Attendees: Peter Backlund, Lecia Barker, Lynne Davis, Mary Hayden, Meg McClellan, Kathy Miller, Katy Schmoll, Cindy Worster

The committee would like to meet annually.

New review procedures and memo templates for HSC: (see attached)

- **Expedited**: On the HSC formal approval memo, we are now indicating the OHRP designation for expedited review.
- **Exempt**: We now list the exemption category in the HSC memo, based on the six categories of research that qualify for exemption from coverage by the regulations as defined in the Common Rule for Protection of Human Subjects.
- **Pending**: This is a new category of review for researchers who are submitting a proposal to a funding agency which requires IRB review of the protocol before proposal submission.

Human Subjects online training:

- For the HSC’s annual PI training we use the NIH’s online training ([http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php))
  
  This is linked from the HSC home page.


  **ACTION**: Meg McClelland and Mary Hayden will talk about Citi training being required.

Miscellaneous:
Leica Barker mentioned that she needs access to HSC manual pages and other pages inside the firewall.

  **ACTION**: Cindy Worster is migrating the current HSC web site to Drupal, which allows setting a password for a single user, and this is planned to be in place by May 14.

ATTACHMENT
HSC Procedures for Expedited Review

Expedited review (excerpted from online HSC Manual):

Research that involves minimal risk (see Section V) qualifies for expedited review. This means that one or more experienced HSC members will review the protocol and keep all HSC members advised of their findings. The reviewer(s) may exercise all of the authority of the full committee, except that they may not disapprove the protocol; that can only be done by full HSC review. Much of the research done at UCAR is minimal risk and involves procedures the HSC has discussed before, understands very well, and can safely handle through expedited review.

The HSC should remember that standard requirements for informed consent (or its waiver, alteration or exception) apply regardless of the type of review, expedited or full, undertaken by the HSC. When conducting an expedited review, the HSC reviewer must designate which category of review is appropriate, and will likely find that most research review at UCAR falls in categories 6, 7, and 8. NIH, through its Office for Human Research Protections (OHRP), has established the following research categories for expedited review:

Research Categories Excerpted from the OHRP web site
(http://www.hhs.gov/ohrp/policy/expedited98.html)

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

   b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat);
(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. **Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**

7. **Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. **Continuing review of research previously approved by the convened IRB as follows:**
   a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b. where no subjects have been enrolled and no additional risks have been identified; or
   c. where the remaining research activities are limited to data analysis.

9. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do
not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1 An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).


MEMORANDUM

TO: 
FROM: UCAR Human Subjects Committee 
OHRP IRB Number: IRB00006222 (U Corp. for Atmospheric Rsch) 
Assurance Number: FWA00012567 

DATE: 
SUBJECT: Human Subjects Committee Review #2012-23 for study “Study Name” (UCAR Proposal Number: ) 

REVIEW: Expedited 
Category: ____ (give expedited category) ____

The Human Subjects Committee (HSC) has reviewed the study protocol “Study Name” and gives expedited approval under 45 CFR 690.110, category ______. Your Informed Consent documents are also approved. Your protocol is approved for a maximum of three years from this date of approval, or the completion of your project (whichever comes first).

You are required to update the HSC at any time if any of the aspects of your study that involve human subjects changes. You are also required to notify the HSC annually, as to the status of the research, as well as send email notification when you have completed the study.
The UCAR HSC's approval of this study is for human subjects research purposes only and in no way reflects any management opinion about the study or its potential results.

We appreciate your conscientious adherence to the requirements of human subjects research. If you have any questions about this process, or if you need assistance at any time, please feel free to contact the HSC (hsc@ucar.edu) or visit our website at http://www.ucar.edu/hsc/.

- END -

HSC Procedures for Exempt Designation

Consistent with the NSF Grant Proposal Guide (http://www.nsf.gov/pubs/policydocs/pappguide/nsf13001/gpg_index.jsp) and all other federal agencies:

If human subject activities are exempt from UCAR Human Subjects Committee (IRB) review, the HSC must provide the exemption number(s) corresponding to one or more of the exemption categories. The six categories of research that qualify for exemption from coverage by the regulations are defined in the Common Rule for Protection of Human Subjects.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   (i) research on regular and special education instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:
   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   (i) public benefit or service programs;
   (ii) procedures for obtaining benefits or services under those programs;
   (iii) possible changes in or alternatives to those programs or procedures; or
   (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,
   (i) if wholesome foods without additives are consumed or
   (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found
to be safe, or agricultural chemical or environmental contaminant at or below the level found to
be safe, by the Food and Drug Administration or approved by the Environmental Protection
Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Examples of memo text to PIs to let them know their protocol is Exempt

1. **Exempt under Category 1 of the Common Rule:**
   “The Human Subjects Committee (HSC) has reviewed the study protocol and has determined
   that it is exempt under 45 CFR 46.101(b) category 1, because the study involves interviews and
   survey procedures in normally conducted educational settings."

2. **Exempt under Category 2 of the Common Rule:**
   “The Human Subjects Committee (HSC) has reviewed the study protocol and has determined
   that it is exempt under 45 CFR 46.101(b) category 2, because the study involves the use of
   (educational test, survey procedures, or observations of public behavior) that is (Anonymous or
   unidentifiable; and Exposure of responses outside research does not pose any risks of civil or
   criminal liability, or damage to the subject’s financial standing, employability, or reputation; and
   human subjects are not under 18 years of age or part of a vulnerable class).”

