Salient Points of the Biological Infectious Agents Research Regulation Law, *5769* – 2008[1]

1. General

1.1. The law applies to "institutions" engaging in scientific-investigative, medical, industrial-commercial or educational activities, including hospitals and government institutions.

1.2. "Infectious Agents" are defined in the law as bacteria, viruses, funguses, prions and toxins or components thereof, which are liable to induce diseases in humans, and which are listed in the addendum to the law. The list of infectious agents is attached to this document as **Appendix A**.

1.3. Pursuant to the law:

1.3.1. The possession of infectious agents and conducting research studies with them require approval by the Institutional Committee established by virtue of the law.

1.3.2. Possession of infectious agents and conducting research with them are prohibited, unless such possession or study are in a manner not posing a hazard to State security or public safety, health or security.

1.3.3. The Minister of Health, after consulting with the Minister of Defense, and with the approval of the Science and Technology Committee of the *Knesset*, shall prescribe provisions regarding the possession of infectious agents and conducting research with them, including in relation to the transport, storage and management of inventory in a manner not posing a hazard to State security or public safety, health or security.

1.3.4. Conducting research, of which the sole purpose is to induce a disease or exacerbate it or impair the ability to prevent or treat disease, is prohibited.

1.3.5. If a research study is being conducted of a type for which prior approval is not required by the law, and findings are discovered during the course of the study that could cause an amplification of the violence of infectious agents not included in the addendum to the law, or increase their communicability, or could change the host range of such infectious agents, so that the disease could be transmitted to humans, the study shall cease, and the following orders must be followed:

a. The investigator shall submit an application to the Institutional Committee to receive approval to proceed with the study;

b. In special cases, and in the event that the Institutional Committee deems that the anticipated harm to the study exceeds the concern of harm to State security or to public safety, health or security, the committee may instruct the investigator regarding the continuation of the study until a decision is reached by the committee, regarding the application as stated.

[1] The binding version of the law is the version as published in the Codex. The full version is available here: http://www.weizmann.ac.il/RGP_open/compliance/Infectious_Agents_Research-Regulation_Act-2008.pdf

2. The Council for Research Studies on Infectious Agents[2]

2.1. Appointment of the Council

The Minister of Health, after having consulted with the president of the National Academy of Sciences and the head of the National Security Council, has appointed a Council for Research Studies on Infectious Agents.

2.2. The Council's roles:

To advise the minister in drafting provisions regarding the possession of and research on infectious agents; to advise regarding the recognition of institutions; to advise in the inquiry of appeals pursuant to the law (see clause 4.7 hereunder); to initiate publicity campaigns and advanced training plans; to approve operative rules for institutional committees; to supervise the implementation of the provisions of the law and the compliance with the operative rules for institutional committees.

2.3. Visits by Council members

Any Council member, with the approval of the Council chairperson, and after having issued prior notice, may visit any location where research is being conducted, provided that he/she shall take all accepted measures necessary in order to avoid harm to the research study.

3. Internal Institutional Committee

3.1. An internal Institutional Committee is comprised of three members, who are senior researchers at the institution, and whose fields of expertise are microbiology, infectious diseases or biotechnology; one of them shall serve as the committee chairperson ("the Institutional Committee").

3.2. In decision-making, the Institutional Committee shall consult with the institution's security officer and safety officer and these shall be allowed to attend its meetings as observers.

3.3. The Institutional Committee shall be responsible for issuing approvals for the possession of infectious agents and for conducting research with them in conformity with the provisions of the law, and shall oversee the studies and their compliance with the provisions of the law.

3.4. For the purpose of fulfilling its roles, the Institutional Committee may ask a duly authorized supervisor to exercise his/her powers and may accompany the supervisor to the location where an approved research is being conducted, in order to inspect the location and the manner by which the study is being conducted. The Institutional Committee may also demand from any person information and documents that relate to approved research studies.

4. Authorization for Possession of Infectious Agents and for Conducting Research with them

4.1. An Institutional Committee shall approve the possession of infectious agents and conducting research with them if it has been convinced that all of the following preconditions have been met:

[2] For the council's website, see: http://www.health.gov.il/pages/default.asp?maincat=95

4.1.1. Conducting the research study would not pose a hazard to State security or public safety, health or security. The committee shall take into account the following considerations:

(a) The increased damage that infectious agents are liable to cause;

(b) The increased resistance of infectious agents to pharmaceuticals, to disinfectants or to various physical conditions;

(c) Whether the study might cause infectious agents to become more difficult to discover or identify;

4.1.2. Conducting the research study complies with all requirements and procedures, including all statutory safety rules relating to the possession of infectious agents or regarding the conduct of research studies with them, including with regard to the required equipment, the research team and its training.

