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Sent via Electronic Mail

Journal of Medical Internet Research
JMIR Publications
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CANADA

Subject: Reader Concerns about Published Work

This letter raises concern about consent and conflict of interest within the work published in the Journal of Medical Internet Research, 2019, Volume 21, Issue 1 titled *Protecting User Privacy and Rights in Academic Data-Sharing Partnerships: Principles From a Pilot Program at Crisis Text Line* (the “2019 Paper”). [\[1\]](#)

I am writing as a former volunteer at Crisis Text Line and am advocating for data ethics reforms within the organization. As a reader of the 2019 Paper, I do have biases which can be understood by referencing two personal works: my opinion paper questioning data ethics [\[2\]](#), and my change.org petition titled Ask Crisis Text Line to Reform Its Data Ethics [\[3\]](#).

Summary. Crisis Text Line, Inc. is a non-profit corporation that provides a crisis response service to the public. Anyone can use the service and its success lies in the human volunteer response, and conversation techniques for helping bring calm to persons experiencing crisis. In addition, the texting format is popular with young people and makes the service easily accessible. The conversations are stored by Crisis Text Line as transcripts, anonymized, and thus become data. This data and other conversation-related data was subject of the 2019 Paper. The 2019 Paper specifically investigated ethical issues for research using the data, and the protocols needed for researchers to ensure security and privacy.

The principal objections I raise here are that informed consent for use of the data for research purposes cannot have been granted under the mechanism claimed by the authors. Persons in crisis are in no position to read a lengthy Terms of Service & Privacy Agreement (Terms), are unlikely to find or understand its key provisions, and have no choice except to agree if they are to receive help. Regarding conflict of interest, 11 of the 13 co-authors had affiliations as advisory board members to Crisis Text Line, Inc., yet those affiliations are not mentioned in the author information section on the report 1st page. Finally, Crisis Text Line itself had a vested monetary interest in commercial use of the data, and therefore vested interest in the 2019 Paper’s finding that the crisis conversation data is ethically sourced for research purposes. Without the recognition of ethical sourcing for research, the ethical basis for commercial use would likely be jeopardized.

A. Consent for Research on Stored Crisis Conversations

Within the 2019 Paper, consent is discussed within Table 1 titled *Open data program: challenge, principles, and protocols*

Challenges and principles:

Research ethics

“Inform users in an unobtrusive way that anonymized data are shared with select research partners.”

Crisis Text Line protocols

“CTL provides texters with a link to an easy-to-understand Terms of Service^b, including a disclosure of potential future data use, before every crisis conversation”

^b Terms of service: “We have created a formal process for sharing information about conversations with researchers at universities and other institutions. We typically share data with trusted researchers when it will result in insights that create a better experience for our texters. We follow a set of best practices for data sharing based on the University of Michigan’s Inter-University Consortium of Social and Political Research, one of the largest open data projects in the U.S., which includes stringent ethical, legal, and security checks. For more details, see our policies for open data collaborations” [here the 2019 Paper cites to Crisis Text Line Terms of Service and Privacy Policy last updated December 9, 2016 at 1:35pm EST and 1:40pm EST, respectively, see link and citation repeated herein at [\[4\]](#)].

This is the given answer for how ethical consent was achieved to use the crisis conversations for research. There are many problems with this protocol and claim.

It should be understood there is no physician or therapist relationship with the individuals (human subjects of study) who seek help from the Crisis Text Line service. [\[4\]](#) This means that legal requirements such as HIPAA regulations have not been binding on the organization to date, and it has been largely free, legally, to set its own ethical standards for its own purposes.

With this background, I raise the following ethical objections to consent for research on Crisis Text Line anonymized conversation data. *Also see* the Belmont Report for ethics reference [\[5\]](#), and ethical standards of the Economic and Social Research Council in the UK [\[6\]](#).

