NIH's Human Subjects System (HHS)

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As part of the ongoing changes and updates to human subjects and clinical trial research, NIH launched the Human Subjects System (HSS) on June 9, 2018, which replaces the Inclusion Management System (IMS) to add/update study information and enrollment reports. The HSS is automatically populated by the human subjects and clinical trial data entered on the Human Subjects and Clinical Trial Information (HSCTI) form in applications submitted January 25, 2018 and forward.

Post-submission updates to human subjects and clinical trial-related information (including human subjects protections, participant and enrollment information, and Clinicaltrials.gov registration and reporting information) must be made in HSS after June 9, 2018.

Training Resources:

NIH has provided a user guide and 3 short video tutorials (5-10min each). We strongly recommend viewing the videos before accessing the system.

How is HSS accessed?

1. eRA Commons Status Page  

Who can access HSS?

1. Principal Investigator (PI)  
2. Signing Official (PIs can check with their assigned RSC to determine their SO)

Who can submit the HSS form?

1. Signing Official (after the PI changes the status to Ready for Submission)

How is the data in HSS populated?

For previously reported data:

1. As of June 8, 2018 all data from the Inclusion Management System (IMS) has been migrated to the new HSS system
2. Information entered into the Human Subjects and Clinical Information form* as part of the proposal will automatically populated the new HSS system

For new data:

1. PI can edit existing studies.
2. PI can add a new study and complete the required fields similar to the Human Subjects and Clinical Information form.
3. Within the studies there are links to Inclusion Enrollment Report(s). PIs can update the report either by editing the cells online or by downloading, completing, and uploading a Participant Level Data template.

*For applications submitted on or after January 25, 2018