AdventHealth Orlando

WORKSHEET: Criteria for Approval

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This worksheet is used to determine whether non-exempt <Human Research> can be approved.

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All criteria in 1 through 6 must be met

1. Criteria for approval *45 CFR §46.111 and 21 CFR §56.111*

1.1	☐	Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk (see Footnotes 1 and 2)
1.2	☐	Risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for other purposes
1.3	☐	Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result (see Footnote 3)
1.4	☐	Selection of subjects is equitable (see Footnote 4)
1.5	☐	One of the following is true: ○ The research involves no more than <Minimal Risk> to subjects ○ There are adequate provisions for monitoring the data collected to ensure the safety of subjects (see Footnote 5)
1.6	☐	There are adequate provisions to protect the privacy of subjects
1.7	☐	There are adequate provisions to maintain the confidentiality of data
1.8	☐	One of the following is true: ○ Subjects are not likely to be vulnerable to coercion or undue influence ○ Additional safeguards are included to protect the rights and welfare of subject vulnerable to coercion or undue influence
1.9	☐	The consent process will be: (check all that are true)
1.9.1	☐	Waived (Use "CHECKLIST: Waiver of Consent HHS (HRP-300)," "CHECKLIST: Waiver of Consent Emergency Research (HRP-301)," or "CHECKLIST: Waiver of Consent Leftover Specimens (HRP-302)")
1.9.2	☐	Obtained in accordance with all criteria in Section 2
1.10	☐	Consent documentation will be: (check all that are true)
1.10.1	☐	Waived (Use "CHECKLIST: Waiver of Documentation of Consent (HRP-303)")
1.10.2	☐	Documented using the short form (See "WORKSHEET: Short Form (HRP-404)")
1.10.3	☐	Documented in accordance with all criteria in Section 3

2. Consent process *45 CFR §46.116 and 21 CFR §50.20*

2.1	☐	The consent process will be legally effective
2.2	☐	Circumstances provide the prospective subject or LAR sufficient opportunity to consider whether to participate
2.3	☐	Circumstances minimize the possibility of coercion or undue influence
2.4	☐	The information will be provided be in language understandable to the subject or LAR
2.5	☐	There is no exculpatory language (see Footnote 6)
2.6	☐	The required and appropriate additional elements of consent in Section 4 will be disclosed
2.7	☐	<2018 Requirements> Subject or LAR provided information a reasonable person would want to have & opportunity to discuss that information

3. Consent documentation *45 CFR §46.117, 21 CFR §50.27, and ICH-GCP 4.8.8*

3.1	☐	The document is accurate and complete
3.2	☐	The document embodies the required and appropriate additional elements of consent in Section 4
3.3	☐	The document will be signed and dated by the subject or LAR
3.4	☐	The document will be signed and dated by the person obtaining consent
3.5	☐	A signed and dated copy will be given to the person signing the form
3.6	☐	The investigator will give the subject or LAR adequate opportunity to read it before it is signed and dated
3.7	☐	For clinical research: If the subject cannot read, an <Impartial Witness> will witness the consent process and sign and date the form

4. Elements of consent *45 CFR §46.116 and 21 CFR §50.25*

4.1	☐	Study involves research	
4.2	☐	Purposes of the research	
4.3	☐	Expected duration of the subject's participation	
4.4	☐	Procedures to be followed	
4.5	☐	Identification of *any* procedures which are experimental	
4.6	☐	*Any* reasonably foreseeable risks or discomforts	
4.7	☐	*Any* benefits to the subject or to others	
4.8	☐	*Any* appropriate alternative procedures or courses of treatment that might be advantageous	
4.9	☐	The extent, if *any*, to which confidentiality of records identifying the subject will be maintained (see Footnote 7)	
4.10	☐	How to contact the investigator for ☐ questions ☐ concerns ☐ complaints	
4.11	☐	How to contact someone independent of the investigator for ☐ questions ☐ concerns ☐ complaints ☐ subject rights	
4.12	☐	Whom to contact in the event of a research-related injury	
4.13	☐	Participation is voluntary	
4.14	☐	Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled	

