SAIC Frederick, Inc. has established a mechanism to allow a pilot activity to provide excess capacity (EC) services to be charged on a fee-for-service basis starting in the second quarter, fiscal year 2005. The excess capacity of the NCI's Core Genotyping Facility (CGF) will be determined based on the current CGF fiscal year budget, such that the CGF shall possess the capability to fulfill excess capacity requests for an additional 15% of its fiscal year budget. The availability of the EC services will temporally fluctuate during the fiscal year with virtually none available during the 4th quarter. The excess capacity services offered by the CGF will include:

- sample handling of human genomic DNA or whole genome amplified human genomic DNA
- genotyping of human genomic DNA or whole genome amplified human genomic DNA
  - TaqMan
  - Fluidigm BioMark 48.48 and 96.96
  - Illumina Infinium (whole genome amplified (WGA) DNA **cannot** be used)
  - Illumina GoldenGate
- SNP resequencing and high throughput genotype assay development.

The effective cost structure would be based on the required work and the size of the project as well as the availability of samples and will be determined on a project-by-project basis. All new samples that the CGF has not already sample-handled (quantified and performed Identifiler™ STR genotyping) would be subject to a per sample charge. The cost of this service would cover the aliquoting of the sample, evaluation of the sample's concentration and total amount of DNA based on Pico-Green, and generation of a genetic profile fingerprint (15 STR markers plus Amelogenin "sex" determination). Samples that already exist at the CGF, which have been sample handled by the CGF, and that have enough DNA available at the CGF to do the requested genotyping, would be not be subject to the initial sample handling charge. Once the sample handling of a particular set of samples has been completed, a Pre-Genotyping QC report will be delivered to the investigator. This report includes all of the information on samples that qualify for genotyping on the particular platform to be used and those that don't meet the criteria and why. Based on this data, applicants can choose to proceed with the genotyping.

Genotyping costs are based on the size and scope of the project. All of the genotyping costs are based on using CGF "validated" assays (SNPs that have been sequenced in the SNP500Cancer N=102 population, or genotyped in the N=270 HapMap individuals, and having assays developed demonstrating a greater than 95% completion rate and 99% genotype concordance between the assay-determined genotypes and the reference genotypes for the SNP500Cancer or HapMap population), which are available on the SNP500Cancer website http://snp500cancer.nci.nih.gov.

Existing Services: Currently the CGF provides services to various principal investigators, and a monthly activity report is provided to Donna Siegle, ARC Manager, DCEG. This report summarizes the monthly costs of the lab as well as the user activity. The report is then used to process a series of funding transfers to allocate the supplies costs of the Core Genotyping Facility center (20769123) across the various requestors. It is understood that the funding transfers will remain unchanged for existing customers.

Excess Capacity, NIH affiliated: SAIC Frederick has established a billing mechanism to be used to charge excess capacity support. This mechanism will model the existing method of transferring costs on a fee-for-service basis used by various other core service areas. A monthly activity report will be supplied by Amy Hutchinson, Director of Operations of the CGF, and will detail the services rendered along with a valid SAIC center number for billing purposes. The monthly billing report will be provided to DMS, who will in turn process the transactions and upload into SAIC's accounting system (Smartstream), providing a charge to the requestor's SAIC center number under account 5965, titled, "Core Genotyping Facility Services". An offsetting credit amount will then be applied to the DCEG credit center number (20769888) thereby reimbursing the CGF for the services provided to NIH affiliated excess capacity users.

Excess Capacity, External, non-NIH Affiliated: A separate billing mechanism has been established to allow CGF services to be offered to customers outside of the NIH. As with the previous examples, a monthly report will be provided to SAIC Finance, which summarizes excess capacity efforts along with customer and billing information. Based on the information provided, SAIC Accounting will then prepare an invoice to the external customer for the services provided.

The CGF will provide a web-based application form in order to gain fair access to utilize its excess capacity. This form must be filled out in its entirety and submitted to the CGF before a pre-determined deadline. Determination of priority and suitability will be assessed one quarter prior to commencement of work, if approved. It is anticipated that the quarterly deadline will be 30 days prior to the beginning of new quarter. Deadlines and applications will be posted on the CGF web site. All applications must be completed via the web application, and will be reviewed by the CGF senior management. Assessment criteria include the scope of work and approximate usage of the excess capacity. Acceptance of projects to the prioritization process: All projects will receive a "yes/no" determination according to the criteria provided below. In addition all "qualified" projects will also receive a priority. Those projects with the best priority score will be done first, those with a lower score will be shuffled down in the queue for the current quarter. The priority scoring will be based on a 1-5 scale (1 being highest) based on the following four items: scientific rationale, scientific content study design (including sample related issues) and feasibility.

Applications that fall within the CGF's excess capacity for that quarter will be reviewed and evaluated for priority by the DCEG Users Oversight Committee. In the event that an application is accepted, the applicant will be notified before the new quarter. In the event that an application does not receive a high enough priority, written notification will be

provided. Applicants can reapply next quarter. Requests do not roll over from quarter to quarter.

The Checklist for accepting requests to be prioritized should include the following:

1) Is the request to genotype Human genomic DNA? (The CGF will only work with human DNA-based samples)

2) Is >2 ug of each of the samples available immediately? (If no, then submit request when the samples are available)

3) Are > 92 samples to be tested? (The CGF will not entertain requests for < than 92 samples)

4) Is the investigator requesting at least 10 SNPs be done? (The CGF will not entertain requests for less than 10 SNPs)

5) Is the request for assays that the CGF has validated assay available for, or for an assay development request for that can be fulfilled on one of the CGF's available platforms (TaqMan Illumina Infinium, Illumina GoldenGate, Fluidigm BioMark (96.96 or 48.48), sequencing)?

In Summary, SAIC has taken action on establishing the necessary mechanisms to allow for excess capacity requests to be processed in the SAIC billing systems. Prior to the FY05 launch of this charge back, a coordination meeting will take place with SAIC, DMS, and DCEG to specify the particular data needed in order to process the monthly billings.