RESEARCH ETHICS · HUMAN SUBJECTS PROTECTION · COLLECTION DISPLACEMENT · INTERMEDIARY SHIELD · INSTITUTIONAL REVIEW BOARD · DECISIONAL CAPACITY · SECONDARY DATA USE · DATA BROKERAGE · PSYCHIATRIC CRISIS · INFORMED CONSENT · DIGITAL MENTAL HEALTH · COMMON RULE

Outside the Perimeter

Commercial collection of crisis data and the subpart that was never written

The rule asks the institution whether the information is identifiable. It does not ask who gathered it, or what they told the person they took it from.

Travis Gilly, *Outside the Perimeter: Commercial Collection of Crisis Data and the Subpart That Was Never Written*, working paper, August 2026 (v1.2)

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A RULE PLACED WHERE THE HARM WAS

Every major instrument was written after somebody was hurt, and each was written to reach the place where the hurt occurred.

The Nuremberg Code

Answered physicians acting under a state.

The National Research Act and Belmont

Answered a Public Health Service study and the institutional research culture that tolerated it.

The Common Rule

Answered how a federally supported institution should govern its own investigators.

> *The placement was correct for the harm it addressed. The argument here is that it no longer reaches the collection that matters most, and that the reason is structural rather than a failure of will by any review board.*

SOURCES National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), *The Belmont Report*; U.S. Department of Health and Human Services (2018), Protection of human subjects, 45 C.F.R. pt. 46.

THE MECHANISM, AND ITS TWO NAMES

The collection happens outside the perimeter and arrives inside it as material that already exists.

OUTSIDE

A commercial or quasi-institutional actor, under no assurance and no review, solicits sensitive material from people in acute distress.

→

THE TRANSFER

The material is delivered to university researchers, who receive it as information that already exists. Their own conduct begins at receipt.

→

INSIDE

The analysis turns on identifiability. If the material is not identifiable, this is not human subjects research. If it is, a secondary research exemption may apply.

Collection displacement

Regulation drawn around an institution displaces collection outward rather than eliminating it.

The intermediary shield

A third party whose interposition converts a recruitment problem into a data receipt.

SOURCES 45 C.F.R. §§ 46.102(e)(1), 46.102(e)(5), 46.104(d)(4).

III

Before the Perimeter

Two histories, usually told apart

The common feature is not cruelty. It is availability.

THE ABUSE HISTORY, READ BY POPULATION

A population held by an institution, whose refusals can be characterized as symptoms, is the cheapest research material that has ever existed.

Tuskegee, 1932 to 1972

The Public Health Service followed several hundred Black men with syphilis without treating them and without telling them what they had.

Willowbrook State School

Children with intellectual disability were deliberately infected with hepatitis, with parental permission obtained where admission was scarce.

Jewish Chronic Disease Hospital, 1963

Live cancer cells were injected into chronically ill elderly patients who were not told what was being injected.

Beecher, 1966

A survey of published studies showed that violations of this kind were ordinary rather than exceptional in the mainstream literature.

Each happened inside an institution, performed by that institution's own investigators, on a population the institution already held. When Congress and the Department responded, they placed the requirement exactly where the abuse had been.

Read by population, it is one practice. Psychiatric hospitals supplied subjects for malaria inoculation, insulin coma, lobotomy, and drug trials; asylums furnished bodies for anatomical demonstration; and the practice reaches back as far as institutional confinement itself.

Three populations received dedicated protection in 1991, and each had an organized constituency that could speak in its own name. Prisoners had litigation and a civil rights movement. Children had parents. Pregnant women had a political coalition.

SOURCES Beecher, H. K. (1966). Ethical problems and clinical research. *New England Journal of Medicine*, 274(24), 1354-1360; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), *The Belmont Report*.

THE PANIC HISTORY

A new medium arrives, harm is attributed to it, and a research rush follows in which the affected people become a contested resource.

