MUSC
Medical University of South Carolina

IRB Insights

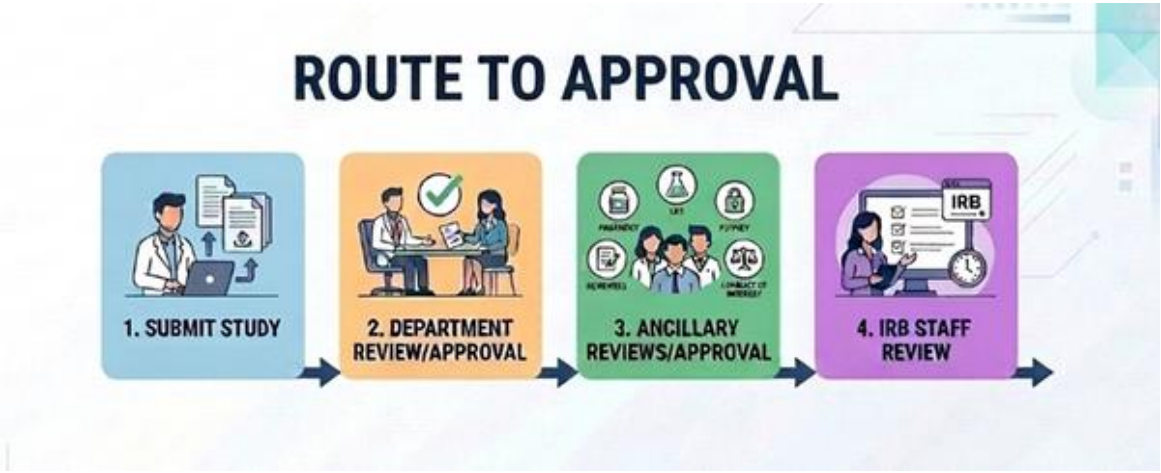
May 2026

We're excited to share updates and reminders with everyone in this quarter's IRB newsletter. Our top priority is human subject protections. As personnel join and leave MUSC, we want to send out some reminders as well as provide important research related information.

IRB Forms

SUCCESS Center

IRB News & Information



Route to approval: Departmental review and approval in eIRB

IRB Status: Department Review:

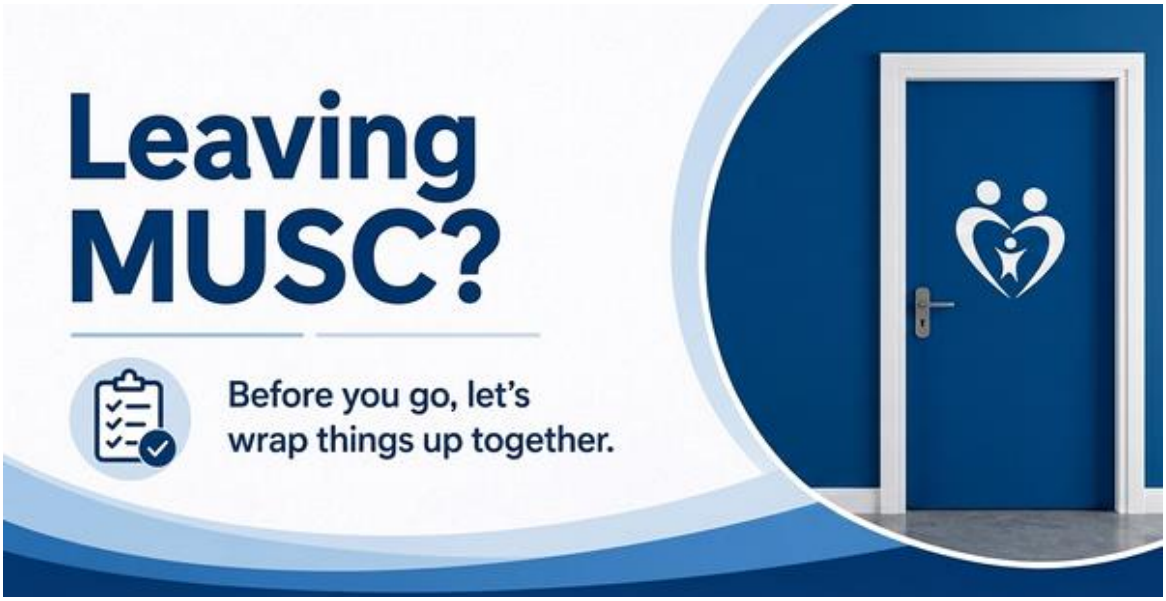
Before a study is submitted to the IRB, departmental approvals must be obtained (check the Meeting Dates & Deadlines). There **is** a way for you to track your application throughout the ancillary approval process. Please see the information below from our eIRB FAQ page for guidance.

- ***The PI has submitted the study, but it doesn't seem to have gone through to the IRB. What is the hold-up?***
    - Studies may require mentor, department or other ancillary reviews before it will route to the IRB. In these cases, the eIRB system automatically routes the study to the approving individuals along with a notification email. If required approvals are incomplete, the current state of the study will read "Department Review". To check on required approval, locate the "Pre-Review Status" tab on the protocol's main page. This will display an update of pending and received ancillary approvals. You can also check the study's History tab to see who in a department or ancillary group was sent an email request to review the study. These details are accessible by clicking on the particular history line that documents submission to the IRB, then accessing the Notification tab within that history line. A study is not considered

‘submitted’ to the IRB unless all of the necessary approvals have been granted.

Our policy on Mentor, department, and ancillary reviews can be found here:

IRB HRPP 1.7



Leaving MUSC? PI Responsibilities!

Principal Investigators (PI) are responsible for either closing a study or transferring the study to a new PI when leaving MUSC. PI’s need to notify the IRB well **in advance** of their departure so this can be completed **prior** to their departure.

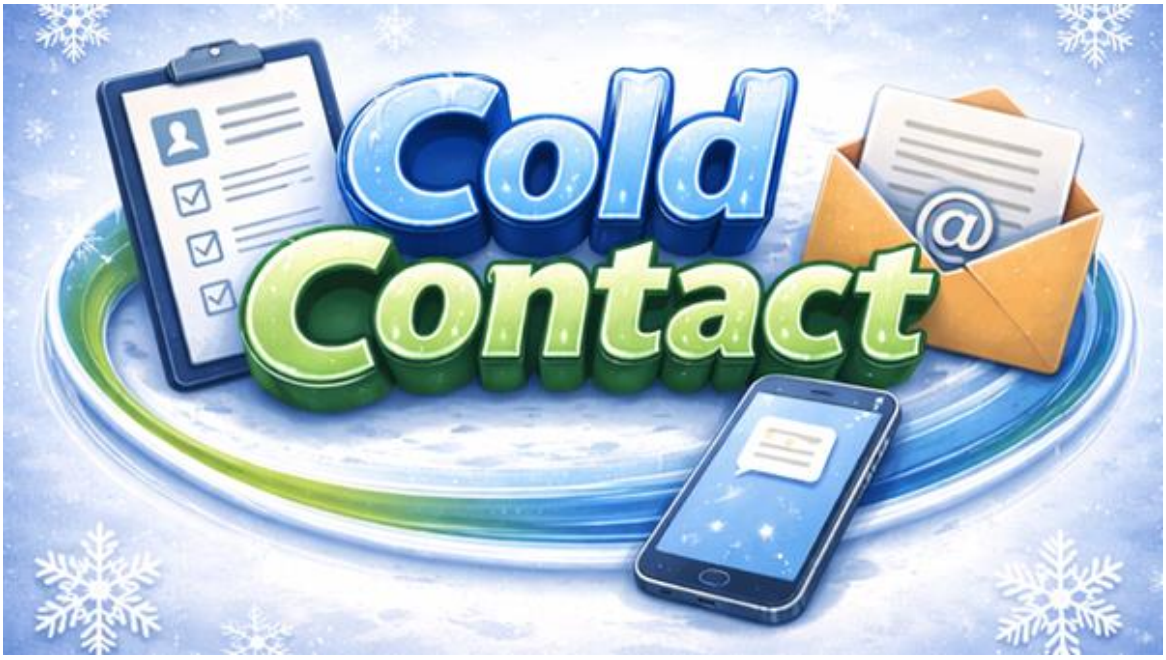
Closing a study: Submit a continuing review with ‘Permanently Closed – All study activities are completed’ selected as the study status.