4.2. The investigator must submit a signed affidavit to the Institutional Committee, certifying that he/she has not been convicted of security offences, as this term is defined in the law.

4.3. The Institutional Committee may demand from the applicant any data or additional information that the committee needs in order to review the application.

4.4. The Institutional Committee shall not refuse to approve an application if it can be conditionally approved.

4.5. If the Institutional Committee finds that an approval that it had issued is liable to pose a hazard to State security or to public safety, health or security, or that such approval was issued in error, or on the basis of erroneous data, or that the study is not being conducted in compliance with the prescribed conditions and restrictions, the committee may prescribe new conditions for approval of the study or restrict it, and may revoke an approval that it had issued. A decision by an Institutional Committee pursuant to this clause shall be issued after having given the investigator an opportunity to voice his/her arguments; however, the Institutional Committee may hear such arguments after having revoked its approval, if it deems that postponing such revocation is liable to pose a risk to State security, or to public safety, health or security.

4.6. The Institutional Committee shall report the issuance of approvals to the director-general of the Ministry of Health within three days of the issue date of the approval.

4.7. The institution or the investigator may appeal the Institutional Committee's decision to the director-general of the Ministry of Health, who shall issue his/her decision within 30 days of the submission date of the appeal.

5. Control

The director-general of the Ministry of Health may delegate authorities to a supervisor, who shall be authorized to enter any institution; to demand any information and document; to conduct measurements and take samples for testing; to seize and destroy infectious agents or other substances, if there is a concern that they might pose a hazard to State security or to public safety, health or security. The confiscation or destruction of substances shall be done after having given the institution or the investigator an opportunity to voice their arguments, unless an immediate danger exists; under such circumstances, the right to object shall be granted at the first opportunity thereafter.

6. Punishment

Possession of infectious agents or conducting research with them in violation of the provisions of the law constitutes a criminal offense punishable by incarceration or a fine.

7. Confidentiality

Any person fulfilling a function by virtue of the law is subject to confidentiality obligations.

Appendix A

"Infectious Agents," as this term is defined in the Addendum to the Biological Infectious Agents Research Regulation Law, *5769* – 2008

Abrin;

Avian influenza virus (highly pathogenic);

Bacillus anthracis;

Botulinum neurotoxins;

Botulinum neurotoxin producing species of Clostridium;

Bovine spongiform encephalopathy agent;

Brucella abortus;

Brucella melitenis;

Brucella suis;

Burkholderia mallei (formerly Pseudomonas pseudomallei);

Camel pox virus;

Central European Tick-borne encephalitis;

Ceropithecine herpesvirus 1 (Herpes B virus);

Clostridium perfingens epsilon toxin;

Coccidioides immitis;

Coccidoides psadiasii;

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 influenza virus);

Conotoxins;

Coxiella burnetii;

Crimean-Congo haemorrhagic fever virus;

Diacetoxyscirpenol;

Eastern Equine Encephalitis virus;

Ebola virus;

Far Eastern tick-borne encephalitis;

Flexal;

Fransicella tularensis;

Guana rito;

Hendra virus;

Japanese encephalitis virus;

Junin;

Kyasanur Forest disease;

Lassa fever virus;

Machupo;

Marburg virus;

Menangele virus;

Monkeypox virus;

Nipah virus;

Omsk Haemorrhagic Fever;

Ricin;

Rickettsia prowazekii;

Rickettsia rickettsii;

Rift Valley fever virus;

Russian Spring and Summer encephalitis;

Sabia;

Saxitoxin;

Shiga-like ribosome inactivating proteins;

Shigatoxin;

Staphylococcal enterotoxins;

T-2 toxin Venezuelan Equine Encephalitis virus;

Tetrodotoxin;

Variola major virus (Smallpox);

Variola minor virus (Alastrim);

Yersina pestis;

Excluding the chemical preparations listed in the register of chemical preparations being kept pursuant to clause 47.A of the Pharmacists' Ordinance [New Version], *5741* – 1981.