1. Informed Consent: Respect for Persons – Adequate Information.

The information given to the human subjects is contained within a lengthy (4000+ word) Terms of Service & Privacy Agreement (Terms), which is not readable in an accessible way to persons using the service. [\[4\]](#)

- a. Few users of any crisis service could be expected to read such a document.
- b. Too much information, or information provided in a manner that is not accessible to the human subject, is to be avoided when seeking informed consent.
- c. It is a testable hypothesis as to how many users clicked the link to the Terms, and even to survey (optional exit survey) how many read the Terms. To my knowledge, this critical point of information wasn't tested. Those in positions of authority and control have a responsibility to test fundamental claims made on behalf of human subjects, when such claims can easily be proven or, more likely here, disproven.
- d. The Terms contain language in which the human subjects, supposedly, grant unlimited consent for use of anonymized data. "We may collect, use, transfer, and disclose non-Personally Identifiable Information for any purpose..." [4] The unequal power in the relationship between the organization offering the service and the person in crisis seeking help is abused by this language and its location more than half-way through the Terms. For such broad permission language, verification of informed consent should be made.

2. Informed Consent: Respect for Persons – Comprehension.

In a crisis response context, persons are experiencing power imbalances in relationships, abuse, sexual assault, and debilitating anxiety. Here, the meaning of the word consent deserves extraordinary consideration. In this context, control, autonomy, respect for boundaries, protection of rights of the powerless, and self-determination—these attributes are begging for affirmation. The health community specializing in mental health and well-being, and the researchers who support their work, should be held to high standard. Communications with human subjects of research should use the word consent with its full meaning, and understanding should be verified, not assumed.

- a. Users of the service are a highly vulnerable population.
- b. Users of the service may be younger than 18 years old.
- c. Users of the service may be under adult guardianship.
- d. Users with guardians or under-age may be reluctant, for various good reasons, to seek permission from their guardian before using the service.
- e. Users of the service are likely to be experiencing emotional or physical distress, and unlikely capable of giving informed consent. For example, they may be hiding from an abusive person, or having difficulty breathing during a panic attack.
- f. Key permissions are written in vague legalese ("other data") or in a misleading manner. For example, the information stored is more often characterized as being data "about" the conversation (age, zip code, area code, time zone, average length of conversation), and rarely identifies the data or information subject of consent as including the conversation transcripts themselves. [4]
- g. Even the "note 'b'" language from the Terms, quoted above from the 2019 Paper, says "We have created a formal process for sharing information about conversations with researchers..." [underline emphasis added]

3. Informed Consent: Respect for Persons – Voluntary Entry to Research.

Crisis Text Line, Inc., the service provider and organization responsible for collection, custodianship, and use of crisis conversations as data, does not provide an authentic voluntary choice to the research subjects. Research subjects include users of the service and the trained volunteers who answer. Together, they create the conversations of interest for research.

- a. A user of the service (person experiencing a crisis moment) has no choice but to agree and grant consent. “If you don’t agree to these Terms, you may not use the Service”. [4]
- b. Key permissions and information within the Terms are difficult to find. For example, the command to request a purge of conversation data is located 80% of the way through a 4000 plus word agreement. [4]
- c. The Terms have changed over time. Users of the service in 2015, for example, were under a different set of Terms [7] than users of the service in 2016 [4] and 2017-2018 [8]. Yet the research is being done on all conversations since the service began in 2013. [9]
- d. The trained volunteers who create the crisis conversations along with users of the service, are not asked consent for use of their conversations as data for research.
- e. The human subjects of the research, with already diminished autonomy, are denied self-determination by the lack of authentic choice at entry to the service.

In summary, it is my opinion that the anonymized crisis conversation data subject of the paper is unethically sourced.

B. Conflict of Interest and Undeclared Affiliations

There is another ethical issue. This relates to conflict of interest, vested monetary interest, and declaration of affiliations.

Under Conflicts of Interest, the 2019 Paper (page 10) states “None declared”.

Returning to Table 1 we have:

Challenges and principles:

Business challenges

“Prioritize research that can benefit users and the service”

Crisis Text Line protocols

“CTL reviews applications for *value* to texters and crisis community. Projects cannot target for-profit ventures or have plans to monetize research output” [underline emphasis added]

Conflict of Interest, Vested Monetary Interest in Data by Crisis Text Line, Inc. The 2019 Paper is framed as a non-profit organization taking care to help the crisis community by making its data available for non-commercial uses such as research “with the attendant possibility of having a wider impact across other fields and organizations that are focused on improving mental health across the world. In addition to sharing insights from its data, CTL has a culture of transparency, continuous learning, and sharing what they have learned in the process of innovation. The information shared in this paper accords with this mission.” (page 2)

While the research to be allowed under the pilot study was clearly stated to prohibit targeting for-profit ventures (page 5, Table 1), the study accepted and established a standard relating to consent for use of the Crisis Text Line data. Crisis Text Line had monetary incentive for establishing the standard at their historic and status quo practice. I will refer to their status quo practice as the “Terms of Service consent standard”.

