

29.3 Limited Waiver of Authorization solely for the purpose of prescreening, contacting and/or recruiting potential research participants

In addition to the scenarios that would support a waiver of authorization for the full study activity, there is the potential need to grant a limited waiver of authorization solely for the purpose of prescreening, contacting and/or recruiting potential research participants. The waiver is “limited” in that it is temporary and will be followed by full authorization, when applicable. An example of a scenario in which a limited waiver may be appropriate is if a researcher needs to review health care records to make recruitment contacts. Since a researcher cannot practicably obtain a potential research participant’s authorization for review of PHI in advance of contacting the potential participant, the IRB may issue a limited waiver of authorization permitting specified access and use of the minimum necessary PHI solely for prescreening and recruitment contact pursuant to an approved protocol.

IRB approval of a limited waiver of authorization will be in accord with the criteria for a waiver of authorization as applied to the limited portion of study activity to which the waiver will apply, e.g., to prescreening, contact and recruitment procedures described in the protocol and IRB application.

Physicians and other health care professionals who have a direct treatment relationship with an individual may review that individual’s PHI for eligibility with respect to a research protocol and may initiate a discussion with the individual about potential participation as a research subject in a protocol relevant to the treatment relationship. This limited scenario of health care-patient conversation prior to any actual research enrollment does not require an authorization or a waiver of authorization.