

*IEC Best Practices:
Effective Use of Checklists
and Forms*

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Introduction

- IECs sometimes struggle to operate in a consistent, efficient manner.
- Many of the functions of the IEC – both administrative and research reviews – are done following repetitive processes
- Standardized checklists and forms may enhance the quality, consistency, and efficiency of IEC operations

Learning Objectives

- Review examples of the use of forms/checklists in other contexts
- Identify common IEC functions/practices that may benefit from the use of forms/checklists
- Identify resources for IECs

Use of Checklists in Other Professions

- Aviation

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APPROVED B-17F and G CHECKLIST
REVISED 3-1-44

PILOT'S DUTIES IN RED
COPILOT'S DUTIES IN BLACK

<p>BEFORE STARTING</p> <ol style="list-style-type: none"> Pilot's Preflight—COMPLETE Form 1A—CHECKED Controls and Seats—CHECKED Fuel Transfer Valves & Switch—OFF Intercoolers—Cold Gyros—UNCAGED Fuel Shut-off Switches—OPEN Gear Switch—NEUTRAL Cowl Flaps—Open Right—OPEN LEFT—Locked Turbos—OFF Idle cut-off—CHECKED Throttles—CLOSED High RPM—CHECKED Autopilot—OFF De-icers and Anti-icers, Wing and Prop—OFF Cabin Heat—OFF Generators—OFF <p>STARTING ENGINES</p> <ol style="list-style-type: none"> Fire Guard and Call Clear—LEFT Right Master Switch—ON Battery switches and inverters—ON & CHECKED Parking Brakes—Hydraulic Check—ON—CHECKED Booster Pumps—Pressure—ON & CHECKED Carburetor Filters—Open Fuel Quantity—Gallons per tank Start Engines: both magnetos on after one revolution Flight Indicator & Vacuum Pressures CHECKED Radio—On Check Instruments—CHECKED Crew Report Radio Call & Altimeter—SET 	<p>ENGINE RUN-UP</p> <ol style="list-style-type: none"> Brakes—Locked Trim Tabs—SET Exercise Turbos and Props Check Generators—CHECKED & OFF Run up Engines <p>BEFORE TAKEOFF</p> <ol style="list-style-type: none"> Tailwheel—Locked Gyro—Set Generators—ON <p>AFTER TAKEOFF</p> <ol style="list-style-type: none"> Wheel—PILOT'S SIGNAL Power Reduction Cowl Flaps Wheel Check—OK right—OK LEFT <p>BEFORE LANDING</p> <ol style="list-style-type: none"> Radio Call, Altimeter—SET Crew Positions—OK Autopilot—OFF Booster Pumps—On Mixture Controls—AUTO-RICH Intercooler—Set Carburetor Filters—Open Wing De-icers—OFF Landing Gear <ol style="list-style-type: none"> Visual—Down Right—DOWN LEFT Tailwheel Down, Antenna in, Ball Turret Checked Light—OK Switch Off—Neutral Hydraulic Pressure—OK Valve closed RPM 2100—Set Turbos—Set Flaps 1/2—1/2 Down <p>FINAL APPROACH</p> <ol style="list-style-type: none"> Flaps—PILOT'S SIGNAL RPM 2200—PILOT'S SIGNAL
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	NORMAL CHECK LIST	REV 35	7.01
		SEQ 130	