3. **Exempt under Category 3 of the Common Rule:**
   “The Human Subjects Committee (HSC) has reviewed the study protocol and has determined
   that it is exempt under 45 CFR 46.101(b) category 3, because the study involves the use of
   (educational test, survey procedures, or observations of public behavior) where (The Human
   Subjects are Elected or appointed public officials or candidates for public office; or Federal
4. **Exempt under Category 4 of the Common Rule:**

“The Human Subjects Committee (HSC) has reviewed the study protocol and has determined that it is exempt under 45 CFR 46.101(b) category 4, because the study involves research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, where (these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects).”

5. **Exempt under Category 5 of the Common Rule:**

“The Human Subjects Committee (HSC) has reviewed the study protocol and has determined that it is exempt under 45 CFR 46.101(b) category 5, because the study involves research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

If the project involves human subjects and is to be performed outside of the U.S., evidence of IRB approval also is required. If there is no IRB approval provided, and the foreign country is not included in the 2008 HHS OHRP International Compilation of Human Research Protections (http://www.hhs.gov/ohrp/international/HSPCompilation.pdf), nor is an Assurance on file with OHRP (http://ohrp.cit.nih.gov/search/asearch.asp#ASUR), NSF may decline to support the project.
MEMORANDUM

TO:                        
FROM: UCAR Human Subjects Committee
OHRP IRB Number: IRB00006222 (U Corp. for Atmospheric Rsch)
Assurance Number: FWA00012567

DATE: 

SUBJECT: Human Subjects Committee Review #2012-23 for study “Study Name.” (UCAR Proposal Number: )

REVIEW: Exempt
Category: ___(give exempt category under 45 CFR Part 690)___

The Human Subjects Committee (HSC) has reviewed the study protocol “Study Name” and finds that it is exempt under 45 CFR 690.101, category ______ because <insert text related to the category of exemption>.

You are required to update the HSC at any time if any of the aspects of your study that involve human subjects changes. The UCAR HSC’s approval of this study is for human subjects research purposes only and in no way reflects any management opinion about the study or its potential results.

We appreciate your conscientious adherence to the requirements of human subjects research. If you have any questions about this process, or if you need assistance at any time, please feel free to contact the HSC (hsc@ucar.edu) or visit our website at http://www.ucar.edu/hsc/.

- END -
HSC Procedures for Pending Review

Consistent with the NSF Grant Proposal Guide
(http://www.nsf.gov/pubs/policydocs/pappguide/nsf13001/gpg_index.jsp) and all other federal agencies:

When a researcher submits a proposal to a federal agency or sponsor that will involve human subjects research and

- the portion of the project involving human subjects does not yet have a definite plan for involvement of human subjects; or
- human subjects will be involved, but the scope is not yet defined

the HSC may review the researcher’s “Pending Review” request and provide a pending review memo. This is consistent with the following guidance from the NSF Grant Proposal Guide:

If the research is not designated as exempt, the IRB approval date should be identified in the space provided. This date, at minimum, should cover the period at which the project is initiated. If IRB approval has not been obtained prior to submission, the proposer should indicate "Pending" in the space provided for the approval date. If a decision is made to fund the proposal, the organization must provide a signed copy of the IRB approval letter to the cognizant program. The letter should indicate approval of the proposed activities and must be submitted prior to an award being issued.

Checklist for administrative follow-up to Pending Review proposals:
1. No human subjects may be involved in a project until that project has completed a review with the HSC, and HSC approval is received by the researcher.
2. If the proposal is funded, the researcher must submit a protocol to the HSC.
3. The researcher then submits the HSC approval memo to the funding agency.
4. On an annual basis, the administrator for the HSC will contact researchers to determine the status of any “Pending Review” proposals. However, it is the Researcher’s responsibility to make sure that her/his project is in compliance with the federal Human Subjects Research regulations, including timely submitting protocols and updates to the UCAR HSC.
   - HSC administrator will provide one researcher reminder per “pending” study protocol
   - Draft of an email to the Researcher

   Dear __<Researcher Name>__,
   This is a follow-up to the request for review you submitted for your study to the HSC in order to submit a proposal for outside funding. The HSC provided an initial review, with the requirement that you submit a complete study protocol for HSC review prior to commencement of the work. Please use the Requirements for a Study Protocol form (found online at http://www.ucar.edu/hsc/) to submit a complete study protocol.
   Best Regards,
   HSC Committee
MEMORANDUM

TO: UCAR Human Subjects Committee
FROM: OHRP IRB Number: IRB00006222 (U Corp. for Atmospheric Rsch)
Assurance Number: FWA00012567

DATE: Human Subjects Committee Requirement for Pending Review for study “Study Name.” (UCAR Proposal: )
(HSC Memo # 2013-11)

REVIEW: Pending

Dr. Mary Smith as PI is familiar with UCAR’s Human Subjects Committee policy and procedures. We understand that Dr. Smith will submit a proposal for “Study Name,” and that this project may involve human subjects research.

Dr. Smith has notified the HSC of this proposal. Dr. Smith understands that the HSC requires a complete review of the study protocol to ensure compliance with human subjects regulations prior to the commencement of the work.

We appreciate your conscientious adherence to the requirements of human subjects research. If you have any questions about this process, or if you need assistance at any time, please feel free to contact the HSC (hsc@ucar.edu) or visit our website at http://www.ucar.edu/hsc/.

- END -