Transferring to a new PI: Submit a personnel amendment to change the PI.

Note: Exempt studies do not require close-out via continuing review, but an amendment must be submitted if there is a change in PI.

Information about the study closure process can be found at the bottom of this page:

Study Closure Process



Cracking the COLD CONTACT Code

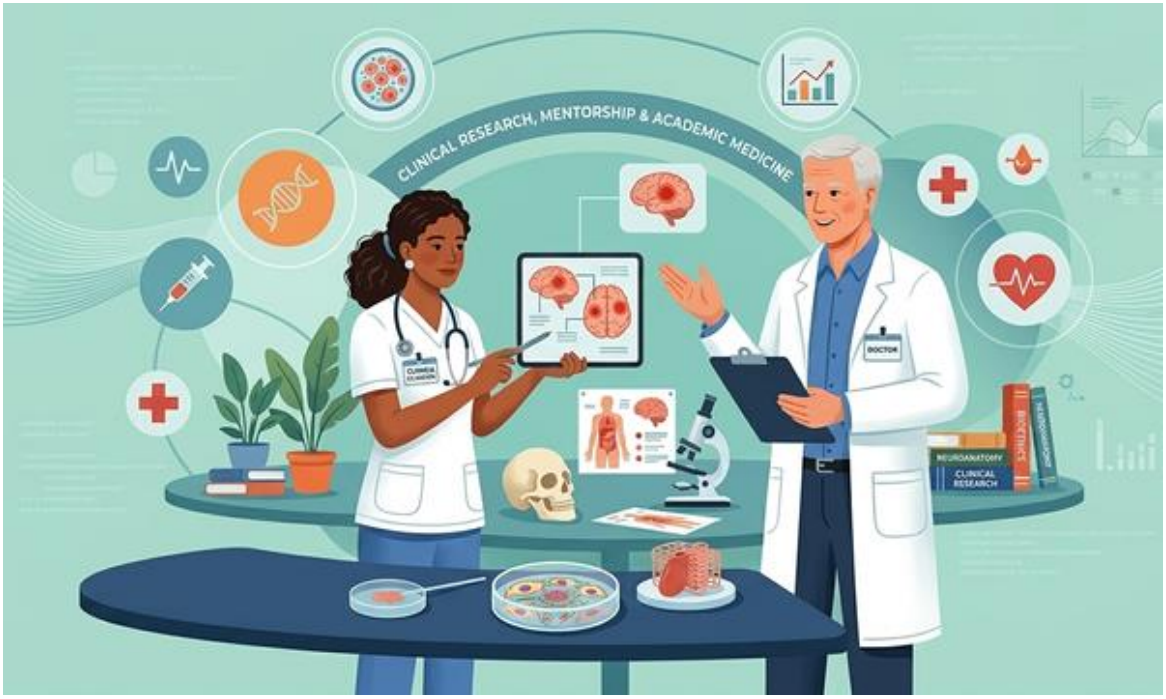
Cold contact (also known as patient-outreach recruitment), is when an individual is contacted by someone they **do not know** and the **contact is unexpected**. In clinical research, this is when a patient is contacted by a study team where neither the PI or Co-Investigator(s) is a member of the patient's clinical care team.

MUSC is an opt-out institution with regards to cold-contacting patients for study recruitment purposes. Being an opt-out institution means that, with proper IRB approval, research personnel, regardless of their clinical relationship with a patient, can contact anyone who has not indicated an "Opt-Out" Research Contact Preference. IRB approval of the cold contact plan and recruitment items (emails, MyChart messages, direct mail, phone scripts, text messages) is needed **before** cold contacting potential research subjects. Documentation of patient contact is also required as part of the cold contact process (with training in this process provided by the POR team when patient recruitment lists are ready).

Contacting one of the PI's or Co-Investigator's patients about a research opportunity? That is **not** considered cold contact. Please note, advertising materials still need to be IRB approved.

More information can be found here, including guidance on submitting a cold-contact recruitment plan to the IRB, the cold call script, and the opt-out language:

Patient Outreach Recruitment



Research Roots: The Power of Great Mentorship

Who can serve as a mentor?