<p style="text-align: center;">BEFORE START</p> <p>COCKPIT PREP. COMPLETE (BOTH) GEAR PINS and COVERS. REMOVED SIGNS. ON / AUTO ADIRS. NAV FUEL QUANTITY. KG.LB TO DATA. SET BARO REF. SET (BOTH)</p> <p>WINDOWS/DOORS. CLOSED (BOTH) BEACON. ON THR LEVERS. IDLE PARKING BRAKE. AS RQRD</p>	<p style="text-align: center;">APPROACH</p> <p>BRIEFING CONFIRMED ECAM STATUS CHECKED</p> <p>SEAT BELTS ON BARO SET (BOTH) MDA/DH SET (BOTH) ENG MODE SEL AS RQRD</p>
<p style="text-align: center;">AFTER START</p> <p>ANTI ICE. AS RQRD ECAM STATUS CHECKED PITCH TRIM SET RUDDER TRIM ZERO</p>	<p style="text-align: center;">LANDING</p> <p>CABIN CREW ADVISED A/THR SPEED/OFF ECAM MEMO LDG NO BLUE</p> <p style="font-size: small;">L/G DOWN SIGNS ON CABIN READY SPLRS ARM FLAPS SET</p>
<p style="text-align: center;">BEFORE TAKEOFF</p> <p>FLIGHT CONTROLS CHECKED (BOTH) FLT INST CHECKED (BOTH) BRIEFING CONFIRMED FLAP SETTING CONF - (BOTH) V1, VR, V2/FLX TEMP. (BOTH) ATC SET ECAM MEMO TO NO BLUE</p> <p style="font-size: small;">AUTO BRK MAX SIGNS ON CABIN READY SPLRS ARM FLAPS TO TO CONFIG NORM</p> <p>CABIN CREW ADVISED ENG MODE SEL AS RQRD PACKS AS RQRD</p>	<p style="text-align: center;">AFTER LANDING</p> <p>FLAPS RETRACTED SPOILERS DISARMED APU START RADAR OFF/STBY</p>
<p style="text-align: center;">AFTER TAKEOFF / CLIMB</p> <p>LDG GEAR UP FLAPS RETRACTED PACKS ON BARO REF. SET (BOTH)</p>	<p style="text-align: center;">PARKING</p> <p>APU BLEED ON ENGINES OFF SEAT BELTS OFF EXT LT AS RQRD FUEL PUMPS OFF PARK BRK and CHOCKS AS RQRD Consider HEAVY RAIN</p>
	<p style="text-align: center;">SECURING THE AIRCRAFT</p> <p>ADIRS OFF OXYGEN OFF APU BLEED OFF EMER EXIT LT OFF NO SMOKING OFF APU AND BAT OFF Consider COLD WEATHER</p>

Use of Checklists in Other Professions

- Medical care

Figure 1

Pause—Patient identity verified Is this the correct procedure

Catheter-related Bloodstream Infection Checklist

- If there is an observed violation of infection control practices, line placement should stop immediately and the violation should be corrected. If a correction is required, mark yes to question # 6.
- If there are any concerns, the bedside nurse should contact the Senior Resident directly.

1. Today's date/time _____ / _____ / _____ start time
 month day year

2. Location SICU MICU CCU Livingston

3. Procedure: New line Rewire Triple Lumen Single

4. Is the procedure: Elective Emergent (during an arrest)
 Location of CVC: Subclavian IJ Femoral

5. Procedure: *did the physician/PA do the following in the appropriate order?* **Yes** **No** (ask if needed)

A. Wash hands (chlorhexidine or soap) immediately prior

B. Was hand washing directly observed

C. Don unsterile gloves, hat, and mask

D. Sterilize procedure site (using ChloroPrep)

E. Don sterile gown and sterile gloves

F. Drape entire patient in a sterile fashion

G. Maintain a sterile field

H. Did all personnel assisting with procedure follow the above precautions?

After the procedure:
 Was a sterile dressing applied to the site

6. Was a correction required to ensure compliance with infection control practices? **Yes** **No**

7. Time procedure was completed: _____
 STOP TIME

How to be Reasonably Sure a Client is Not Pregnant

Ask the client all of these questions, check the correct box, and follow the instructions.