Neurasthenia, 1881

Beard blamed the telegraph, the railway, and the periodical press for an epidemic of nervous exhaustion.

The Payne Fund Studies, 1929 to 1933

Investigated the effects of motion pictures on children, and were criticized for method and for moralizing.

War of the Worlds, 1940

Cantril established a mass panic in the scholarly record. Later work argued the panic was substantially a newspaper artifact, which makes the study the durable evidence for an event it helped construct.

Comic books, 1954

Wertham's campaign drove federal hearings. Archival work in 2012 found he had altered and combined the case histories of the children he cited.

THREE FEATURES RECUR

The affected population is described by people who did not collect its accounts under any standard. Institutional prestige attaches to whoever reaches the population first. And the research produced during the rush outlives the phenomenon that produced it, becoming the record even where the record was wrong.

WHAT SEPARATES THE PRESENT CASE

In every historical instance the researchers gathered their own material and answered for it, however badly. In the present case the material arrives already gathered.

SOURCES Beard, G. M. (1881). *American nervousness: Its causes and consequences*; Cantril, H. (1940). *The invasion from Mars*; Pooley, J., & Socolow, M. (2013). The myth of the War of the Worlds panic. *Slate*; Wertham, F. (1954). *Seduction of the innocent*; Tilley, C. L. (2012). Seducing the innocent. *Information and Culture*, 47(4), 383-413.

IV

The Perimeter, and the Subpart Never Written

Three populations protected, and one asked for and not delivered

The absence is not an oversight discovered later. It was identified at the beginning and has been objected to continuously for forty-eight years.

WHAT 1991 DELIVERED

Three special protections, each for a population an institution already held.

SUBPART B

Pregnant women, human fetuses, and neonates

SUBPART C

Prisoners

SUBPART D

Children

NO SUBPART

Adults whose decisional capacity is uncertain or impaired

Belmont set out respect for persons, beneficence, and justice. Respect for persons carries the requirement of informed consent and, in Belmont's own terms, the requirement of additional protection for persons with diminished autonomy.

Subpart A made institutional review the operative device. An institution holds an assurance, constitutes a board, and the board reviews the protocols of that institution's investigators.

SOURCES National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979), *The Belmont Report*; U.S. Department of Health and Human Services (2018), Protection of human subjects, 45 C.F.R. pt. 46, Subparts A to D.

A DOCUMENTED REFUSAL

Asked for in 1978. Asked for again in 1998. Asked about in 2007. Drafted in 2013. Still absent.

1978	The National Commission published a report recommending that the regulations cover persons described in the language of the period as mentally infirm. The Department did not adopt the recommendation.
1991	Three subparts arrived. This population was the one that had been asked for and not delivered; contemporary analysis records that the proposed regulations covering mentally disabled persons were abandoned against strong opposition.
1998	The National Bioethics Advisory Commission published *Research Involving Persons with Mental Disorders That May Affect Decisionmaking Capacity*, with twenty-one recommendations to boards, investigators, and federal regulators.
2007	The Department published a request for information asking the public whether existing protections were adequate. The solicitation is the admission: it was asking, twenty-nine years later, whether the gap needed filling.
2013	Tovino argued for a new Subpart E governing research involving adults with impaired decision-making capacity, with the drafting problem worked through.
2018	The Common Rule was comprehensively revised. It restructured the exemptions, introduced limited review, created broad consent for secondary use, and renumbered the definitions. It did not add the subpart.

SOURCES National Bioethics Advisory Commission (1998); U.S. Department of Health and Human Services (2007). Request for information and comments on research that involves adult individuals with impaired decision-making capacity. *Federal Register*, 72, 50966; Tovino, S. A. (2013). A "common" proposal. *Houston Law Review*, 50, 787.

WHAT INSTITUTIONS DID INSTEAD

41.5% require **exclusion** of people with uncertain or impaired decisional capacity unless their inclusion is scientifically justified.