Only compensated full or part time faculty may serve in this role. They must be approved by their Department Chair or designee as capable and available to serve in this role, and they will be included on the list of mentors maintained by the Vice President for Research and accessible to the IRB.

What are a mentor's responsibilities?

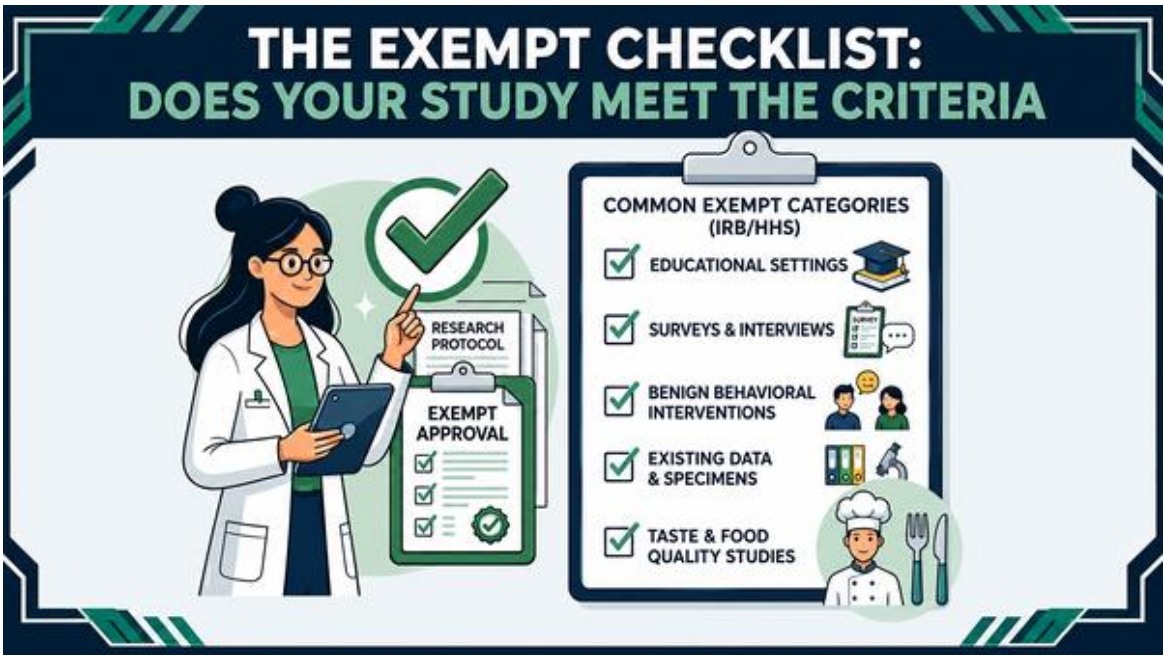
When a student or trainee is listed as a study's Principal Investigator (PI), a faculty member must also be listed on the protocol submission as a Mentor. Faculty must meet criteria to be considered eligible mentors. The student or trainee PI and their Mentor are both responsible for the conduct of human research, but the Mentor has additional responsibilities to ensure the integrity of the research is maintained. The Mentor will review the study protocol prior to submission to the IRB to ensure that

the study has a valid research question and the research procedures are sufficient to answer the research question. The Mentor will meet with the student/trainee Principal Investigator on a regular basis to monitor study progress. If the Mentor will be unavailable for an extended period of time (e.g., on sabbatical or extended leave), they will arrange for an alternate faculty member to assume mentoring responsibility during their absence. The Mentor will advise the MUSC IRB in advance via both by letter and submitting change in personnel amendment of such arrangements. For further information on PI and Mentor Responsibilities please see the following links:

IRB HRPP 5.1 Principal Investigator Responsibilities - Supervision of Staff and Protection of Subjects

IRB HRPP 5.2 Principal Investigator Responsibilities - Recordkeeping and Record Retention Requirements

PI and Mentor Eligibility



The Exempt Checklist: Does Your Study Meet the Criteria

The 2018 Common Rule impacted exempt research studies by providing additional flexibility and clearer guidance for investigators and IRBs. One of the impacts of the Common Rule was the expansion from six to eight exempt categories as well as providing clarification of the existing categories.

