HUMAN SUBJECTS RESEARCH · COMMON RULE · SECONDARY RESEARCH EXEMPTION · SOLICITED COLLECTION · INTERMEDIARY SHIELD · DECISIONAL CAPACITY · SUBPART E · INSTITUTIONAL REVIEW BOARD · HIPAA COVERED ENTITY · PSYCHIATRIC CRISIS · RESEARCH PROVENANCE · INFORMED CONSENT

Solicited, Not Secondary

The Common Rule exemption, the seam between two regimes, and research on adults in psychiatric crisis

The exemption for secondary research carries an unstated premise: that a governed collection already happened. Where it did not, the consent inquiry does not fail. It never opens.

Travis Gilly, *Solicited, Not Secondary: The Common Rule Exemption, the Seam Between Two Regimes, and Research on Adults in Psychiatric Crisis*, working paper, August 2026 (v0.5)

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A RULE WITH AN ADDRESS

Federal human subjects protection is built around a place.

The scheme placed its review requirement at the point where an institution holding a federal assurance touches a person. That answered the abuses that produced it, every one of which happened inside an institution, performed by that institution's own investigators, on a population the institution already held.

IF NOT IDENTIFIABLE
The activity is not human subjects research. No board reviews anything.

IF IDENTIFIABLE
One of the secondary research exemptions may apply.

EITHER WAY
The conduct of the party that assembled the material is not an element of any determination the institution makes.

This paper is about the second route and the assumption buried in it.

SOURCES National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974); 45 C.F.R. §§ 46.102(e)(1), 46.104(d)(4) (2018).

THE CLAIM

Nothing was reused. Something was collected.

INCIDENTAL MATERIAL

Came into existence for another reason

A clinical record was made to treat a patient. A registry was built for surveillance. A dataset was produced by an earlier study with its own protocol and its own consent. A governed collection already occurred, and the exemption's premise holds.

SOLICITED MATERIAL

Was assembled by asking

The request is the collection. There was no prior governed event to reuse, because the only event was the asking, and the asking was performed by a party the regulations do not reach.

The current text nonetheless covers the second category, and the covering is an accident of drafting rather than a policy choice anyone defended. This paper does not argue that any researcher violated a rule. The argument is that they complied with one, and that compliance is the problem.

SOURCES 45 C.F.R. § 46.104(d)(4) (2018); Holly Fernandez Lynch, Barbara E. Bierer & I. Glenn Cohen, *Confronting Biospecimen Exceptionalism in Proposed Revisions to the Common Rule*, 46 Hastings Ctr. Rep. 4, 4-5 (2016).

II

The Architecture and the Seam

One regime regulates an activity. The other regulates a category of institution.

A private collector standing between a person in crisis and a university is doing something neither rule was written to see.

WHERE THE TWO RULES STOP

Two sectoral rules, meeting at a party neither describes.

THE COMMON RULE

Attaches to investigators

A human subject is a living individual about whom an investigator obtains information through intervention or interaction, or obtains, uses, studies, analyzes, or generates identifiable private information. The conduct of a third party who assembled the material before the investigator saw it is not an element.

THE PRIVACY RULE

Attaches to covered entities

Health plans, health care clearinghouses, and providers that transmit health information electronically in connection with covered transactions. It does not apply to de-identified health information at all. Health information not held by a covered entity may be used and disclosed without regard to it.

THE COLLECTOR

Attaches to neither

An organization soliciting conversation records from people describing a mental health crisis is not a health plan, not a clearinghouse, and not a provider transmitting claims. It holds no federal assurance and receives no federal research support.

> *The comparison with the European regime makes the design choice visible. The General Data Protection Regulation attaches to anyone processing personal data within its territorial scope. The Privacy Rule attaches to a defined class of entities.*

SOURCES 45 C.F.R. § 46.102(e)(1)-(e)(5) (2018); 45 C.F.R. § 160.103 (2013); 45 C.F.R. § 164.502(d)(2) (2013); Nicolas Terry, *Developments in Genetic and Epigenetic Data Protection in Behavioral and Mental Health Spaces*, 33 Behav. Sci. & L. 653, 657-58 (2015); Tonya White, Elisabet Blok & Vince D. Calhoun, *Data Sharing and Privacy Issues in Neuroimaging Research*, 43 Hum. Brain Mapping 278, 283 (2020).

