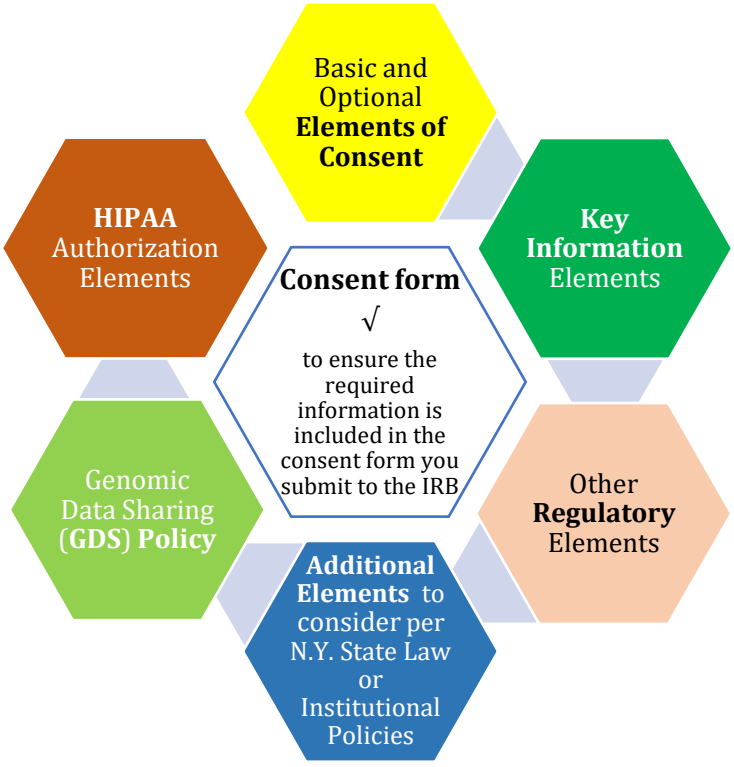
Columbia University Human Research Protection Office/IRBs

Newsletter #15 – August 2025

Consent requirements

Consent Process: Before including someone in a research study, investigators must obtain legally effective informed consent from the individual or their legally authorized representative unless the requirement has been waived by the IRB in accordance with federal regulations or the research is exempt from IRB review. This consent must be sought in a setting that allows enough time for thoughtful consideration and avoids pressure or coercion. The information provided must be clear and understandable, and contain everything a reasonable person would need to know to make an informed decision. Consent must begin with a concise summary of key information and be presented in a detailed, organized manner to support understanding. Importantly, consent forms cannot include any language that waives the participant's legal rights or releases researchers or institutions from liability.

The informed consent process is an ongoing exchange of information between the investigator and the research participant. The consent form is intended, in part, to provide information for the potential research participant's current and future reference and to document the interaction between the participant and the investigator. However, even if a signed consent form is required, it alone does not constitute an adequate consent process.



Follow this diagram and the associated checklists, below, which outline the information to consider when preparing a consent form.

Required Basic and Additional Elements of Consent 45 CFR 46.116 (b)(c) unless waived by the IRB			
#	**Required Basic Elements**	#	**Additional Elements when appropriate**
1	**Research basics** — that the project is research, its purpose, expected time in the study, study procedures, and which procedures are experimental.	10	**Unforeseeable risks (including to an embryo or fetus).**
2	**Risks / discomforts** that are reasonably foreseeable.	11	**Circumstances under which the investigator may end participation.**
3	**Potential benefits** to the participant or others.	12	**Any additional costs to the participant.**
4	**Alternatives to participation, if any,** that could benefit the participant	13	**Procedures & consequences of participant withdrawal.**
5	**Confidentiality** — how records that identify the participant will be protected and maintained.	14	**Sharing of significant new findings that may affect willingness to continue.**
6	**Compensation** and Treatments if an injury occurs (only if the study is more than minimal risk).	15	**Approximate number of participants in the study.**
7	**Research team contact information** for questions about the study and **IRB contact information** for questions about participant rights and research-injury.	16	**Whether biospecimens may yield commercial profit and, if so, whether the participant will share in it.**
8	**Voluntary participation** — no penalty for refusal or withdrawal at any time.	17	**Whether clinically relevant results (including individual results) will be returned** and under what conditions.
9	**Future use of data/biospecimens** (choose one): a) Identifiers may be stripped and materials reused/shared without extra consent, **or** b) Materials will *not* be used or shared for future studies.	18	**Whether the research will** (if known) or **might** involve whole-genome sequencing.

