BACKGROUND
The Department has been directed by the Office of Regulatory Affairs (ORA) to develop a set of procedures to monitor compliance with regulations regarding human consent procedures, and proper storage/archiving of consent documents. An annual “spot-checking” of ongoing or recently completed studies is performed to ensure compliance. This auditing will be accomplished by members of the Department’s IRB/Human Subjects Committee. Studies to be audited will be selected at random, stratified by sponsored and non-sponsored projects; approximately 70% of projects so selected will be drawn from the “sponsored” category. For every project, all consent forms must be made available for review, and 30 randomly selected individual-subject records will be audited. The “REPORTING FOR EACH PROTOCOL” section at the end of this document summarizes the types of information that will be audited.

The Department also has been directed to clarify procedures for training of researchers at different levels and to maintain adequate records of such training with respect to researchers who work directly with human subjects. The following guidelines were developed to help faculty, staff, and students comply with the appropriate regulations and to facilitate the annual auditing process.

RECORD-KEEPING

Protocol documentation. The researcher should keep copies of the following information in one folder: the original IRB protocol (including correspondence regarding stipulations), consent form, and ancillary documents (ads, questionnaire forms, etc.); the original IRB approval memo; yearly progress reports; yearly Continuing Approval memos from the IRB; requests for changes in protocol, along with IRB approval; requests for the addition of new investigators to the study; and copies of any other correspondence with the IRB (e.g., unanticipated adverse events). All of these documents can be maintained in digital format, provided they are backed up on the departmental server.

Consent forms and documentation. It is recommended that department researchers use the standard IRB templates for developing their consent forms. These forms are available, for both Social & Behavioral Science and Medical & Health studies, at:
http://www.irb.umn.edu/guidance/consent.html

It should be noted that these templates are somewhat “sparse” documents, and do not include all of the details that the University of Minnesota requires and the IRB suggests. These additional details can be seen by clicking the first link, “What must be included on a consent form?”, in the “Consent Form Help” section of the link above. These include such items as page numbering (e.g., page 1 of 3 pages) and proper headers on the first page (e.g., letterhead for faculty researchers). It is particularly important to add the IRB code number to consent forms after IRB approval is granted, and also to print the version
date of the IRB approval (as a footer to the consent form), to ensure that current consent forms are being used. (The version date should be updated if any consent form changes are later submitted and approved by the IRB.)

The consent templates include lines only for signatures. Because signatures are often incomprehensible, we recommend that department researchers add lines in the consent form for the printed name of the subject, the researcher, and (where appropriate) a parent. Also, note that the IRB in the vast majority of cases requires us to give subjects a signed copy of the consent form (either by photocopying, or by having the subject and researcher sign two forms). Although a large percentage of REP participants may dispose of their copy immediately, this step is important in case of later complaints by subjects, and provides participants with essential study and out-of-study contact information, should they wish to follow-up after the study is completed.

Maintaining consent forms and appropriate documentation. Auditors must obviously be able to determine the total number of subjects from whom consent was obtained, so as to determine whether all consent forms are available for review. From the IRB’s point of view, a critical value is the number that the investigator reports on the annual report of progress to the IRB; it must be possible to match this reported figure with the number of consent forms in the files. Similarly, it must be possible to determine how many subjects have been run in a current “IRB year” and match the consent forms. Either a Master Enrollment Log (described next) or a similar log (e.g., a REP points log, or a cash reimbursements log) should be kept to allow auditors to readily tabulate the number of participants who have undergone consent on a given protocol in a given time period.

A simplified Master Enrollment Log (Simplified MEL) spreadsheet has been created to assist researchers in keeping track of subjects on an experiment-wise basis, and it is strongly suggested that researchers use this spreadsheet (with minor modifications as necessary for individual projects), or an alternative log, to facilitate record-keeping and auditing. **Note that participant codes should not be entered in the MEL, with subject names, if the approved IRB protocol involves de-identified data: only enter information in a log that is consistent with the IRB protocol for an individual study.** From the researcher’s point of view, multiple experiments may be conducted under a single IRB protocol number; however, it is necessary that the total number of subjects for each protocol be obtained readily to carry out the audit. Therefore, the MEL has a blank both for an overall protocol name and for a specific experiment name. Depending on the N and type of study, it is also acceptable to have separate MELs for each major condition of an experiment, e.g., age group, between-subject condition, etc.