The most commonly submitted exempt research studies fall under Categories 2 and/or 4, which we will focus on in this article.

Category 4 research: Under the Common Rule, recording of HIPAA identifiers or links to identifiers, as well as use of not yet existing (or not currently 'on the shelf') data is now allowable. Sub-category ii allows for secondary research use of identifiable health information. The IRB application should include a HIPAA waiver of authorization request when this sub-category applies.

Please note, research involving storage and use of identifiable biospecimens must still be reviewed at the ***expedited level****.*

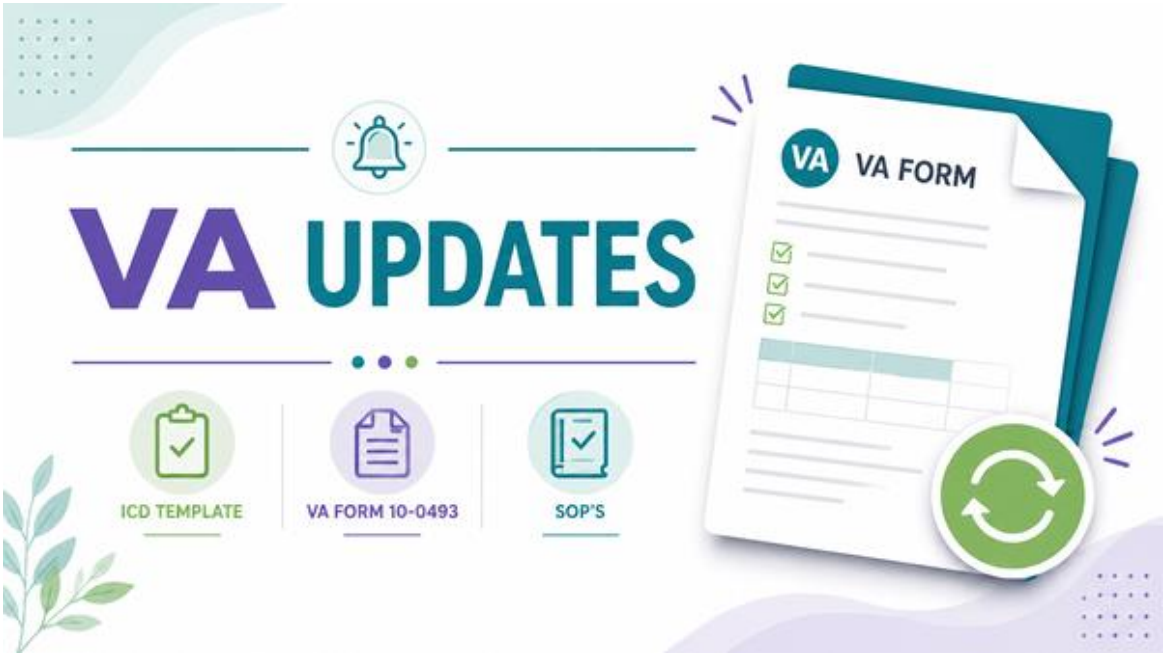
Exempt category 2 research includes educational tests, surveys, interviews, and observation of public behavior. Information obtained under exempt category 2 may be recorded by the investigator in such a manner that the identity of the participants cannot be readily ascertained, directly or through identifiers linked to the subject. If this sub-category applies and health information will be collected, the application should include a request for a HIPAA waiver of authorization.

Please note, the only research activities involving children that may fall under this exemption are those involving educational tests or observation of public behavior where the PI does not participate in the activity being observed.

2018 Revised Common Rule: Exempt Guidance

Exempt Category 2 Tip Sheet

Exempt Category 4 Tip Sheet



VA: Informed Consent and HIPAA Authorization SOP, ICD Template, and new VA Form 10-0493

Please be advised that the Informed Consent and HIPAA Authorization SOP, along with the updated informed consent template and new VA Form 10-0493 (HIPAA Authorization), have been updated and are available in IRBNet under Forms and Templates > RHJ VA Research Administration > Documents for Researchers.

