The New 2019 Institutional Review Board Common Rule Update: Implications for Plastic Surgery Research

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Summary: Clinical research remains at the forefront of academic practice and evidence-based medicine. Unfortunately, history has shown that human subjects are vulnerable to experimentation without regard for their own dignity and informed decision-making. Subsequently, it is vital for research institutes to uphold safeguards and ethical conscientiousness toward human subjects. The establishment of federal regulations and the development of institutional review boards have set guidance on these processes. On January 21, 2019, final revisions to the Federal Policy for the Protection of Human Subjects (the "Common Rule") went into effect. The purpose of this article is to review changes to the Common Rule and discuss their impact on plastic surgery research. (*Plast. Reconstr. Surg.* 145: 1323, 2020.)

World history contains notable cases of ethical violations in medical research. Following experiments in Nazi Germany and the United States, development of the Nuremberg Code and the Declaration of Helsinki set the modern stage for ethical guidance in medical research. In 1979, the Belmont Report on human subjects research was published to identify the basic ethical principles and protections necessary for research involving humans.[1] The federal government was subsequently tasked with designating regulations that uphold these fundamental principles. In 1991, the Federal Policy for the Protection of Human Subjects (the "Common Rule") was put forth. This policy established federal statutes defining and regulating clinical research, the function and composition of institutional review board (IRB) teams, and the requirements for informed consent.[2]

With the significant growth of clinical studies, the implementation of IRB processes has not been without debate or critique. Particularly, the notable growth in interventional clinical research and trials has considerably increased the assignments and regulatory demand for IRBs.[3] From the expansive growth of federally funded trials in the early 2000s, calls for IRB reform have been suggested.[4]

Since inception and publication, the Common Rule had not been amended, that is, up until January of 2017, when the Department of Health and Human Services announced final changes to update the Common Rule.[5] These modifications, which ultimately took effect on January 21, 2019, are an effort to make the IRB process more amenable to accommodate the changes and growth in clinical research. To further discussion and understanding, we aim to provide a concise update identifying and explaining the relevance of these changes.

UPDATED TERMINOLOGY AND DEFINITIONS

The updated Common Rule provides a host of new and modified definitions in an effort to clarify and to describe certain research terminology. New definitions include clinical trial, identifiable private information, identifiable biospecimen, interaction, institution, federal department or agency, certification, public health authority, and written or in writing. In addition, modifications or

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Table 1. Definitions of Salient Research Terms Reported in the Common Rule*

Term (46.102)	Old Definition	New Definition
Research	"A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity (e.g., Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or nonresearch in nature (e.g., wage and hour requirements administered by the Department of Labor)."	"A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research: (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions."
Human subjects	"A living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information."	"A living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."
Private information	"Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."	"Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record)."
Legally authorized representative	"Means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."	"An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research"

(Continued)

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Term (46.102)	Old Definition	New Definition
Intervention	"Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.*	"Includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes."
Interaction	*Above	"Includes communication or interpersonal contact between investigator and subject."
Clinical trial		"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes."
Identifiable private information		"Is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information."
Identifiable biospecimens		"Is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen."
Written, or in writing		"Refers to writing on a tangible medium (e.g., paper) or in an electronic format."
Public health authority		"An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate."
Institution		"Any public or private entity, or department or agency (including federal, state, and other agencies)."
Federal department or agency		"A federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency)."
Minimal risk	Unchanged: "Means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."	

*Adapted from Department of Health and Human Services. Title 45 Public Welfare, Part 46.102 (U.S. Department of Health and Human Services. Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects. Available at: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/regulatory-text/index.html. Accessed December 10, 2018; and U.S. Department of Health and Human Services. Title 45 Public Welfare, Part 46 Protection of Human Subjects. Electronic Code of Federal Regulations. Available at: https://www.hhs.gov/ohrp/sites/default/files/revised-common-rule-reg-text-unofficial-2018-requirements.pdf. Accessed February 14, 2019).

clarifications have been made for several terms, including research, human subjects, private information, legally authorized representative, and intervention. Definitions for some of the most pertinent changes and their comparison to the old Common Rule are identified in Table 1. Several key differences to be cognizant of include changes to the definition of research, which now explicitly defines activities that are not considered research. Moreover, specifications have been made for biospecimens such that researchers may obtain and possess biospecimens without meeting the definition of "human subject" until those biospecimens are used for studies or research purposes.

