Although the fees charged represent real costs in staff time and are based on the fee guide in the *Act* itself, the University of Calgary is willing to reduce the total fee by $113.94 in recognition of the fact that we were not able to provide most of what you requested. You have already forwarded a cheque for $200. There is, therefore, no outstanding balance.

UNIVERSITY OF CALGARY

INFORMATION RESOURCES

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

01-010

November 7, 2001

Mr. Marvin Ross
Bridgeross Communications Inc.
54 Melville Street
Dundas, Ontario
L9H 1Z9

Dear Mr. Ross:

RE: Freedom of Information and Protection of Privacy Act

I am replying to your request of September 12, 2001 for access to information relating to the nutritional research on bipolar affective disorder conducted by Dr. Bonnie Kaplan and others.

Most of the information which you requested is excluded from consideration or excepted from disclosure under the *Freedom of Information and Protection of Privacy Act*. We have severed the excepted or excluded information so that we could disclose the remaining information in the records.

I have not provided you with copies of those pages from which all information has been severed. I have, instead, attached a table which outlines the sections of the *Act* on which we have relied in making disclosure decisions. If you have any questions about the application of certain sections, please write or call me at (403) 220-3602. You might also want to review the actual wording of the *Act* which is available online at: www3.gov.ab.ca/foip/legislation/foip_act/index.cfm.

With respect to the fees, the final account is as follows:

Location and retrieval:	11 hours @ $27/hour	$297.00
Prepare records:	.5 hour @ $27/hour	13.50
Photocopy records:	10 pages @ $ .25/page	2.50
Shipping:	actual	.94
Total:		**$313.94**

Access Request 01-010
Documents Requested

1. Research proposal, including the scholarly bibliographies that support the proposed research, for following two open label studies on bipolar affective disorder:

- "Successful treatment of bipolar disorder with a nutritional supplement: Ten cases" (presented at the Canadian Psychiatric Association annual meeting October 4, 2000, Victoria, British Columbia) Conducted by: Bonnie J. Kaplan, PhD, J. Steve A. Simpson, PhD, MD, Richard C. Ferre,MD, Chris P. Gorman, MD, David McMullen, MD

- "Effective mood stabilization with a broad-based nutritional supplement: 20 adults and children" (presented at the Society of Biological Psychiatry, Annual meeting, New Orleans, Louisiana, May 4, 2001) Conducted by: Bonnie J. Kaplan, PhD, J. Steve A. Simpson, PhD, MD, Richard C. Ferre, MD, Chris P. Gorman, MD, David McMullen, MD, Susan G. Crawford, MSc

2. Research proposal, including the scholarly bibliography that supports the proposed research, for the following Randomized Clinical Trial [RCT]:

- "Nutraceutical Treatment of Mental Disorders: an RCT with Bipolar Disorder" (Research Grant, Alberta Science and Research Authority (Awarded) $588,757 for the year 1999) Conducted by Kaplan, Bonnie, JSA Simpson, C Gorman, W Friend, M Trew, R Dickson and others.

3. Research proposal, including the scholarly bibliography that supports the proposed research, for the following Randomized Clinical Trial [RCT]:

- "Trial of a Nutrient Supplement in the Treatment of Fibromyalgia" Conducted by Liam Martin, MD, University of Calgary

4. Minutes of the Conjoint Health Research Ethics Board with respect to the studies listed at #1, 2, and 3 above.

5. Analytical reports on safety and toxicity studies for vitamin supplement being given to patients (animal and human) under studies listed at #1 and 2 above.

6. The roster of committee members on the Conjoint Health Research Ethics Board, both current and for the year 1999.

7. University of Calgary guidelines for the Conjoint Health Research Ethics Board – specifically the method of decision making (i.e. majority, consensus, etc.), procedure to be observed if one or more committee members is either the lead researcher or involved with a research proposal being evaluated by the Conjoint Health Research Ethics Board.

8. Statement of disclosure of funding for the studies listed at #1 above and if that was monetary rather than in kind (ie. a box of supplements), a copy of the check paid to Calgary or the researchers.

9. Statement of disclosure of how research subjects' prescription medications were paid for during the two studies listed at #1 above.

10. Statement[s] of change of protocol in the studies listed at #1, 2,and 3 above.

11. Copies of informed consent given to subjects in the studies listed at #1, 2, and 3 above. The applicant anticipates that the names of the patients will be severed.

12. Copy or facsimile of verbal informed consent read to minors participating in open label study as reported via poster at the Annual Meeting of the Society of Biological Psychiatry 2001.

13. Statement of recruiting procedures for studies listed at #1, 2, and 3 above and approval of same by the Conjoint Health Research Ethics Board.

14. Statements of criteria for inclusion of research subjects for studies listed at #1, 2, and 3 above.

15. Statements of exclusion criteria of research subjects for studies listed at #1, 2, and 3 above.

16. Statements describing the procedure for reporting and recording adverse events during each of the studies listed at #1, 2, and 3 above.

