Proactive Quality Assurance through Dual Review of Eligibility and Consent

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BACKGROUND

Enrolling participants on clinical trials that meet protocol specified eligibility criteria not only establishes a homogenous patient population allowing for adequate data analysis, but it is also critical for the safety and well-being of participants. Factors that might impact consent eligibility deviations include:

- Protocol complexity continues to rise.
- Staff turnover.

METRICS/GOALS

- Reduce the number of deviations related to consent and eligibility compared to the number of participants enrolled on therapeutic trials.

METHODS

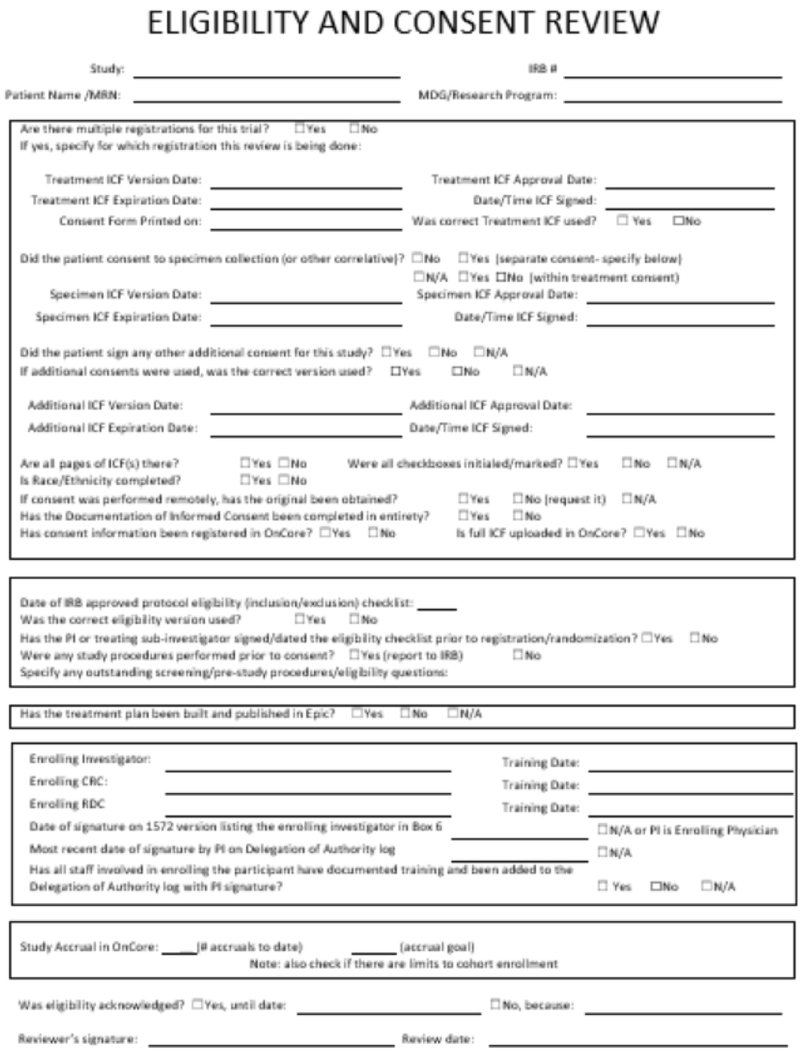
Dual Review of Eligibility and Consent confirming the following as shown in Figure 1:

- Eligibility criteria appear to be met.
- Consent forms are complete.
- Informed consent process is documented.
- Screening procedures have been completed with results.
- Regulatory requirements and version control.
- Training, delegation, and 1572, if applicable.
- General GCP/ALCOA+ standards have been followed

OUTCOMES

Overall, we've seen a decrease in the percent of deviations related to consent and eligibility from 7.5% in 2016 to 2.5% of total accruals in 2021 as shown in Figure 2.