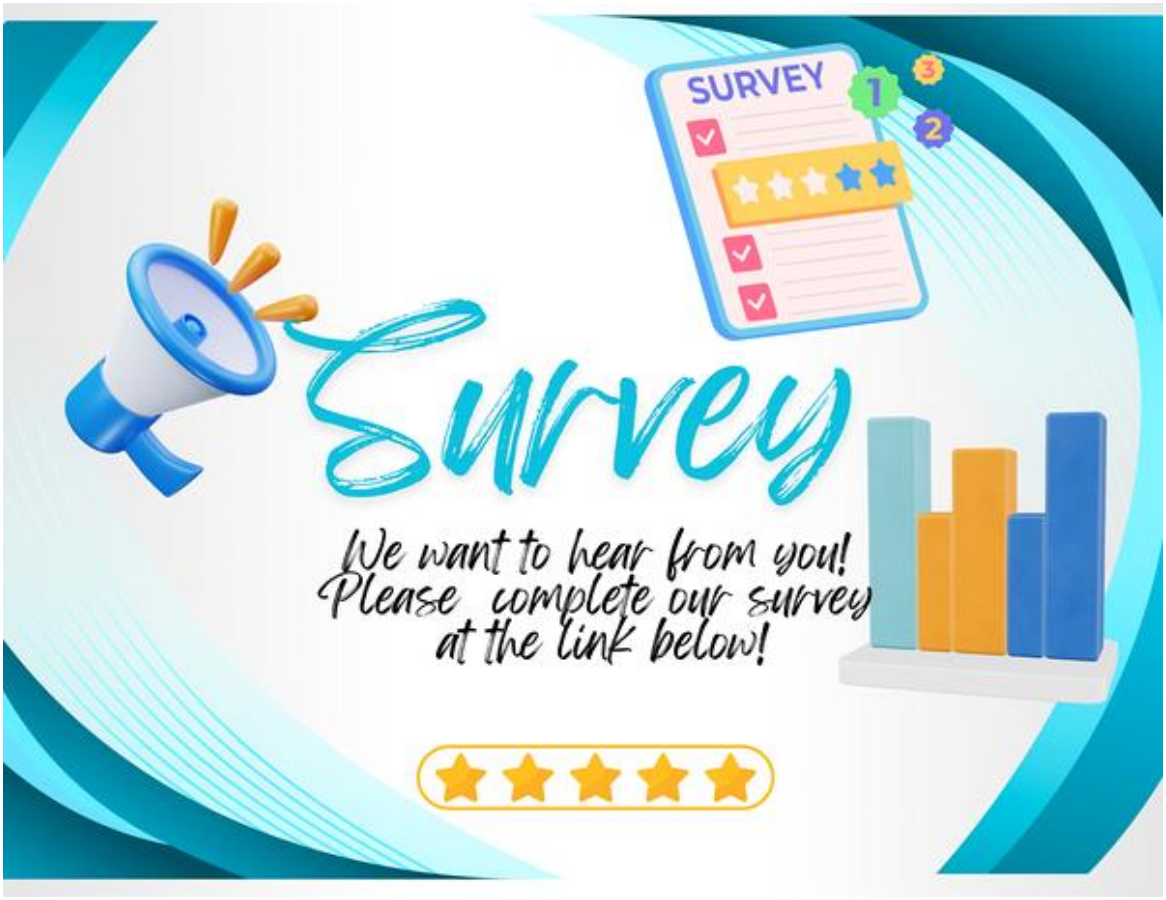
ICD changes include language regarding the new IRB tax threshold, clarification for studies that require notes to be entered into participant's medical records, and required Office of Research and Development (ORD) ICD language.

VA Form 10-0493 has been updated, and usage is required for studies making changes to their HIPAA Authorization forms and for new studies. Summary of changes for VA Form 10-0493 can be found on the ORD Webinars website.

MUSC IRB Policies

Our policies are updated frequently. Please check our website often to review the newest versions of our policies.

Policies & Procedures


SURVEY
Survey
We want to hear from you!
Please complete our survey
at the link below!

IRB Survey

CONTACT US

Have feedback or suggestions you would like to share?

Want to receive the quarterly IRB newsletter?

EMAIL US

irb-news@musc.edu

171 Ashley Avenue

Charleston, SC 29425