17. Statement from Health Canada attesting that the EM Power + supplement, manufactured by Cornerstone Nutritional Labs for Evince International LLC did not require either an IND or DIN to be used in the studies listed at #1, 2, and 3 above.

18. Copy[ies] of researchers' letter of inquiry to Health Canada asking if the EM Power + supplement required either an IND or DIN to be used in the studies listed at #1, 2, and 3 above. If done via telephone, name and phone number of person who gave approval and date of contact.

19. Copies of researchers' master data files or logs for the studies listed at #1 above, specifically to include the dates on which all psychometric testing reported in the study results were done.

20. Name of the company that makes the placebo used in the studies listed at studies #1, 2, and 3 above.

Disclosure Decisions

	Document		Decision
1	1-17 18-28	• Protocol for Open Trials of a Nutraceutical Treatment for Mental Disorders in Adults; • Protocol for Open Trials of Nutrient Supplements for the Treatment of Children with Anxiety/ Mood Problems (NOTE: titles in request incorrect)	The protocols are considered to be the research information of Dr. Bonnie Kaplan and are, therefore, excluded for consideration under s. 4(1)(e.1) of the *Freedom of Information and Protection of Privacy Act*. This section states that the *Act* does not apply to research information of an employee of a post-secondary educational body. 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 them under s. 24(1)(a), (b), (c)(ii), and (d). S. 24 deals with disclosures that would be harmful to the interests of the public body.
2	29-45	Protocol for Nutraceutical Treatment of Mental Disorders: An RCT with Bipolar Disorder	
3	46-62	Protocol for A Randomized Controlled trial of a Nutrient Supplement in the Treatment of Fibromyalgia	
4	63-119, 140-143	Minutes of the Conjoint Health Research Ethics Board (includes names of committee members)	The majority of the text on pages 63-119 and 140-143 deals with other research projects and will not be provided since it is not responsive to the access request. The small portion that does deal with the projects named above will not be disclosed because it constitutes the research information of the faculty member. (s. 4(1)(e.1)) If that interpretation of research information is not supported, the University of Calgary will exercise its discretion to refuse to disclose the minutes under s. 23(1)(b) and (f). S. 23(1) deals with advice from officials.
5	120	Toxicity Report	The report will not be disclosed under s. 4(1)(e.1) of the *Act* since it constitutes the research information of the faculty member. 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 analysis under s. 23(1)(a) which allows the public body to refuse to disclose information that could reasonably be expected to reveal advice, proposals, recommendations, analyses or policy options developed by or for the public body.
6	121 (see 4 above)	roster of committee members on the CHREB for 1999 and 2001	The University of Calgary will disclose a document which outlines gender balance and representation of the committee members. Actual names of committee members that are included in the minutes (see document 4) will not be disclosed under s. 24(1)(c)

	Document		Decision
			which allows the public body to refuse to disclose information which could be expected to result in financial loss or prejudice the competitive position of the public body.
7		ethics policy	This information is publicly available on the web at: http://www.ucalgary.ca/UofC/research/policies/policies.html. It will not, therefore, be disclosed under the *Act*. S. 28(1) allows the public body to refuse to disclose information that is available to the public.
8		disclosure of funding	No such record exists because there was no funding for these protocols.
9		funding for prescriptions	No such record exists.
10	122-130	protocol changes	The protocols and any amendments are considered to be the research information of Dr. Bonnie Kaplan and are, therefore, excluded for consideration under s. 4(1)(e.1) of the *Freedom of Information and Protection of Privacy Act*. [see doc. 1-3 above] 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 protocol changes 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.
11	131-139	informed consent documents	The informed consent documents will be disclosed with the exception of the names of researchers other than Dr. Bonnie Kaplan and the names of certain corporate participants. The names are severed under s. 4(1)(e.1) or s. 24(1)(a), (b), (c)(ii), and (d).
12		verbal informed consent	No such record exists.
13		recruiting procedures	This information is contained in the protocols which are considered to be the research information of Dr. Bonnie Kaplan and, therefore, excluded for consideration under s. 4(1)(e.1) of the *Freedom of Information and Protection of Privacy Act*. This section states that the *Act* does not apply to research information of an employee of a post-secondary educational body. 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 information 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.
14		inclusion criteria	
15		exclusion criteria	
16		adverse events reporting	
17		Health Canada statement re IND, DIN	No such record; verbal conversation only.
18		letter to Health Canada	No such record.
19		researcher's master data file	The date are considered to be the research information of Dr. Bonnie Kaplan and are,

			therefore, excluded for consideration under s. 4(1)(e.1) of the Freedom of Information and Protection of Privacy Act. This section states that the Act does not apply to research information of an employee of a post-secondary educational body.
20		name of manufacturer	This information was disclosed previously to the applicant by the Interim Vice-President (Research) in a letter dated September 17, 2001.