5.3% require **inclusion** unless exclusion is justified.

Human subjects policies of ninety-four top funded American research institutions, cross sectional study.

In the absence of a rule, institutions have converged on avoidance.

That is the opposite of protection. The population is neither safeguarded when it is enrolled nor reliably included in the research that concerns it.

The general instruction that boards include additional safeguards for subjects vulnerable to coercion or undue influence is the whole of what governs, and it names no standard.

SOURCES U.S. Department of Health and Human Services (2018), Protection of human subjects, 45 C.F.R. pt. 46, Subpart A; Tovino, S. A. (2013). A "common" proposal. *Houston Law Review*, 50, 787.

VI

Collection Displacement

A gap in where the rule reaches, not in what it covers

Not a loophole in the sense of a drafting error. The predictable operation of a rule whose subject is the institution, applied to a world in which collection is a service that can be bought.

THE TEXT, AND WHAT FOLLOWS FROM IT

The definition attaches to the investigator, and asks what the investigator did.

CONSEQUENCE ONE

It asks what the investigator did, at the moment of the investigator's contact. The conduct of a non-covered third party who assembled the material before the investigator saw it is not an element of the definition.

CONSEQUENCE TWO

Where the material is not identifiable, the second prong is not satisfied and the first was never engaged, because there was no intervention or interaction. The activity is not human subjects research. No board reviews it, no consent standard applies, and no record of the collection is created at the institution.

AND WHERE IT IS IDENTIFIABLE

The secondary research exemption reaches uses of identifiable private information where the information is publicly available, or where the investigator records it so identity cannot readily be ascertained, does not contact the subjects, and will not re-identify them. A sensible provision for the reuse of research and clinical datasets, which is what it was written for.

SOURCES 45 C.F.R. §§ 46.102(e)(1), 46.102(e)(5), 46.104(d)(4).

ONE PARTY, ADDED

The same conduct, with and without a third party in the middle.

WITHOUT THE INTERMEDIARY

Human subjects research on the face of the definition

An investigator who solicits conversation records from a person in acute psychiatric distress is interacting with that person, obtaining information, and analyzing it. That requires a protocol, board review, informed consent, and, because of who the subject is, the capacity assessment that no subpart specifies.

WITH THE INTERMEDIARY

The investigator receives a file

The recruitment was performed by an entity with no assurance. The consent, if any, was obtained by that entity under terms it wrote for itself. The de-identification, if performed, was performed by that entity and is represented to the researchers rather than verified by them. The investigator's own conduct begins at receipt.

> *This is not a loophole in the sense of a drafting error. It is the predictable operation of a rule whose subject is the institution, applied to a world in which collection is a service that can be bought.*

SOURCES 45 C.F.R. §§ 46.102(e)(1)(i), 46.104(d)(4).

THE SUPPLY SIDE

37 data brokers approached about bulk mental health data.

26 responded.

11 were willing and able to sell what was requested.

Every broker asked what the data would be used for. None of them checked the answer.

Prices ran from roughly two hundred seventy-five dollars for five thousand aggregated record counts to subscriptions in the range of seventy-five to one hundred thousand dollars covering data on individuals' mental health conditions, with some records carrying names and addresses. The report concluded that the industry lacks best practices for handling this category of data, particularly around privacy and the vetting of buyers.

Purchasing a dataset is an ordinary procurement act inside a research institution. Nothing in the procurement pathway asks how the material at the far end was obtained, because the regulatory question at the institution is about identifiability rather than provenance.

SOURCES Kim, J. (2023). *Data brokers and the sale of Americans' mental health data*. Duke University Sanford School of Public Policy, Cyber Policy Program; Enos, G. (2023). Duke public policy report suggests federal law restricting data brokers. *Mental Health Weekly*, 33(10), 1-7.

ALREADY ON THE RECORD

Incidental data and solicited data arrive at the same exempt door, and only one of them was gathered by asking a person in crisis to hand it over.