THE SAME CONDUCT, TWICE

Maximum scrutiny when an investigator performs it. None when a non-covered party performs it first.

THE INVESTIGATOR DOES IT

An investigator who approached a person in acute psychiatric distress, obtained their conversation records, and analyzed them would be conducting human subjects research on the face of the definition. That requires a protocol, board review, and documented informed consent.

A COLLECTOR DOES IT FIRST

The same records, gathered by a party outside the perimeter and delivered as a file, reach the same investigator through a door that asks only whether the names have been removed.

This is not a loophole in the sense of a drafting error exploited against the drafters' intent. It is the ordinary and predictable result of a rule that governs what institutions do with people meeting a rule that governs what a defined set of health entities do with records.

SOURCES 45 C.F.R. § 46.102(e)(1)(i)-(ii) (2018); 45 C.F.R. § 160.103 (2013).

III

The Population Congress Never Covered

Three subparts, and one asked for since 1978

The account offered here for why is not that anyone thought this population was safe.

FORTY-EIGHT YEARS OF ASKING

Subparts exist for pregnant women and neonates, for prisoners, and for children. None exists for adults whose decisional capacity is uncertain or impaired.

1978	The National Commission recommended that the regulations cover persons then described as mentally infirm. The Department did not adopt it.
1991	Three subparts arrived. Contemporary analysis records that the proposed regulations for mentally disabled persons were abandoned against strong opposition, leaving the population governed by the general provision alone.
1998	The National Bioethics Advisory Commission issued twenty-one recommendations to boards, investigators, and federal regulators.
2007	The Department asked the public whether existing protections were adequate. The solicitation is itself the admission: twenty-nine years after being told the gap existed, it was asking whether it did.
2013	Tovino argued for a new Subpart E and worked through the drafting problem.
2019	General compliance with the revised Common Rule. It restructured the exemptions, introduced limited review, created broad consent for secondary use, and renumbered the definitions. It did not add the subpart.

SOURCES 45 C.F.R. §§ 46.201-.207, 46.301-.306, 46.401-.409, 46.111(b); Nat'l Bioethics Advisory Comm'n (1998); Request for Information and Comments, 72 Fed. Reg. 50,966 (Sept. 5, 2007); Stacey A. Tovino, *A "Common" Proposal*, 50 Hous. L. Rev. 787 (2013); Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149 (Jan. 19, 2017).

WHY THOSE THREE

Each covered population had an organized constituency able to speak in its own name from outside the institution holding it.

Prisoners had litigation and a civil rights movement.

Children had parents.

Pregnant women had a political coalition.

Adults whose capacity is in question had, and largely still have, no equivalent, and the condition that makes them vulnerable is the condition that makes a constituency hardest to build.

WHAT INSTITUTIONS DID INSTEAD

41.5% require exclusion unless inclusion is scientifically justified.

5.3% require inclusion unless exclusion is justified.

Human subjects policies of ninety-four top-funded American research institutions.

In the absence of a rule, institutions converged on avoidance. That is the opposite of protection: the population is neither safeguarded when enrolled nor reliably included in the research that concerns it.

SOURCES Carrie Hoyt et al., *An Analysis of Institutional Review Board Policies for Enrollment of Adults with Impaired or Uncertain Decision-Making Capacity* (2025); Idil Abdillahi, *Algorithmic Surveillance in the Era of the Mental Health Appsphere*, 73 Am. J. Cmty. Psych. 17, 22-23 (2024).

THE DYNAMIC, STATED IN THE LITERATURE

People living with mental health conditions are not trusted with information about themselves, while their most sensitive information is sought from them.

