January 4, 2016

Jerry Menikoff, M.D., J.D.
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852


Dear Dr. Menikoff,

Citizens’ Council for Health Freedom, a national organization existing to support individual health care choices, individualized patient care, and medical and genetic privacy, is actively engaged in protecting the right of citizens to consent or to refuse to consent to the collection, storage, use and sharing of private information for research or other purposes, including biospecimens, and in particular, newborn DNA collected by state government agencies as part of the 50 state government newborn screening programs. Our organization offers the following public comments on these issues:

• Undoing Baby DNA Parent Consent Requirements in NBSSLR Act of 2014
• Public Input Limited by Legalese
• Large Loopholes in Consent Requirements
• Brief Consent Process at Vulnerable Time
• Research at the Bedside
• Extending Bad Policy Beyond Federally-Funded Research

UNDOING BABY DNA PARENT CONSENT REQUIREMENTS IN NBSSLR ACT OF 2014

Our organization worked with Senator Rand Paul’s office to secure in the “Newborn Screening Saves Lives Reauthorization Act of 2014” informed parent consent requirements for federally-funded research using newborn DNA collected by government agencies after the birth of each newborn.

Importantly, the Notice of Proposed Rulemaking (NPRM) discusses newborn dried blood spots just twice. First as a historical mention of the 2014 law, and second to claim that regarding the exemption to the rule in _.104(f)(1) and _.104(f)(2) which will require a “broad consent” as designed by HHS:

   It is presumed that research involving newborn blood spots would frequently take place using this provision.

We disagree. Given the history of this issue, which our organization began making public in 2003, we believe that while that may be the case in some circumstances, it is more likely that much research involving newborn DNA would be excluded from the rule entirely (see list of 11 exclusions below).

Thus, because the parent consent law secured by the NBSSLR Act 2014 expires when this “Protection of Human Subjects” rule is finalized, this NPRM seeks to undo and upend the consent requirement.
provisions secured in the NBSSLR Act of 2014.

PUBLIC INPUT LIMITED BY LEGALESE

This proposed rule is voluminous and complex, making it difficult for the average American citizen – the person whose lives will be most impacted by the rule – to understand what is being proposed or how to respond to the volumes of questions proposed. There are, in fact, 129,609 words on 131 regulation-formatted pages, written in small font three columns wide. In short, it has not been written with the patient and the patient's parents and representatives in mind. Yet, it proposes to impact their personal lives in ways they may not appreciate now or in the future.

Most of the American public is quite unaware of this proposed rule. Most don't even know that such a thing as a Federal Register exists. And for those that do, does the federal government expect them to read 131 pages of convoluted legalese text in small print over several days in order to be able to protect their personal privacy and to either support or protest the proposal?

Additionally, does the agency presume the American public understands that this regulation anticipates that “6,428 ... institutions (80 percent) will develop an institution-wide research repository of biospecimens and identifiable private information available for future research”? Do they know that biospecimens (tissue, blood, DNA, organs, urine, sputum, nails, bone, placenta, and more) “are collected from as many as 30 million individuals and are stored each year for both clinical and research purposes? Approximately 9 million individuals' biospecimens (30 percent) are collected for research purposes...” The rest are collected for clinical and treatment purposes. All this would soon be available for research with one signature, for up to 10 years without another whisper about it from the institutions.

LARGE LOOHOLES IN CONSENT REQUIREMENTS

As noted above, despite making much of the new proposed requirements for informed consent for use of biospecimens, identified or deidentified, as well as identifiable private information (medical records), we find many loopholes to the consent requirements. They include:

- Exclusions (research considered outside the scope of the regulations)
- Exemptions (research not subject to the rule, except as specified)
- IRB Waivers (part or all of informed consent altered or eliminated)

Exemptions

Since most of the public has never read the ANPRM or this NPRM and will not do so but may indeed read a public comment to the rule, it's important that they see a list of the loopholes, which we'll provide here as part of our stated objection to the broad-ranging list of loopholes in the proposed rule.