On November 16, 2017 non-profit Crisis Text Line, Inc. formed a for-profit spinoff company with entity name Loris.ai, Inc., File Number 6619934. [10] The company was formed to create commercial software to help customer service agents respond to customer complaints. [11,12] During 2018, Crisis Text Line entered into a non-exclusive licensing agreement that obligated it to share “CTL[Crisis Text Line], Inc. materials” to its for-profit spinoff company. [13, page 14] The for-profit company also has private investors, including Omidyar Network which had representation on the Crisis Text Line Board of Directors [14,15]. During 2019 the for-profit was beta testing product [14] and officially launched product during 2021. [16]

In addition to whatever altruistic motive the organization had, it also had a monetary interest which was not declared. The success or failure of Crisis Text Line’s data sharing model depends on an affirmation that the data is ethically sourced from the broader scientific, health, and data science communities. The 2019 Paper, as it now stands, provided that necessary acceptance of the Terms of Service consent standard.

At what point does publicly available information show that a for-profit interest entered? The study documented in the 2019 Paper appears to have begun sometime around early 2016, and is characterized within the 2019 Paper as an 18-month pilot.

“CTL convened a panel of academic and technology sector experts to form a data ethics committee. Literature reviews and personal recommendations from the CTL advisory board [later known as clinical advisory board] were used to identify researchers with expertise in data security, research ethics, mobile health interventions, and psychology who would be appropriate committee members. The final data ethics committee had 15 members from 13 institutions and was chaired by CTL’s chief data scientist (see Multimedia Appendix 1).

Between January 2016 and April 2017, the data ethics committee met for 4 full group meetings and multiple smaller topic-specific subcommittees via conference call and

utilized regular email communications to discuss specific aspects of the data-sharing program..." (page 3) [A link to Multimedia Appendix 1 is given herein at citation [\[17\]](#)]

Consider the following events.

August 6, 2015 (approximate) Crisis Text Line, Inc. website lists members of its Data Ethics Committee, consisting of eleven members. "The Data Ethics Committee reviews Crisis Text Line's data collection, storage and sharing practices. Members have expertise in the ethical, legal, and security risks of data, especially with regard to health issues and Personally Identifiable Information (PII)". The plain language reading is this was a Data Ethics Committee to the corporation. [\[18\]](#)

February 6, 2016 (approximate) the Crisis Text Line website lists updated members of its Data Ethics Committee, increased to 16 members [\[19\]](#), 15 of which were on the listing of Data Ethics Committee members for the 2019 Paper. [\[17\]](#)

February 16, 2016 Crisis Text Line adds the "note 'b'" (see beginning of letter) language regarding researchers to its Terms, prefaced with "As of Feb 16, 2016, ..." [\[20\]](#)

February 16, 2016, the Crisis Text Line public website posted an information page relating to the 18-month pilot study, titled "ENCLAVE DATA FAQ". Excerpts follow.

...“Who is blocked from access to the data?”

Like, almost everyone on the planet! Only a handful of researchers are going to be approved.

All researchers must pass through a stringent application. In addition, we will NEVER share data...

- For commercial use.
- With individuals not associated with a university or research institution.
- "Just because." Yep. We reserve the right to reject any application, for any reason.

Are you selling this?

Nope. Heck no. Not gonna happen. Yuck. Gross.

(Read: no commercial use. Never ever ever.)" [\[21\]](#)

November 3, 2016 (approximate), the 16th member of the Data Ethics Committee is no longer listed on the website, and the 15 members listed match the 2019 Paper list. [\[22\]](#)

October 3, 2017 (approximate) Crisis Text Line removes the Enclave Data FAQ from its website. Another webpage titled Data Philosophy is posted, and a Data section is added to the FAQ portion of the website. Language about prohibitions on commercial use of data were removed. [\[23,24\]](#)

November 16, 2017 Crisis Text Line, Inc. incorporates for-profit spinoff company Loris.ai, Inc., a state of Delaware general corporation.

