



Human Subject Research and Blood Sampling: Lessons from the Kaplan Medical Center Report

Client Update – October 2026

Dear Clients,

According to media reports, suspicions were raised at Kaplan Medical Center that patients' blood samples had been used for laboratory research without informed consent (click [here](#) to read the report).

For sponsors and companies working with Israeli hospitals, the report is a reminder that research compliance risk can arise not only from a study's scientific design, but also from how an approved protocol is implemented at the study site. The practical question is whether the study's regulatory classification, institutional approvals, consent documents, and actual sample collection and handling practices are aligned.

What Israeli regulations require

The Israeli Public Health Regulations (Clinical Trials in Human Subjects), 1980 address medical experiments involving human participants. Whether a particular blood draw or use of a sample falls within the relevant framework depends on the study's design and on how the sample is obtained and used.

For a medical experiment conducted in a hospital, the approval process includes approval by the hospital's Helsinki Committee and written approval by the hospital manager, subject to any conditions imposed. The study plan and the actual site procedures should be consistent with the approvals in place.

The informed consent process is central. Participants should receive appropriate information about the research, including its objectives, methods, expected benefits, risks, and potential discomforts. Participation should be voluntary, and participants should be told that they may withdraw. Particular care may be appropriate where the participant is also a patient receiving care from the investigator, so that the patient does not feel dependent on or pressured by the treating physician.

The regulations classify certain activities as “special medical experiments.” These include, subject to specified limits and exclusions, certain blood collections from healthy adults, and certain research using existing records or samples collected for medical purposes. These categories are not blanket exemptions from the approval and consent framework. The specific activity must meet the applicable conditions, and the relevant approval requirements should be assessed for the study in question.

A limited pathway for certain blood draws from healthy adults should not be assumed to apply to patients receiving care. Likewise, if blood samples are used for genetic research, additional requirements may apply, including requirements concerning written consent and the use of identifiable or previously collected samples. Confidentiality and the handling of medical information should also be considered throughout the sample lifecycle.

The report is an opportunity to restate sponsor obligations

A study’s low risk classification, or the fact that a blood draw takes place during clinical care, does not eliminate the need to confirm that the applicable approvals and informed consent are in place. Sponsors and companies should verify that the approved study documents and the site’s actual practices remain aligned before research begins and throughout the study.

Practical guidance for sponsors:

1. **Identify the source and intended use of each sample.** Distinguish between a sample collected specifically for research, one collected during clinical care and later used for research, and a previously stored sample. Document the sample’s source,

purpose, intended testing, storage, future use, and any transfers. Do not assume that a sample collected for clinical purposes may automatically be used for research.

2. **Confirm the regulatory classification and approval pathway.** Assess whether the research is a medical experiment and whether a special medical experiment category applies. Confirm the required institutional approvals and any conditions attached to them. Record the basis for the classification and retain the approval documents.
3. **Align the protocol, consent documents, and site workflow.** The protocol and consent materials should accurately describe any research specific blood draw, including its purpose, anticipated amount and frequency, planned analyses, storage, and potential future use. If the study uses samples originally collected for clinical care, confirm that the proposed use is covered by the relevant approvals and consent.
4. **Build consent verification into sample collection and use.** Assign responsibility at each site for confirming that the required approval and consent are in place before a sample is collected or used for research. Train investigators, research nurses, phlebotomists, and laboratory personnel on the process. Make clear that declining research participation will not affect the patient's care.
5. **Establish oversight, reconciliation, and escalation procedures.** Periodically compare consent and enrollment records with collection records, laboratory data, sample inventories, and protocol deviations. Site agreements and monitoring plans should specify how deviations are reported, who may pause collection or testing, and how affected samples are handled pending review. Protect confidentiality throughout the sample lifecycle, including when samples or related information are transferred or disclosed for research purposes.

The reports concerning Kaplan do not establish what occurred or whether the relevant procedures were followed. The broader takeaway for sponsors is to confirm that the approved study documents, consent process, and actual handling of samples are aligned at every research site.

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As always, the team at Agmon with Tulchinsky remains at your disposal.



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