The receiving end is settled doctrine

De-identified data falls outside the threshold definition, secondary research with identified data is exempt where the investigator does not record it identifiably, and waivers of consent for secondary research are routinely granted. One review concluded that both the existing regime and its proposed replacement were critically flawed; the rule that emerged kept de-identified data outside the definition entirely.

The privacy statute does not fill it

The Privacy Rule reaches protected health information held by covered entities and does not apply to de-identified information at all. Health information not held by a covered entity may be used and disclosed without regard to it. An organization soliciting conversation records from a support community is outside both regimes at once.

Good practice is already written

A consensus statement developed through a modified Delphi process with twenty-four experts, including people with lived experience, addresses inclusion criteria, consent, data review during a study, and responding to elevated risk in real time for digital monitoring with people at risk of suicide. It is guidance. Nothing requires it.

One further cost, even where every actor complies: public trust is lost when people discover a practice they were never told about, and the reaction is not an assessment of risk but a question about disclosure. If this is innocent, why did nobody mention it. The proposed answer is notice and an opt-out, and the arrangement in the next part offers neither.

SOURCES Friesen, P., et al. (2021). Governing AI-driven health research: Are IRBs up to the task? *Ethics & Human Research*, 43(2), 35-42; Lynch, H. F., Bierer, B. E., & Cohen, I. G. (2016), *Hastings Center Report*, 46(1), 4-5; Hall, M. A., & King, N. M. (2016), *Hastings Center Report*, 46(2), 30-32; Terry, N. (2015), *Behavioral Sciences & the Law*, 33(5), 653-661; White, T., Blok, E., & Calhoun, V. D. (2020), *Human Brain Mapping*, 43(1), 278-291; Botkin, J. R. (2017), *Learning Health Systems*, 2(1); Nock, M. K., et al. (2020), *Psychiatric Research and Clinical Practice*, 3(2), 57-66.

VII

Two Instances

One with a settled record, one still forming

The first is the calibrated case: a reader can check every claim.

THE CALIBRATED CASE

A crisis service, a for-profit company with a shared founder, and the conversation data that moved between them.

Politico reported the arrangement in January 2022. Within days the service announced it had ended the data sharing relationship, requested that the company delete the data it had received, and updated its terms of service. What makes the case useful is the published record around it: a 2019 journal paper describing the principles of the organization's academic data sharing pilot, authored in part by members of its external data ethics committee; a later commentary raising the conflict question directly; and a reply and editorial published in January 2025 noting that the ethics committee members who authored the 2019 paper were apparently not involved in or consulted about the decision to share data with the commercial subsidiary.

FEATURE ONE

The organization published its own ethics assurance, and that assurance became the document outside parties relied on.

FEATURE TWO

The assurance was produced by people who did not know what the organization was also doing.

FEATURE THREE

The consent instrument at collection was a terms of service acceptance presented to a person in crisis, which a former board chair later acknowledged in public is not consent.

SOURCES Crisis Text Line (2022, January 31). *An update on data privacy, our community and our service*; Eysenbach, G. (2025). *Journal of Medical Internet Research*, 27, e67878; Pisani, A. R., et al. (2025). Authors' reply. *Journal of Medical Internet Research*, 27, e59734.

THE MECHANISM, STATED BY THE INTERMEDIARY

The organization holds the access. Partners arrive after the population has been assembled, on terms that are not theirs.

WHAT THE ORGANIZATION IS

The Human Line Project solicits conversation records and personal accounts from people who describe crises connected to chatbot use, through intake surfaces that collect names and contact details alongside the records. Its founder describes a support community of more than 450 people across 32 countries, and reports within that population 212 cases of psychosis, more than 109 hospitalizations, and 20 deaths by suicide.

THE ROLE, DESCRIBED FROM THE INSIDE

Asked at a recorded public event how researchers might connect with the affected population, the founder answered that the organization does not do research in-house and works only with partners who connect with the community afterward and make their own request of it. That is the intermediary role stated without apparent recognition that it is a regulatory position rather than an administrative one.

