Clinical and Translational Support Laboratory
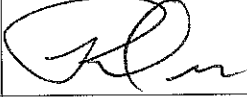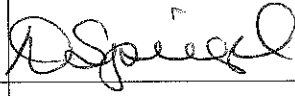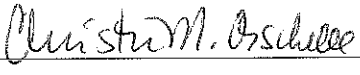
Unit Procedure

Timers: Operation and Maintenance

SOP No./WI No.:   CTSI-CRC-PL-305

Department: Processing Laboratory

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Page No: 1 of 3

Review Period: 2 years

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Signature			
Date	28 DEC 2016	28 Dec 2016	Dec 24, 2016

1. OBJECTIVE

This Standard Operating Procedure (SOP) describes the process for how timers are maintained and operated in a manner which complies with all appropriate regulatory and protocol specific requirements at the Indiana Clinical and Translational Sciences Institute (CTSI) Clinical and Translational Support Laboratory (CTSL).

2. SCOPE

This SOP applies to CTSL staff providing lab processing activities requiring the use of timers. This procedure is intended to provide the basic procedure for operating and maintaining timers.

3. RESPONSIBILITIES

The clinical and lab staff is responsible for appropriately operating and maintaining timvers in a compliant manner.

4. DEFINITIONS

4.1. Principle: All refrigeration/freezer units owned by CTSL are supported by CTSL Staff. The units store samples for which defined storage conditions are critical. Routine monitoring and maintenance is important to minimize risk of the units failing to maintain specified storage conditions and for quickly detecting out of specification (OOS) conditions.

CRC: Clinical Research Center	CTSI: Clinical and Translational Sciences Institute
CTSL: Clinical and Translational Support Laboratory	NIST: National Institute of Standards and Technology
PL: Processing Lab	SOP: Standard Operating Procedure

5. ASSOCIATED DOCUMENTS

5.1. CTSI-CRC-QA-003 "Document Control and Management"
5.2. CTSI-CRC-CLN-030 "Handling of SOP Deviations"

6. PROCEDURE

6.1. Operation

6.1.1. For multiple channel timers, choose one channel and set the desired time so it reads on the digital display.

6.1.2. Push the start or enter button.

6.1.3. Reset timer when timer goes off.

6.2. Maintenance

6.2.1. NIST traceable timers can be in service until the expiration date.

6.2.2. When expiration date is approaching, a new time can be place in service or the existing time can be taken out of service and recalibrated by a qualified and approved calibration service vendor.

6.2.3. Document the details of Timer maintenance and service in the CTSI-CRC-PL-LG609 "Timer Maintenance and Service Log".

6.2.4. Replace batteries as needed.

6.2.5. Clean with warm soap solution and 10% bleach solution or equivalent as needed.

6.2.6. .

7. REFERENCES

None

8. APPENDICES

None

9. AMENDMENT HISTORY

Date of Amendment:	22 Dec 2016
Amendment Request by:	Robert Orr
Change Control No, if applicable:	CTSI-CRC-PL-DC-2016-014
Details of Amendment:	Updated to footer file location; updated the SOPs in 5.2; removed 6.2.6 step for annual review of records.