NO	1. Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then?	YES
NO	2. Have you abstained from sexual intercourse since your past menstrual period?	YES
NO	3. Have you had a baby in the past 4 weeks?	YES
NO	4. Did your last menstrual period start within the past 7 days (or within the past 12 days if you are planning to use an IUD)?	YES
NO	5. Have you had a miscarriage or abortion in the past 7 days?	YES
NO	6. Have you been using a reliable contraceptive method consistently and correctly?	YES

If the client answered NO to all of the questions, pregnancy cannot be ruled out. Client should await menses or use a pregnancy test.

If the client answered YES to at least one of questions and she is free of signs or symptoms of pregnancy, provide client with desired method.



Skills Checklist for Immunization

The Skills Checklist is a tool used to assess and monitor a student's performance. It is used to ensure the competency assessment and the clinical skills, techniques, and procedures outlined for each activity. Learners should be able to perform each activity. If you do not, then you may need to do a remedial activity or change model. When you do, then you should be able to perform the activity with the expected level of competence, or higher.

Signature: Use the Skills Checklist to identify specific areas of competence for each activity. When you are able to perform the activity, sign off the competency.

Competency	Clinical Skills, Techniques, and Procedures	Self Assessment			Supervisor/Instructor	
		Not to Progress	Almost or Excellent	Need to Progress	Meets or Exceeds	Pass
A. Basic Skills	1. Measure temperature, weight, height, and vital signs.					
	2. Explain oral suctioning to parent and child (type of suction and site).					
	3. Administer oral care to infant/child and explain how to perform oral care to parent.					
	4. Perform oral care to infant/child and explain how to perform oral care to parent.					
B. Medical Procedures	1. Perform a physical exam of the head, neck, chest, abdomen, and extremities.					
	2. Perform a physical exam of the head, neck, chest, abdomen, and extremities.					
	3. Perform a physical exam of the head, neck, chest, abdomen, and extremities.					
	4. Perform a physical exam of the head, neck, chest, abdomen, and extremities.					
C. Written History	1. Obtain a written history from the client and/or parent/guardian.					
	2. Administer appropriate history.					
	3. Obtain a written history from the client and/or parent/guardian.					
	4. Obtain a written history from the client and/or parent/guardian.					

Use of Checklists in Other Professions

- Military

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PILOT'S DUTIES IN RED
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<p>BEFORE STARTING</p> <ol style="list-style-type: none"> 1. Pilot's Preflight—COMPLETE 2. Form 1A—CHECKED 3. Controls and Seats—CHECKED 4. Fuel Transfer Valves & Switch—OFF 5. Intercoolers—Cold 6. Gyros—UNCAGED 7. Fuel Shut-off Switches—OPEN 8. Gear Switch—NEUTRAL 9. Cowl Flaps—Open Right—OPEN LEFT—Locked 10. Turbos—OFF 11. Idle cut-off—CHECKED 12. Throttles—CLOSED 13. High RPM—CHECKED 14. Autopilot—OFF 15. De-icers and Anti-icers, Wing and Prop—OFF 16. Cabin Heat—OFF 17. Generators—OFF <p>STARTING ENGINES</p> <ol style="list-style-type: none"> 1. Fire Guard and Call Clear—LEFT Right 2. Master Switch—ON 3. Battery switches and inverters—ON & CHECKED 4. Parking Brakes—Hydraulic Check—ON—CHECKED 5. Booster Pumps—Pressure—ON & CHECKED 6. Carburetor Filters—Open 7. Fuel Quantity—Gallons per tank 8. Start Engines: both magnetos on after one revolution 9. Flight Indicator & Vacuum Pressures CHECKED 10. Radio—On 11. Check Instruments—CHECKED 12. Crew Report 13. Radio Call & Altimeter—SET 	<p>ENGINE RUN-UP</p> <ol style="list-style-type: none"> 1. Brakes—Locked 2. Trim Tabs—SET 3. Exercise Turbos and Props 4. Check Generators—CHECKED & OFF 5. Run up Engines <p>BEFORE TAKEOFF</p> <ol style="list-style-type: none"> 1. Tailwheel—Locked 2. Gyro—Set 3. Generators—ON <p>AFTER TAKEOFF</p> <ol style="list-style-type: none"> 1. Wheel—PILOT'S SIGNAL 2. Power Reduction 3. Cowl Flaps 4. Wheel Check—OK right—OK LEFT <p>BEFORE LANDING</p> <ol style="list-style-type: none"> 1. Radio Call, Altimeter—SET 2. Crew Positions—OK 3. Autopilot—OFF 4. Booster Pumps—On 5. Mixture Controls—AUTO-RICH 6. Intercooler—Set 7. Carburetor Filters—Open 8. Wing De-icers—OFF 9. Landing Gear <ol style="list-style-type: none"> a. Visual—Down Right—DOWN LEFT Tailwheel Down, Antenna in, Ball Turret Checked b. Light—OK c. Switch OFF—Neutral 10. Hydraulic Pressure—OK Valve closed 11. RPM 2100—Set 12. Turbos—Set 13. Flaps $\frac{1}{2}$—Down <p>FINAL APPROACH</p> <ol style="list-style-type: none"> 14. Flaps—PILOT'S SIGNAL 15. RPM 2200—PILOT'S SIGNAL
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DEPLOYMENT CHECKLIST