CHANGES TO INFORMED CONSENT

Under the new Common Rule, the process of informed consent has been modified in several ways. Principally, the eight basic elements of informed consent are unaltered. Informed consent must still maintain statements that the study is for research purposes, describe foreseeable risks and benefits, provide alternative treatment

courses, identify how confidentiality will be maintained, and expresses any potential compensation for participants. Furthermore, informed consent documentation must provide contact information for the study investigator in the event of concerns or injury and must specify that participation is voluntary, and that refusal is without penalty.

The new Common Rule now incorporates a ninth component to informed consent in research that collects identifiable private information or biospecimens [46.116(b)(9)]. In these instances, informed consent must incorporate a statement either (1) acknowledging that identifiers may be stripped from the gathered information/biospecimens and that they may be used/distributed (deidentified) in future studies without any additionally obtained informed consent or (2) that the information/biospecimens were collected as a definitive component of a research study and will not be used or distributed for any additional, future studies.

The additional elements necessary for informed consent [46.116(c)] are largely unchanged, with three exception: 46.116(c)(7), (c)(8), and (c)(9). More specifically, if biospecimens are to be collected, a statement must include the potential for commercial profit and whether or not subjects will share in said commercial profits. In addition, if biospecimens are collected with the potential for whole genome sequencing, a statement regarding sequencing must be included. Lastly, a statement regarding the potential disclosure of study results to subjects is to be included.

As a unique change to the Common Rule, it is now permitted for patients to provide "broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens" as an alternative to traditional informed consent [46.116(d)]. Fundamentally, broad consent is a prospectively obtained consent for undefined future research. Broad consent can be obtained in lieu of informed consent if appropriately adhering to certain parameters. That is, the basic elements of informed consent are maintained and still required. In addition, an explanation of the types of potential research that may be conducted must be provided with a description of how the information may be disseminated or shared within or between institutes or researchers. The period (which can be indefinite) that the collected information/biospecimens will be stored and used must also be noted. Moreover, as broad consent and data collection implies a potential for research and information/biospecimens sharing, a statement must be included to inform subjects that their information/biospecimens may be used for research not otherwise disclosed. The potential for disclosure of results to subjects and the contact information for investigators must be included.

These modifications to informed consent are a sign of the modern era of research. The changes allow for development of repositories of information/biospecimens that could potentially be used for future studies. To our knowledge, a majority of institutional centers are not implementing broad consent, as it requires considerable infrastructure to systematically track and update patients who have agreed to or declined broad consent. In such cases, researchers can still collect and maintain identifiable information/biospecimens and process these studies through expedited IRB review. Broad consent is necessary for exemptions 7 and 8 (defined below).

ELIMINATION OF CONTINUING REVIEW

As a considerable change to the pre-2018 rule, the final revisions to the Common Rule eliminated requirements for continuing review in studies deemed minimal risk. Conventionally, IRBs were required to conduct, at a minimum, annual review of approved research studies. Most significantly, this new guidance specifies that research newly approved as "expedited" no longer requires continuing review [46.109(f)(i)]. Expedited studies are research projects that pose no more than minimal risk to subjects and falls within one of the seven expedited review research categories (Table 2).[6] Moreover, research projects no longer require continued review if they have progressed to a stage of data analysis or a stage in which follow-up data gathered from standard clinical care procedures is accessed [46.109(f)(iii)(A) and (iii)(B)]. More succinctly, research that has finished intervention with subjects and has now progressed to data processing may no longer be subject to continuing review. These changes significantly reduce the regulatory burden on research investigators and the excessive volume placed on the IRB. Investigators should have open communication with IRB teams to evaluate whether or not their study meets the inclusion or exclusion criteria for continuing review. It should be noted that investigators are still required to submit modifications or amendments to IRB–approved studies despite being waived from continuing review.