January 10 and 12, 2018

“Effective January 12, 2018, CTL, Inc. acquired a 53% interest in Loris.ai, Inc. (“Loris AI”). Additionally, CTL, Inc. and Loris AI entered into a resource sharing agreement, which governs Loris AI’s desire to retain CTL, Inc. to provide certain management resources and administrative and professional services.

In addition, on January 10, 2018, CTL, Inc. and Loris AI entered into a non-exclusive, non-transferable, non-sub-licensable, license agreement to use the CTL, Inc. materials for Loris AI’s internal business operations. The license includes the right to modify and create derivative works of the CTL, Inc. materials, and governs limitations on Loris AI’s access to CTL, Inc.’s training modules for use in developing their product. Loris AI will pay to CTL, Inc. an annual license fee of 1% of its net annual revenues in excess of \$2,000,000 earned by Loris AI during each fiscal year”. [13, page 14]

January 12, 2018 Ikigai Alpha, Inc., incorporation date January 10, 2018 [26] files Notice of Exempt Offering of Securities with United States Securities and Exchange Commission reporting sale of \$2,000,000 USD total amount sold, date of first sale for the filing is given as January 12, 2018. Use of proceeds clarification stated as “The proceeds from the offering will be used for general working capital purposes including the payment of payroll. Officers listed in item 3 will be among the Issuer’s employees who may receive a portion of regularly scheduled salary from such proceeds.” The persons listed in Item 3 included Nancy Lublin, then CEO of Crisis Text Line, Inc. and Rob Stavis, then member of Crisis Text Line Board of Directors. [27] Though the company name is unfamiliar, the facts match with the initial offering for Loris.ai, Inc. [28] and it is listed as a previous name to Loris.ai in a December 9, 2019 filing listed below.

March 12, 2018 Blog titled “What is Loris.ai?” is posted to the Crisis Text Line website. “How can we fundraise in a way that helps us further our purpose of putting more empathy in the world? The answer: a subsidiary for-profit venture called Loris.ai...” ... “Crisis Text Line is the majority shareholder in Loris.ai. We literally own it. (And we share a Founder/CEO – Nancy Lublin – so it’s all in the family.)” [11]

March 2018 (approximate) Loris.ai launches website. “PROPRIETARY EDGE Crisis Text Line has trained over 12,000 Crisis Counselors who have handled over 62 million messages with an 86% approval rating. Simply, the organization knows how to handle hard conversations. The intelligence gleaned from both the Crisis Text Line training and large sentiment-rich data corpus will be leveraged to create Loris.ai enterprise software.” [25]

July 13, 2018 2019 Paper submitted to Journal of Medical Internet Research.

November 13, 2018 2019 Paper accepted for publication in Journal of Medical Internet Research.

December 15, 2018 (approx.) the Loris.ai website had posted the following:

“FOUNDING PARTNERS

We’ve heard from nearly 100 companies who value compassion, empathy, and the ability to navigate hard conversations. The beta is full. Would you like to be on our waitlist?” [\[14\]](#)

January 17, 2019 2019 Paper is published in Journal of Medical Internet Research.

December 9, 2019 Loris.ai, Inc. (previous name Ikigai Alpha, Inc.) files Notice of Exempt Offering of Securities with United States Securities and Exchange Commission reporting sale of \$5,139,857 USD total amount sold, date of first sale for the filing is given as November 27, 2019. Use of proceeds clarification stated as “The gross proceeds of the offering will be used for general corporate purposes, which may include the salaries of certain persons listed in Item 3.” The persons listed in Item 3 included Nancy Lublin, then CEO of Crisis Text Line, Inc. [\[29\]](#)

This timeline demonstrates that during the time that the study was in progress and the 2019 Paper submitted for publication, Crisis Text Line, Inc. was launching a for-profit commercial enterprise that would feature “learnings” from its crisis conversation data and provide direct monetary benefit.