We start with the Exemptions, about which the NPRM states: "Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraphs (d) through (f) of this section are not subject to the requirements of this policy, other than those specified in the category." [Emphasis added.] Thus, as long as an institution follows the specific instruction in this proposed rule for a particular exemption (having used
the exemption decision tool (\S.104(c)), the institution can disregard the rest of the rule. These **nine exemptions** include:

1. **Education**: Research conducted in established or commonly accepted educational settings when it specifically involves normal educational practices. ...

2. **Federal Agency**: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine public benefit or service programs...

3. **Oral/Written**: Research involving benign interventions in conjunction with the collection of data from an adult subject through verbal or written responses (including data entry) or video recording if the subject prospectively agrees to the intervention and data collection...

4. **Food**: Taste and food quality evaluation and consumer acceptance studies.

5. **Educational**: Research, not including interventions, involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), if the information obtained is recorded in such a manner that human subjects can [sic??] be identified directly or through identifiers linked to the subjects.

6. **Secondary**: Secondary research use of identifiable private information that has been or will be acquired for non-research purposes, if the following criteria are met:
   - (i) Prior notice has been given to the individuals to whom the identifiable private information pertains that such information may be used in research; and
   - (ii) The identifiable private information is used only for purposes of the specific research for which the investigator or recipient entity requested access to the information.

7. **Biospecimen/Medical Record Storage**: \S.401(f)(1)(i) Storage or maintenance for secondary research use of biospecimens or identifiable private information that have been or will be acquired for research studies other than for the proposed research study, or for non-research purposes, if the following criteria are met:
   - (A) Written consent for the storage, maintenance, and secondary research use of the information or biospecimens is obtained in accordance with \S\ ll.116(c) and (d)(2), and the template published by the Secretary of HHS in accordance with \S\ ll.116(d)(1) must be used.
   - (B) The reviewing IRB makes the determinations required by \S\ ll.111(a)(9).

8. [Reserved.]

9. **Biospecimen/Medical Record Secondary Research**: \S.401(f)(2)(i) Research involving the use of
biospecimens or identifiable private information that have been stored or maintained for secondary research use, if consent for the storage, maintenance, and secondary research use of the information and biospecimens was obtained as detailed in paragraph (f)(1)(i)(A) of this section.

The last three appear to be the heart of much of the revision of this rule, as much of the rule discusses biospecimens and the __.104 sections of the rule. We are concerned that the “informed broad consent” is a 10-year consent, that most people may not understand what they’re being asked to sign or what’s at stake with their signature and so could be taken advantage of during a time of vulnerability, panic, pain, emotional distress, exhaustion or time and treatment pressures.

In addition, the agency appears to be planning for an exemption regarding biospecimens and medical records that is not yet listed for public comment, but is labeled “Reserved.”

We ask the agency: why all the “Reserves” in this proposed rule? What new is being planned that we are not able to comment on, and if you say we can comment on these in the final rule, we consider that a very high burden to place on organizations and individuals.

*Exclusions*

Exclusions include a list of activities specifically designated as outside the scope and authority of the proposed rule to protect human subjects of research. These are research activities for which no consent will be required. For example, the agency proposes that “the definition of human subject be expanded to include all biospecimens,” which is sound policy and we appreciate that designation, however, the agency then states the following on page 53946:

- e. What would change in the definition of “human subject” under the primary proposal?

  - It is anticipated that the compliance date for the proposed expansion of the definition would be three years after the publication date. The main consequence of this change would be that informed consent … would generally be required before research use of biospecimens not covered by an exclusion. (All emphasis added.)

  - All biospecimens used for research purposes that do not fall under an exclusion (see proposed § ll.101(b)(3)(i), and also § ll.101(b)(1)(i), (iii)–(vi)) and are collected after the compliance date would be subject to the requirements of this rule, regardless of identifiability. (All emphasis added.)

So while private institutions and organizations in general may be required to get informed consent for storage, maintenance, and use of biospecimens (baby DNA) and identifiable private information (medical records), government agencies, health care institutions and others involved in “excluded” activities will have those storage, maintenance, use and sharing of private information excluded from the entire rule, including its consent requirements, as though all of these activities were not the research that they actually are.