1. Do you have the following **MILITARY DOCUMENTS** updated and in your possession right now?

Military ID Card	Military ID/Dog Tags	Military Shot Record	Military Meal Card
Military Weapon's Card	Military Driver's License	Military Allergy Tag	

 - Other Cards/Doc: Geneva Convention Card, Credit Card, Medical Card, Phone Card, Civilian Driver License, Passport, Travel/Assign Orders.

 2. Do you have the following **IMPORTANT DOCUMENTS** updated?

Power of Attorney	Last Will & Testament	Life Insurance Policy	Family Care Plan
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 3. Have you made advance **PAYMENTS OR ALLOTMENTS** for...

Car/ Truck Loan	Home Mortgage	School/Class	Credit Bill
Vehicle Insurance	Home Insurance	Health Insurance	Utilities

 4. Do you have **SUFFICIENT AMOUNT** of...

Traveler Checks	Blank Checks	Foreign/US Currency
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 5. Do you, your spouse or next of kin have **COPIES** of...

Last Pay Voucher	Marriage Certificate	Divorce Papers	Assignment Orders
Passport/Other ID	Imm. Green Card	Birth Certificate	Leave/Travel Order
Travel Tickets	Medical Records	DA 201/2-1 Record	School Records
Training Records	Car/Home Ownership	Social Sec. Card	Product Warranties
Dental Records	Extra Car/Home Keys	School/Library Card	Change of Address
Strip Map to Home/Hospital			













 6. Do you and your spouse or next of kin have **PHONE NUMBERS...**

Parents	Friends	Relatives	Chain of Command	Unit
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 7. Does your spouse or next of kin have **EMERGENCY PHONE NUMBERS...**

Operator	Hospital	Ambulance	Fire Dept.	Church/Clergy
Police	Doctor	Dentist	Lawyer	Auto Repair Service
- Do you have in your possession at least one **COMPLETE SET OF** civilian clothes in case of emergency? Shoes, Pants, Shirt, Belt, Socks, Jacket, etc?

Checklist for IEC Members?

			
CONVENTIONAL	PERFECTIONIST	VERSATILE	HARD WORKING
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			
OVER-WORKED	PROLIFIC	FLAMBOYANT	DULL
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			
NEUROTIC	COUNTERPRODUCTIVE	PROCRASTINATING	DERIVATIVE
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Common IEC Tasks

- Administrative
 - Review of submission for completeness
 - Assuring proper quorum at meetings
 - Recordkeeping
- IEC reviewers/meetings
 - Required ethics findings (e.g. risk / benefit)
 - Informed consent elements
 - Specific regulatory findings (e.g. waivers)

Examples

Use the following determination key when evaluating each requirement:

Y = requirement fulfilled

N = requirement **not** fulfilled (the membership must be revised)