Key Information Elements

Additional information about this section of the consent form is available on the HRPO website

1	2	3	4	5	6	7
The project is research and participation is voluntary.	**Summary of the purposes of the research**	**Brief description of the main study procedures**	**Duration of participation**	**Main reasonable, foreseeable risks & discomforts**	**Reasonable, expected benefits**	**Alternatives to participation, if any**

Other Regulatory Consent Elements to consider

FDA Requirement for Clinical Trials	The following exact statement should be included for clinical trials: *A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.*
Study is federally funded and involves collection, use, or analysis of personally identifiable information and a Certificate of Confidentiality (CoC) was issued with the award - OR - **The study is not federally funded but there is a plan to obtain a Certificate of Confidentiality**	Add a statement informing subjects that a certificate of confidentiality has been granted. An example of language can be found at: https://grants.nih.gov/policy/humansubjects/coc/suggested-consent.htm
NIH Data Management and Sharing Policy for NIH studies (grant applications submitted on and after 01/25/2023)	Clearly communicate information about data management and future sharing of scientific data, including limitations on future secondary uses. Refer to the Guidance and Sample Language for Informed Consent to address Requirements of the NIH Data Management and Sharing (DMS) policy and Points to consider for Future Use and/or Sharing.

Additional consent elements or information to be communicated through the consent (per New York State Law or per CU Institutional Policies)		
EPIC statement required when the study will be linked in EPIC to the participant's medical record.	√	Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and NewYork-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.
Elements to consider when studies involve audio/video/photographic recording.	√	• Type of recording that will be utilized; • Specific identifiers that will be recorded, e.g., partial facial features, full facial features, subject's name; • People who will have access to the recording(s); • Mechanisms in place to protect the confidentiality of the person(s) being recorded; • Clear indication of when the recording(s) will be destroyed or that recording(s) will be kept indefinitely; • Use(s) of the recording(s), including educational or commercial purposes, analysis by the research team, or future unspecified use; • Compensation, if any, to subjects for allowing themselves to be taped.
For research studies involving genetic testing as defined by New York Civil Rights Law (section 79-l): additional information to be included in the written consent before collecting a biologic sample for genetic testing	√	• A general description of the Genetic Test; • A statement of the purpose of the Test and that the individual may wish to obtain professional genetic counseling prior to signing the consent form; • A statement that a positive Test result is an indication that the individual may be predisposed to or have the specific disease or condition tested for and may wish to consider further independent testing, consult his/her physician or pursue genetic counseling; • A general description of each specific disease or condition tested for; • The level of certainty that a positive Test result for that disease or condition serves as a predictor of such disease or condition unless no level of certainty has been established; • The name of the person or categories of persons or organizations to whom the Test results may be disclosed; • A statement that no test other than that authorized shall be performed on the biological sample and that the sample shall be destroyed at the end of the testing process or not more than 60 days after the Sample was taken, unless a longer period of retention is expressly authorized in the consent; and • The signature of such individual or, if such individual lacks the capacity to consent, the signature of the person authorized to consent for such individual.

Incidental finding statement required for studies using radiation performed beyond standard of care.	√	**For use when the PI or a co-I is a physician and is qualified to explain incidental findings from a scan:** *Although the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, we will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.* **For use when the PI and co-Is are not physicians and not otherwise qualified to explain incidental findings from a scan:** *Although the imaging you will have in this study is being undertaken for research purposes only, it is possible that doctors may notice something that could be important to your health. Although not likely, it is possible that the doctors may notice something that may be very serious and could immediately affect your life. If so, a doctor working with our research team will contact you to explain what was observed. If you so desire, we will also talk with your private physician. If you do not have a private physician, we will refer you to an appropriate clinic for follow-up. It will be your choice whether to proceed with additional tests and/or treatments to evaluate what we observed, and you or your insurer will be responsible for these costs.*
For written consent (i.e., the IRB has not waived the requirement for the investigator to obtain a signed informed consent form)	√	Wet ink or electronic signature of the person obtaining consent and date of consent, in addition to the signature (wet or electronic) of the research participant and date of consent.
For written consent from subjects hospitalized at the time of enrollment if study involves medical intervention (*requirement*) **- Or -** **Study procedures are initiated on the day of the consent (*recommendation*)**	√	Time of consent

	Additional Elements to address in Consent **for NIH-funded research that generates human or non-human genomic data** **or** **for non NIH-funded research when there is a plan to submit genotype/phenotype data to one of the NIH-supported genomic repositories** ***(as recommended by the NIH)*** https://www.genome.gov/about-genomics/policy-issues/Informed-Consent/GDS-policy-sample-language
√	Genomic and phenotypic data, and any other data relevant for the study (such as exposure or disease status) will be generated and may be shared broadly and used for future research in a manner consistent with the participant's informed consent and all applicable federal and state laws and regulations.
√	Prior to submitting the data to an NIH-designated data repository, data will be stripped of identifiers such as name, address, account and other identification numbers and will be deidentified by standards consistent with the Common Rule and HIPAA. Safeguards to protect the data according to Federal standards for information protection will be implemented.
√	Access to de-identified, individual-level participant data will be controlled, unless participants explicitly consent to allow unrestricted access to and use of their data for any purpose.
√	Aggregate study information (including genomic summary results) and study analyses may be shared in scientific literature or through other public scientific resources, such as data repositories or other data sharing resources that provide broad or unrestricted access to the information.
√	Because it may be possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed, and reidentified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks due to computational methods, analytic technologies, or techniques (e.g., generation of information that could allow participants' identities to be readily ascertained).
√	No direct benefits to participants are expected from any secondary research on de-identified individual-level data or genomic summary results that may be conducted.
√	Participants may withdraw consent for research use of genomic or phenotypic data at any time without penalty or loss of benefits to which the participant is otherwise entitled. In this event, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be retrieved.
√	The privacy protections, and limitations of those protections, afforded by a Certificate of Confidentiality to individual-level data do not apply to summary results.