> *The result is expectation without explanation, which the same author describes as a formula for exploitation and disenfranchisement.*

SOURCES Idil Abdillahi, *Algorithmic Surveillance in the Era of the Mental Health Appsphere*, 73 Am. J. Cmty. Psych. 17, 22-23 (2024).

IV

The Exemption at Work

A provision written for reuse, applied to collection

The exemption presumes that the collection happened somewhere governed. That clause is load bearing, and it is doing silent work.

THE JUSTIFICATION, AND ITS SILENT CLAUSE

Three reasons the exemption exists, and only the third carries the weight.

The material already exists

Generated for care, or surveillance, or an earlier study with its own protocol and its own consent.

Re-contact would burden without protecting

For large historical datasets it would be impossible, and for the rest it imposes real cost on sources who have already been asked once.

The collection was already governed

The marginal protection gained is small because the collection itself was governed at the time it occurred. This is the load-bearing clause, and no provision states it.

Interpose a third party between the person and the investigator and the presumption fails without any provision noticing. Recruitment is performed by an entity holding no assurance. Consent, if obtained, is obtained by that entity under terms it drafted for itself. De-identification, if performed, is performed by that entity and represented to the researchers rather than verified by them. Every determination the institution makes is about the file rather than about how the file came to exist.

SOURCES 45 C.F.R. § 46.104(d)(4)(i)-(ii) (2018); Lynch, Bierer & Cohen, 46 Hastings Ctr. Rep. 4 (2016); Mark A. Hall & Nancy M. P. King, *Conscience, Courage, and "Consent,"* 46 Hastings Ctr. Rep. 30, 30 (2016).

THE SUPPLY SIDE IS A MARKET

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 verified the answer.

Prices ran from a few hundred dollars for aggregated record counts to flat fees and subscriptions in the tens of thousands, with some records carrying names and addresses.

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

SOURCES Joanne Kim, *Data Brokers and the Sale of Americans' Mental Health Data* (Duke Sanford Cyber Pol'y Program 2023); Gary Enos, *Duke Public Policy Report Suggests Federal Law Restricting Data Brokers*, 33 Mental Health Wkly. 1, 3 (2023).

A METHODS SECTION, READ AS A REGULATORY DOCUMENT

Four things the passage does, none of which the authors were required to do differently.

It identifies the collector as outside the institution

The team received chat logs via an outside organization, described as a nonprofit community for people with lived experience.

It attributes consent to that party

With individuals' consent, the organization removed identifiers from the logs before the research team reviewed them.

It attributes de-identification to that party

No demographic data was transferred. Twelve of the study's nineteen participants were sourced this way.

It reports both as facts

Rather than as representations the authors received and did not audit. Nothing in the Common Rule required them to audit either one.

A methods section is not a compliance document, and the authors were writing for readers who wanted to know what the data was, not for a regulator asking where it came from. The scheme asked the institution whether the information was identifiable. The institution answered.

The question of what the people in those logs were told, by whom, and in what condition, was never put to anyone with the standing to insist on an answer. These were people describing psychiatric crises, reached through a channel no subpart would govern even if one existed.

SOURCES Jared Moore et al., *Characterizing Delusional Spirals Through Human-LLM Chat Logs*, in Proceedings of the 2026 ACM Conference on Fairness, Accountability, and Transparency (2026); 45 C.F.R. § 46.104(d)(4) (2018).

THE DILEMMA IS THE EXHIBIT

Each account is, on its own, a legal conclusion. The two conclusions condemn the same structure from opposite directions.

IF THE PUBLISHED METHODS ARE ACCURATE

The exemption 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 institution's regulatory analysis began at receipt.

IF THE FOUNDER'S ACCOUNT IS ACCURATE

Researchers approached individuals in a crisis community, enrolled them, and paid them, which is interaction with living individuals on the face of the definition. That is not secondary research at all. No exemption for existing data reaches it, and it would have required a protocol, review, and consent obtained by the investigators from each person, with compensation operating as an inducement.

A published methods section and the organization it names give incompatible accounts of how material from people in psychiatric crisis reached a research team, and nothing in the regulatory structure requires either account to be reconciled with the other. There is no actor in the system with both the duty and the standing to ask which one is true.

