

An Israeli Central IRB Model: How and Why

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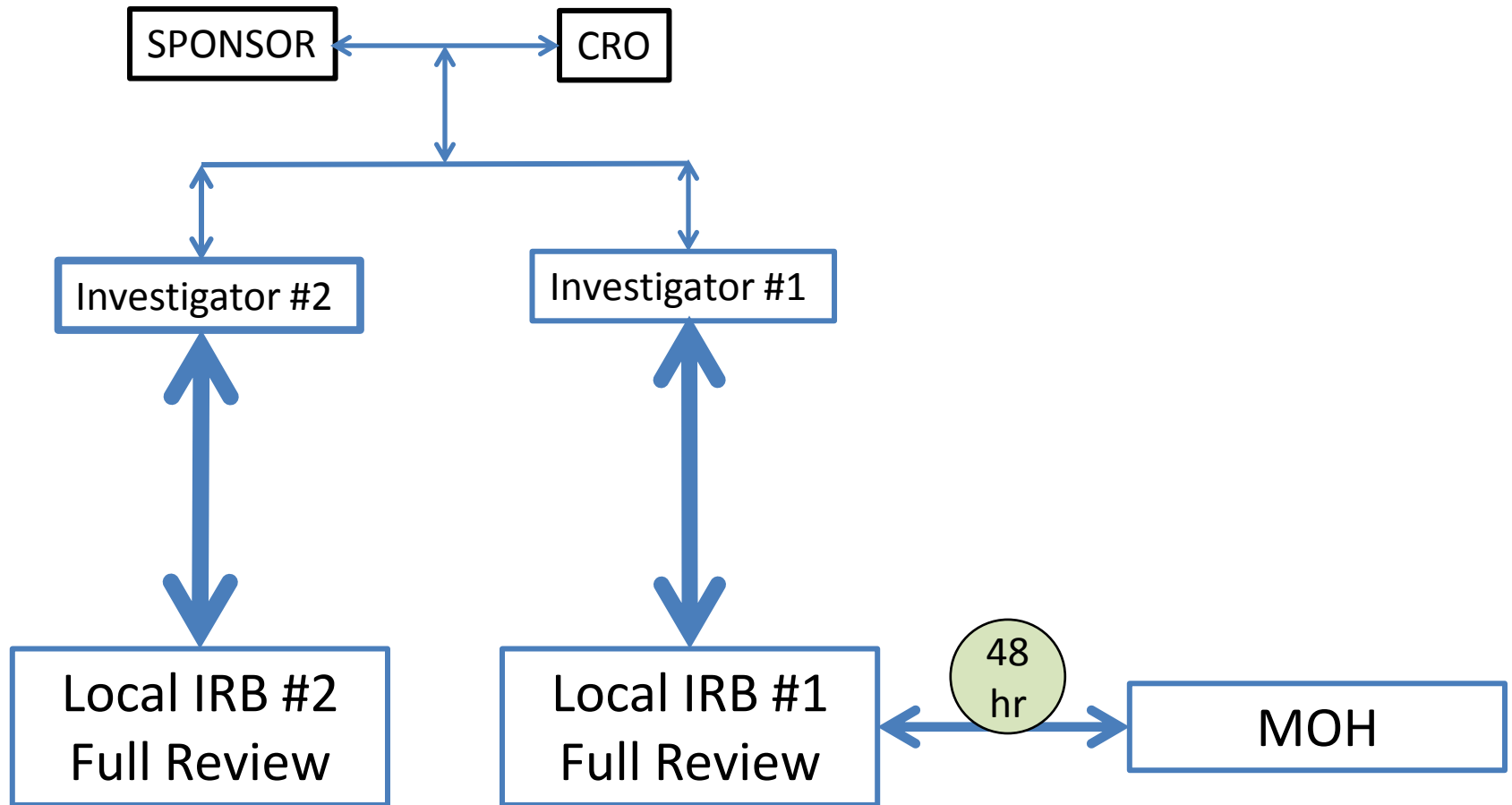
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Agenda

- Current Israeli IRB model and its challenges
- Proposed Israeli Central IRB (cIRB) Model
- Unique features / advantages of an Israeli cIRB
- Frequently Asked Questions (FAQs)