Table 2. Expedited Review Categories as Adapted from the Department of Health and Human Services*†

Minimal Risk Research	Qualifier
1. Clinical studies of drugs/medical devises	Research on drugs and/or medical devices not requiring investigational device exemption.
2. Collection of blood samples	From the average, healthy, nonpregnant patient. Variability with respect to amounts drawn per week based on age and weight.†
3. Prospective, noninvasive collection of biospecimens for research	Such as collecting external secretions (i.e., sweat), minor/nondisfiguring hair or nail clippings, skin cells obtained through buccal swabs, and others.
4. Collection of data through noninvasive, routinely used means	Data collected as part of clinical practice such as ultrasound imaging or magnetic resonance imaging, among others. Procedures involving ionizing radiation are not considered minimal risk.
5. Research involving materials collected for nonresearch purposes	Such as diagnosis codes or medical treatments.
6. Data collected from recordings made for research purposes	Such as voice, video, digital, or image recordings.
7. Research on population characteristics or research through surveys, interviews, oral history, focus groups, or quality assurance methods	Including research on perception, motivation, identity, communication, and societal/cultural beliefs.

*Expedited research must pose no more than minimal risk to subjects and must not place subjects at risk for criminal or civil liability.
†From U.S. Department of Health and Human Services. OHRP expedited review categories. Available at: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html. Accessed July 19, 2019.

EXEMPT RESEARCH

One of the most significant changes in the 2018 iteration of the Common Rule involves the restructuring of exempt status, which is outlined in Table 3. Exempt studies refer to human subjects research that is determined to be of sufficiently low risk so as to obviate the need for governance under the Common Rule, such as collection of institutional patient data (i.e., a retrospective chart review), which previously required an expedited application. The noteworthy modifications to this component of the Common Rule, which will substantially expand the scope of exempt research, include the creation of three entirely new categories and expansion of the criteria for two others. Examples of plastic surgery research that may fall under these exempt categories are shown in Table 4.

In conjunction with the revisions and additions to the exempt category list is the creation of the "limited IRB review" process. Seemingly a "middle-ground" between the rigor of full or even expedited IRB review and the complete absence of oversight inherent in nonhuman subjects research, the limited IRB review essentially involves determination of the adequacy of safeguards present in certain studies. Specifically, limited IRB review is required to ensure appropriate provisions for privacy and confidentiality in studies that collect identifiers in conjunction with interviews, surveys, and observations (category 2), and benign behavioral interventions (category 3). In addition, storage or maintenance of identifiable private information or biospecimens (category 7) and secondary research using such data (category 8) are subject to limited IRB review to determine the adequacy of "broad consent," as described previously.

Many institutions mandate that researchers submit an exempt application before commencing research to ensure that the study activities meet criteria for exemption. Importantly, institutions may elect not to adopt some of these changes or may limit the extent to which they can be applied. As such, establishing clear lines of communication with one's institutional regulatory departments is the optimal way to maintain the ethics and integrity of research while still continuing to advance knowledge in the field.

CLINICAL DATA REGISTRIES

As the essence of "big data" becomes increasingly apparent in health care, many researchers, regulatory officials, and lawmakers have sought to better understand the freedoms and limitations of clinical data registry activities within the context of the Common Rule. Section 511 of the Medicare Access and CHIP Reauthorization Act of 2015 mandates that the Department of Health and Human Services provides guidance regarding the application of the Common Rule to clinical data registries and all related activities.[7] Ultimately, the preamble to the final rule states that clinical data registry activities are not under the purview of the Common Rule in the following scenarios:

1. Activities not conducted or supported by a Common Rule department.
2. Activities that do not qualify as research, such as quality improvement activities.
3. Research involving the collection and analysis of nonidentified information, as this does not qualify as human subjects research.