The exclusions are more hidden than the exemptions, which have their own title (“Exempt Research”).
The exclusions are instead found under the title “To What Does This Policy Apply?” on page 54045. The NPRM states,

“(a) **Except as** provided in paragraph (b) of this section, and as detailed in § II.104, this policy applies to the research described in paragraphs (a)(1) and (2) of this section.” (Emphasis added)

The words “**Except as**” should not be missed. Paragraph (b) includes 12 exclusions. The rationale given for excluding these areas of research for this proposed research rule include:

- **“Deemed not to be research...for the purposes of this regulation – 6 exclusions**
- **“Low-risk human subjects research, when already subject to independent controls without application of these regulatory requirements” – 4 exclusions**
- **“Low-risk human subjects research activities that do not meaningfully diminish subject autonomy” - 2 exclusions (one “reserved” and thus not yet revealed in the NPRM)**

Although 11 of the exclusion categories are conducting analysis and research, the agency uses the following rationale to dismiss patient privacy and autonomy in their support three government-specific exclusions:

“...three exclusions include some activities that fall into to [sic] a gray area that encompasses some activities that arguably might be judged to be research, but that are part of inherently governmental functions that have purposes other than research, such as responsibilities to protect public health and welfare (see exclusions for criminal investigations, public healthy [sic] surveillance, and intelligence surveillance). These activities promote recognized specific goods that are crucial to the public welfare, and should be carried out without any hindrances that satisfying regulatory requirements might impose. **For these activities, the principles of beneficence and justice outweigh any intrusions on individual autonomy that the regulations might have prevented.**

The 12 research activities which will be completely excluded from the requirements, oversight, and consent requirements of the proposed research rule include (**as described in the NPRM, minus the titles**):

1. **Internal Operations**: Data collection and analysis including use of biospecimens for an institution’s own internal operational monitoring and program improvement purposes...

2. **History**: Oral history, journalism, biography and historical scholarship activities...

3. **Criminal Justice**: Collection and analysis of data, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order...

4. **Delivery of Care**: Quality assurance or improvement activities involving the implementation of an accepted practice to improve the delivery or quality of care or services...

5. **Surveillance**: Public health surveillance activities, including the collection and testing of biospecimens, conducted, supported, requested, ordered, required, or authorized by a public
health authority...

6. **National Security**: Surveys, interviews, surveillance activities and related analyses or the collection and use of biospecimens conducted by a defense, national security or homeland security authority...

7. **Educational/Observational**: Research, not including interventions, that involves the use of educational tests..., survey procedures, interview procedures or observations of public behavior...

8. **Deidentified**: Research involving the collection of study of information that has been or will be acquired solely for non-research activities or were acquired for research studies other than the proposed research study, when either of the following two criteria is met...

9. **Government**: Research conducted by a Federal department of agency using government-generated or government-collected information obtained for non-research purposes (including criminal history data), if the information originally involved a collection of information subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.; the information is maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note; and all of the information collected, used, or generated as part of the research is maintained in a system or systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a.

10. **HIPAA-Allowed With No Accounting of Disclosures**: Research as defined by this policy that involves only data collection and analysis involving the recipient’s use of identifiable health information when such use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for the purpose of “public health activities” as described under 45 CFR 164.512(b).

11. **Test Development**: The secondary research use of a non-identified biospecimen that is designed only to generate information about an individual that already is known, including but not limited to the development and validation of certain tests and assays (such as research to develop a diagnostic test for a condition using specimens from individuals known to have the condition and those known not to have the condition), quality assurance and control activities, and proficiency testing.

12. **Reserved** (this is the title of this exclusion)

**IRB Waivers**

The proposed rule allows all the requirements of the rule for consent to be voided by an Institutional Review Board (IRB). IRBs have been charged by the HHS Division of Compliance Oversight with insufficient quorums, improper consent forms, lack of expertise, “Approval of Research Not Approved by the IRB” and much more: http://www.hhs.gov/ohrp/compliance/findings/index.html.
In the current Human Subjects protection regulation, according to HHS, there are only six reasons for a waiver. This proposal to revise the current regulation adds four more, specific to biospecimens (tissue, DNA, organs, blood, urine, sputum, etc):

Additional criteria for waiver or alteration of consent for biospecimens. For research involving the use of biospecimens, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the above requirements to obtain informed consent, provided the IRB finds and documents the criteria in paragraph (e)(1) of this section, and the following additional criteria:

(i) There are compelling scientific reasons to conduct the research; and

(ii) The research could not be conducted with other biospecimens for which informed consent was obtained or could be obtained.