HIPAA Authorization Core Elements

√ **Required when the research study includes Protected Health Information (PHI). Please refer to the IRB Policy on the Privacy Rule and the Use of Health Information in Research. Ensure the core elements and required statements are addressed in the Combined Consent and HIPAA Authorization Form. If you use a standalone HIPAA Authorization Form, a HIPAA form A should be attached to your Rascal application. A combined form is strongly recommended.**

1	**Specific Description of PHI to be Used/Disclosed** Clearly identify what health information will be accessed (e.g., medical records, lab results, imaging, billing data).
2	**Who May Disclose the PHI –** Name or other specific identification of the person(s) or class of persons authorized to perform or make the requested uses or disclosures.
3	**Who May Receive the PHI -** Identify the person(s) or class of persons (e.g. researcher(s), institution(s), or sponsor(s)) who will receive or use the PHI.
4	**Purpose of the Use/Disclosure** A description of each purpose of the requested use or disclosure.
5	**Expiration Date or Expiration Event** An indication that the Authorization does not have an expiration date, or that the authorization will expire when the study is completed, or an expiration date are all acceptable.
6	**Signature & Date** The authorization must be signed and dated by the individual or their legally authorized representative.

√ Required HIPAA Statements

1	**Right to Revoke Authorization in writing** Explain that participants may revoke the authorization at any time in writing, and how to do so.
2	**The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization.**
3	**The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected.**

√ Other requirements

1	**The authorization should be written in plain language**
2	**A copy of the signed authorization must be provided to the subject**

Incoming Presentations

Rascal Submission Workshops (Microsoft Teams):

Below is the list of upcoming workshops. To register, please follow the link provided below for each workshop:

Monday, August 25, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: Consent Form Builder

Monday, September 22, 2025: 3:00 PM -4:00 PM
IRB Rascal Workshop: New Protocol involving more than minimal risk procedures

Monday, October 27, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: Renewal/Annual Report/Modification

Monday, November 24, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: New Protocols involving minimal risk procedures

Monday, December 15, 2025: 3:00 PM - 4:00 PM
IRB Rascal Workshop: Rascal-Generated Consent Form

Recent Presentations/Announcement

- Monthly Investigator Meetings (MIM):
  Slides of recent MIM presentations are available on the HRPO website (Informational Materials) at https://research.columbia.edu/human-subjects-protection-training-program-educational-resources

- All HRPO newsletters are available on our website with a list of topics that are addressed in each newsletter.

HRPO Staff: Contact Information

HRPO Directory

HRPO main phone line: 212.305.5883
This line is answered by HRPO Staff during normal business hours.
For calls outside of normal business hours, please leave a message and HRPO Staff will respond on the next business day.

Tips on How Best to Contact HRPO Staff

If you have not yet submitted the protocol in Rascal and/or have specific questions about how to submit a new protocol	For research originating from CUIMC: Please contact IRB Liaison, Tasha Smith, at ts2257@cumc.columbia.edu or 929-996-1455. For research originating from the Morningside and Lamont-Doherty campuses: email askirb@columbia.edu.
If you need a determination letter posted in Rascal or documents stamped for an approved event (these documents are expected to be available approximately one week following approval of the event)	Add a protocol-specific correspondence in Rascal. Or Email the IRB Specialist assigned to your protocol (see above HRPO Directory).
If you have questions about the conduct of an IRB-approved study or to clarify an IRB request before resubmission	Add a protocol-specific correspondence in Rascal. **Or** Email your questions to the HRPO team assigned to your protocol (see above HRPO Directory) or ask for a phone consultation.
General questions not related to a specific protocol	Email irboffice@columbia.edu.
Questions about reliance	Email irbreliance@cumc.columbia.edu.
Questions about emergency use or subject safety issues	Contact Laurence Butaud-Rebbaa at lb2643@cumc.columbia.edu or 917-679-3867.
Questions about an issue related to CITI courses	Contact Mark Leneker at ml2307@cumc.columbia.edu or 917-634-0625. Requests to update CITI training information in Rascal should be made via email and include the name of the person whose training requires updating, their UNI, and the name of the specific training.

Please contact us with any questions and/or feel free to provide us with feedback at irboffice@columbia.edu.