Table 3. Changes to Exempt Review Categories B, C, and D*

Pre-2018 Categories	Change	Revised Categories
1. Research in common educational settings	Minimal change	More restrictive definition that emphasizes protection of (1) students' opportunity to learn required educational material and (2) educators' ability to provide instruction
2. Educational tests, surveys or interviews	Expansion	With the establishment of a *limited IRB review*, studies involving collection of information that could be used to identify subjects may still meet criteria for exemption
3. Research involving public officials	New category	*Benign behavioral interventions:* Allows for research involving brief, harmless, and not physically invasive interventions in conjunction with collection of information, provided that the subject prospectively consents to the intervention • Similar to category 2, identifying information may be collected in this setting and still meet criteria for exemption if a limited IRB review is conducted
4. Research involving existing data, records, or specimens	Expansion	*Secondary research for which consent is not required* (i.e., collected or generated for purposes other than the present research): this category covers research using protected health information that falls under HIPAA; importantly, data used for research under these provisions does not need to be in existence at the time of the research study
5. Departmental or agency demonstration projects	Minimal changes	Emphasis on public transparency with respect to research: • The department or agency conducting the research must publicly list the research and demonstration projects prior to commencing research
6. Taste and food quality	No change	
7. N/A	New category	*Storage or maintenance for secondary research for which broad consent is required:* covers activities involving identifiable information or biospecimens that are to be stored or maintained for potential secondary use • Requires a limited IRB review
8. N/A	New category	*Secondary research for which broad consent is required:* Covers the use of identifiable information or biospecimens that have been stored or maintained for research purposes, as outlined in category 7 • Also requires a limited IRB review

HIPAA, Health Insurance Portability and Accountability Act of 1996.
*B, subpart B (pregnant women), all exempt categories may be applied to this population; C, subpart C (prisoners), exemptions *do not* apply to this population, except for research aimed at involving a broader subject population that only incidentally includes prisoners; D, subpart D (children); exemption categories 1, 3, 4, 5, 6, 7, and 8 may be applied to children. Exemption category 2 may only be applied if the investigator(s) do not participate in the activities being observed and if the identity of the human subjects cannot be readily ascertained.

4. Activities that meet criteria for exemption.
5. Institutions that submit to a clinical data registry private patient information obtained during a clinical encounter, as this institution is not involved in human subjects research.

There are several ways in which the Common Rule's statement on clinical data registries apply to plastic surgery. Large database studies, such as those using deidentified data from the American College of Surgeons National Surgical Quality Improvement Program and the Nationwide Inpatient Sample, among others, are not subject to the regulations put forth in the Common Rule. Despite the growing interest in exempting clinical data registries from the regulatory requirements of the Common Rule, as was proposed in the 2015 Notice of Proposed Rulemaking, this suggestion was not adopted.

Practically speaking, this determination effectively allows researchers the freedom to conduct retrospective studies using deidentified data from large databases (clinical data registries) without necessitating IRB approval. By definition, the collection and analysis of this deidentified data is not considered human subjects research, and therefore falls outside of the purview of the Common Rule. Thus, provided that all data are obtained and used in accordance with the appropriate data use agreements as set forth by the specific registry, these studies can be conducted without IRB review. Descriptions of these types of studies are shown in Table 3.

COOPERATIVE RESEARCH

Finally, the revised Common Rule puts forth important guidelines regarding "cooperative" or multi-institution research. With the exception of specific legislative mandates or predetermined exclusions, all U.S. institutions engaged in cooperative research must rely on approval from a *single* IRB, as determined by the federal department conducting or supporting the research or by the lead institution.