Additional criteria for waiver or alteration of consent for research involving biospecimens. For research involving the use of biospecimens, an IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth above, or waive the above requirements to obtain informed consent, provided the IRB finds and documents the criteria in paragraph (f)(1) of this section, and the following additional criteria:

(i) There are compelling scientific reasons for the research use of the biospecimens; and

(ii) The research could not be conducted with other biospecimens for which informed consent was obtained or could be obtained.

We have never agreed to the current waiver options, such as, “The research could not practicably be carried out without the waiver or alteration.” Furthermore, the four-point “minimal risk” rationale is a broad loophole that the NPRM proposes to continue despite “risk” being in the eye of the beholder. A researcher cannot know how to define “risk” for the prospective human subject, or know how the rights and welfare of the subjects would be impacted. Thus, we have opposed the following criteria to allow IRBs to alter or eliminate some or all of the informed consent requirements:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

All of these newly proposed and ongoing regulatory loopholes should be eliminated, and individuals should be asked for their voluntary, written, informed consent to participate in research projects.

**BRIEF CONSENT PROCESS AT VULNERABLE TIME**

CCHF supports consent that is fully informed – including risks and benefits and reasons people may or may not want to participate -- voluntary, written and not presented at a time of great medical distress or
patient vulnerability.

As other commenters have suggested, it's not clear how well people understand consent forms, but the proposed rule suggests that research "subjects would spend an estimated five minutes engaging in the process of having their broad consent for future research uses of their biospecimens or information sought" and that in a clinical setting, a regulatory impact analysis (RIA) estimates "10 minutes of a subject's time to engage in the consent process."

This is insufficient time for an informed consent process or decision.

The ANPRM proposed a consent process that for many institutions would be a “one-time broad consent” (p. 54037) and it appears that the NPRM retained this process. The broad consent will last 10 years and will include all current medical records data and biospecimens as well as data and biospecimens collected over the next 10 years by that institution. No one will come asking again, or reminding the patient that every medical record note, every diagnosis, and every blood sample and their DNA will be part of a research project they know nothing about.

Furthermore, the consent form will likely take longer than 5 or 10 minutes to read, even for the most educated. Then there will be questions that will need to be answered by the practitioner.

The department has not placed sufficient emphasis on the informed consent process for the protection of the human subject...or the person who does not want to be a human subject, but feels perhaps pressure to sign the form, to make their doctor happy, or to just get the treatment that awaits.

In addition, the NPRM retained the oral consent provision which the ANPRM described as “typically provided their oral consent for future research at the time of the initial data collection; a written consent form would not have to be signed in that circumstance.” (p. 54037) All consent should be written.

It should be noted, that the NPRM does nothing to protect individuals from having their de-identified medical records and other records used without their consent, even though the data could be used in an objectionable manner, for research the individual opposes, or for research that is used to restrict their access to individualized patient care. The NPRM notes,

“As is currently the case, consent would not be required for the secondary research use of non-identified private information, such as the research use of medical records that have had all identifiers removed.” (p. 53973)

“No change would be made in the current regulatory framework allowing research use of non-identified private information without consent, except that, when relevant, individuals would be given an option to consent or refuse to consent to the inclusion of their data, with the removal of certain identifiers, in a publicly available database.” (p. 53974)

Furthermore, we do not support the “broad consent” proposal. So many things could be done that the patient would find quite objectionable. As noted in the NPRM, “Other commenters have opposed broad
consent, stating that investigators and clinicians should obtain specific consent from individuals for each research project. Their opposition was made on the ethical grounds that because individuals are not fully informed of specific research purposes for broad consent, they can never be truly informed about the use of their data.” We agree.

**RESEARCH AT THE BEDSIDE**

We are also very concerned about the plan to sweep “quality improvement” (as referred to in this NPRM) or as this NPRM calls the “‘learning’ healthcare system for continual quality improvement” (CQI) into the proposed protection of human subjects rule.