Requirement	45 CFR 46.107	Y / N	Comments
<i>Minimum of five members</i>	"Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution."		
<i>Diversity of membership</i>	"Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession."		
<i>Appropriate expertise</i>	"...the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice."		
<i>Scientist member</i>	"Each IRB shall include at least one member whose primary concerns are in scientific areas...."		
<i>Nonscientist member</i>	"Each IRB shall include at least one member ... whose primary concerns are in nonscientific areas."		
<i>Non-affiliated member</i>	"Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution."		
<i>Vulnerable Populations</i>	"If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects."		

INFORMED CONSENT REVIEWER'S CHECKLIST

PHSC Study # _____



		Applicable Regulation	
Introduction to the Research		21CFR50.25	45CFR46.116
<input type="checkbox"/>	Simple explanation of the informed consent process.	(a)(1)	(a)(1)
<input type="checkbox"/>	Statement that the study involves research.	(a)(1)	(a)(1)
General Information about the Research			
<input type="checkbox"/>	General purpose of the study.	(a)(1)	(a)(1)
<input type="checkbox"/>	Description of the study methods, procedures, products or drugs.	(a)(1)	(a)(1)
<input type="checkbox"/>	Approximate number of subjects involved in the study.	(b)(6)	(b)(6)
Your Part in the Research			
<input type="checkbox"/>	Expected duration of the subject's participation, frequency of trips to the study site, etc.	(a)(1)	(a)(1)
<input type="checkbox"/>	Procedures to be followed and identification of those <u>that are</u> experimental.	(a)(1)	(a)(1)
Possible Risks and Benefits			
<input type="checkbox"/>	All reasonably foreseeable discomforts and risks to the subject. Whenever possible, likelihood, severity and duration of risks.	(a)(2)	(a)(2)
<input type="checkbox"/>	When applicable: statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.	(b)(1)	(b)(1)
<input type="checkbox"/>	Benefits to subjects, or to others, which can reasonably be expected.	(a)(3)	(a)(3)
If You Decide Not to Be in the Research			
<input type="checkbox"/>	Participation in voluntary.	(a)(8)	(a)(8)
<input type="checkbox"/>	Subject is free to refuse to participate in the study at any time without penalty or loss of benefits to which you are otherwise entitled.	(a)(8)	(a)(8)
Confidentiality			
<input type="checkbox"/>	Statement that confidentiality will be maintained and identification of	(a)(5)	(a)(5)

Proposal Summary Part 1

Note: Put all responses on this form in boldface type.

- Initial
- Amendment [Complete item 25]
- Continuing Review
- Expedited Review
- Exempt Research Review

1. PHSC Study #:
2. Research Study Title:
3. Sponsor/Donor:
(Note: If NIH is this sponsor please have Resource Development submit a copy of the complete NIH application to the PHSC Manager)
4. FCO Number:
5. FHI Project Leader:
6. This research includes the following activities (check all that apply):

Check	Item
<input type="checkbox"/>	Review of existing clinical/medical records, data, pathological specimens
<input type="checkbox"/>	Interviews, surveys, or focus groups
<input type="checkbox"/>	Collection of biological specimens
<input type="checkbox"/>	Storage of specimens for future research
<input type="checkbox"/>	Clinical procedures
<input type="checkbox"/>	Approved drugs/devices
<input type="checkbox"/>	Experimental drugs/devices
<input type="checkbox"/>	Minors
<input type="checkbox"/>	Pregnant women
<input type="checkbox"/>	Prisoners
<input type="checkbox"/>	Hidden or stigmatized or otherwise vulnerable populations
<input type="checkbox"/>	Testing for HIV, STI, and other communicable diseases

7. Is this FDA-regulated research? Yes No

For investigational drugs provide IND #:

For investigational devices provide IDE or 510(k) #:

9. Briefly describe the study population(s):

Number of subjects in research study:

Adults:

Children*:

**Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (45CFR46.402(a))

10. Describe what mechanisms, if any, which were used to assess the attitudes of the study population and/or community towards this research.