The value of multi-institution data is difficult to underestimate, as evidenced by the growing popularity of big data studies and systematic reviews. Before these 2018 revisions, cooperative research required approval from each institution's IRB, or alternatively, from a preapproved third-party IRB. Elimination of this requirement

Table 4. Examples of Exempt and Clinical Data Registry Studies

Revised Category	Example(s)
2. Educational tests, surveys, or interviews	• An anonymous (i.e., without collection of IP address or other identifying information) online survey on the preferred aesthetics of the nasal tip (including studies using crowdsourcing techniques) • An anonymous (i.e., without collection of IP address or other identifying information) online educational test sent to members of ASPS designed to assess and improve physician knowledge of the cost of various surgical materials • A survey of patient satisfaction given immediately after botulinum toxin type A injection followed by a phone interview at a later date ° *Note: Use of non–publicly available e-mail addresses and/or phone numbers constitutes identifiers; therefore, such a study may require limited IRB review*
3. Benign behavioral interventions	• Providing abdominoplasty patients with educational materials regarding smoking and risk of postoperative complications, with the intention of reducing rates of smoking
4. Secondary research for which consent is not required	• If (identifiable) breast tissue specimens are routinely collected and maintained in a repository as part of mastectomy standard of care, an investigator may conduct a histologic analysis of such specimens as part of a research study ° *Note: The investigator cannot record any identifying information* • Retrospective and/or prospective review of medical records to identify predictors of complications following head and neck reconstruction ° *Note: The investigator may access identifiable private information but cannot record information in such a way that it could be linked back to identifiers, even temporarily* • Prospective review of changes in body mass index during successive postoperative follow-up visits after gender-affirming top surgery ° *Note: Since the investigator will need to retain data containing HIPAA elements (i.e., name or medical record number), a waiver of HIPAA authorization must be approved*
7. Storage or maintenance for secondary research for which broad consent is required	• An investigator may collect and store tissue specimens following brachioplasty for *potential* use in secondary research (i.e., the brachioplasty is performed for indications *other than* purely research purposes); see example in category 8 below ° *Note: Broad* consent is required at the time of brachioplasty, and a *limited IRB review* is required to ensure adequacy of broad consent (for further explanation of broad consent, see main text beginning on line 127)
8. Secondary research for which broad consent is required	• After collecting and storing brachioplasty tissue specimens, an investigator wishes to analyze these specimens to compare skin elasticity between smokers and nonsmokers ° *Note: Broad consent for secondary research obtained at the time of brachioplasty covers the use of these biospecimens for purposes of secondary research; limited IRB review is required to ensure adequacy of broad consent*
Clinical data registry	• A retrospective cohort study using deidentified data from the American College of Surgeons National Surgical Quality Improvement Program database to determine infection rates following prosthetic breast reconstruction with and without acellular dermal matrices • A retrospective cohort study using deidentified data from the Nationwide Inpatient Sample database to evaluate socioeconomic and geographic characteristics associated with cleft lip repair ° *Note: Collection and analysis of deidentified data does not qualify as human subjects research, and therefore IRB review is not required*

IP, Internet Protocol; ASPS, American Society of Plastic Surgeons; IRB, institutional review board; HIPAA, Health Insurance Portability and Accountability Act of 1996.

and the mandate for a single IRB is likely to substantially decrease the redundancy associated with multiple IRBs governing the same research activities. Ultimately, this will serve to encourage cooperative research.

CONCLUSIONS

The new Common Rule has introduced significant changes to facilitate human subjects research. It is imperative that academic plastic surgeons understand these modifications and their impact on research. Summary of key changes include the following:

- Broad consent offers prospectively obtained consent for undefined future research on identifiable private information or identifiable biospecimens.
- Expedited studies no longer require continued review.
- Exempt studies are broadened to encompass additional categories of research.
- Clinical data registry activities are not under the purview of the Common Rule.
- Multi-institutional studies are streamlined to obtain IRB approval by a single institute.
- We recommend that all researchers collaborate with their respective IRBs to effective abide by local policies and the new Common Rule.

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