The plan to use hospital and clinic patients as research subjects without their consent has long been a contentious issue. CQI is considered by many to be research, and perhaps of the worse kind. No patient should have to wonder if they are getting the care that’s best for them or being used by management to see if something else or something less or something less expensive might work too, or work over a longer period of time – unless they have been fully apprised and given their informed written consent.

The controversy over QI and CQI and research has been long-lived. According to The Commonwealth Fund,

“Over the last two decades, quality improvement (QI) initiative have burgeoned in hospital sand health care systems. While enhancing the quality of health care is important and often required by accrediting organizations and others, the process of improvement can raise ethical issues. Perhaps not surprisingly, there has been occasional, yet intensive, professional and public scrutiny regarding the ethical oversight of QI initiatives.

For instance, in 2001, questions were raised about a project on end-stage renal disease funded by the Centers for Medicaid and Medicare Services (CMS.) Although CMS considered it to be a QI initiative, the Office for Human Research Protection (OHRP) determined the project was human subject research and that it should have been reviewed as such by an institutional review boards [sic] (IRB) prior to its implementation. In 2007, an anonymous whistleblower accused the leaders of a project funded by the Agency for Health Care Research and Quality (AHRQ) to reduce life-threatening infections in intensive care units of not having received proper ethical review. That project involved testing the effectiveness of a checklist for improving the safety of intravenous catheters across hospitals in Michigan. The primary questions raised related to ethics oversight were whether the project constituted research and needed to be reviewed by IRBs at all participating hospitals, and whether informed consent should have been obtained from all patients who were involved.

As noted by many commentators, QI and patient safety can be stymied unless there is a coherent approach to the ethical oversight of QI initiatives. However, achieving this turns out to be surprisingly complicated.

In the early 1990s, questions began to be raised as to whether quality improvement initiatives
out to be considered human subject research and reviewed and regulated as such.”¹

Thus we are very concerned with Exclusion #4 from our list above (§...101(b)(1)(iv):

Quality assurance or improvement activities involving the implementation of an accepted practice to improve the delivery or quality of care or services (including, but not limited to, education, training, and changing procedures related to care or services) if the purposes are limited to altering the utilization of the accepted practice and collecting data or biospecimens to evaluate the effects on the utilization of the practice. This exclusion does not cover the evaluation of an accepted practice itself.

Here is the agency’s description in the NPRM, which does not allay our organization’s concerns given that “measuring and reporting provider performance data for practice management, clinical, or administrative uses” is how institutions, government, and health plans often attempt to control the practice of medicine and reduce payments to “non-compliant” independent-practicing physicians:

Over the past several years, including in response to the 2011 ANPRM, OHRP has received comments from many individuals and organizations expressing concern that some readings of the definition of “research” would imply that the regulations apply to quality improvement activities, thereby potentially interfering with the ability of health care and other professionals to enhance the delivery or quality of care or services involving the use of accepted practices.

Indeed, a majority of commenters to the 2011 ANPRM supported excluding quality improvement activities from the scope of the Common Rule. These quality improvement activities are in many instances conducted by health care and other organizations under clear legal authority to change internal operating procedures to increase safety or otherwise improve performance, often without the consent of staff or clients, followed by monitoring or evaluation of the effects. These activities are generally conducted in circumstances where independent privacy, confidentiality, and security safeguards are in place, minimizing the chances of harm.

These efforts, some of which could be judged to be research, should be carried out because of the recognized public good they achieve. This exclusion is intended to avoid impeding such efforts where the Common Rule’s requirements might have a chilling effect on the ability to learn from, and conduct, important types of innovation.

Recognizing that some quality improvement efforts should not be considered to involve research as it is defined in the Common Rule can allay many of these concerns. Thus, this exclusion is being proposed to deal with quality improvement activities that are aimed at implementing practices that are already accepted, with the goal of improving the delivery or quality of treatments or services. This exclusion would permit measuring and reporting

provider performance data for practice management, clinical, or administrative uses. As proposed, this exclusion does not include evaluations of different accepted practices themselves, however, such as activities designed to determine whether a particular accepted medical treatment is or is not more effective than another.