> *Under the amendment proposed here, the question would have been answered before the exemption issued, because the institution would hold the collection instrument and the terms presented at solicitation. The two accounts could not both survive contact with that file.*

SOURCES Moore et al. (2026); Presentation and Question Period with Etienne Brisson, The Human Line Project, Montreal AI Safety, Ethics and Governance Event Series (2026) (recording, Internet Archive); 45 C.F.R. § 46.102(e)(1)(i) (2018).

V

The Standard the Regulations Decline to Write

Two state courts have already written it

The content of the missing rule is not unknown. It has been articulated in litigation, on records made by actual subjects.

WHAT TWO COURTS ALREADY HELD

Surrogate consent cannot reach nontherapeutic research, and researchers owe subjects a duty of care.

NEW YORK

T.D. v. New York State Office of Mental Health

The court invalidated regulations governing research on patients in facilities operated or licensed by the Office of Mental Health for want of authority. It went further because the defendants intended to continue the research: surrogate consent for greater than minimal risk nontherapeutic research is impermissible where there is no evidence of the patient's personal intent and the research offers no benefit. On due process, capacity provisions fail where they give no adequate notice that capacity is being evaluated and no mechanism for patient-requested review of a determination of incapacity.

MARYLAND

Grimes and White v. Kennedy Krieger Institute

A parent, relative, or surrogate cannot consent to the participation of a child or other person under legal disability in nontherapeutic research carrying any risk of injury. Informed consent agreements in nontherapeutic projects can constitute special relationships giving rise to duties whose breach supports a negligence action. And governmental regulations can create duties on the part of researchers out of which such relationships arise. The duty was put to a jury in plain terms: protection of participants from unreasonable harm, and complete and prompt disclosure of hazards existing during the study.

THE DECLARATION BEHIND IT

New York Public Health Law provides that safeguarding the rights and welfare of individual human subjects is a matter of vital state concern, and that every human being has the right to be protected against the possible conduct of medical or psychological research upon his or her body without voluntary informed consent.

SOURCES *T.D. v. N.Y. State Office of Mental Health*, 228 A.D.2d 95, 106, 114-15, 123-24 (N.Y. App. Div. 1996) (relying on *Rivers v. Katz*, 67 N.Y.2d 485, 496 (1986)); N.Y. Pub. Health Law § 2440 (McKinney); *Grimes v. Kennedy Krieger Inst., Inc.*, 366 Md. 29, 113-14, 782 A.2d 807 (2001); *White v. Kennedy Krieger Inst., Inc.*, 110 A.3d 724 (Md. Ct. Spec. App. 2015).

THREE LIMITS

The missing subpart is not merely an omission. It is an active subtraction.

They are state law, and they vary

T.D. is New York. Grimes and White are Maryland. A federal court applying North Carolina law found the state's informed consent statute reached health care providers and treatment, and therefore did not apply to nontherapeutic experimentation at all. A subject's protection turns on where the study happened.

They attach to researchers, not collectors

Every proposition runs against a party conducting the research. None reaches an organization that assembles material and hands it over. Courts have declined to extend the treating physician's duties to supervisors and sponsors, reasoning that non-physicians holding no fiduciary relationship can be liable, if at all, only secondarily. A sponsor at the center of a study can sit outside the duty; an assembler sits farther outside it.

They run in tort, after harm

The wrong instrument for a consent failure producing no physical injury, no identifiable damages, and no plaintiff who knows what happened to their file. Even in governed settings the residue of control is thin: consent forms characterize the transfer as a gift, disclaim ownership of anything derived, and say nothing about withdrawal or redirection.

Grimes held that governmental regulations can generate the duty from which a special relationship arises. Where no regulation governs research with adults of uncertain capacity, there is no regulatory source from which such a duty can be built, and a plaintiff must construct it from general principles that other subjects can take from a subpart. The absence leaves this population with less common law than the populations that were covered.

