



UNIVERSITY OF
CALGARY

INFORMATION RESOURCES

University Archives
MLT 1218
Telephone: (403) 220-3602
Fax: (403) 210-3075
Email: munnigafu@ucalgary.ca

01-015

February 25, 2002

Marvin Ross
Bridgeross Communications Inc.

Dear Mr. Ross:

RE: Freedom of Information and Protection of Privacy Act

I am replying to your request of November 26, 2001 for access to information relating to specific research being conducted at the University of Calgary.

As I mentioned during our telephone conversation on February 11th, it was somewhat difficult to deal with portions of your request because you asked for discrete information rather than documents. You indicated at the time that you would be satisfied if we simply answered the questions in those cases where documents were not specifically requested. That information has been supplied in the attached table.

With respect to the documents requested, the University of Calgary has determined that they are either excluded or excepted from disclosure. I have decided not to provide you with and charge you for 148 copies of blank pages. I have, instead, included information about the documents requested and the sections of the *Act* on which we have relied in making disclosure decisions on the table mentioned above. If you have any questions about the application of certain sections, please write or call me at (403) 220-3602.

With respect to fees, although chargeable time has been spent in retrieving the records, the University of Calgary has decided not to assess any charges beyond the \$25 application fee in view of the fact that we were not able to provide much of what you requested.

Under section 62 of the *Freedom of Information and Protection of Privacy Act*, you may ask the Information and Privacy Commissioner to review the decision not to disclose information that you requested. You have 60 days from the receipt of this notice to request a review by writing the Information and Privacy Commissioner at 410, 9925-109 Street, Edmonton, Alberta, T5K 2J8.

If you wish to request a review, please provide the Office of the Commissioner with the following information:

1. The reference number quoted at the top of this notice.
2. A copy of this letter.
3. A copy of your original request for information that you sent to the University of Calgary.

If you have any questions about this letter, please write or call me at (403) 220-3602.

Sincerely,



Jo-Ann Munn Gafuik
University Archivist/Information and Privacy Co-ordinator

Access Request 01-015

Documents Requested

Information, as outlined below, relating to the following five studies:

- (a) "Open trials of a Nutraceutical Treatment for Mental Disorders in Adults", Bonnie J. Kaplan, PhD *et al.*
- (b) "Open Trials of Nutrient Supplements for the Treatment of Children with Anxiety / Mood Problems", Bonnie J. Kaplan, PhD *et al.*
- (c) "Nutraceutical Treatment of Mental Disorders: an RCT with Bipolar Disorder", Bonnie J. Kaplan, PhD *et al.*
- (d) "Randomized Controlled Trial of a Nutrient Supplement in the Treatment of Fibromyalgia", Bonnie J. Kaplan, PhD *et al.*
- (e) Study title unknown. Study described under heading of "Benefit/Harm" in patient consent form for "Randomized Controlled Trial of a Nutrient Supplement in the Treatment of Fibromyalgia" (see doc 131/ request number 01-010)

- 1. number of children involved in the study referenced as (e) above
- 2. number of adults involved in the study referenced as (a) above
- 3. number of children involved in study referenced in (b) above
- 4. disclosure of dates of CHREB approval of studies (a) to (e) above
- 5. CHREB approved start and finish dates for studies (a) to (e) above
- 6. disclosure of manufacturer of investigational nutrient supplements in studies (d) and (e). Include any changes of manufacturer during the course of studies (d) and (e)
- 7. investigator's brochure for investigational nutrient supplement in study (e)
- 8. investigator's brochure for investigational nutrient supplement in study (d)
- 9. investigator's brochure for investigational nutrient supplement / nutraceutical in studies (a), (b), and (c)
- 10. disclosure of funding and sponsorship for studies (d) and (e) and form of sponsorship, eg. cash or kind, and specify

11. citation for publication of study (e) or documentation of close-out or abandonment and date of same

12. for study (c) I would like the following documents:

- a. copies of the study budget
- b. copy of the financial contract
- c. cover letters or accompanying information from the investigator
- d. copies of the scientific and ethical reviews
- e. copies of the minutes from the scientific review committee meeting
- f. copies of the correspondence to the investigator from the committees
- g. copies of the annual reports