SOURCING NOTE

In the same session the founder named six universities as research partners, including MIT, King's College London, Stanford, McGill, and Yale. All of these associations are therefore sourced to the organization itself in a recorded public session, which is a stronger source than the partner display on its own website and is the source relied on here. On the founder's own description, every named partner arrives after the population has been assembled.

SOURCES Horizon Omega (2026). *Etienne Brisson (The Human Line Project) at the Montreal AI Safety, Ethics and Governance Event Series* [Audio recording of public livestream]. Internet Archive.

TWO ACCOUNTS OF THE SAME TRANSFER

The published methods and the intermediary's account do not agree.

THE PUBLISHED METHODS

The authors state that they received chat logs via the organization, describe it as a nonprofit set up as a community for people with lived experience, and state that with individuals' consent the organization removed identifiers from those logs before the research team reviewed them, with no demographic data transferred. Twelve of the study's nineteen participants were sourced this way.

THE FOUNDER, AT THE RECORDED SESSION

He stated that the study did not go through the organization for the transcripts, that the researchers asked people directly in the community, and that the researchers compensated those people directly. He directed questions about the review board to the university, and stated that the paper does not say the organization provided transcripts, only that the researchers had been in contact.

> *The paper says otherwise, and any reader can check it. Later in the same session, answering a different question, the founder referred to the study as one in which the organization analyzes transcripts and reported figures from it. The disclaimer and the claim of participation occur in one recorded conversation.*

SOURCES Moore, J., Haber, N., et al. (2026). Characterizing delusional spirals through human-LLM chat logs. *Proceedings of the ACM Conference on Fairness, Accountability, and Transparency*; Horizon Omega (2026), Internet Archive recording.

WHY THE CONTRADICTION DOES NOT NEED RESOLVING

Both accounts implicate the same failure, from opposite directions.

IF THE PUBLISHED METHODS ARE ACCURATE

The intermediary shield operated exactly as described. Consent was obtained by a party under no assurance, de-identification was performed by that party and represented rather than verified, and the receiving institution's regulatory analysis began at receipt. Nobody with authority reviewed the collection, and a subpart for decisional capacity would not have changed that.

On the second account the arrangement also reproduces the historical form with unusual fidelity. Direct approach to a population assembled by a third party, enrollment from inside it, and a modest payment as inducement is the Willowbrook and prison-study shape, minus the physical custody, with the custody function performed by a support community instead.

IF THE FOUNDER'S ACCOUNT IS ACCURATE

Investigators who approach individuals in a crisis community, enroll them, and pay them are interacting with human subjects on the face of the definition. That is not secondary research and no exemption for existing data reaches it. It requires a protocol, review, and informed consent from each person, obtained by the investigators, from a population in acute psychiatric distress, using compensation as an inducement.

The one thing established by both accounts together is that no participant in the arrangement can say with authority how the material was obtained, and that there is no mechanism anywhere in the system for resolving the question. A published methods section and the organization it names give incompatible accounts, and nothing in the regulatory structure requires either to be reconciled with the other.

SOURCES 45 C.F.R. § 46.102(e)(1)(i); Moore, J., Haber, N., et al. (2026), *Proceedings of the ACM Conference on Fairness, Accountability, and Transparency*; Horizon Omega (2026), Internet Archive recording.

WHAT THE REPRESENTATIONS RESTED ON

The regulations ask the receiving institution whether the information is identifiable. They do not ask whether the party that de-identified it has a privacy officer.

The privacy policy

Asked whether the organization publishes one, the founder was unable to confirm that one existed, stated that he does not run the website, and asserted that the organization operates in accordance with Quebec's Law 25. Asked whether a designated person responsible for the protection of personal information is identified publicly, as that statute requires, he stated the designation exists internally in a job description but did not believe it appeared on the website.

