

# ENU Helsinki Procedures Update 2018

## New procedures – applicable to all labs

### Signing Informed Consent Forms

1. ***The previous demand that only faculty members will sign the informed consent forms has been cancelled.*** The PI can delegate this authority, in written, to anyone who has been approved as a 'Hoker Mishne' by the Helsinki committee. The forms can be signed at ENU or any other place, on the day of the scan or before that.
2. The hour of signature must be written down in the informed consent form (next to the date, e.g. 31/12/2017, 12:30).
3. The participants should sign the consent form and fill in the date & hour themselves.
4. If the participant signs in English (i.e. the signature is in Latin letters), it should be explicitly stated in writing that the participant speaks Hebrew and was able to read the form.
5. The technician will scan the signed form and upload it to the ENU system. The technician will verify that the following are present:
  - a. Participant name
  - b. Participant signature
  - c. Date & hour
  - d. Investigator Name
  - e. Investigator Signature
6. The investigator has sole responsibility for the completeness of the form, as well as its content, correct version, & validity.
7. Every participant who have signed the consent form is counted in the overall number of participants in the research, even if ending up not performing the experiment, and should be included in the numbers (N subjects) reported to the Helsinki committee. This holds true even if the person's details were not entered to the MRI system (e.g. the participant suddenly remembers some detail that prohibits him/her from entering the magnet room, or has some safety concerns).

### Preparing & Using Informed Consent Forms

1. The ENU reservation system now has a new '**forms**' module, to hold the latest consent form version. All labs are invited to keep the latest version online (for ENU protocols - i.e. with Prof. Gomori as PI - the latest version *must* be kept there, see below). At present, uploading of the forms will be done by ENU staff only.

## Scanning limitations

1. The number of scans and frequency at which a single participant may be scanned under a single research protocol should not exceed what is stated in the research protocol. This holds even for two different 'researches' (i.e. papers) under the same Helsinki protocol. For example, if you stated that participants may be scanned 2 times annually for 2 years, that means that they can be scanned 2 times in each of the first 2 years, and no more - even if you started a completely different project a couple of years later. You will need to apply for a new Helsinki protocol.
2. FYI: In general, participating in more than one research concurrently is not allowed. Since most of our protocols remain open for many years, this is not practical – a person may choose to participate in a new research even though the previous one is not officially 'closed'. The Helsinki committee has acknowledged our needs and will not enforce this rule.

## Additional procedures – for ENU protocols only (research under Prof. Gomori)

### Preparing & Using Informed Consent Forms

1. Upon approval of a consent form version by the Helsinki committee (be it first version or upon modification), ENU staff will upload it, in PDF format, to a new 'forms' section of the ENU reservation system. You can find the current version of your form in the system.
2. Any investigator (i.e. Hoker Mishne) will have access to their lab's current version of the informed consent form, and *must use only that latest version*.

### Filing & Maintaining Helsinki Approvals & Consent Forms

1. All hardcopy informed consent files & Helsinki approval files will be placed at ENU.
2. Upon finishing scanning, the investigator will file the hardcopy of the informed consent form in the file and leave it at ENU. The investigators have sole responsibility for keeping the organization, handling, editing, and updating of the files.
3. The Helsinki coordinator of each lab is in charge of filing and documenting changes, updates, & Helsinki approvals in the physical *Helsinki Approvals* file, located at ENU.
4. The Helsinki coordinator of each lab should update all lab investigators on changes in protocol or consent forms.

### Additional Updates

1. The ENU staff will perform routinely checks to verify that all forms are being signed and filed properly.
2. Investigators may be asked to go through periodic training that will cover GCP principles & ENU Helsinki procedures.