A Review of the Toronto Faculty of Dentistry Research Institute Clinic

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Issues

1. Introduction and mandate

2. Current clinical research within the faculty and RIC
   - 2.1 Research activity
   - 2.2 Facilities and staffing
   - 2.3 Funding
   - 2.4 Current Research Institute Clinic

3. Regulatory directives / good clinical research practice
   - 3.1 Good clinical research practice

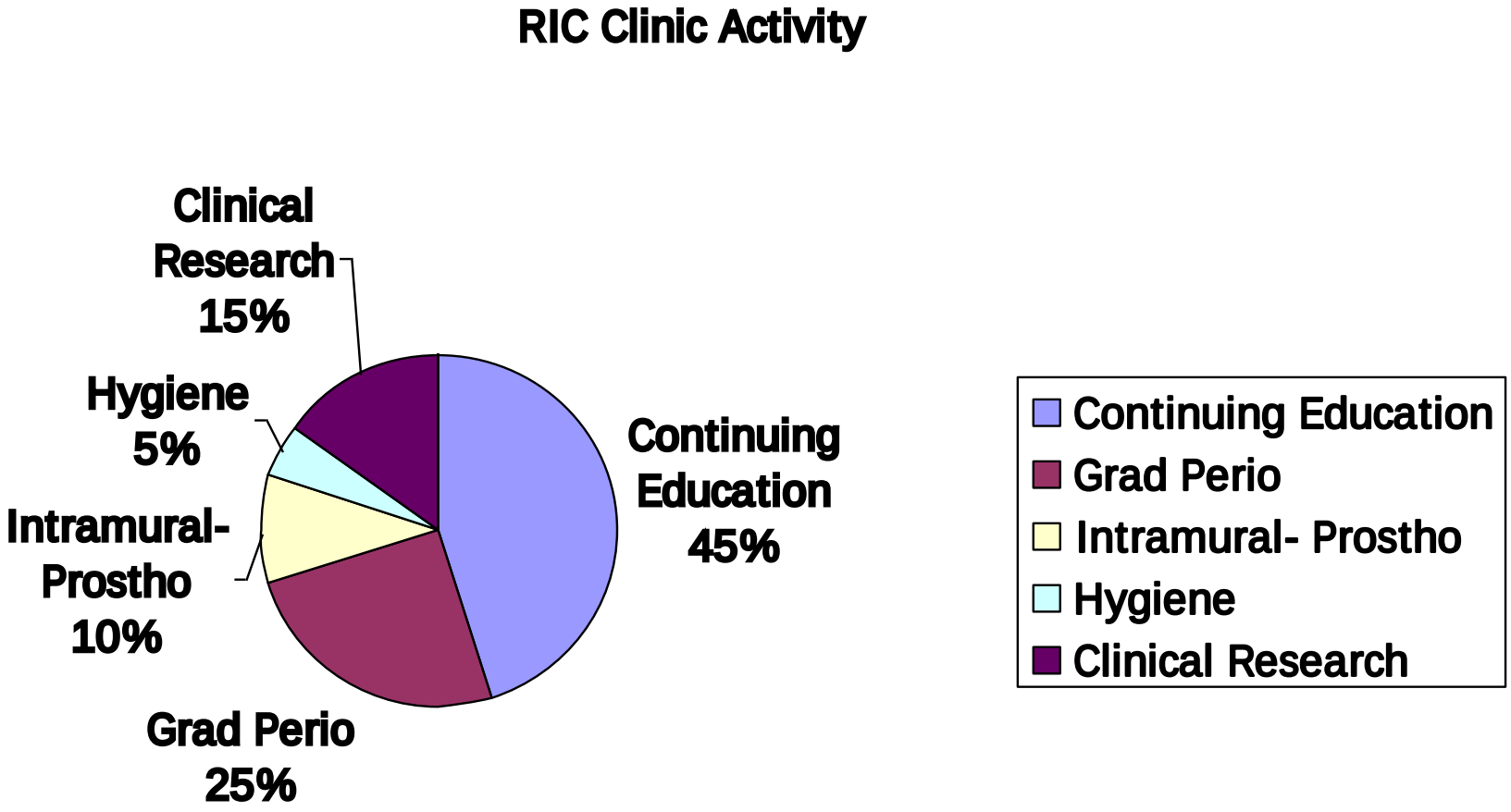
2.1 Research activity

- About 100 papers
- Emphasis on basic research, mainly in the field of biology
- basic (58%), clinical trials (15%), epidemiological research (10%), and education/reviews (17%)
- several patents filed and technology transfer agreements with companies

2.2 Facilities and staffing

- Absence of a well defined financial model for cost recovery of research activity within the context of the cost recovery model for the teaching clinics.
- Lack of identified resource team to assist with appropriate costing for projects prior to start.
- Current use of the RIC resources for teaching and continuing education rather than establishing research projects as its priority.
- Lack of appropriate staffing
- Lack of a financial plan for directed growth and activity priorities
- Shortage of dedicated infrastructure facilities

