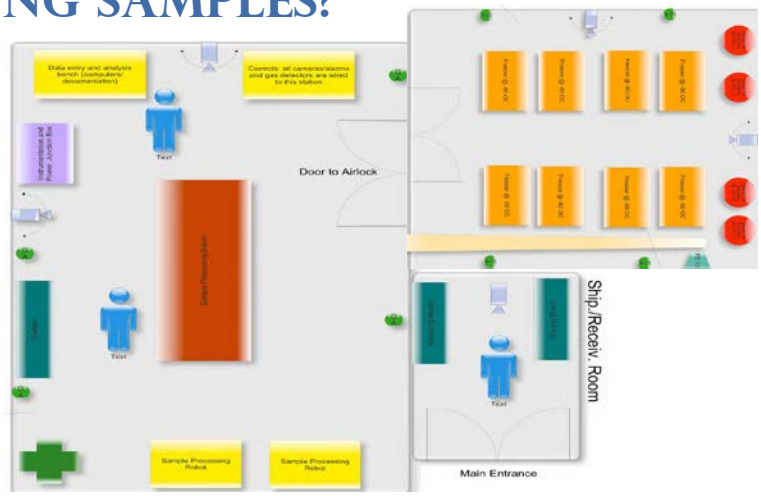
For sample security. The biobank facility is secured with strictly controlled smart-code access entry (card readers). This provides restricted access in and out of the facility. In addition, each freezer is monitored 24/7 by University of Alberta Central Alarm System. The CBSR staff are on 24/7 call to respond to any emergency located in these areas. In the event of power failure/shutdown, each freezer is also equipped with a CO2 backup system, and liquid nitrogen storage units are automatically refilled using a level monitoring system. 20% of each freezer is assigned for "reserve space" in order to accommodate sample transfer from a failing unit. There is also redundant storage of samples, meaning samples are stored amongst many freezers. Lastly, internet access to the Biobank software utilizes 128-bit encryption, securing all the data from unwanted access.



CEGIIR: From Patient to Lab

9. HAS THE SAME PROTOCOL ALWAYS BEEN USED FOR PROCESSING SAMPLES?

Yes, CEGIIR has a standardized protocol used in processing samples. Through the years, different sample sources have been added such as stool and variations on processing blood samples.



CEGIIR: From Biobank to Lab

10. What types of equipment exist in the CEGIIR Biobank?

- **24** ultra low temperature freezers (-50 °C to -86 °C)
- **3** liquid nitrogen cryptogenic dewars (containers)
- **2** biological safety cabinets
- **2** Tecan Freedom EVO® 200 Sample Processing Robots
- **1** uninterruptible power supply

Ultralow freezers

Liquid nitrogen containers

Tecan Freedom EVO® 200 Robot

Biological Safety Cabinet

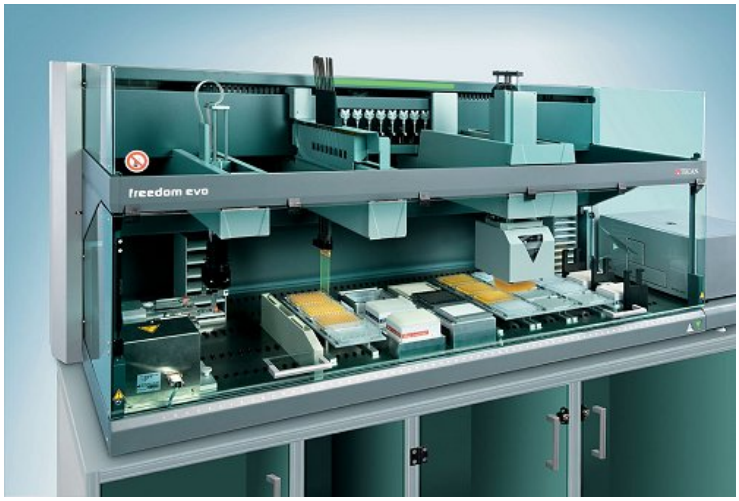
Uninterruptible Power Supply

11. TELL ME MORE ABOUT THIS ROBOT!

There are two Tecan Freedom EVO® 200 robots located in the CBSR premises. Each robot is designed to perform a variety of tasks that any human lab technician can do such as pre-sorting, centrifugation, volume check and clot detection, decapping, secondary tube labelling, aliquoting and destination sorting. Each robot is valued at over half a million dollars.