SOURCES *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1470-71 (M.D.N.C. 1986); *Suthers v. Amgen, Inc.*, 372 F. Supp. 2d 416 (S.D.N.Y. 2005); *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir. 2007); *Grimes v. Kennedy Krieger Inst., Inc.*, 366 Md. 29, 113-14 (2001).

VI

Solicited Collection Is Not Secondary Research

Text, purpose, history, and the objections

A use cannot be secondary to nothing.

THE WORD IS DOING WORK

A use cannot be secondary to nothing.

TEXT

Secondary denotes a use that follows a primary one, and the ordinary sense presupposes an antecedent use for a different purpose. Where the sole purpose of the collection was transfer to researchers, the proposed research is the first and only use.

WHY THE READING HAS NOT BEEN ADOPTED

The enumerated conditions in subparagraphs (i) through (iv) do the practical work in institutional determinations, and the threshold word rarely receives attention. A determination that runs straight to whether identity can readily be ascertained never reaches the question of what the use is secondary to.

HISTORY

The 2015 proposed rule and the debate around it concerned biospecimens and data generated in clinical care and prior research, and the arguments on both sides ran in terms of reuse. Neither the proposal, the comments, nor the final rule addressed material solicited by a non-covered party for research supply, because the practice was not on anyone's mind in 2015.

The field's own foundational document states the governing instinct. The Belmont Report's discussion of the boundary between practice and research closes on a general rule: if there is any element of research in an activity, that activity should undergo review for the protection of human subjects. Solicited collection is an element of research on any reading, because it exists for no other purpose. The exempt door contradicts the rule the field recites.

SOURCES 45 C.F.R. § 46.104(d)(4) (2018); Lynch, Bierer & Cohen, 46 Hastings Ctr. Rep. 4, 4-5 (2016); Hall & King, 46 Hastings Ctr. Rep. 30, 30-32 (2016); Nat'l Comm'n for the Prot. of Human Subjects, *The Belmont Report* (1979), *as quoted in Ancheff v. Hartford Hosp.*, 260 Conn. 785, 799 A.2d 1067 (2002).

THE OBJECTIONS

Three, each answered on its own terms.

Burden

The exemption is load-bearing for legitimate research, and a provenance requirement would burden registry, archival, and clinical reuse heavily. Correct as to incidental material, and the reason the amendment is drawn as narrowly as it is. A rule reaching only material solicited for transfer to researchers leaves every ordinary reuse case exactly where it is.

Line drawing

The line will be contested at its edges. A support community that collects accounts for its own purposes and later shares them is a harder case than an organization whose intake form states a research purpose on its face. A contested edge is not an argument against a line, the text keys to the stated purpose rather than the collector's character, and the alternative is an arrangement in which the question is never asked.

Beneficence

Research on this population is badly needed and friction will produce less of it. The premise is right and the conclusion does not follow. Institutions have already converged on avoidance without any rule requiring it. A documentation requirement that makes lawful collection legible is more likely to increase defensible research than to decrease it, because the present alternative is not careful inclusion but a channel nobody inspects.

SOURCES Carrie Hoyt et al., *An Analysis of Institutional Review Board Policies for Enrollment of Adults with Impaired or Uncertain Decision-Making Capacity* (2025); 45 C.F.R. § 46.104(d)(4) (2018).

VII

Proposal

One clause, and three levers that need no rulemaking

A documentation duty rather than a review duty. The institution obtains two files and reads them.

PROPOSED TEXT, ADDED TO § 46.104(D)(4)

> This exemption does not apply to information that was solicited from individuals by any person or entity for the purpose of transfer to investigators for research. Where an institution obtains information described in this paragraph, the institution shall obtain and retain the instrument by which the information was solicited and the record of any consent obtained at the time of solicitation, and shall determine whether the information may be used consistent with the terms under which it was provided.

It keys to purpose, not character

The clause turns on the stated purpose of the collection rather than the identity or character of the collector, so it does not require the institution to evaluate an outside organization.

It documents rather than reviews

The institution obtains two files and reads them. That is a documentation duty, not a second review board.

It reaches any person or entity

So it does not depend on the collector's tax status, jurisdiction, or corporate form.

