SUPPORTING STATEMENT
U.S. Department of Commerce
National Institute of Standards and Technology
Identification of Human Cell Lines Project
OMB Control No. 0693-XXXX

A. JUSTIFICATION

This is a request for the Office of Management and Budget approval of a new information collection.

1. Explain the circumstances that make the collection of information necessary.

The NIST Biochemical Science Division will administer this project. Human cell line samples are cells taken from a human being that can be grown in the laboratory and are considered immortal (alive and reproduce forever in a petri plate, given appropriate conditions). They can be used for scientific experiments, as examples of the tissue they're from. Once cells from a tissue have been grown in the lab they are called a cell line. There is a tremendous need for investigators to know with confidence that the cells they are using are truly the cells they think they are. This interactive database will be used by the research and development community to validate cell lines of interest. The database will offer DNA profiles of commonly used standard cell lines, as donated by interested parties. The database will allow disparate laboratories to compare their lines, thereby facilitating the validation of experimental data. Thus the database will address the need for investigators to know much more about the samples used in their research. The database will fulfill an overarching need of researchers to characterize their substrates with an accepted standard.

For scientists to compare the cell lines that they are using in their individual laboratories to those in the National Center for Biotechnology Information (NCBI) database, information is needed regarding the cell lines (name and possible synonyms of cell line, organism, tissue of origin, morphology, pathologic or disease-state, hybrid or mixed culture, feeder cells, date of origin, etc), the short tandem repeat (STR) markers and procedures used in identification, the submitter and appropriate links, other descriptive material, and the STR profile (electropherogram) of the cell line. This information, plus that determined in the NIST laboratory and in the scientist's own laboratory by the STR profiling, will enable the database user to determine if his cell line is the same as one of the published cell lines. The information requested will be done through publication of a Federal Register Notice (FRN).

2. Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with all applicable Information Quality Guidelines.

The information will be collected from scientists submitting human cell lines and will only be collected when they submit their cell lines. The information will be included in a National Institutes of Health (NIH)/National Center for Biotechnology Information (NCBI) database enabling scientists around the world ready access to the data for comparison to their own cell lines.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.

The information may be collected electronically. Participants have the option of creating a document and e-mailing the requested information to NIST.

4. Describe efforts to identify duplication.

All submitted cell lines that meet the criteria outlined in the FRN will be identified using short tandem repeat (STR) profiling by NIST with no effort made to avoid duplication. Short tandem repeat profiling counts the number of repeated base pairs in sections of DNA that are not known to code for genetic information. An example is ATCATCATC in which the ATC sequence is repeated three times. This project will use nine locations on the human chromosomes to count repeats and use for comparison to a reference profile. No judgment as to duplication will be made on the part of NIST. In some cases the information collected may be duplicated but the experimental results may not be identical; i.e the numbers of repeats for each chromosome location may not be the same even though the information about the cell line may be identical. It is important to use all the data as submitted.

5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

The burden for each cell line will be the same no matter the size of the submitting entity.

6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.

Collection of the required information is fundamental to the Identification of Human Cell Lines Project. The project has no value without collection of the requested information.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

This information will not be collected in a manner inconsistent with OMB guidelines.

8. Provide information of the PRA Federal Register Notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

The 60 Day Federal Register Notice soliciting public comments was published on March 24, 2011. One comment was received (in ROCIS). The comment consisted of clarification questions regarding the collection. NIST responded to the questions and did not receive any additional questions from the commenter.

9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

Not Applicable.

10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.

Not Applicable.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Not Applicable.

12. Provide an estimate in hours of the burden of the collection of information.

Total burden of **250 hours** is based on 2 hours and 30 minutes per response (10 minutes per cell line x 15 cell lines).

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in Question 12 above).

It is estimated that only 10 respondents will submit their cell lines via mail at $20 per response = $200.

14. Provide estimates of annualized cost to the Federal government.

This is a one-time data collection process and is estimated to cost approximately $10,000.

15. Explain the reasons for any program changes or adjustments.

This is a new information collection.

16. For collections whose results will be published, outline the plans for tabulation and publication.

After short tandem repeat (STR) profiling the submitted human cell lines the data will be posted in a publicly held database at NIH/National Center for Biotechnology Information (NCBI).

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

This collection of information does not involve a form to display the expiration date. NIST will include in the Federal Register notice that the collection is subject to Paperwork Reduction Act requirements and approved by the Office of Management and Budget under the control no. 0693-XXXX, Expiration Date: XX-XX-XXXX.

18. Explain each exception to the certification statement.

There will be no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methodology.