To learn more about the robot, please take a look at this demonstrational video:

http://www.tecan.com/platform/content/element/5261/evo_morphing_final.avi



Tecan Freedom EVO® 200 robot

12. WHAT IS THE CEGIIR BIOBANK DATABASE?

The CEGIIR Biobank database is used to store all data obtained through sample collection. Data is also collected from the environmental questionnaire (subject information: DOB/ethnicity/etc, familial disease, smoking and alcohol history, reproductive history, residential history, dietary habits, medication history, etc.) and medical chart review (retrospective/prospective collection, disease diagnoses, disease phenotype & behaviour, medication history, surgical history, etc.)

To date, over 2500 environmental questionnaires and 600 medical chart reviews have been completed!

Health Canada

Health Canada Santé Canada

Health Canada

Did you know?

You can find updated information on Canadian Research Ethics at:

www.hc-sc.gc.ca

CEGIIR in the Media

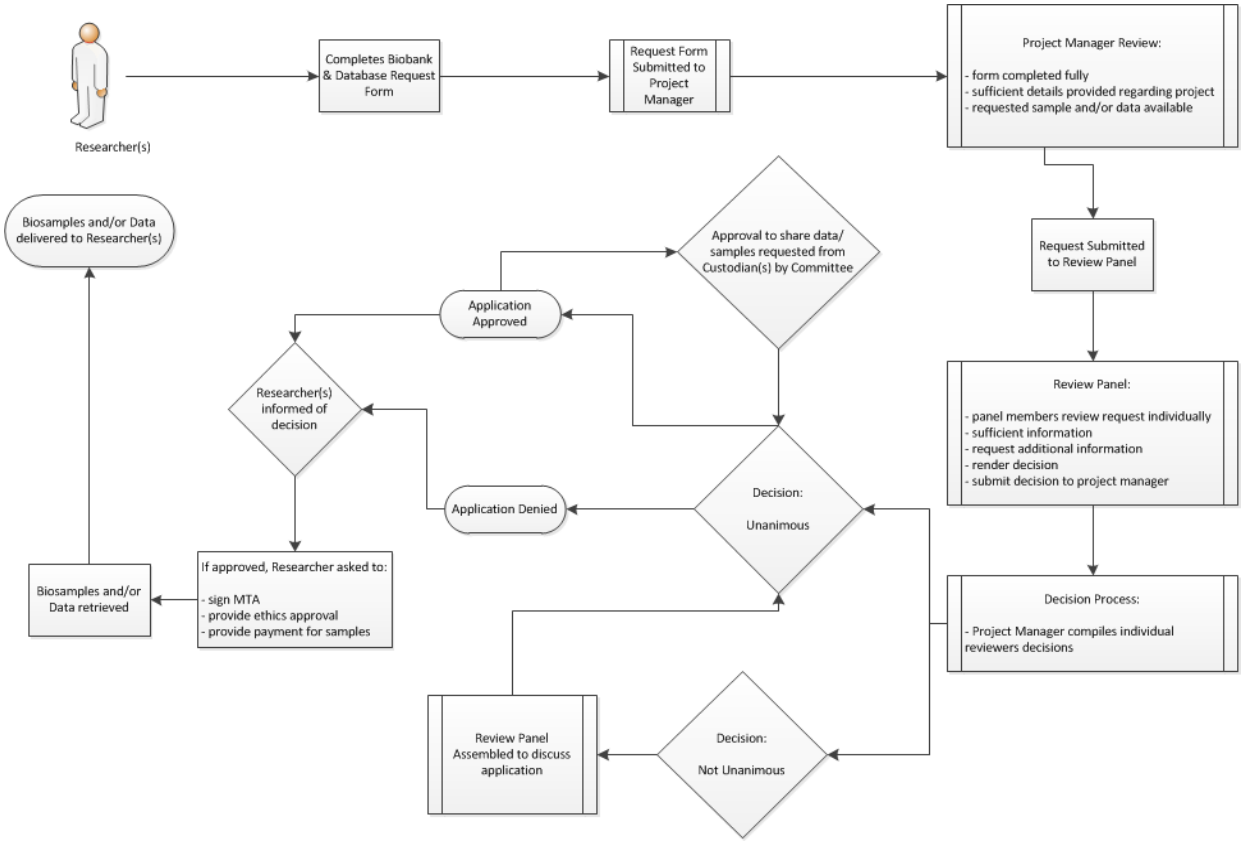
Learn more about CEGIIR on YouTube:

https://www.youtube.com/watch?v=dx4RWm3rjSA

Fast Facts: Informed Consent

- The language of the document should be at a grade 6-8 level
- Informed consent is an on-going process that starts with the researcher's first contact with the individual
- It should not be stated to the participant that a Research Ethics Board has approved the study, since this may appear to offer a guarantee of safety

13. HOW ARE SAMPLES WITHDRAWN?



An extensive process is required when withdrawing a sample.

