# CRU Setup Checklist

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| Getting started – Things to consider and expect |
| 1. Evaluate existing processes and structures that can be utilized (for example, monthly faculty meetings where new studies are presented and discussed)    1. Assess how they would need to be adapted and modified to meet CRU review needs |
| Notes: |
| 1. Estimate amount of prospective clinical research the department is conducting:    1. Non-funded Investigator Initiated Trials (IITs)    2. NIH and other government-funded research    3. Industry-sponsored research |
| Notes: |
| 1. Estimate how many CRUs you will eventually need    1. You would probably start with just one or two and add more once you gain experience, but good to have an initial estimate |
| Notes: |
| 1. Identify where you would like to start (e.g., a group that already has a structured review process) |
| Notes: |
| 1. Expect an iterative process |
| Notes: |

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| CHECKLIST | | |
| Identify Personnel | | |
|  | Identify Faculty Lead | Experienced clinical researcher  Can be more than one  Can be on a rotational basis |
|  | Identify Operations Lead | Experienced Stanford research professional  Each CRU should have its own Operations Reviewer, who may be different than the Lead if there are more than one or two CRUs.  Spectrum CRU can provide job descriptions, if relevant. |
|  | Identify the Scientific Reviewer Pool  (CRU will either complete scientific review or submit study to SoM Scientific Review Committee) | These should be all Investigators involved in related or relevant research.  Consider differentiating between and pairing senior and junior reviewers as an additional training opportunity. |
|  | Identify Biostatistician(s) | As needed |
|  | Identify Finance reviewer(s) | As needed |
| Communications | | |
|  | Department leadership engages with identified personnel and research teams | Provide department/division level communication introducing CRU initiative |
|  | Operations Lead contact OnCore Support to setup CRU in OnCore ePRMS committee management   * Schedule [training on using ePRMS](https://stanfordmedicine.app.box.com/s/tdrxkimckujivrl5utwdx437bijf3gpz) | While use of the ePRMS is not mandatory, it is strongly recommended, as it supports a clear CRU review process and compliance with the [SoM Policy on Using OnCore](https://stanfordmedicine.box.com/s/4fbvzu8c2mscor5binjhp0g5bgn388lg) |
|  | Operations and Faculty Lead contact Spectrum CRU for guidance, templates, and training (meetings and materials) | Spectrum CRU can also connect you with other CRU leads to share experiences and lessons learned |
| Internal Review and decisions | | |
|  | Within your selected CRU team, review Spectrum process templates and merge, as appropriate, with existing processes in the Department/Division/Group | Expect a learning period and several adjustments to tools and processes along the way |
|  | Decide on CRU review cadence and process   * Consider differentiating between a **Full Review** (for Unfunded Investigator Initiated Trials) and an **Expedited Review** (for NIH-funded, Industry-Sponsored, and Registries) * See Figure 1 Below for an example CRU Review Workflow | A Full Review can involve all reviewers, involve the full scope of review criteria, occur only monthly, and require a scheduled meeting.  An expedited Review can involve limited reviewers, involved a limited scope of review criteria, occur at an increased frequency and via email.  For NIH-funded research, a full review may be offered as a bonus to investigators – providing additional internal scientific review and input prior to submitting the grant application. |
| implement CRU Process | | |
|  | Start with one or two CRUs |  |
|  | CRU will reviewed for:   * Scientific validity (may be reviewed at SoM level) * Financial sustainability * Operational (including recruitment) feasibility |  |
|  | Adjust process per internal feedback |  |
|  | Expand review to every new prospective clinical research study in scope of the CRU |  |
|  | Adjust process per internal feedback |  |
|  | Gradually add CRUs per initial plan and as appropriate for the department |  |
| future steps | | |
|  | Ongoing annual evaluation | The scope for this is not yet final, but at a minimum review budget status and projections, as well as accrual. |
|  | Compliance review | Scope TBD |

Figure 1: Example CRU Review Workflow