The corporate structure

Asked about a for-profit incorporation preceding the nonprofit, he stated that only the nonprofit exists and characterized the earlier incorporation as a transition of a month or two. Public corporate filings, held by the author, record the two entities as separated by a longer interval and as concurrently existing.

The reported findings

The founder reported that in 100 percent of analyzed conversations the system presented itself as sentient. The published finding concerns a different subject, and the figure as stated appears to derive from a summary document hosted by the organization rather than from the paper.

None of these establishes bad faith and none is offered as doing so. What they establish is that the consent and de-identification representations on which a receiving institution relied came from an organization that could not, on the record, confirm the existence of its own privacy policy or the public designation its governing statute requires.

SOURCES Horizon Omega (2026). *Etienne Brisson (The Human Line Project) at the Montreal AI Safety, Ethics and Governance Event Series* [Audio recording of public livestream]. Internet Archive; public corporate filings held by the author.

ONE CONTRIBUTOR'S ACCOUNT

Two withdrawal requests, at two separate nodes of one pipeline. The material continued at both.

She asked in writing that her records be kept private. They were transferred for research regardless. She then contacted the receiving researcher directly to withdraw them, and was refused a copy of her own file.

> *The structural argument establishes that no review body sees the collection. This establishes what that absence costs the person at the far end: there is no node in the pipeline at which a withdrawal has to be honored, because no node was ever assigned the duty.*

The account is held by the author, is reported here with consent limited to this form, and is not published in any identifying form.

SOURCES Contributor account held by the author, reported with consent limited to this form.

IX

What Should Change

Four asks, ordered by how little they depend on anyone in Washington

The failure is jurisdictional rather than substantive. The material never reaches the body with authority to ask about it.

FOUR ASKS

The fastest lever requires no rulemaking and no new authority.

ONE

Journals and conferences

Extend the existing review board statement one step, to a provenance statement in the methods: who collected the material, under what instrument, who obtained consent and in what form, and whether the authors verified either or are reporting a representation made to them. A program committee can adopt this in one meeting.

TWO

Institutional review boards

The determination workflow turns on identifiability. It should also ask whether the material was solicited from individuals, by any party, for the purpose of transfer to researchers. An affirmative answer should require the institution to obtain the collection instrument and the consent record before accepting the material.

THREE

The Office for Human Research Protections

Guidance is available without rulemaking, and there is precedent in the existing guidance on coded private information. Parallel guidance should state that the secondary research exemption was written for the reuse of data generated for other purposes, and does not describe material assembled for research transfer by a party outside any assurance.

FOUR

The Department

Write the subpart, which is on the record with the drafting problem worked through. Then narrow the secondary research exemption so it does not reach information solicited from individuals for the purpose of supply to researchers. Insufficient is not a reason to keep declining the subpart for a fifth decade.

The published methods discussed earlier would satisfy the first ask partly and fail it in the part that matters. They state who collected and who de-identified. They do not state that both facts are representations the authors did not verify, and a reader has to infer it. A required provenance statement makes the inference unnecessary and puts the question in front of the authors while the paper is being written.

SOURCES Burris, S. (2008). Regulatory innovation in the governance of human subjects research. *Regulation & Governance*, 2(1), 65-84; Tovino, S. A. (2013). A "common" proposal. *Houston Law Review*, 50, 787; 45 C.F.R. §§ 46.104, 46.104(d)(4).

WHAT IS NOT ESTABLISHED HERE

Nobody knows how much research rests on displaced collection, because the arrangement generates no institutional record by design.

Prevalence

The paper shows the mechanism exists, that a market in mental health data exists, and that at least two organizations have operated it. Any figure offered would be an estimate presented as a count. This is addressable by a bounded audit: code recent methods sections for whether data was collected by the team, received from a named non-institutional intermediary, or purchased.