2.4 Current Research Institute Clinic



time commitment for a typical week

3.1 Good clinical research practice

Health Canada Guidance Documents

1. Guidance for Records Related to Clinical Trials (GUIDE-0068)
2. Inspection Strategy for Clinical Trials
3. Preparation of an Application for Investigational Testing – Medical Devices V.3
4. Preparation of an Application for Investigational Testing – In Vitro Diagnostic Devices V.3
5. Application for Investigational Testing Authorization
6. Registration and Disclosure of Clinical Trial Information
7. Other Guidance Documents on Medical Devices
8. Other guidance Documents on Drug Products

Issues

1. Introduction and mandate
2. Current clinical research within the faculty and RIC
3. Regulatory directives / good clinical research practice

4. Essential needs for the conduct of good clinical research practice
   - 4.1 Staffing, clinical & administrative management
   - 4.2 Infrastructure, clinic & research equipment
   - 4.3 Space
   - 4.4. Standard operating procedures

5. Potential future clinical research areas
   - 5.1 Clinical experimental trials
   - 5.2 Design and development of a clinical environment that may enable testing of devices and equipment used in dentistry
   - 5.3 Funding possibilities
     - 5.3.1. Company funding opportunities
     - 5.3.2 Public funding opportunities
     - 5.3.3 Other funding opportunities

Possible future clinical research areas

Patient / Condition	Study focus:		
	Etiology / Harm	Diagnosis – establish sensitivity/specificity	Intervention (prevention/therapy)
Periodontal diseases	-	X	X
Caries	-	X	X
Pain	X	X	X
TMD	X	X	X
Local tooth pain	-		X
Dry mouth / Halitosis	-	X	X
Oral Mucosal diseases	-	-	X
Oral and other Cancers	X	X	-
Rehabilitation	X		X
Fluorides	X	X	X
General health	-	X	-

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1. Introduction and mandate
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4. Essential needs for the conduct of good clinical research practice
5. Potential future clinical research areas

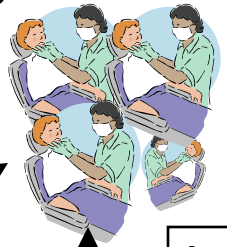
6. Viable initiatives that may improve clinical research activities
   - 6.1 Undergraduate training
   - 6.2 Graduate training
   - 6.3 Possibilities for GDPs to obtain CE points

7. Recommendations and schedule for implementation
   - 7.1 Within existing confines
     - 7.1.1 Staffing, clinical administration and management & public relations
     - 7.1.2 Infrastructure
     - 7.1.3 Standard Operation Procedures and Space Requirements
     - 7.1.4 Consequences of changes
     - 7.1.5 Financial model
   - 7.2 New faculty building
   - 7.3 Schedule

Research Institute Clinic

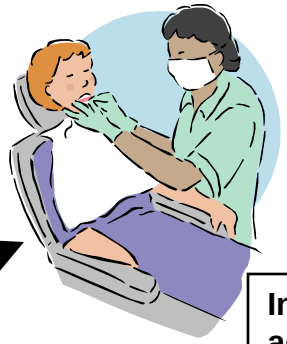
Patient Flow & advertisement for patient recruitment

Undergrad & Grad Students



Clinical departments

Faculty diagnostics



Internal advertisement

Internal advertisement

External advertisement

GPs

Professional media advertisement

1. Information
2. Screening
3. Consenting
4. Data

Research proj. 1

Research proj 2

Research proj. 3

Research proj. etc..

?

Patients not fulfilling trial inclusion criteria / non-consenting

Competencies:

- Study design
- Study execution
- Study analysis
- Study presentation
- Study interpretation
- Study content omission

Recommendations:	Resource Allocation:
7.1.1: Staffing, clinical administration and management & public relations	
1.Establish a management structure	Faculty salaried positions assigned from current faculty and clinic teaching staff
1.Establish a Clinical Project Reviewer Committee	Faculty salaried positions assigned from current faculty
1.Assign current clinic staff allocation as detailed in section 7.1.1	Faculty salaried positions assigned from clinic teaching staff.

Recommendation	2006 Q3	2006 Q4	2007 Q1	2007 Q2	2007 Q3	2007 Q4	2008 Q1	2008 Q2	2008 Q3	2 Q
7.1.1	x	x								

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7.1.2: Infrastructure	
1. Review and Implement the RIC model	**To be determined**

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7.1.1	x	x								
7.1.2		**x**	**x**	**x**	**x**					

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7.1.2: Infrastructure	
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7.1.3 Standard Operation Procedures and Space Requirements	
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7.1.1	x	x								
7.1.2		x	x	x	x					
7.1.3			**x**	**x**	**x**	**x**				

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7.2 New faculty building	
To be determined	To be determined

Recommendation	**2006 Q3**	**2006 Q4**	**2007 Q1**	**2007 Q2**	**2007 Q3**	**2007 Q4**	**2008 Q1**	**2008 Q2**	**2008 Q3**	**2008 Q8**
7.1.1	x	x								
7.1.2		x	x	x	x					
7.1.3			x	x	x	x				
7.1.4		x	x	x						
7.1.5	x	x	x	x	x	x				
7.2	x	x	x	x	x	x	x	x	x	x