NIS Considerations - Israel
An overview of the considerations when conducting Non-interventional Studies in Israel

Stuart McCully • Compliance Healthcheck Consulting UK Ltd • NIS-C-IL-2012
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## Disclaimer

## Regulatory Requirements

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Disclaimer

Although this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new standards are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to non-interventional studies. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.
## Regulatory Requirements

### Country-Specific Regulatory Requirements

### Regulatory Bodies

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<th>Competent Authority</th>
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| Pharmaceutical Code of Practice | • The Marketing Code of Ethics of the Pharmaceutical Companies Operating in Israel (October 2004)^  
                              | • Code of Ethics of the Israel medical Association (IMA) (October 2004) |

* For example - The Tel Aviv Sourasky Medical Center Institutional Review Board (Helsinki Committee)

^ Refer to page 25 onwards of the The Joint Ethical Convention between the Israel medical Association (IMA) and the Pharmaceutical Companies Operating in Israel (October 2004)
Study Conduct Considerations

CONSIDERATIONS WHEN CONDUCTING NIS IN ISRAEL

REGULATORY APPROVALS

A clinical study on human may not be carried out in Israel unless it conforms with the requirements of the Public Health regulations and guidelines for the conduct of clinical studies on human subjects (Koren, 2007).

The clinical study must be approved by both the Medical Institute’s Helsinki Committee and by the General Director of the Ministry of Health or his designees i.e., the Directors of the Medical Institute to whom he has delegated his authority for the approval of “special” studies (Koren, 2007).

Ministry of Health Approval

Ministry of Health approval is required only for “non-special” studies. Ordinarily, a non-interventional study would generally be classed as a “special” study and would therefore only require approval from the Institutes Helsinki Committee and the Director of the Medical Institute. However, studies where blood and tissues are taken for the purposes of genetic research must be submitted to the Ministry of Health for approval by the Supreme Helsinki Committee on Genetic Experiments on Human beings.

Helsinki Committee Approval

All clinical studies on human beings require prior approval by the Institute’s Helsinki Committee.
Ethics Committee Submission Package Considerations

- The submission documents must be in Hebrew.
- The content of the submission documents varies depending on the nature of the clinical study (Refer to the Regulatory Submission Documents section).
- The medical institutions Helsinki Committee reviews the submission package, determines whether or not to approve the study in accordance with defined criteria, and determines whether or not the clinical study falls under the definition of a “special” clinical study.
- The submission requirements and Helsinki Committee submission dates will differ for each medical institute. Most medical institutes publish theirs SOPs which contain this information on their websites.
- Most institutional Helsinki Committees meet every four to six weeks. The EC submission package generally needs to be submitted at least two weeks before the meeting.
- The EC submission package is the Principal Investigators responsibility. However, in order to meet the timeline of the institutional Helsinki Committees, the Sponsor can prepare the EC submission package on behalf of the PI, ask for his review and signature, and then submit all of the required copies to the institutional Helsinki Committee.
- For special clinical studies, the institutional Helsinki Committee’s approval takes approximately two to three weeks and the medical institution director’s final approval takes another two weeks.

Service Fees

Each medical institution may charge a service fee to handle the request for approval. Not all medical institutes charge the same fee, if any. For a “non-special” clinical study, the 2006 guidelines set the service fee maximum at $1000, to be divided between the medical institute of the Ministry of Health.
RESEARCH APPROVAL

Genetic testing for research purposes shall not take place unless the research has been approved under any law (as per Section 3(c) of the Genetic Information Law (2000)).

License for Genetic Testing for Research Purposes?

According to Sections 4 and 5 of the Genetic Information Law (2000), a license is required to conduct genetic testing. However, Section 4 of the same law states that genetic testing for research purposes does not need to be conducted at a genetic institute or in a genetic testing laboratory. The reader will therefore need to clarify if such a license is required for research purposes.

APPROVAL OFGENETIC SAMPLE BANKS

Genetic Sample Banks and Export of Samples

In January 2005, the Ministry of Health issued regulations on ‘the establishment and utilization of genetic samples banks’. These provisions are legally binding. Besides the definition of central terms (such as ‘identified’ and ‘unidentified’ samples, ‘DNA-samples bank’, etc.), they require anybody who plans to establish such a collection to seek approval from the Helsinki Committee on Genetic Experiments on Human Beings within the Ministry of Health. The decision of this Supreme Helsinki Committee will depend on parameters such as the size and character of the prospective bank, its purpose, measures to protect the
RESEARCH

A physician or association will be able to participate in research funded by a commercial company subject to any law and to the following rules:

- The researching physician will act in accordance with professional discretion and from the perspective of the good of the patient. The physician will be subject to the rules of ethics and to any law in this matter.

- "A medical trial in humans" is the use of a drug, radiation or chemical, biological, radiological or pharmacological substance in contradiction to the authorization granted in accordance with an act of legislation, or when the said use is not customary or has not yet been tried in Israel and is liable to affect the health of an individual.

- "A special medical trial" also includes a trial whose principal goal is to examine the efficiency of a medical product relative to the indication, to the form of delivery and to the recommended dose.
A medical trial in humans requires receipt of "final authorization for the implementation of research" signed by the director-general of the medical institution at which the trial takes place. The authorization is granted after the chief researcher has met the requirements of the institutional Helsinki Committee and of the Ministry of Health (including an informed consent form). The authorization is granted to the chief researcher and the medical institution specified therein, and may not be transferred.

An authorized physician (MD) is entitled to submit an application to his/her institutional Helsinki Committee and is entitled to undertake a medical trial and to serve as its chief researcher. Any correspondence between a commercial company and the Helsinki Committee must take place through the chief researcher responsible for the research.

A physician, association or scientific society is entitled to participate in research initiated and funded by a commercial company. A physician or association that wishes to initiate research will contact several commercial companies for the purpose of securing sponsorship for the research. It is, however, possible, due to considerations of the physician or the association, to contact a single company.

A physician, association or scientific society are entitled to accept remuneration in consideration for conducting the research, provided that the remuneration shall be financial and completely independent of the outcomes of the research.

Remuneration on account of research will be forwarded to the researcher via the institution in which he/she works or through the scientific association. A physician conducting research privately may receive remuneration on account of his/her investment subject to any law and to the content of these rules.

A grant for the purpose of a trial will be given to the research physician in the form of a research grant or the allocation of drugs and/or medical equipment for the purpose of the trial.

A physician who has an economic interest in a commercial company, or whose relative has such an interest, and regarding whom there is concern of a possible conflict of interests, will refrain from participating in research sponsored by that company, whether he/she is conducting the research, is a partner in the research work or is writing an article relating directly or indirectly to the company, unless he/she has