4.15	☐	The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.	
4.16	☐	One of the following: ○ Statement that after removal of identifiers from private information/biospecimens, information/biospecimens could be used or distributed in future ○ The subject's information/biospecimens collected as part of the research, even if identifiers are removed will not be used or distributed in future	
		Required for research involving more than <Minimal Risk> to subjects *45 CFR §46.116 and 21 CFR §50.25*	
4.17	☐	Whether any compensation is available if injury occurs and, if so, what they consist of, or where further information may be obtained	
4.18	☐	Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained	
		Required for FDA-regulated research *21 CFR §50.25*	
4.19	☐	FDA may inspect the records	
4.20	☐	For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."	
4.21	☐	The consent document does not give the subject the option of having data removed (see Footnote 8)	
		Required for research funded or supported by NIH	
4.22	☐	Certificate of Confidentiality language	
		Required for research subject to ICH-GCP *ICH-GCP 4.8.5 and 4.8.10*	
4.23	☐	A description of the IRB and its role	
4.24	☐	The probability for random assignment, if *any*	
4.25	☐	*Any* subject responsibilities	
4.26	☐	The reasonably foreseeable risks to an embryo, fetus, or nursing infant, if *any*	
4.27	☐	When there is no intended clinical benefit to the subject, a statement to that effect	
4.28	☐	The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.	
4.29	☐	If the results of the trial are published, the subject's identity will remain confidential	
		When appropriate *45 CFR §46.116 and 21 CFR §50.25*	
4.30	☐	The research may involve risks to the subject which are currently unforeseeable	
4.31	☐	The research may involve risks to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable	
4.32	☐	Anticipated circumstances under which the subject's participation may be stopped without the subject's consent	
4.33	☐	Any additional costs to the subject that may result from participation in the research	
4.34	☐	The consequences of a subject's decision to withdraw from the research	
4.35	☐	Procedures for orderly termination of participation by the subject	
4.36	☐	New findings that may relate to the subject's willingness to continue participation will be provided to the subject	
4.37	☐	The approximate number of subjects involved in the study	
4.38	☐	Amount and timing of all payments	
4.39	☐	Biospecimens (even if identifiers are removed) may be used for commercial profit and whether subject will or will not share in that profit	
4.40	☐	Whether the research will or might include whole genome sequencing	
4.41	☐	Whether clinically relevant research results will be shared with subjects and under what conditions	
		Required for research subject to <2018 Requirements>	
4.42		When the body of the consent is longer than 4 pages:	
	☐	Concise/focused key information presented in organized way to assist in understanding why one might want to participate and help comprehension.	
	☐	Key information does not exceed 3 pages or 1/3 of length of remaining consent	

5. Primary presenter considerations

5.1	●	Are the submitted materials (including the DHHS grant, if any) consistent?
5.2	●	If the investigator is the lead of a multi-site study, is the management of information relevant to the subject protection adequate?

6. Additional considerations

6.1	●	Does the IRB have sufficient expertise to review this research?
6.2	●	Does the research involve more than minimal risk to subjects?
6.3	●	Based on risk, should continuing review be conducted more often than annually?
6.4	●	Is there limited reliability of submitted information such that verification is needed from sources other than the investigator?
6.5	●	Are there new findings that may relate to the subject's willingness to continue participation which should be provided to the subject?

7. Notes

8. Footnotes

8.1 Consider physical, psychological, social, legal, and economic harms.

8.2	Evaluate whether these resources are sufficient to protect participants: Time to conduct and complete the research, number and qualifications of investigators and staff, facilities, access to a population that will allow recruitment of the necessary number of subjects, and availability of medical or psychosocial resources that subjects may need as a consequence of the research.
8.3	For clinical trials, consider whether the available non-clinical and clinical information on an investigational product is adequate to support the research.
8.4	Take into account: the purposes of the research; the setting in which the research will be conducted; whether prospective subjects will be vulnerable to coercion or undue influence; the selection (inclusion/exclusion) criteria; subject recruitment and enrollment procedures; the influence of payments to subjects.
8.5	Consider what safety information will be collected; how it will be collected; the frequency of collection, when collection starts; the frequency or periodicity of review; whether a data monitoring committee is needed; statistical tests for analyzing the data to detect harm; provisions for the oversight of safety data; stopping conditions
8.6	Exculpatory language is language through which the subject or LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence
8.7	When appropriate, disclose any limits on confidentiality imposed by mandatory reporting and any possibility of loss of confidentiality due to media attention
8.8	When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed (Guidance for Sponsors, Clinical Investigators, and IRB Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials)