

## OHRS Information Sheets – Index

**Overview:** This is a list of Information Sheets (IS) provided by OHRS organized by category: Policy, Guidance, Operations and External Resources. All Information Sheets are available on the OHRS Website.

### Info Sheet - Policy:

- IS - Policy - Adverse Event Reporting
- IS - Policy - Blood Draws from Healthy Volunteers
- IS - Policy - Collecting - Sharing Data and Tissue Specimens
- IS - Policy - Continued Participation
- IS - Policy - Determining if Project Is Human Subjects
- IS - Policy - Deviation-Violation-Exception and Other Event Reporting
- IS - Policy - DFCI IRB Requirements Relating to the Honest Broker in Biobanking
- IS - Policy – DFCI IRB Visitor Policy
- IS - Policy – DFCI SRC Visitor Policy
- IS - Policy - Drug Shortages
- IS - Policy - Implementing Dose Escalation Changes in Phase I Research
- IS - Policy - IND and IDE Safety Reports
- IS – Policy – Institutional Conflicts of Interest
- IS - Policy - Legally Authorized Representatives
- IS - Policy - Linked and Anonymous Specimens
- IS - Policy – NIH Genomic Data Sharing Policy
- IS - Policy - Non English Speaking Subjects
- IS – Policy – Outside Interest Disclosure
- IS - Policy - Overall PI or Site PI Leave of Absence
- IS - Policy - Pregnant Partner Consent and Data Collection
- IS - Policy - Prisoners in Research
- IS – Policy – Required Subject Injury Language
- IS - Policy - Sharing Protocols
- IS - Policy - Short Form Translation Procedure
- IS - Policy - Single Patient IND and Emergency Use of a Test Article
- IS - Policy - Sponsor Requests for PHI related to Adverse or Severe Adverse Events
- IS - Policy - Two Year CR
- IS - Policy - Use of Alert Pages

### Info Sheet - Guidance:

- IS - Guidance – Audio Recording in Human Subjects Research
- IS - Guidance – Guidance on Patient Case Reports and When IRB and HIPAA Regulations Apply
- IS - Guidance – Consent Form Guidance for Gene Transfer Studies
- IS – Guidance – IRB Review Requirements for Secondary Use Research
- IS – Guidance – Institutional Certification Process for Genomic Data Sharing
- IS – Guidance – Electronic Consent
- IS – Guidance – DFCI IRB Approved Standard Drug Risk Language
- IS – Guidance – DF/HCC Consortium Guidance
- IS – Guidance – DF/HCC Specimens and Data - External Sites Checklist
- IS – Guidance – Guidance for Study Teams and Sponsor – Information Regarding Approvable and Not-Approvable Language in Consent Forms
- IS – Guidance – Massachusetts State Law Involving Human Research
- IS – Guidance – Procedures for Monitoring the Consent Process
- IS – Guidance – Research Funded or Supported by the Department of Defense
- IS – Guidance – Research Procedures at External Sites
- IS – Guidance – Return of Results
- IS – Guidance – Return of Results Sample Consent Language

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IS – Guidance – Review of Data/Specimen Collection and Use Protocols  
IS – Guidance – Scientific Progress Review  
IS – Guidance – Statistical Guidelines for Non-Clinical Research  
IS – Guidance – Withdrawal of Consent to Continue in Research Form

#### Info Sheet - Operations:

IS - Operations - Common Issues in Protocol Reviews  
IS - Operations - Completing Endorsement Forms  
IS - Operations - Completing Nursing & Pharmacy Screening Form  
IS - Operations - Application Questions Relevant to OnCore (Formerly "Completing the Front Sheet")  
IS - Operations - Frequently Asked Questions  
IS - Operations - Guidance Priority List  
IS – Operations – Guidelines for Single IRB Review Process  
IS - Operations – Information Sheet Categories  
IS - Operations - New Protocol Submission Requirement Chart  
IS - Operations - Non Clinical FAQ  
IS - Operations - OHRS Submit Guide  
IS - Operations - OncPro Guide  
IS - Operations - Overview DFCI IRBs  
IS - Operations - PDF Files and Electronic Signatures  
IS - Operations - Quick Reference for New Protocol Submissions  
IS - Operations - Request to Add Site Checklist  
IS - Operations - Use of Informed Consent Documents Posted to OncPro  
IS – Operations – Procedures for Increasing Accrual after Accrual Goal is Met in OnCore  
IS – Operations – Procedures for Subject Replacements and Transfers  
IS - Operations – Quick Reference for New Protocol Submissions  
IS - Operations – Request to Add Sites Reference

#### Info Sheet - Resource:

IS - Resource - Additional Protections for Children  
IS - Resource - Adverse Event Ranking Scale  
IS - Resource - Criteria for IRB approval of Research  
IS - Resource - Expedited and Exempt Categories  
IS - Resource - FDA Drug Review Process  
IS - Resource - FDA Guidance Recruitment  
IS - Resource - FDA Medical Devices  
IS – Resource – How to Contact the FDA  
IS - Resource - Massachusetts Law on Insurance Coverage  
IS - Resource - MSWord Tips  
IS - Resource - Partners Recruitment of Subjects  
IS - Resource - Requirements for Informed Consent  
IS - Resource - Successful Research Participation Communication

#### Worksheets & Checklists:

HRP-306 – Worksheet – Drugs  
HRP-307 – Worksheet – Devices  
HRP-310 – Worksheet – Human Research Determination  
HRP-311 – Worksheet - Engagement Determination  
HRP-312 – Worksheet – Exemption  
HRP-313 – Worksheet – Expedited Review  
HRP-314 – Worksheet – Criteria for Approval  
HRP-317 – Worksheet – Short Form of Consent Documentation  
HRP-321 – Worksheet – Reportable New Information  
HRP-330 – Worksheet – HIPAA Authorization

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HRP-332 – Worksheet – NIH GDS Institutional Certification  
HRP-410 – Checklist – Waiver or Alteration of Consent Process  
HRP-411 – Checklist – Waiver of Written Documentation of Consent  
HRP-412 – Checklist – Pregnant Women  
HRP-415 – Checklist – Prisoners  
HRP-416 – Checklist – Children  
HRP-417 – Checklist – Cognitively Impaired Adults  
HRP-419 – Checklist – Waiver of Consent Process for Emergency Research  
HRP-441 – Checklist – HIPAA Waiver of Authorization