Board practice

The analysis states the structure of the definitions and their consequence. It does not survey how boards apply them, and practice varies. Some institutions may ask provenance questions as local policy. Evidence of that would narrow the claim without defeating it, since local policy is precisely what the absence of a rule leaves to chance.

The strongest counterargument

The intermediary shield is load bearing for legitimate research. Secondary use provisions exist because reusing existing data avoids re-contacting subjects, which is itself a protection. A rule making receiving institutions responsible for the provenance of every dataset would burden ordinary archival and registry research heavily.

Any remedy has to separate collection performed for the purpose of supply to researchers from data that came into existence for other reasons, and that line is not obvious. Drafting that provision and testing it against the exemption structure is the work that would turn this diagnosis into a proposal.

The account also finds nothing in the ordinary case. A researcher analyzing a public health registry, a census extract, or a curated corpus assembled under an assurance is not doing what this paper describes. And the second instance has a forming record: several elements rest on documents held by the author, and their absence from the public record should be weighed by the reader.

SOURCES Kim, J. (2023). *Data brokers and the sale of Americans' mental health data*. Duke University Sanford School of Public Policy; 45 C.F.R. § 46.104.

WHERE THE WATCHING HAPPENS

The institution is now the safest part of the pipeline, because it is the only part anybody watches.

The people supplying the material at the far end of that pipeline are, in the current instance, in psychiatric crisis. They are the one population every advisory body since 1978 has asked the Department to protect specifically, and the one population for which no subpart was ever written. They are now being reached by parties no subpart would govern, through instruments the parties draft themselves, and their accounts arrive at universities as files with the provenance question already closed.

> *The remedy does not wait on a rulemaking. A journal can require a provenance statement in the methods section, and a program committee can adopt that requirement in a single meeting. An institution can ask, before it accepts a dataset, who solicited this and what were they told. Those two questions would have reached every case in this paper.*

None of this requires anyone to have acted in bad faith, which is what makes it durable. The harm is distributed across a set of individually defensible steps, and the person whose worst hours are in the file is the only party to the arrangement who is not represented anywhere in it.

SOURCES U.S. Department of Health and Human Services (2018), Protection of human subjects, 45 C.F.R. pt. 46; Burris, S. (2008), *Regulation & Governance*, 2(1), 65-84.

References

Travis Gilly, *Outside the Perimeter: Commercial Collection of Crisis Data and the Subpart That Was Never Written*, working paper, August 2026 (v1.2). Complete list of 28 entries, in the order the paper gives it, across 3 slides.

Abdillahi, I. (2024). Algorithmic surveillance in the era of the mental health appsphere. *American Journal of Community Psychology*, 73(1-2), 17-26. https://doi.org/10.1002/ajcp.12743

Beard, G. M. (1881). *American nervousness: Its causes and consequences*. G. P. Putnam's Sons.

Beecher, H. K. (1966). Ethical problems and clinical research. *New England Journal of Medicine*, 274(24), 1354-1360.

Botkin, J. R. (2017). Transparency and choice in learning healthcare systems. *Learning Health Systems*, 2(1). https://doi.org/10.1002/lrh2.10049

Burris, S. (2008). Regulatory innovation in the governance of human subjects research: A cautionary tale and some modest proposals. *Regulation & Governance*, 2(1), 65-84. https://doi.org/10.1111/j.1748-5991.2007.00025.x

Cantril, H. (1940). *The invasion from Mars: A study in the psychology of panic*. Princeton University Press.

Crisis Text Line. (2022, January 31). *An update on data privacy, our community and our service*. https://www.crisistextline.org/blog/2022/01/31/an-update-on-data-privacy-our-community-and-our-service/

Enos, G. (2023). Duke public policy report suggests federal law restricting data brokers. *Mental Health Weekly*, 33(10), 1-7. https://doi.org/10.1002/mhw.33562

Eysenbach, G. (2025). Crisis Text Line and Loris.ai controversy highlights the complexity of informed consent on the internet and data-sharing ethics for machine learning and research. *Journal of Medical Internet Research*, 27, e67878.