13. for study (e), I would like the following documents:

- a. copies of the study budget
- b. copy of the financial contract
- c. cover letters or accompanying information from the investigator
- d. copies of the scientific and ethical reviews
- e. copies of the minutes from the scientific review committee meeting
- f. copies of the correspondence to the investigator from the committees
- g. copies of the annual reports
- h. copies of the informed consent, original, current, and any version in between, along with copies of any accompanying written information, and the assent form for minors

14. copy of document certifying IRB approval from the University of Utah under Multiple Project Assurance #M1082, for R.C. Ferre MD to engage in studies (a) and (b)

Disclosure Decisions

	Document	Decision or Information Requested
1	Number of children involved in study 'e'	12 children finished the trial
2	Number of adults involved in study 'a'	11 adults finished the trial
3	Number of children involved in study 'b'	9 children finished the trial
4	Dates of CHREB approval for all five studies	(a) May 6, 1999 (b) May 26, 1999 (c) August 24, 1999 (d) June 16, 1999 (e) April 3, 1997
5	CHREB approved start and finish dates	CHREB does not approve start and end dates.
6	Manufacturer of supplements in (d) and (e)	(d) Evince International L.L.C. (e) Melaleuca, Body Systems, T.J. Clark
7	Investigator's brochure for (e)	None required, therefore, none produced
8	Investigator's brochure for (d)	None required, therefore, none produced
9	1-S9 Investigator's brochure for (a), (b), (c)	Refuse to disclose. The brochure is considered to be the research information of Dr. Bonnie Kaplan and is, therefore, excluded for consideration under s. 4(1)(f) of the <i>Freedom of Information and Protection of Privacy Act</i> . Even if they are considered to be within the scope of the Act, the University of Calgary will exercise its discretion to refuse to disclose the investigator's brochure under s. 24(1)(a), (b), (c)(ii), and (d). S. 24 deals with disclosures that would be harmful to economic and other interests of the public body.
10	Funding and sponsorship for studies (d) and (e) and form of sponsorship	(d) Alberta Heritage Foundation for Medical Research – cash (e) no funding

	Documents	Decision of Information Requested
13a	ADHD study budget	No record exists
13b	ADHD contract	No record exists
13c	Cover letters	No records exist
13d	Science/ethics reviews	No science review committee. The University of Calgary exercises its discretion to refuse to disclose the minutes of the Ethics Committee under s.24(1)(b).
13e	Science minutes	No records exist
13f	137-142 Correspondence from science/ethics	No science review committee. The University of Calgary exercises its discretion to refuse to disclose the correspondence of the Ethics Committee under s.24(1)(b).
13g	Annual reports	No records exist
13h	143-148 ICD all versions	This information is considered to be the research information of Dr. Bonnie Kaplan and is, therefore, excluded for consideration under s. 4(1)(i) of the Freedom of Information and Protection of Privacy Act. Even if it is considered to be within the scope of the Act, the University of Calgary will exercise its discretion to refuse to disclose the Annual Report under s. 24(1)(a) and (c). S. 24 deals with disclosures that would be harmful to economic and other interests of the public body.
14	Utah IRB approval	We have no record responsive to this request.

	Documents	Decision of Information Requested
13a	ADHD study budget	No record exists
13b	ADHD contract	No record exists
13c	Cover letters	No records exist
13d	Science/ethics reviews	No science review committee. The University of Calgary exercises its discretion to refuse to disclose the minutes of the Ethics Committee under s.24(1)(b).
13e	Science minutes	No records exist
13f	137-142 Correspondence from science/ethics	No science review committee. The University of Calgary exercises its discretion to refuse to disclose the correspondence of the Ethics Committee under s.24(1)(b).
13g	Annual reports	No records exist
13h	143-148 ICD all versions	This information is considered to be the research information of Dr. Bonnie Kaplan and is, therefore, excluded for consideration under s. 4(1)(i) of the Freedom of Information and Protection of Privacy Act. Even if it is considered to be within the scope of the Act, the University of Calgary will exercise its discretion to refuse to disclose the Annual Report under s. 24(1)(a) and (c). S. 24 deals with disclosures that would be harmful to economic and other interests of the public body.
14	Utah IRB approval	We have no record responsive to this request.