Current Israeli IRB Model

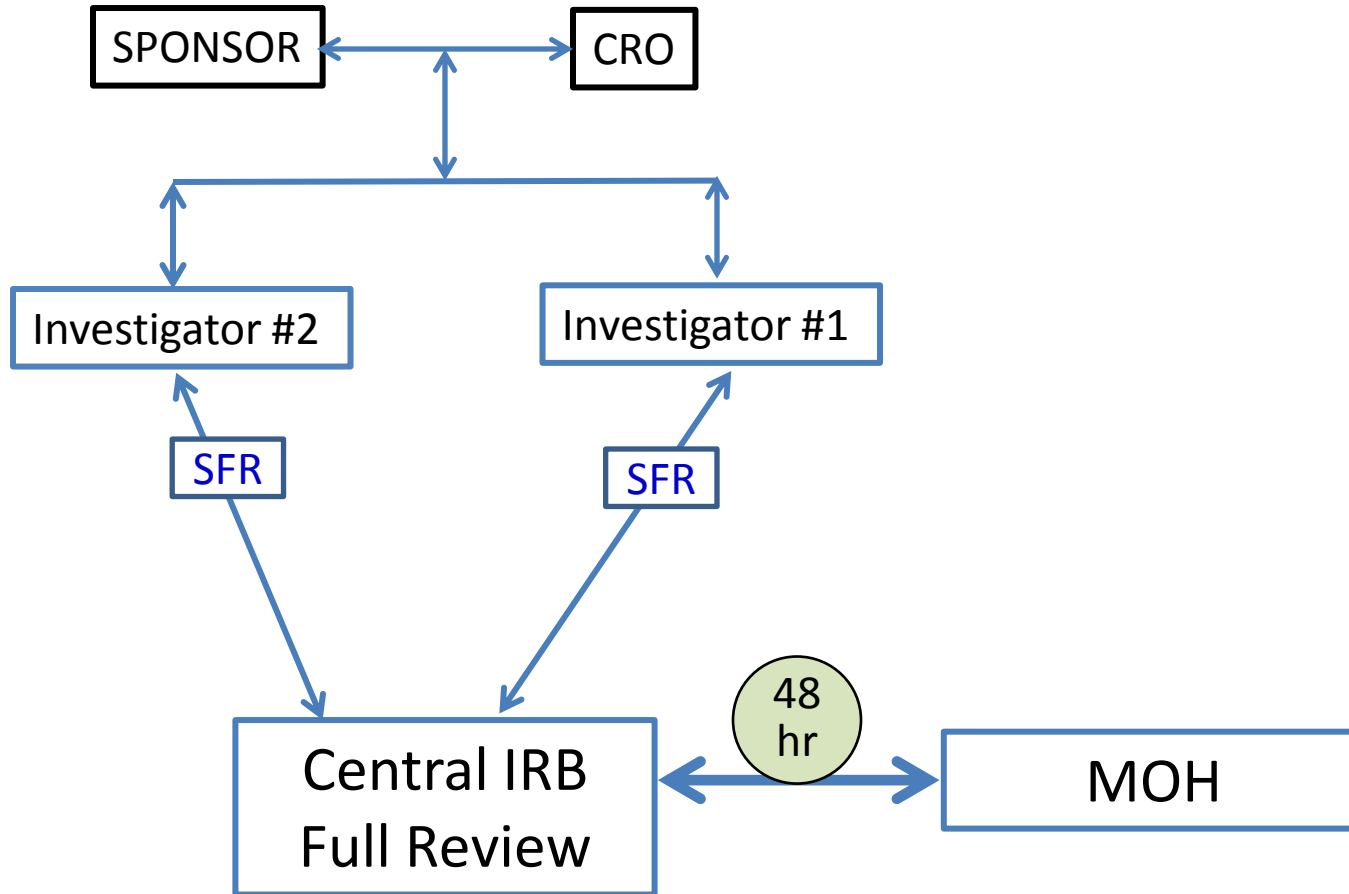


Challenges of the Current Model

- Redundant reviews and paperwork by each IRB
- Differences between sites in ICF quality, formats, and content
- Once-monthly IRB meetings prolong review timelines
- Potential Conflicts of Interest (COI)
 - IRB members review submissions of their own hospital colleagues
 - IRB members, spouses, or children may have undisclosed COI with Sponsors or competing Sponsors
 - No formal COI disclosures required
- High volume of submissions doesn't allow IRB members sufficient time to carefully review the meeting material
- Chairmen may take longer than 48 hrs to determine whether submission is מיוחד או לא מיוחד
- IRB members may lack basic training in important non-clinical areas



Israel Central IRB Model



SFR=Local IRB Site Facilitated Revue

Site Facilitated Review

- SFR Process
 - Chairman assures appropriateness of protocol review by the cIRB
 - Chairman assures Principal Investigator, staff, patient population, and facility are appropriate for the proposed study
- SFR Approval
 - Chairman or designee transfers review responsibility to cIRB
- SFR occurs in parallel to the preparation of the electronic submission to the cIRB
- Local IRB and hospital maintain control of clinical research in its premises