11. Briefly describe the inclusion/exclusion criteria. Justification should be provided for exclusions based on race, ethnicity, sex, age or pregnancy.

12. Duration of research study:

13. Statement of objectives of research:

14. Describe interactions and procedures involving subjects. How are they (a) consistent with sound research design, (b) not exposing subjects unnecessarily to risk and, (c) whenever possible, already being performed on the subjects for diagnostic or treatment purposes?

15. Summarize anticipated risks to the subjects. Include risk of social harm (e.g., emotional distress, loss of confidentiality, stigmatization) economic harm (e.g., loss of employment, professional standing or reputation within the community) and legal risks (e.g., disclosure of illegal activity, negligence or abuse), as well as physical side effects, pain and/or physical injury resulting from participation in the study.

16. Summarize the benefits, if any, for the subjects and/or the study community:

17. When applicable, what provisions have been made to monitor the data collected to ensure the safety of the subjects? Will there be a DSMB/DMC?

18. How will research subjects be recruited?



FHI Project Leader:		Reviewer Name:	
PHSC Number:		Review Date:	
Protocol Title:			

Type of Review: Expedited Full

1. BACKGROUND/RATIONALE/PURPOSE

<input type="checkbox"/> YES <input type="checkbox"/> NO	A. There is adequate justification for the study.
	Review Tips: <ul style="list-style-type: none">• Is the research problem/hypothesis adequately stated?• Are the specific aims of the research and how these will contribute to scientific/medical knowledge adequately described?
Comments: [Redacted]	

2. RISKS ARE MINIMIZED

<input type="checkbox"/> YES <input type="checkbox"/> NO	A. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not expose subjects to unnecessary risk.
	Review Tips: <ul style="list-style-type: none">• Consider physical, psychological, social, legal, and economic risks.• Has the appropriate departmental scientific review occurred?• Are the aims and objectives clearly defined?• Are there adequate preliminary data and is there appropriate justification for the research?• Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?• Are there qualified staff and resources to conduct the research?• Is there appropriate monitoring of the subject during and after the research?• Are medical or psychological resources available that Subjects might require as a consequence of the research?• Are adequate references provided?
Comments: [Redacted]	

3. RISKS ARE REASONABLE

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.

YES

NO

Review Tips:

- In evaluating risk, consider physical, psychological, social, economic, and legal risks. Consider only those risks and benefits that may result from the research, not risks and benefits of therapies subjects would receive even if not participating in the research.
- Consider physical, psychological, social, legal, and economic risks. Are the risks and benefits adequately described?
- Does the investigator have access to a population that will allow recruitment of the necessary number of Subjects?
- Does the investigator have sufficient time to conduct and complete the research?
- Is the research and timeline for completion feasible?
- Does the knowledge expected to result have importance?
- Are there adequate plans to notify the subjects about the research results (clinical issues, suicidal, referrals)

Comments:

4. SELECT RISK / BENEFIT ASSESSMENT

Regulatory definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(h)(i)).

***Choose Category 1 or 2 (and 2a or 2b):**

Category 1: The research involves no more than minimal risk to subjects.

Category 2: The research involves more than minimal risk to subjects.

Sub-category 2a: The risk(s) represents a minor increase over minimal risk

Sub-category 2b: The risk(s) represents more than a minor increase over minimal risk.

Definition of Benefit: The Belmont Report says that "the term 'benefit' is used in the research context to refer to something of positive value related to health or welfare. Unlike, 'risk,' 'benefit' is not a term that expresses probabilities." Benefit can be realized at the individual and community/societal levels. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Reminder

- Forms and checklists **must be used consistently** to achieve maximum return
- F & C must be assessed on a recurring basis to ensure that they are still adequate
- F & C will not make up for a lack of experience or training – they are a tool.