If there are more than 2-3 experiments under a given protocol, investigators are strongly encouraged to maintain a master list of all the experiments, with titles, conducted under the auspices of a given IRB. This will save considerable time and confusion in the audit.

Most columns in this form are obvious, but a few points should be noted: (1) It is important that the name of the researcher obtaining consent be entered clearly in the “Researcher” column, so as to allow matching of the researcher’s name with the
corresponding signatures on the consent forms; (2) it is particularly important that researchers enter the type (e.g., REP points, cash, gift card) and amount of remuneration, for general record-keeping but also in case of later questions from subjects; (3) If the research is sponsored by NIH, additional columns for "Ethnicity" and "Hispanic" status may be added to facilitate reporting of this information as required for that funding source.

All subjects from whom consent is obtained should be listed on the MEL. The ORA indicates that particular care should be taken in cases where subjects withdraw (or are excluded) from a study after signing consent is obtained: The amount of prorated compensation should be listed, along with a note in the “Status” section as to why the subject withdrew or was excluded (e.g., “failed to return for final session,” “lost to follow-up”). It is recommended that further notation be added if the subject became upset in any way, even at a level that did not require an Adverse Event report. Subjects who decline participation before signing consent do not need to be listed, although it is a good idea to list such subjects if prorated compensation is given for their time in coming to the research site.

Subject compensation. The number of REP points is to be indicated on the MEL (or similar log). For payments of cash, it is necessary to keep a separate subject receipt form to document payment. Researchers should make photocopies of these receipt forms, for their own records, before turning them in to Accounting for payment. Auditors will check that the signatures on the consent form and the subject receipt form match.

Consent form storage. Consent forms should be stored in folders, in the same organization as the MELs (i.e., multiple folders for multiple experiments and/or conditions). Consent forms should be stored in an order that permits ready matching of each consent form with an entry on the MEL – either alphabetically, or in the same order as the entries on the MEL.

Internet-based studies. In cases where subjects enroll and complete studies on the internet, the “Researcher” should simply be the person listed on the protocol as the PI. It is still necessary to maintain a Master Enrollment Log for IRB purposes, although this may be the only documentation available for an internet survey (and may be computer-generated). For studies using the department REP pool, the MEL may consist of a list of student ID numbers, as these are how points are typically awarded.

Experimenter signature log. The ORA also directs that investigators maintain an Experimenter Signature Log. The purpose of this log is to maintain a single document listing all experimenters who are working on a particular study. One purpose of this form, according to the ORA, is that this log makes it easier to determine the researcher’s identity from an illegible signature if a particular consent form does not contain the printed name of the researcher. As with the MEL, it is permissible for researchers to maintain multiple signature logs, one for each experiment under an overall protocol, as long as the number of such experiments (and their titles) is clear.
The log also provides documentation for the type and date of human subjects training. The faculty member should also keep a list of the actual certifications for human subjects training (e.g., printouts of certificates for Completion of Human Subjects Training) for inspection, as these will be checked during the audit. The log also contains an entry for other training and the dates completed.

REPORTING FOR EACH PROTOCOL

Reporting will follow the ORA format. This format has sections and sub-sections, as follows. This section represents the format that the committee will follow in writing each report.

**Study Summary:**
Title:
IRB Protocol #:
Date of Approval:
Number of Subjects Approved:
Principal Investigator:
Study Purpose and Goals: [1-2 sentences]
Research Methods: [2-3 sentences]

**Study Review**
Overall results of review:
1. Protocol Documentation
   a. Check that all records have been kept (e.g., original IRB application, consent form, renewals, correspondences with IRB, etc.) for as long a period as the IRB protocol stipulates.
   b. Check that the investigator has kept the IRB informed of protocol changes: records of any changes in protocol, new experimenters, etc.
2. Consent Form Documentation and Checking
   a. Adequacy of consent form
   b. Consent form elements (IRB #, version date, header, etc.)
   c. Check that # of subjects on the MEL (or similar log) matches the # of consent forms
   d. Check for appropriate match of dates on the MEL (or similar log) and consent forms
   e. Check that researchers obtaining consent are identified in the Experimenter Signature Log
3. Compensation Forms Documentation and Checking
   a. Check (where applicable) that signatures on the consent form and subject receipt form (for cash payment) match
4. Human Subjects Training Certifications
   a. Check that all researchers are listed on the Experimenter Signature Page, and check printouts of their certifications for human subjects training
5. Any Other Issues Noted