

**COLUMBIA UNIVERSITY
INSTITUTIONAL REVIEW BOARD**

GUIDANCE ON USE OF CONSENT TO CONTACT FOR RESEARCH REGISTRY

I. BACKGROUND

Columbia University will transition the Consent to Contact for Research (CCR) Registry from an “opt-in” to an “opt-out” recruitment framework on January 1, 2027. Under the opt-out framework, adult patients are included in the CCR Registry unless they affirmatively decline participation. A patient’s research contact preference if left blank or “undecided” will be changed to “OK to Contact”. Patients will no longer be asked upon their initial encounter with the health system at Columbia University Irving Medical Center (CUIMC) if they would like to consent to be contacted for research. Instead, CUIMC’s Notice of Privacy Practices has been updated to clarify that patients may be contacted by researchers other than their treating physicians and that they can update their contact preferences at any time.

This document provides the Institutional Review Board (IRB)’s guidance on the appropriate use of the CCR Registry, including considerations for specific participant populations and types of research that may require additional safeguards or review.

II. EFFECTIVE DATE

The effective date of this guidance is October 1, 2026.

III. GUIDANCE

The IRB’s support of an opt-out framework is grounded in an ethical balance between promoting broad inclusion and safeguarding vulnerable participants. This position reflects several key considerations: minimizing disparities in access to research participation, maintaining a diverse recruitment pool to improve the representativeness of study populations and support the applicability of research findings across the broader patient population, and respecting individual autonomy by allowing prospective participants to make their own informed decisions about involvement, rather than being excluded by default through restrictive policies.

As of the date of this guidance, minors are not included in the CCR Registry.

A. IRB Considerations

Use of the CCR Registry is not automatic; it requires a protocol-specific request and explicit IRB approval for each study. The IRB evaluates such requests to ensure that unsolicited contact is appropriate given the study design and target population.

In reviewing requests to use the CCR Registry, the IRB considers several factors, including:

- Whether the target population includes individuals who may be at increased risk of coercion, undue influence, impaired decision-making capacity, or other circumstances that could affect their ability to make a voluntary decision regarding research participation.
- Whether the study involves greater than minimal risk procedures, complex interventions, or other characteristics that may warrant additional recruitment safeguards.

- Whether the research involves medical conditions that warrant specialized recruitment approaches due to heightened privacy concerns associated with sensitive or potentially stigmatizing diagnoses or conditions.
- Whether recruitment occurs in settings where patients may be less able to make fully informed decisions about research participation, e.g., emergency care settings or other circumstances in which patients may be experiencing acute illness or distress.

Researchers should address each of these considerations in their IRB submission when seeking approval to use the CCR Registry if they are applicable to the study.

The IRB retains the authority to require additional protections, impose restrictions, or disallow the use of the CCR Registry for any specific study based on the nature of the research, participant vulnerability, or sensitivity of the condition under study.

B. Additional Protections for Vulnerable Populations and Sensitive Research

Research involving individuals who may be vulnerable to coercion or undue influence (such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), as well as research on certain medical conditions may raise heightened privacy concerns and therefore warrant increased sensitivity, and may warrant additional IRB oversight and safeguards. Examples of such medical conditions include:

- Psychiatric studies
- HIV-related research
- Substance use research, including research on illegal drug or alcohol use
 - Additional attention is required for studies involving pregnant women with substance use disorders
- Sexual and reproductive health research, including research on sexually transmitted infections, pregnancy termination, infertility, gender dysphoria, erectile dysfunction, and other sexual disorders

For these types of research, the IRB may request enhanced protections to ensure that the outreach method minimizes the possibility of coercion or undue influence, protects participant privacy, and is commensurate with the sensitivity of the condition. Examples of additional protections include:

- Communications should avoid condition-specific references so that third parties cannot infer a participant's medical status, e.g., use neutral study identifiers in the subject line and recruitment message.
- Restrict the number, frequency, or timing of contact attempts to reduce privacy risks and intrusion.
- Use phased outreach or waiting periods, when appropriate, to reduce unexpected or intrusive communication.
- Provide simple, consistent methods to decline further contact about the study.
- Use encrypted, institutionally approved systems for outreach.
- When appropriate, and consistent with study objectives and participant autonomy, consider notifying or consulting treating clinicians regarding recruitment plans for particularly sensitive conditions.
- Avoid outreach during acute care episodes or immediately following sensitive diagnoses unless justified.

For research involving vulnerable populations and/or sensitive research topics, researchers should clearly describe any additional safeguards in their IRB submission necessary to protect participant

privacy and confidentiality. It is noted that as of the date of this guidance, minors are not included in the CCR Registry.