What it does not reach: clinical records used for research, public health registries, specimens and datasets from completed studies, publicly available information, administrative data, and anything that came into existence for a reason other than supplying researchers. The amendment does not touch the reuse the exemption was written to permit.

SOURCES 45 C.F.R. § 46.104(d)(4) (2018).

TWO INSTRUMENTS, NEITHER SUFFICIENT ALONE

The amendment is not a substitute for the subpart, and the subpart would not reach this arrangement.

THE SUBPART ALONE

A subpart binds covered institutions and their investigators. The collection at issue is performed by a party that is neither. A rule specifying how investigators must assess capacity before enrolling a subject does not reach a party that is not enrolling subjects and is not an investigator.

THE AMENDMENT ALONE

It produces documentation without a standard against which to read it. An institution that obtains a consent instrument still needs a rule telling it what adequate consent looks like when the person signing was in acute distress. That rule is the subpart, and its absence has been the answer to the same question for forty-eight years.

Tovino's argument for a Subpart E governing research with adults whose decisional capacity is impaired remains correct and remains unadopted.

SOURCES Stacey A. Tovino, *A "Common" Proposal*, 50 Hous. L. Rev. 787 (2013); 45 C.F.R. §§ 46.101(a), 46.111(b) (2018).

LEVERS THAT DO NOT REQUIRE RULEMAKING

The review board is one node among many, and journals hold one of the sharpest levers: refusal to review or publish.

Journals and program committees

Extend the existing board-approval statement one step, to a provenance statement in the methods: who collected the material, under what instrument, who obtained consent, and whether the authors verified either or are reporting a representation. The passage examined earlier would satisfy the first half and fail the second.

Determination workflows

Ask provenance alongside identifiability. An affirmative answer should not bar the research; it should require the institution to obtain the collection instrument before accepting the material.

The Office for Human Research Protections

Issue guidance parallel to the existing guidance on coded private information, stating that the exemption was written for reuse of material generated for other purposes and does not describe material assembled for research supply by a party outside any assurance.

Courts, already

A Texas appellate court, resolving a public records dispute, read the federal policy's informed consent requirements, including the required description of confidentiality protections, as bearing on what a university could be compelled to disclose. A regulation whose promises are enforceable in litigation it did not choose is one whose gaps are equally consequential.

Guidance for research with this population already exists and is required by nothing. A consensus statement developed through a modified Delphi process with twenty-four experts, including people with lived experience, addresses inclusion criteria, elements of consent, data review during a study, and real-time response to elevated risk. Nothing about the arrangement examined here would have brought it into play.

SOURCES Scott Burris, *Regulatory Innovation in the Governance of Human Subjects Research*, 2 Reg. & Governance 65, 71-73, tbl.1 (2008); *Univ. of Tex. Sys. v. Paxton*, No. 03-13-00329-CV (Tex. App. July 7, 2015); Matthew K. Nock et al., *Consensus Statement on Ethical and Safety Practices for Conducting Digital Monitoring Studies with People at Risk of Suicide and Related Behaviors*, 3 Psychiatric Rsch. & Clinical Prac. 57 (2020).

WATCHED AT THE WRONG POINT

The consent inquiry does not fail. It never opens.

Fifty years on, the institution is the most closely watched part of the chain, and it is watched at receipt, on a question about names. Where a party outside the perimeter solicits sensitive records from individuals and supplies them to a university, the exemption's premise is false and nothing in the text notices.

None of this requires bad faith from anyone, which is what makes it durable. A researcher who receives a de-identified dataset and asks no further questions has complied with the rule as written. A board that never sees the transaction cannot review it. An organization that solicits from a crisis community and drafts its own consent terms is doing what no federal rule forbids. 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 represented nowhere in it.

> *Two questions would have reached every case in this paper. Who solicited this, and what were they told. Neither requires a rulemaking to ask.*

SOURCES 45 C.F.R. §§ 46.102(e)(1), 46.104(d)(4) (2018); Scott Burris, 2 Reg. & Governance 65 (2008).

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