North American Central IRBs

CENTRAL IRB	COUNTRY	ACCREDITATION	TYPE
Quarum	USA	√	Private Company
IRB Services	Canada	√	Private Company
Chesapeake IRB	USA	√	Private Company
Schulman IRB	USA	√	Private Company
Copernicus	USA	√	Private Company
Western	USA	√	Private Company
Aspire	USA	√	Private Company
Midlands	USA	√	Private Company
NCI	USA	√	Government
NIH	USA	√	Government
NY Health Dept	USA	√	Government
Florida Health Dept	USA	√	Government
Veterans' Admin x 9	USA	√ x 9	Government

Features of a Private Israel Central IRB

- Conforms with all GCP/ICH/MOH regulations
- Site Facilitated Review: addresses site's needs / sensitivities
- Optional MOH staff (non-voting) participation in cIRB meetings
- Short timelines: meets once or twice /week
- Standardized procedures (SOPs), documents, and forms
- No duplication of submissions by each site
- Internal and external training & education programs
- Reviews of routine SAEs and scheduled safety reports at each meeting
- Financial compensation
 - Sponsor pays local and central IRBs per respective activity
 - Central IRB pays the committee members and consultants per activities
- Audits: Internal and external by MOH and/or AAHRPP*

*AAHRPP – Association for the Accreditation of Human Research Protection Programs

Israeli Central IRB Advantages

■ Risk Reduction

- ✓ Quality enhancement
 - Internal and external audits
 - Expert and trained reviewers
 - SAE & scheduled safety report review at weekly meetings
- ✓ Site Facilitated Review
 - Respects and supports site's needs / sensitivities
- ✓ Partnering with MOH
 - MOH member may participate
- ✓ External AAHRPP audits, accreditation, and internal plans
 - Conflict of Interest Plan
 - Training and Education Plan
 - Informed Consent Process & Documentation Plan
 - Site Evaluation Plan
 - Continuous Quality Improvement Plan

Israeli Central IRB Advantages

▪ **Subjects Gain**

- ✓ Increased subject welfare and protection
- ✓ Easy and direct access to cIRB

▪ **Sponsors Gain**

- ✓ Short timelines
- ✓ Professional reviews
- ✓ AAHRPP accreditation implying quality
- ✓ Easy and direct access to a single cIRB

▪ **Clinical CROs Gain**

- ✓ Streamline paperwork
- ✓ Short timelines
- ✓ Easy and direct access to a single cIRB

Israel Central IRB Advantages

■ Hospitals Gain

- ✓ Clinical trial risk reduction – improved reviews (submissions, AEs)
- ✓ **Increased number of trials from international Sponsors**
- ✓ International scholarship publications, presentations, opinion leaders
- ✓ Access to cutting edge treatments, technologies and science
- ✓ Lighten IRB workload
- ✓ Physicians do what they do best: treat patients
- ✓ Reduce conflicts of interest

■ Ministry of Health Gains

- ✓ Quality of reviews and follow up enhanced
- ✓ Risks reduced
- ✓ Easy and direct access to a single cIRB

■ Israel Gains



FAQ

Could the Sponsors' payments to a cIRB create a conflict of interest in that the cIRB members might approve submissions in order to increase their own business?

- FDA, NIH, AAHRPP, etc. have not found that to be an issue
- cIRB selects and trains appropriate and professional IRB members
- Conflict of Interest SOP and annual attestation form
- Members are not compensated directly by the sponsor
Sponsor → IRB company → IRB member
- Committee members are paid no matter what the outcome of vote
- Committee members cannot have any financial connection to cIRB
- Neither the Sponsor nor cIRB employees may be present, vote, or participate in the cIRB's closed meeting
- Consequences of a biased vote or error due to COI are severe – lost credibility, jeopardizes MOH and AAHRPP approvals and lost personal income

FAQ

How can a private central IRB operate under the current MOH guidelines?

- cIRB would be bound by the MOH guidelines.
- Changes could be made via a חוזר מנכ"ל.

For example:

לא ייערך ניסוי רפואי בבני-אדם, אלא אם כן אושר על ידי ועדת
הלסינקי של מוסד רפואי או ועדה מרכזית שאושרה ע"י משרד
הבריאות....

FAQ

Are there any legal precedents for private companies servicing Israeli government institutions?

- Israel's road testing services provided by private companies i.e. איגוד מכוני הרישוי בישראל
- Sharap private medical system in government hospitals
- G4S, a private company, provides services for the Israeli Prison System, IDF, and police

ISRAEL WINS