Furthermore, the federal government has been supportive of research without patient consent. CMS has recently introduced a nationwide “pilot project” to pay only the federally-determined cost for Medicare patients with joint replacements. Doctors and hospitals whose costs exceed the “episode of care” cost will have to pay the federal government back. This research project, which including gainsharing, is being imposed on senior citizens without their consent. Instead the federal government simply writes that:

We believe that by requiring the participation of a large number of hospitals with diverse characteristics, the CJR model will result in a robust data set for evaluation of this bundled payment approach, and will stimulate the rapid development of new evidence-based knowledge. Testing the model in this manner will also allow us to learn more about patterns of inefficient utilization of health care services and how to incentivize the improvement of quality for common LEJR procedure episodes. This learning potentially could inform future Medicare payment policy. ...

Under the CJR model, beneficiaries retain the right to obtain health services from any individual or organization qualified to participate in the Medicare program. Under the CJR model, eligible beneficiaries who receive services from a participant hospital will not have the option to opt out of inclusion in the model. We require participant hospitals to supply beneficiaries with written information regarding the design and implications of this model as well as their rights under Medicare, including their right to use their provider of choice. We will also make a robust effort to reach out to beneficiaries and their advocates to help them understand the CJR model. ...

We have proposed that hospitals in selected geographic areas will be required to participate in the model, and that individual beneficiaries will not be able to opt out of the CJR model when they receive care from a participant hospital in the model. We stated our belief that it is not appropriate or consistent with other Medicare programs to allow patients to opt out of a payment system that is unique to a particular geographic area. ...

It is also important for beneficiaries to know that they can raise any concerns with their physicians, with 1–800–MEDICARE, or with their local QIOs. ...

How many patients will read or understand such written information, and even if they do, what if they cannot travel to a different hospital, or their plan doesn’t offer a different hospital, or their doctor is only at the hospital in the CMS research project, or this is the best hospital for their surgery?

The goal of the proposed rule showcases how the right of consent gets little attention for most planned

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uses of medical records data, biospecimens and DNA. The agency think only "some people" want "some control":

"The goal of this proposed rule is to enable the conduct of research in the rapidly growing area of research involving biospecimens, especially genetic analyses, while recognizing the autonomy interests of people to decide whether or not to participate in this area of research. Some people have a particular interest in whether research will be carried out with their biospecimens, and want to exercise some control over their biospecimens. At the same time, biospecimen repositories are being created to enable innumerable research studies in the future, and the pace of technology development is such that the specific research studies to be carried out with those biospecimens is unknown at the time the biospecimens are collected." (Emphasis added.)

EXTENDING BAD POLICY BEYOND FEDERALLY-FUNDED RESEARCH

We note that the rule proposes to extend its reach beyond federally-funded research to any institution that received federal dollars whether or not their research is federally-funded. From our perspective, this is less protective of patients, human subjects and privacy rights as it extends the reach of the proposed loopholes to all research, attempting perhaps to establish a federal ceiling for research that is the wrong ceiling. Consent should be the floor, but the NPRM doesn’t even have consent as its foundation. Consent is only a mirage throughout much of the proposed rule.

IN SUMMARY

We oppose the undoing of the parent consent protections of the NBSSLR Act of 2014, the sweeping loopholes to informed written consent requirements, broad consent, and the lack of assurance that consent will be fully informed, non-coercive and asked for at a time when the patient is not vulnerable.

We oppose deeming CQI research to be “not research,” approving research on patients at the bedside without informed written consent, and extending the exclusions, exemptions and additional waivers beyond federally-funded research.

We further oppose the general prohibitive language and tenor of the proposed rule to the average American citizen who will be most impacted by the final rule but most unlikely to understand it…and certainly unwilling to read its 131 pages and 129,609 words of legalese.

For the federal protection of human subjects in research, we ask for the proposed rule to either be rescinded or significantly altered to include informed consent requirements specific to the intended research and without loopholes for medical records, health data, DNA, and all biospecimens.

Sincerely,

Twila Brase, RN, PHN
President and Co-founder
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CCHFREEDOM.ORG