1. Researchers to complete Biobank & Database Request Form
2. Request form submitted to Project Manager (Brian Reuter)
3. Project manager (Brian) begins review
4. Request submitted to review panel
5. Review panel review each request individually, determine if there is sufficient information, request any additional information, render and submit final decision to project manager
6. Decision process: Project manager (Brian) compiles individual reviewers' decisions
7. Decision Unanimous - Application is either approved or denied (if decision is not unanimous, a review panel is assembled to discuss the application until a unanimous decision is reached)
8. Researchers are informed of decision
9. If approved, researchers asked to sign MTA (material transfer agreement), provide ethics approval and provide payment for samples
10. Biosamples/data are retrieved
11. Biosamples/data delivered to researchers

14. DEFINE GOOD CLINICAL PRACTICE (GCP)?

"Good Clinical Practice" (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. The International Conference on Harmonization developed the Good Clinical Practice Guideline which was adopted by Health Canada's Therapeutic Directorate Products (TDP).

15. HOW IS A STUDY INITIATED?

16. WHAT IS REQUIRED BEFORE STARTING ANY STUDY?

A. Patient recruitment - the patient must be aware of the study

B. Informed consent

17. WHAT IS INFORMED CONSENT?

To set up a study, each recruited patient must be fully informed and voluntarily consent to participate. Informed consent is an on-going process that starts with the researcher's first contact with the individual and continues until the study is complete or the participant withdraws.

The elements of informed consent are:

o Objective of Study
o Design and length of study
o Sample size
o Risks and Benefits
o Statement of privacy and confidentiality
o Freedom to withdraw participation
o Compensation and/or treatment for any incurred injury during the study
o Contact information

18. CAN A PATIENT PARTICIPATE IN MULTIPLE CLINICAL TRIALS?

It depends. If they are multiple interventional trials that involve drugs, the patient CANNOT participate in multiple studies. If they are multiple observational trials that do not involve drugs, the patient CAN participate in multiple studies. If the patient is participating in multiple observational trials, they can only participate in ONE additional interventional study. There is no limit to the amount of observational studies one participates in, however only one interventional/drug-related study can be done at any given time.

19. WHAT ARE THE KEY ELEMENTS OF PPE?

There are five key elements of personal protective equipment (PPE) used. These include a lab coat, long pants, safety glasses, closed-toe footwear and gloves.

20. WHAT DO YOU DO IF YOU ARE INJURED IN THE LAB?

Report it immediately! Safety first.

REFERENCES

- **CEGIIR**
  - **http://cegiir.med.ualberta.ca**
  - http://cegiir.med.ualberta.ca/overview.html
  - http://cegiir.med.ualberta.ca/whatWeDo.html

- **Role of patient in CEGIIR**
  - http://blogs.scientificamerican.com/molecules-to-medicine/clinical-trials-for-beginners-recipe-for-a-new-drug-2/

- **Good clinical practice**
  - http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php
  - http://www.ccr.med.keio.ac.jp/e_learning/UM_E-Learning_US/mod02/pr1.html
  - http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/tpd-dpt/index-eng.php

- **Informed consent & Health Canada sidebar**
  - http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/consent/index-eng.php

- **Tecan Freedom EVO 200 robot**
  - http://www.tecan.com/platform/apps/product/index.asp?MenuID=2694&ID=5270&Menu=1&Item=21.1.8
  - http://www.tecan.com/platform/content/element/5261/evo_morphing_final.avi

- **Initiating a research study**
  - http://www.fshcglobal.com/services/healthcare-data-analysis/
  - http://article.wn.com/view/2014/08/05/Cesca_Therapeutics_and_Fortis_Healthcare_Announce_Master_Col/

- **Cartoon of the day**
  - http://www.gocomics.com/brevity/2013/08/06