Figure 1



ELIGIBILITY AND CONSENT REVIEW

Study: _____ IRB #: _____
Patient Name /MRN: _____ MDG/Research Program: _____

Are there multiple registrations for this trial? ☐Yes ☐No
If yes, specify for which registration this review is being done:

Treatment ICF Version Date: _____ Treatment ICF Approval Date: _____
Treatment ICF Expiration Date: _____ Date/Time ICF Signed: _____
Consent Form Printed on: _____ Was correct Treatment ICF used? ☐Yes ☐No

Did the patient consent to specimen collection (or other correlative)? ☐No ☐Yes (separate consent- specify below) ☐N/A ☐Yes ☐No (within treatment consent)
Specimen ICF Version Date: _____ Specimen ICF Approval Date: _____
Specimen ICF Expiration Date: _____ Date/Time ICF Signed: _____

Did the patient sign any other additional consent for this study? ☐Yes ☐No ☐N/A
If additional consents were used, was the correct version used? ☐Yes ☐No ☐N/A

Additional ICF Version Date: _____ Additional ICF Approval Date: _____
Additional ICF Expiration Date: _____ Date/Time ICF Signed: _____

Are all pages of ICF(s) there? ☐Yes ☐No Were all checkboxes initialed/marked? ☐Yes ☐No ☐N/A
Is Race/Ethnicity completed? ☐Yes ☐No
If consent was performed remotely, has the original been obtained? ☐Yes ☐No (request it) ☐N/A
Has the Documentation of Informed Consent been completed in entirety? ☐Yes ☐No
Has consent information been registered in OnCore? ☐Yes ☐No Is full ICF uploaded in OnCore? ☐Yes ☐No

Date of IRB approved protocol eligibility (inclusion/exclusion) checklist: ____
Was the correct eligibility version used? ☐Yes ☐No
Has the PI or treating sub-investigator signed/dated the eligibility checklist prior to registration/randomization? ☐Yes ☐No
Were any study procedures performed prior to consent? ☐Yes (report to IRB) ☐No
Specify any outstanding screening/pre-study procedures/eligibility questions:

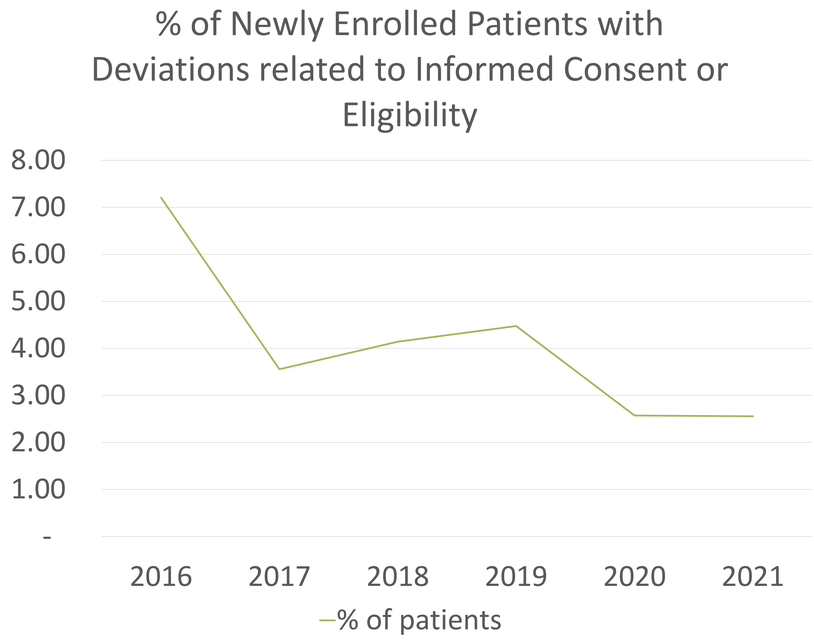
Has the treatment plan been built and published in Epic? ☐Yes ☐No ☐N/A

Enrolling Investigator: _____ Training Date: _____
Enrolling CRC: _____ Training Date: _____
Enrolling RDC: _____ Training Date: _____
Date of signature on 1572 version listing the enrolling investigator in Box 6 _____ ☐N/A or PI is Enrolling Physician
Most recent date of signature by PI on Delegation of Authority log _____ ☐N/A
Has all staff involved in enrolling the participant have documented training and been added to the Delegation of Authority log with PI signature? ☐Yes ☐No ☐N/A

Study Accrual in OnCore: ____(# accruals to date) _____ (accrual goal)
Note: also check if there are limits to cohort enrollment

Was eligibility acknowledged? ☐Yes, until date: _____ ☐No, because: _____
Reviewer's signature: _____ Review date: _____

Figure 2



LESSONS LEARNED

Since implementing an SOP, HCI has made many adjustments to streamline the process including the following:

- Original SOP allowed another CRC to perform the review and we updated the SOP so that dual review must be performed by a Manager or QA professional.
- We added a review for registration/stratification/ randomization assignments for accuracy prior to enrollment.
- Departmental review of re-consents was added.
- Reviews account for hybrid, virtual setting such as confirming witness, Adobe Sign is Part 11 compliant, etc.

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