Kim, J. (2023). *Data brokers and the sale of Americans' mental health data*. Duke University Sanford School of Public Policy, Cyber Policy Program.

References, continued

Friesen, P., Douglas-Jones, R., Marks, M., Pierce, R., Fletcher, K., Mishra, A., Lorimer, J., Véliz, C., Hallowell, N., Graham, M., Chan, M. S., Davies, H., & Sallamuddin, T. (2021). Governing AI-driven health research: Are IRBs up to the task? *Ethics & Human Research*, 43(2), 35-42. https://doi.org/10.1002/eahr.500085

Hall, M. A., & King, N. M. (2016). Conscience, courage, and "consent." *Hastings Center Report*, 46(2), 30-32. https://doi.org/10.1002/hast.546

Horizon Omega. (2026). *Etienne Brisson (The Human Line Project) at the Montreal AI Safety, Ethics and Governance Event Series* [Audio recording of public livestream]. Internet Archive. https://archive.org/details/brisson-human-line-project-montreal-ai-safety-2026_202608

Livingstone, S., Orben, A., & Odgers, C. (2022). Debate: Should academics collaborate with digital companies to improve young people's mental health? *Child and Adolescent Mental Health*, 28(1), 150-152. https://doi.org/10.1111/camh.12630

Lynch, H. F., Bierer, B. E., & Cohen, I. G. (2016). Confronting biospecimen exceptionalism in proposed revisions to the Common Rule. *Hastings Center Report*, 46(1), 4-5. https://doi.org/10.1002/hast.528

Moore, J., Haber, N., et al. (2026). Characterizing delusional spirals through human-LLM chat logs. *Proceedings of the ACM Conference on Fairness, Accountability, and Transparency*.

National Bioethics Advisory Commission. (1998). *Research involving persons with mental disorders that may affect decisionmaking capacity*.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. Department of Health, Education, and Welfare.

References, concluded

Nock, M. K., Kleiman, E. M., Abraham, M., Bentley, K. H., Brent, D. A., Buonopane, R. J., et al. (2020). Consensus statement on ethical and safety practices for conducting digital monitoring studies with people at risk of suicide and related behaviors. *Psychiatric Research and Clinical Practice*, 3(2), 57-66. https://doi.org/10.1176/appi.prcp.20200029

Pisani, A. R., Gallo, C., Gould, M. S., Kanuri, N., Marcotte, J. E., Pascal, B., Rousseau, D., Ranney, M. L., Filbin, B., & Turner, S. (2025). Authors' reply: Commentary on protecting user privacy and rights in academic data-sharing partnerships. *Journal of Medical Internet Research*, 27, e59734.

Pooley, J., & Socolow, M. (2013). The myth of the War of the Worlds panic. *Slate*.

Terry, N. (2015). Developments in genetic and epigenetic data protection in behavioral and mental health spaces. *Behavioral Sciences & the Law*, 33(5), 653-661. https://doi.org/10.1002/bsl.2203

Tilley, C. L. (2012). Seducing the innocent: Fredric Wertham and the falsifications that helped condemn comics. *Information and Culture*, 47(4), 383-413.

Tovino, S. A. (2013). A "common" proposal. *Houston Law Review*, 50, 787.

United States Department of Health and Human Services. (2007). Request for information and comments on research that involves adult individuals with impaired decision-making capacity. *Federal Register*, 72, 50966.

United States Department of Health and Human Services. (2018). Protection of human subjects, 45 C.F.R. pt. 46.

Wertham, F. (1954). *Seduction of the innocent*. Rinehart.

White, T., Blok, E., & Calhoun, V. D. (2020). Data sharing and privacy issues in neuroimaging research: Opportunities, obstacles, challenges, and monsters under the bed. *Human Brain Mapping*, 43(1), 278-291. https://doi.org/10.1002/hbm.25120