Data Ethics Committee (for 2019 Paper) and Author Affiliations. Fifteen members of Crisis Text Line, Inc.’s own Data Ethics Committee comprised, and were one and the same with, the Data Ethics Committee convened for the 2019 Paper. In addition, seven of the Data Ethics Committee members were co-authors of the paper. In addition, two other co-authors, including the corresponding author, were serving on Crisis Text Line’s Advisory Board (later called the Clinical Advisory Board). Yet only two affiliations with Crisis Text Line are listed on the first-page authors’ institutional and educational affiliations. The two declared affiliations were for Crisis Text Line, Inc. staff members, who would ultimately have reported to then-CEO Nancy Lublin. Nancy Lublin was also a director of the for-profit corporation and authorized to receive compensation from it. A point of information that is not accessible to me, is who owned shares in the for-profit.

Was the Data Ethics Committee sufficiently independent and unbiased? Ethical inquiries give more weight to actions than words. Without access to the words exchanged between Crisis Text Line and the Data Ethics Committee itself, the following actions can be weighed: 1) the result that the Terms of Service consent standard was deemed ethical in spite of seemingly obvious limitations; 2) the change in ethical standards from 2016 to 2017 during the tenure of this same Data Ethics Committee--beginning with a vociferous prohibition against commercial use of the data, to creating a commercial use of its own; and 3) the testimony of my personal experience, of being terminated as a volunteer for questioning both ethical standards—consent and commercial use. I experienced a zero-tolerance response to my questioning, even though I was told by the organization that I was an effective volunteer. Would not the Data Ethics Committee members be subject to the same intolerance from Crisis Text Line corporate? It is my presumption that all Data Ethics Committee and Clinical Advisory Board members serve at the pleasure of the Board of Directors of Crisis Text Line. I was told by a person authorized to

speak for the corporation, that my objections to adequacy of consent and monetization of the data were contrary to the Articles of Incorporation of Crisis Text Line, Inc., the objectives of the organization, and its contractual obligations to the for-profit spinoff company. Is there reason to think the corporation would tolerate questioning from a high profile source such as their own Data Ethics Committee, when even a volunteer was singled out and removed?

The Crisis Text Line, Inc. Data Ethics Committee is now called the Data, Ethics, and Research Advisory Board and has reduced in size to nine members. Seven of the current Advisory Board members served dual roles for the 2019 Paper, both as co-authors and in serving on its Data Ethics Committee. One of the current Data, Ethics, and Research Advisory Board members was the corresponding author of the 2019 Paper.

With the information available to me, I believe the Data Ethics Committee lacked sufficient independence from Crisis Text Line corporate to qualify as an unbiased guardian of ethical standards over the study. At the very least, under these circumstances, the affiliations and conflicts should have been declared. I am bringing this information forward understanding that others need to come to their own conclusions based on the evidence and facts.

Regardless of undeclared relationships and vested monetary interests, the Terms of Service consent standard is not credible. Worse, it fails to give respect and autonomy to persons using the service by denying them reasonable opportunity to give informed consent.

C. Response Requested, Concern for Precedent

I am calling for reconsideration of this paper based on the issues raised. I am not commenting on any other aspect of the 2019 Paper.

To date, roughly a million persons have “agreed” to various forms of the Terms, and there will be millions more to come as the service continues to expand internationally. I have no vested interest except to try to speak for those who unknowingly had others in power decide what would happen to their personal, sensitive conversations. I support the Crisis Text Line crisis response service, and the volunteers and staff who devote themselves to the difficult, painful, rewarding work of extending a human touch to someone in desperate need. Because I support that work, I felt a calling to research and respond to the ethical practices of Crisis Text Line’s corporate and financial sides, once I became aware.

The 2019 Paper is being cited at an increasing rate. Research is continuing on the crisis conversations. The 2019 Paper was selected “as a best paper of 2019” for the 2020 International Medical Informatics Association (IMIA) Yearbook, Special Section on Ethics in Health Informatics. [\[30\]](#)

I would be most appreciative of a careful examination of these issues. I know you will provide opportunity to the institutions and persons implicated by these questions to answer. I also understand this may cause discomfort, however, it is most important to see where the facts lead. All can agree there is a need for trust in our mental health and research institutions. Trust, however, must be earned.

Sincerely,

Tim Reiersen

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